

January 10, 2008

MEMORANDUM TO: Deborah A. Jackson, Chief
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FROM: Dennis Morey, Inspector
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SUBJECT: SUMMARY OF THE PUBLIC MEETING WITH THE NUCLEAR ENERGY
INSTITUTE TO DISCUSS RECOMMENDED CHANGES TO NRC
ENFORCEMENT POLICY

On October 11, 2007, staff from Fuel Cycle Safety and Safeguards (FCSS), Region II, and the Office of Enforcement (OE) met with nuclear industry (fuel facility and Nuclear Energy Institute [NEI]) representatives in a working group to discuss the U.S. Nuclear Regulatory Commission (NRC) enforcement policy related to fuel cycle facilities. This continued the work begun in a meeting August 23, 2007.

At the opening of the meeting, James Smith from FCSS summarized the requirements imposed by FACA (Federal Advisory Committee Act). He then proceeded to give a brief background and history of FACA. NRC has determined that the working groups' activities are covered by FACA, which requires the following:

1. Notice must be given of all meetings.
2. Any documents considered by the group must be retained (put into Agency-Wide Document Access and Management System [ADAMS]).
3. Detailed minutes of each meeting must be taken and retained (put into ADAMS).
4. Each working group must have a Chairman and Designated Federal Official. These must be different individuals.
5. The working group must have a charter, but all the working groups can function under the same charter, if there is a parent group (i.e., Part 70 Working Group). If individual working groups do not have a charter, then all products must be voted on and approved by the parent group.

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6. All meetings must provide for public participation (e.g., meeting notices, bridge lines, and convenient reasonable space for the public to meet.)

Some of these activities (items 1 and 6) have been in place already. However, until the charter is in place, working groups may continue to meet, as long as it is not in an advisory collegial manner (i.e., they can meet and ask individuals for their views on issues, but not try to reach consensus). The charter must be approved by General Services Administration Committee Management before these groups can start working as advisory committees under FACA. The alternative to this would be to instead develop Interim Staff Guidance in-house and go through the usual public comment process.

Industry representatives stated that their lawyers believe that FACA does not apply. The group interpreted the requirement to mean that they could discuss issues and try to reach agreement as long as they did not have a draft document on which they would try to gain "consensus." To make effective use of the time, however, no more meetings would be held until the requirements of FACA were met.

ENFORCEMENT POLICY

Maria Schwarz of OE briefed the group on the status of the Enforcement Policy (EP) and Manual revisions. The EP is designed to be a high-level document, and many of the details (e.g., specific to reactors, fuel cycle, etc.) will be moved to the Enforcement Manual (EM). This will be beneficial because the EM could be more easily changed. The revisions to the EP are currently under internal review, and will be followed by revision of the supplements, and around September of 2008 by revisions to the EM. Right now, the plan is to leave the supplements in the EP, but move a lot of other material to the EM.

The group discussed the lack of a "significance determination process" (SDP) for fuel cycle. Some members thought that it should be called something different, so as not to confuse it with the reactor SDP. There is now a dichotomy between "significance determination" (i.e., determining risk-significance) and assigning severity level. There should be a closer correspondence between the two, in the view of the participants. There was discussion about whether the group could comment on the draft Enforcement Guidance Memorandum (EGM), and it was decided that they could as long as they did not attempt to reach consensus.

The group discussed that the current EP (Supplement VI) does not have a way to disposition failures to meet the performance criteria (10 CFR 70.61). This is why the criteria in the draft EGM were developed. The group agreed that there must be an understanding that these criteria only apply if there is an underlying non-compliance; first, it must be determined that a violation of regulatory requirements occurred, and then these criteria are used to determine the severity level (SL). The mere loss of an item relied on for safety (IROFS) does not in itself place a licensee into enforcement space. The group extensively discussed the merits of including in the eventual policy the following sentence from the draft EGM:

Failures of IROFS do not normally constitute a violation if the failure occurred within the reliability defined for the IROFS even if the consequence occurs.

Industry representatives stated that the public will not accept the end of this statement (“even if the consequence occurs”), even though it is technically true. It is possible that all controls in a given sequence could fail and a criticality could occur, without the licensee having violated any NRC requirements. This is very unlikely, because most of the time failures will not result in the ultimate consequence. However, it could occur. NRC representatives stated that this was true but would make it difficult to be accepted up the management line.

The thinking that a failure of controls is not a violation unless there is some underlying non-compliance may be acceptable if applied to an IROFS failure, rather than the end result (e.g., the occurrence of a criticality accident), in NEI’s view. In particular, the concept that an administrative control failure could occur within the predicted frequency and not constitute a failure of 10 CFR 70.61 needs to be included. (This would technically be a violation of the license requirements to follow procedures, as discussed at the last meeting, but should be identified as an example of a “minor violation.”)

OE discussed the intent of the examples in the supplements. They are just intended to be examples, and not controlling or all-inclusive (pointed out prefatory material stating this). The NRC, however, tends to want to force enforcement actions (EAs) to fit one of the examples, and spends a lot of time justifying why a particular case meets one or another example. NEI believes that this is inappropriate, and suggested coming up with a “flowchart” or “roadmap” rather than a list of examples to define the process. Then, if needed, a list of examples could be generated from the flowchart. NEI also believes that there would be benefit to moving the supplements to the EM.

Industry representatives brought up the statement that licensees should be encouraged to use extra margin (and extra controls), without incurring additional “compliance risk.” Issuing them violations for the failure of an IROFS, when the licensee did not do anything wrong, would result in discouraging them from having this additional margin. It was pointed out that the NRC’s goal of “no criticality” is inconsistent with the “highly unlikely” requirement of 10 CFR 70.61(b). The end result was that the group agreed that this concept from the draft EGM should be included and expanded.

The discussion then moved to whether the NRC should consider only IROFS as part of its significance determination, or should take a more “holistic approach” and consider everything. A holistic approach would better align risk-significance with severity level.

The industry then returned to the question of whether procedure violations should be cited, and stated that the NRC’s tendency was to make any procedure violation a notice of violation (NOV) or non-cited violation (NCV). This had been seen more at facilities that have resident inspectors, as residents are encountering issues in real time. Visiting inspectors from NRC Headquarters or Region II often see non-compliances after the licensee has identified and corrected them. Thus, facilities with resident inspectors are more likely not to receive self-identification credit.

The discussion then moved to the issue of minor violations. The industry brought up that in the recent teleconference on Event Reporting, Region II personnel stated that the Licensee Performance Review (LPR) process does not use NCVs to rate licensee performance. However, one licensee representative stated that there were three NCVs in an LPR that took place three months ago. Thus, there seems to be some inconsistency. The group asked the OE representative what the difference is between NOVs and NCVs. The OE representative stated that the only difference is that licensees do not have to respond to NCVs. Issuing an NCV sends the message that the NRC has confidence that the licensee will handle the non-compliance appropriately. However, it is still considered a SL IV violation, just has “a different cover.” It is essentially equivalent to a SL IV violation with no response required. Industry representatives stated that minor violations (MVs) would be better because they don’t “go on the screen.” NOVs and NCVs are both “on the screen” and cause a lot of attention from customers and the public. Having better examples of what would constitute MVs would provide another avenue for the regulator to use.

The discussion then moved to the current Supplement VI criteria, and what is deficient about these. Industry representatives stated that the use of “critical mass” to distinguish between different SLs is arbitrary, since mass is just one of several parameters that can affect criticality. Elevating mass to an artificial significance would be akin to using k-effective as a measure of risk. NRC representatives stated that they agreed, and that also the meaning of “reasonably available” was subject to much internal debate. The merit of retaining or replacing the current Supplement VI criteria was discussed. It was universally thought that the current examples are not risk-informed and are too vague. Participants again suggested a “flowchart” be developed, and then examples built around the flowchart. These would replace the existing examples in Supplement VI. The OE representative stated that, if fuel cycle enforcement went this route, the flowchart and examples should include MVs. An industry representative pointed out the need to make this new flowchart consistent with the generic Civil Penalty flowchart (which includes such considerations as self-identification and willfulness).

The four considerations on pages 8-10 of the EP (actual safety significance, potential safety significance, regulatory impact, and willfulness) were then discussed. The value of considering impact on the regulatory process was discussed. Most participants believed that there needed to be a way to capture items which could impact the regulatory process (such as not making an event report or integrated safety analysis [ISA] update), that were not directly tied to facility safety. One of the important considerations, for example, is who makes a decision that impacts the regulatory process (i.e., an operator or low-level employee versus the Chief Executive Officer). While the four criteria apply to all types of regulated facilities, this working group should develop a flowchart for determining the first two (actual and potential significance). The criteria in the EGM would apply to that part of determining severity level, after which these other considerations would come into play.

The merit of using the draft EGM criteria to cover all types of violations, rather than just those involving 10 CFR 70.61, was discussed. The example of radiation protection (10 CFR Part 20) violations was raised—an event that might be a SL IV event under Supplement VI could be a SL I or II event under Supplement IV (Radiation Protection). Thus, there was a misalignment in the risk profiles of the various supplements. An industry representative stated that trying to solve this would make the working group’s task much more difficult, and it should focus on revising

Supplement VI. Industry representatives stated that, during the development of 10 CFR Part 70, it had wanted to include radiation protection events in the Part 70 framework, but these were removed. That resulted in radiation protection events under Part 20 not being risk-informed. The scope of Supplement VI was then discussed—did it apply to the thousands of materials licensees? Did it apply to Honeywell (Part 40 licensee) as well as Part 70 licensees and the gaseous diffusion plants (GDPs)? It was suggested that the flowchart, once it is developed, be used to see if it could be applied to Honeywell or the GDPs.

The group then discussed to what extent risk-significance should be considered for issuing SL IV violations vs. MVs (text on page 12 of the EP). An industry representative asked what parts of Supplement VI give the fuel cycle industry the most difficulty. Examples B.4 and C.11 were cited. An industry representative remarked that C11 is especially vague (a system designed to prevent or mitigate a serious safety event not being able to perform its intended function under certain conditions, or being degraded), and that one could “drive a truck through it.” There was uncertainty as to what “under certain conditions” meant. NRC staff stated that the uncertainty in practice is usually between C.16 and D.8. An industry representative asked how the examples are used, pointing out that the policy states that the examples are not intended to be comprehensive or limiting. A recent example at a fuel cycle facility was brought up, in which a SL IV violation was cited for failure to follow a posting. A posting specified that extraneous moderating material was not to be placed in a storage array. The inspectors found that the licensee had been storing several sections of polyvinyl chloride pipe on top of the storage array, in violation to the posting. The licensee stated that the requirement on the posting was not an IROFS and was not required for criticality safety (since revision of the criticality safety evaluation), and so it should have been treated as a MV. This event meets the criteria for a minor violation presented as a strawman on the last part of the industry’s presentation at the Atlanta workshop. The industry participants proposed that when the new enforcement framework is established, this would be a good test case to run through the process.

The group then discussed the significance of whether something was an IROFS—the NRC participants stated that whether or not something was an IROFS was not significant in terms of enforcement. Both IROFS and non-IROFS should be credited (a “holistic” approach to risk). An NRC participant stated that, while non-IROFS may be credited, they would need to be declared controls (e.g., double contingency controls that are not IROFS) and not accidental conditions that may or may not be present in the future.

The industry stated that it had identified four main concerns with the enforcement program in its most recent teleconference;

1. That IROFS failures should not be automatically considered violations.
2. That events (especially administrative failures) that occur within predicted frequencies should not be violations, or should at most be minor violations.
3. That better criteria have to be developed for what constitute MV.
4. That how unanalyzed conditions factor into enforcement needs to be defined.

Regarding events that occur within predicted frequencies, an NRC representative asked if the industry will revise its predictions if IROFS fail more often than anticipated. The industry representatives replied that the regulations require them to track IROFS failures and revise frequencies based on observed failures. The industry stated that there is data for doing this,

and that it generally took conservative values for failure frequencies (e.g., $10^{-1}/\text{yr}$ is generally used for administrative failures).

The concept of licensee self-identification was then discussed. Whether an event is licensee or self-identified affects whether a SL IV violation will be cited or non-cited. NRC representatives said that the question of whether something is an MV or a SL IV violation is separate from the question of self-identification; it only factors into whether the violation will be cited or non-cited. The NEI representative stated that it seemed arbitrary whether something became a cited or a non-cited SL IV violation. If one looks at the items in licensee's corrective action programs, what items become cited violations or NCVs seems to be arbitrary. Including the NCVs in the LPR process just means that the NRC is considering an arbitrary subset of items, which is not a valid indicator of licensee performance. The question of whether credit for a licensee's corrective action program requires additional license commitments was discussed. The NRC representatives stated that there need to be license commitments to tie down the requirements that licensees' corrective action programs have to meet. Industry representatives believe that most licensees have adequate corrective action programs and additional commitments are not needed. The industry believes that such prescriptive commitments would not be consistent with performance-based regulation. Though all licensees do not have explicit license commitments to corrective action programs, all are subject to the Part 70 requirement to track IROFS failures and feed that information back into the ISA process. In addition, the most important part of corrective action performance—adequacy and timeliness—are already being inspected. (And if a licensee corrective action program fails to show adequate performance, referral to the corrective action program could be rescinded).

The question of self-identification through audits and assessments was raised. An industry representative pointed out that Inspection Manual Chapter 0610 states that, to be self-identified, the non-compliance must have been identified as part of routine licensee audits and assessments. This does not make sense, because licensees are supposed to encourage operators to identify non-compliances. Licensees should not be punished for doing what the NRC wants them to do, which is to identify problems proactively. As long as licensees are identifying and fixing problems, the NRC should leave them alone. It shouldn't matter who identifies the problem. The NRC representatives agreed that this is counterproductive, and that this should be changed in the next version of Inspection Manual Chapter 0610.

An industry representative brought up a recent example, where a small fire at a fuel facility led to operators using water contrary to criticality requirements. The question is whether this event was self-revealing. A large fire, explosion, or criticality, would be self-revealing but a small fire may not be truly self-revealing. This led to a discussion of unanalyzed events (UEs) in general.

The general approach to dispositioning UEs should be to determine their significance through analysis and then determine their risk-significance using the same scale as for analyzed events, according to NRC representatives. The industry representatives stated that this seemed to be logical. However, it would make a difference whether the UE was discovered as the result of an event (or alternately by NRC inspectors), or was identified through the licensee's re-analysis. The industry stated that "event-driven" and "inquisitive-driven" UEs should be treated differently. The question was raised as to how this was being handled in the event reporting working group. The NRC representative on both groups stated that analysis-driven UEs would be reportable, if it met the criteria in Appendix A, (a)(4), that the licensee had failed to meet the performance requirements—this would generally occur if additional IROFS were needed subsequent to

identifying the UE. An industry representative stated that, during development of Part 70, the understanding was that a licensee was not expected to be “perfect” in identifying all possible accident sequences. The rule as written, however, seems to require such “perfection.” As a result, any time a UE is identified through analysis it could be claimed that a licensee did not meet the performance requirements. It may be appropriate that the analysis-driven discovery of a UE should be considered reportable, but that does not mean that it should be considered for enforcement. A different threshold is appropriate for reporting and enforcement.

All representatives agreed that there are two missing pieces that need to be incorporated into a revised enforcement policy to handle UEs: (1) there needs to be a distinction between “event-driven” and “analysis-driven” UEs, and (2) a process for handling UEs and understanding their significance needs to be developed. What constitutes a UE that “fails to meet the performance requirements” was discussed. Several factors may be appropriate to consider in determining if the performance requirements were not met. These include:

- Whether there are sufficient IROFS in place from other accident sequences,
- Whether there are sufficient non-IROFS in place (declared controls, not accidental factors),
- The natural and credible course of events/physical laws that prevent an accident (e.g., gravity, likelihood low of material forming a sphere),
- Items that are not specifically controlled but are unlikely to change—such as the fact that an unfavorable geometry sump is 35 feet away from where the spill occurred.

The representatives agreed that the last item is somewhat gray, and that the onus should be on licensees to demonstrate why they did not have a violation of 10 CFR 70.61. In some cases, licensees may establish IROFS just because it is easier to get the process re-started, and this should not be automatically viewed as evidence that they didn’t meet 10 CFR 70.61. Whether the above criteria are met, licensees should be encouraged to self-identify problems, and so if UEs are discovered through a licensee’s analysis, then they should not be penalized for this. An NRC representative stated that in some cases (as with the small fire discussed above), it may be difficult to determine what triggered the licensee’s recognition that there was a UE. It may not be clear what “turned on the light bulb.”

The representatives agreed that there needs to be some conceptual alignment between event reporting and enforcement for UEs, though maybe they have different thresholds. There are things the NRC would want to know about, but it should not take EA unless there is bad performance that the NRC wants to discourage. Enforcement should offer both a carrot and a stick, and the NRC should use enforcement to encourage good performance and discourage bad performance. Everyone acknowledged that it’s very difficult to determine if licensees have identified all credible accident sequences. However, NRC representatives stated that there would be a concern if a licensee repeatedly was discovering UEs, whether or not it had self-identified them through analysis. Such a discovery would reveal a weakness in the licensee’s ISA program. There should be a distinction between whether a licensee’s program worked and it just happened to miss something, or whether it didn’t use its program correctly.

The question of how such an analysis-driven UE should be dispositioned was posed. Most of the representatives believed it should be an MV. Because 10 CFR 70.61 requires a licensee to be “perfect,” one cannot make the case that it is not a violation (unless a licensee can show that

it did meet the performance requirements throughout the event). One representative stated that it had had an EA several years ago in a similar situation, and the violation had been eventually downgraded to an MV. The representative agreed to provide the EA number to OE to provide to the NRC representatives (because the case was classified).

An NRC representative raised the question of what if a licensee fails to perform the required management measures, but the IROFS did not fail. Would this still be a violation? It can be difficult to determine the degree to which existing IROFS may have been degraded by failing to apply the management measures. The representatives agreed that, in general, this would be less significant than an IROFS failure. But how much less significant? How much to discount the risk-reduction afforded by the affected IROFS? The industry representatives stated that they had presented some draft criteria at the Atlanta workshop. In general, a programmatic failure is more significant than an isolated failure to apply management measures, so the draft criteria are based (in part) on the extent of the failure. Some examples of these violations may be failure to perform a surveillance often enough, failure to functionally test all parts of a system of IROFS, or failure to re-train all workers within the required time frame. The effect of these violations on risk is difficult to determine, and there should be separate criteria for handling them.

Going back to the question of MVs, there was agreement that only SL IV violations should be referred to licensee corrective action programs (though there is still not consensus about what is required for this). More significant issues should not be handled this way.

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PROPOSED FUTURE ACTIONS

The group then discussed when to reconvene. It was decided that another meeting will not be held until the FACA charter is in place. The next step should be the development of a flowchart/process, which can be used to test some sample cases and, if needed, come up with examples for the revised Supplement VI (or possibly a new Supplement). In addition, the process would have to be flexible enough to apply to the GDPs and to Honeywell.

The participants discussed how this effort would impact the remaining supplements. They looked at the supplement for security, and decided that it was entirely outside the Subpart H framework and should be treated differently from safety. The role of the Part 20 supplement (Supplement IV) was also discussed. Some participants believed that radiological safety at reactors had been pulled out of Supplement IV and was instead treated under the reactor SDP. Similarly, the Supplement IV criteria appear to be more relevant to industrial radiographers, medical applications, etc., than to radiation protection at fuel cycle facilities. It was suggested that the new Supplement VI criteria be broadened to apply to all violations at fuel cycle facilities, including those of Part 20. Thus, Supplement IV would not be used for fuel cycle facilities.

The question of whether there should be a new supplement for fuel cycle facilities was also discussed. The other criteria in Supplement VI appear relevant to non-Part 70 materials licensees. In the end, it was decided that the first step would be developing a flowchart/process and that revision to the existing Supplement VI (or, alternately, the development of a new Supplement) would be decided later.

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NEXT GROUP MEETING

The working group plans to meet again at a location and time to be determined, to continue its work.

Enclosures:

1. NRC Presentation from the 2005 Atlanta Workshop
2. NEI Presentation from the 2005 Atlanta Workshop
3. Draft EGM
4. NRC Presentation from the 2007 FCSS Part 70 Workshop

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