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U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D. C. 20555

References: 1) Fermi 2
NRC Docket No. 50-341
NRC License No. NPF-43

2) Federal Register, Vol. 59, No. 87, PRM-50-59, dated May 6, 1994

Subject: Comments on Notice of Receipt of Petition for Rulemaking on Security Program and Safeguards Contingency Plan Independent Review and Audit Frequency

Detroit Edison agrees with the ideas expressed in Virginia Power's petition for rulemaking, but believes additional changes are warranted. This letter provides comments on auditing of security programs and safeguards contingency plans and also includes a discussion of audits of other areas.

The information provided by Virginia Power provides a strong rationale to decrease auditing in an area of strong performance such as security. Additionally, the drills performed by security personnel provide assessment information that can be utilized to improve performance in any weakening areas.

A performance-based audit program requiring that periodic audits be scheduled based on performance provides for the most effective use of auditing resources. Poor performing areas are audited more often, areas of superior performance less often. Also, audit schedules should be flexible so audits can be scheduled when activities are in progress. For these reasons, Detroit Edison believes the rule should require periodic review of the security program and safeguards contingency plan rather than a review every 12 or 24 months. The description of the performance-based auditing program should be included in each licensee's Quality Assurance Program.

Additionally, the same philosophy applies to other audit frequencies specified by rule. These include audits of Access Authorization, Fitness for Duty Program, Fitness for Duty laboratory and other contractors, Environmental Protection, Radiation Protection, and Emergency Preparedness. The rules governing these audits should also

be revised to require periodic audits versus 12 or 24 month audits or to eliminate covering audits so all audits could be addressed in the Quality Assurance Program rather than have requirements scattered across many rules and guidelines. Since licensees cannot reduce commitments in the Quality Assurance Program without prior NRC review, the NRC would retain mandatory oversight over changes to the audit program that would reduce audit frequency.

This idea of providing flexibility to the audit program to better focus the efforts of audit and surveillance personnel on how to improve weak or declining performance areas was presented during the 1993 Public Workshop on NRC's Program for Elimination of Requirements Marginal to Safety. Attached is an excerpt from that meeting's proceedings, published as NUREG/CP-0129.

In summary, Detroit Edison agrees with Virginia Power's request that the audit requirements for security programs and safeguards contingency plans be revised, but believes further rule changes should be made so that no audit frequencies are specified by rules and auditing can be based on performance. This change would enable development of an improved audit program responsive to plant performance.

If you have any questions regarding these comments, please contact Ms. Lynne S. Goodman at (313) 586-4097.

Sincerely,

Robert McKean for DRG

Attachment

cc: T. B. Colburn
J. B. Martin
M. P. Phillips
K. R. Riemer
NEI

9. Quality Assurance Requirements

9.1 Ernie Rossi
Nuclear Regulatory Commission

The purpose of this session is to obtain input from the panelists and audience on proposed modifications to the NRC's requirements and practices in the area of quality assurance. We are also interested in supporting justification and bases for any proposed modifications that people may have.

Particular issues for consideration include the nature and extent of the regulatory burden, including the cost impact of the NRC's quality assurance requirements and practices, and arguments that any specific requirement or practice is marginal to safety.

We would like participants' input on the definition and use of performance-based quality assurance requirements, the risk significance of quality assurance requirements, and actual Appendix B requirements versus the NRC staff's interpretation of the requirements.

The panel session has been organized in the following sequence. Each panelist will make a 10-minute presentation from the podium, using overhead slides if they wish. Members of the audience who had previously indicated their intention to speak will provide their remarks, taking no more than 10 minutes. We have only one member of the audience who has asked to make formal remarks at this session.

After the formal presentations have been made, the session will be open for other members of the audience to provide remarks, ask questions, and participate in discussions with the panelists or other members of the audience. I ask that anyone speaking provide his or her name and organization/affiliation very clearly, so that our transcriber can take that down.

I would like to emphasize that the purpose of this workshop is not for the NRC to present positions, defend positions, or answer questions. The purpose is to receive input from industry and any members of the public in attendance.

Appendix B to 10CFR Part 50 establishes quality assurance requirements for the design, construction, and operation of structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. There are a number of perceived problems with NRC quality assurance requirements and with our practices in implementing them. I will mention several of the more important ones for you to think about during this session.

1. As implemented, quality assurance programs may emphasize documentation over performance.

2. Responsibility for quality is often perceived to lie in the quality assurance organization rather than the line organization.

3. The list of items to which quality assurance requirements are applied is far larger than was originally contemplated.

Having stated these possible problems with the NRC's approach to quality assurance—and I'm sure there are many other problems that may come up during this session—we will now ask our panelists to make their presentations.

9.2 Lynne Goodman
Detroit Edison

Improving Effectiveness of Performance-Based Audit Programs by Reducing the Regulatory Burden

I'm going to be talking about how to improve—not reduce, but improve—the effectiveness of performance-based audit programs by eliminating some of the regulatory burden. I'm going to be talking about the audit program. An audit is a look at how the organization is performing its activities, how those activities are being accomplished, and comparing them to established requirements and also to our management expectations.

Audit

A formal independent examination with intent to verify conformance with established requirements (ANSI N18.7)

Lynn Goodman - slide 1

We have a performance-based audit program. That means we watch people's performance at work as opposed to just looking at paper.

I'd like to tell you about an audit of our emergency planning organization that we performed in February. We spent 220 hours auditing our emergency preparedness. We determined we did quite well. We did a lousy audit.

We did our audit in February of this year because the regulations require that we audit every 12 months. We could not wait until March, when we had a scheduled drill, because then we would have been out of compliance with the regulations. So we did an audit, we got results, we met every regulatory requirement there was. But as I said, we did a lousy audit.

Requirements for Performance of Audits

- Technical Specifications Section 6
- Environmental Protection Plan
- 10CFR50 Appendix B
- 10CFR73.56 (g) (1) - Access Authorization
- 10CFR50.54 (t) - Emergency Preparedness
- 10CFR71.137 - Environmental Protection - Radioactive Materials
- 10CFR26 - Fitness for Duty
- 10CFR26.80 - Fitness for Duty Testing Lab
- 10CFR20.1101 - Radiological Protection
- 10CFR50.54 (p) - Safeguards Contingency Plan
- 10CFR72.40 (d) - Safeguards Contingency Plan

Lynn Goodman - slide 2

In March, we did a surveillance during the scheduled drill. That's the type of thing I want to talk about—how we can make our audit program more effective so that we're actually looking at things at the time it makes sense to look at them.

There are a number of requirements for audit programs. I am going to go over just a couple of them. One of the key ones is Section 6 of our tech specs. We have an environmental protection plan, Appendix B, and a number of other requirements for audit.

Requirements for Performance Audits (continued)

- 10CFR73.55 (g) (4) - Security Program
- NUREG CR-4640 - Simulator
- Reg Guide 1.155 - Station Blackout
- Reg Guide 1.21 - Environmental Protection - Radioactive Effluents
- Reg Guide 4.1 - Environmental Protection - Environmental Monitoring
- Reg Guide 1.33
- Reg Guide 1.144
- ANSI N18.7
- ANSI/ASME N45.2.12
- QA program as contained in updated Final Safety Analysis Report or QA Topical Report

Lynn Goodman - slide 3

The list goes on and on, including regulatory guides and NUREGs. There are a number of places that have audit requirements. Some have frequency requirements, some have just topic requirements.

Our other governing document is our QA program. For us, that's in our Updated Final Safety Analysis Report. For some plants, it's in a topical report.

The frequency of audits ranges from 6 months to 36 months, depending on the audit topic. With very few exceptions, there is no flexibility permitted for schedule extension. That leads to resource waste, as I mentioned with our emergency planning audit; we got very little benefit from that audit other than meeting our technical specification regulatory requirement.

Frequency of Audits per Requirements and Guidance
6 months - 36 months

With few exceptions, no flexibility permitted for schedule extension. Leads to resource waste with no benefit.

- Perform audits when due regardless of activities in progress
  - Can lead to meaningless audits
  - Can lead to extra audits, e.g., to avoid refueling or to catch refueling
  - Can lead to auditing prior to corrective action completion when waiting a short time could have scheduled audit to measure effectiveness of corrective action
- Can claim resources for non-problem areas that would be better used in monitoring and assessing weak areas

Lynn Goodman - slide 4

We have to perform audits—regardless of what activities are in progress—based on when the audits are due. So we can have a meaningless audit by looking at an activity when there is no work in progress.

We can perform extra audits. For example, if we want to take a look at in-service inspection, it makes sense to do that during a refueling outage, when we are actually doing in-service inspection. However, if the audit is due when we're not in a refueling outage, we might have to do an extra audit. That means we are double auditing.

On the other hand, we might want to avoid a refueling outage. It doesn't make a lot of sense to do an emergency planning audit during a refueling outage; it makes a lot more sense to use our resources to look at the work we're doing during the refueling outage.

The frequency requirement also can lead to audits being performed before expected corrective action is complete. For example, we have an audit that's not required by regulation scheduled for June of this year. Corrective action is going to be done in June. Therefore, it makes more sense to audit in August to see how effective the corrective action is. That's what we are going to do. If that were an audit required by technical specifications or a regulatory audit, we would not have that flexibility, and we would be auditing at a time when we know our program is not yet corrected.

The frequency requirement can take resources from non-problem areas. If you have a problem developing, it would make a lot more sense to look at the problem area. For example, if we have a weakness in our maintenance organization that we'd like to explore, we have to balance the need to look at the maintenance organization with any required audit and determine where to put our resources—toward the required audit, so we can do a good audit, or toward an audit of the problem area. Currently, we usually have to choose to do our required audit, and maybe put limited resources in the problem area. I think our problem areas should get more attention—more audits and surveillance's. That is what an effective performance-based audit program would do.

My proposal is that the licensees control the audit program, with NRC providing oversight instead of control. The Great Lakes QA Managers also support this proposal.

Proposal

Licensees control audit program with NRC oversight instead of NRC control

Lynn Goodman - slide 5

This proposal would involve several actions. It would require technical specification changes, regulation changes, regulatory guidance changes, and QA program changes.

Actions

- Tech Spec Changes
- Regulation Changes
- Regulatory Guidance Changes
- QA Program Changes

Lynn Goodman - slide 6

We're looking at three options. We prefer the first one, but we are willing to pursue any option that would be easier to license, and anything the NRC would be interested in approving.

Tech Spec Changes

- Three options (Option 1 preferable)
- Want to pursue option with greatest chance of timely success

Lynn Goodman - slide 7

Option one is to remove the audits from Section 6 of the Technical Specifications. We would have the audits listed in the QA program. The frequency of core audits, such as maintenance, engineering, operations, rad protection, design change, and so forth, would also be listed in the QA program.

Tech Spec Changes (continued)

Option 1 - Remove Audits from Section 6

- Audits list in QA Program
- Frequency of core audits list in QA Program, e.g. Operations, Maintenance, Radiation Protection, Design Change, Corrective Action
- Changes in Audit Coverage specified in QA Program treated per 10CFR50.54 (a)
  - Reduction in audit coverage requires NRC review
- Audits required by rules conducted at specified frequency (unless rule changes or exemption granted)
- Provides more control to QA Management on audit and other oversight activities
- Permits greater flexibility based on performance and plant activities
- Allows licensees to better focus QA efforts on how to improve weak or poor performance areas
- Consistent with draft Standard Review Plan 17.3

Lynn Goodman - slide 8

Changes in audit coverage would be handled like any other change in our QA program: It would be reviewed to determine whether it reduces the commitments in the audit program and whether it still meets Appendix B. NRC approval would still be needed for any changes that resulted in a reduction in commitments. We would conduct audits required by rules at the frequency required by the rules, at least until we had a rule change or an exemption. There are a lot of frequency requirements in some of the rules.

What this would do is provide more control to QA management on audit and other oversight activities—such as surveillances, special examinations, or inspections—in terms of applying the resources toward the activity where we feel we have the problems and where we could really get more bang for the buck. It would provide greater flexibility based on the plant performance and plant activities, and allow us to better improve our weak areas. This is also consistent with draft Standard Review Plan 17.3.

Tech Spec Changes (continued)

Option 2 - Tech Specs retain requirement to audit QA organization activities under Offsite Review Committee cognizance (otherwise same as option 1)

- Assures Offsite Review Committee retains oversight of QA activities and this is not changeable by QA program change

Lynn Goodman - slide 9

The second option is very similar to the first, except we would leave one audit in the technical specifications—the audit that audits the QA organization. That would mean the Offsite Review Committee would continue to have control over that audit.

Tech Spec Changes (continued)

Option 3 - Remove audit frequencies only from Tech Specs

- Audited areas not affected
- Provides some flexibility to adjust frequency based on performance and plant activities
- Consistent with approach in revised Standard Tech Specs to remove audit frequencies

Lynn Goodman slide 10

The third option is to remove only the audit frequencies from the technical specifications, but leave the audits in. This would give us a little flexibility to change the frequency of our schedule, but it would not really give us as much flexibility as we would like. This is

consistent with the new standard technical specifications.

Regulation and Regulatory Guidance Changes

- Currently requirements for audits are contained in multiple locations
- Consolidate into one requirement for Audit Program
- Revise Regulatory Guides
- Control over Audit Program in QA Program

Lynn Goodman - slide 11

Currently, audit requirements are contained in multiple locations. We think they should be contained in one location in the regulation. We should also look at the regulatory guides and determine whether we could revise and consolidate them, and put control of the audits in the QA program.

QA Program Changes

- QA Program revised to include listing of audited areas and frequencies of core audits
- QA Program change implementing this major revision to receive NRC review in parallel with Tech Spec change review

Lynn Goodman - slide 12

The QA program would be revised to include a listing of the audited activities and frequencies, and that first QA program change would be reviewed at the same time the technical specification change would be reviewed.

Licensee Actions

- Meet with NRR to discuss Tech Spec change options
- Submit first Tech Spec change and QA Program change
- Other licensees submit Tech Spec changes
- Submit further QA Program changes as appropriate following rule changes and Regulatory Guide changes

Lynn Goodman - slide 13

Actions that we would need to take as licensees include meeting with NRR to discuss the technical specification change options, submitting the first technical specification change and QA program change, and following up with the rest of us submitting technical specification changes. We would then submit additional technical specification changes as the rules or regulatory guidance allowed us to change.

NRC Actions

- Meet with licensee on Tech Spec changes
- Review and approve submitted Tech Spec and QA Program changes
- Perform review of all rules and regulatory guidance on audits
- Propose rule consolidating rules into one. May be just revision to 10CFR Appendix B
- Propose changes to Regulatory Guides
- Approve revised rule
- Approve revised Regulatory Guides

Lynn Goodman - slide 14

We are asking the NRC to do the following:

1. Meet with us to discuss this QA program change and the technical specification change;
2. Review and approve our submittals;
3. Review the rules and regulations that cover the audit program; and
4. Determine the best rule change and regulatory guidance changes to better consolidate the requirements, making them more usable and more flexible so licensees could have better, more effective QA audit programs.

I'm talking about how to improve, not reduce, but how to improve the effectiveness of performance-based audit programs by eliminating some of the regulatory burden.