



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION II
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February 23, 2006

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SUBJECT: NRC REVIEW OF COMMENTS BY THE NUCLEAR ENERGY INSTITUTE ON
PROPOSED DRAFT REVISIONS OF FUEL CYCLE INSPECTION
PROCEDURES

Dear Dr. Farrell:

This is in response to your letter dated September 22, 2005, in which the Nuclear Energy Institute (NEI) provided written comments on our draft fuel cycle facility inspection procedures. We very much appreciate the comments made in your letter and in our interactions at the workshop held on August 4, 2005.

We have evaluated your comments, and have incorporated many of them in our re-drafted procedures. Enclosed are responses to your comments.

Copies of the re-drafted procedures can be found in ADAMS (ML060330192). As you can see from the enclosed list of procedure changes, several existing procedures have been eliminated and their contents included in other proposed procedures as appropriate. There is a new procedure for fire protection. However, a fire protection procedure describing a more thorough triennial inspection has not been completed. We will forward that procedure for your review at a later date. Further, the procedure addressing the resident inspection program for Category I Fuel Cycle Facilities is being withheld due to the inclusion of possible sensitive information in parts of that procedure.

We are finalizing our internal review of the procedures and would appreciate any further comments you might have on them within 30 days from the date of this letter. We believe these procedures will result in better inspections and we want to begin using them in the very near future. If we are unable to make changes based on your review prior to our proposed implementation date, we will consider your comments when we revise the procedures after initial use. You are, of course, invited to comment on the procedures at any time and we will evaluate comments as we receive them to determine if any changes should be made.

C. R. Farrell

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If you have any questions, please contact me at (404) 562-4721.

Sincerely,

/RA/

Thomas R. Decker
Senior Materials Analyst
Division of Fuel Facility Inspection

Enclosures: 1. NEI Comments
2. Procedures Changes

X PUBLICLY AVAILABLE ☐ NON-PUBLICLY AVAILABLE ☐ SENSITIVE X NON-SENSITIVE

ADAMS: XYes ACCESSION NUMBER: _____

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NEI COMMENTS/NRC RESPONSES

COMMENT 1

Base inspections on regulations, license commitments, codes and standards, and occasionally may even consider adherence to good industry practices rather than “guidance” such as Standard Review Plans, Interim Staff Guidance, NUREG-1520, or Inspection Procedure guidance that is overly prescriptive could cause inspectors to turn it into a “checklist” (cover letter and Attachment 1).

RESPONSE

Inspectors should evaluate programs and performance to determine if they are safe, secure, and meet regulatory requirements such as the regulations, license, license application, and ISAs. This includes determining whether licensees are following procedures in areas where the license requires procedures. Licensees are *required* to implement Regulatory Guides, industry standards (ANSI, ASTM, etc.) only to the degree that they are required by regulation or license. If there are no specifics concerning a licensee’s program to meet NRC requirements in a specific area, staff may use NRC-approved guidance such as IP guidance, Regulatory Guides, ISGs, BTPs, and SRPs to assist in determining if the licensee’s programs provide reasonable assurance that operations are safe and high assurance that they are secure, recognizing the limitations below that are conveyed to new NRC inspectors as part of their qualification (quotes from Expectations for Inspectors manual):

- a. “Regulatory Guides (Reg Guides) describe acceptable methods to implement specific parts of the Commission’s regulations, techniques used by the staff to evaluate specific problems or postulated accidents, and data needed by the staff in its review of applications for permits or licenses. Thus, Reg Guides do not represent requirements. However, an inspector that finds a licensee adhering properly to a Reg Guide can rightly conclude that the applicable regulation is satisfied by the licensee’s actions. An inspector who finds that a licensee is not properly complying with a Reg Guide to which they have committed cannot conclude, *a priori*, that the applicable regulation is *not* met. In all cases, the licensee’s actions have to be fully understood in comparison to the regulations before a determination of noncompliance can be made.”
- b. “Licensees are not required to adhere to NRC inspection procedures. While regulatory requirements are certainly discussed in inspection procedures, inspection procedures also include guidance to the inspector on the attributes of effective licensee programs which, while useful to the inspector, are not embodied in the regulations. Thus, as in the case of Reg Guides, the failure of a licensee to meet a definition or attribute found in an inspection procedure does not mean that a regulatory requirement has necessarily been violated. The inspector must, in such a case, compare the licensee’s actions to the regulations themselves, to the licensee’s formal commitments, and to the degree to which the licensee is adhering to its internal procedures.”

- c. “Applicants are not required to meet the requirements of SRPs unless specific regulations reference them; however, SRPs describe to licensees and NRC technical staff the information required by the agency to properly review a proposed licensee action.”

In the case of changes to fuel facilities licensed under Part 70, NUREGs 1513 and 1520 offer guidance on NRC expectations regarding one acceptable way to perform safety analyses to support plant changes. These are referenced in the IP as supporting information to be used in conjunction with the ISA Summary process used by licensees to make plant changes under 70.72.

In addition, ISGs may also be used in evaluating such changes since the ISGs also present one acceptable method for certain technical evaluations.

COMMENT 2

Inspections of prescriptive requirements, such as radiation protection, radwaste management, Part 19 worker training, and emergency preparedness should be “compliance-based.” A licensee either complies or does not comply with a prescriptive set of requirements (Attachment 1).

RESPONSE

It is the intent of the inspection program that all inspections determine whether licensees are operating safely and securely, and, to the degree reasonable, be risk-informed and performance based. Even with several of the referenced inspections, we do and will inspect using these principles. For example, an emergency preparedness (EP) inspection might emphasize observation of the emergency classification and protective action recommendation development during an exercise rather than review of offsite monitoring team activities since the classification and PARs are more risk-significant. As the Expectations for Inspectors course book notes in quoting a Commission discussion of safety and compliance:

“As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The Atomic Energy Act of 1954, as amended, establishes ‘adequate protection’ as the standard of safety on which NRC regulation is based. In the context of NRC regulation, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials.

The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements.

What is the nexus between compliance and safety?

1. Safety is the fundamental regulatory objective, and compliance with NRC requirements plays a fundamental role in giving the NRC confidence that safety is being maintained. NRC requirements including other license conditions, orders, and regulations have been designed to ensure adequate protection -- which corresponds to "no undue risk to public health and safety" -- through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.
2. Adequate protection is presumptively assured by compliance with NRC requirements. Circumstances may arise, however, where new information reveals, for example, that an unforeseen hazard exists or that there is a substantially greater potential for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.
3. The NRC has the authority to exercise discretion to permit continued operations despite the existence of a noncompliance--where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances pose an undue risk to public health and safety. When non-compliances occur, the NRC must evaluate the degree of risk posed by that non-compliance to determine if specific immediate action is required. Where needed to ensure adequate protection of public health and safety, the NRC may demand immediate licensee action, up to and including a shutdown or cessation of licensed activities. In addition, in determining the appropriate action to be taken, the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e., the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. Based on the NRC's evaluation, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection).
4. Where requirements exist that the NRC concludes have no safety benefit, the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licenses. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative safety impact. They also can tend to create an inappropriate NRC and licensee focus on "safety versus compliance debates. As the Commission states in its Principles of Good Regulation, 'There should be a clear nexus between regulations and agency goals and objectives, whether explicitly or implicitly stated.'

5. Since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities (this includes enforcement).

Based on the accumulation of operating experience and the increasing sophistication of risk analysis, the NRC should continue to refine its regulatory approach in a manner that enhances and reaffirms our fundamental safety objective.

These principles attempt to describe the nexus between compliance and safety. The misperception that compliance and safety are somehow incompatible or unrelated arises when the principles just outlined are not understood or are wrongly applied. When understood and applied correctly, the result should be a consistent, credible regulatory approach--as applied to licensing, inspection, enforcement, performance assessment processes, and rulemaking."

COMMENT 3

Inspections of IROFS and management measures applicable to IROFS such as facility change management, maintenance, corrective action, and configuration management should be "risk-based." Licensees use a graded approach whereby the licensee tailors a safety program to match the risk posed by credible accidents. Inspections of these disciplines should focus on the adequacy of licensee methodologies and programs to ensure adequate safety and that performance goals of 70.61 are met (Attachment 1).

RESPONSE

Inspections should be risk informed and we plan to review changes in processes and programs as well as the implementation of the processes and procedures through operational safety inspections, plant change inspections, etc.

COMMENT 4

NRC inspectors should focus on plant activities where a credible accident could cause the 70.61 performance thresholds to be exceeded (Attachment 1).

RESPONSE

We agree that selections of activities to be reviewed as part of operational safety, management measures, etc. should focus on the more risk significant areas. Staff will also inspect regulatory requirements beyond those in 70.61.

COMMENT 5

Knowing that a licensee's problem identification and resolution system is well designed and operational, that self-identification of problems is occurring, and that corrective actions are being implemented in a timely fashion are actions that the NRC inspector should assess (Attachment 1).

RESPONSE

We agree and they have been so instructed in their training. This inspection activity is addressed in IP 88005, Management Organization and Controls."

COMMENT 6

Inspections should focus on changes made to the plant and its operations to ensure for example that the facility change process was correctly used, that compliance with regulations and license commitments is in place, and that the updated ISA continues to accurately reflect plant safety. Those changes that could never threaten non-compliance with 70.61 performance requirements should not receive high levels of inspection (Attachment 1).

RESPONSE

Our plant change inspections will focus on these areas, and will also review plant changes in other areas to assure that they meet other regulatory requirements, provide assurance of safety and security, and assure that the processes do not present a risk of exceeding performance requirements of 70.61.

COMMENT 7

Inspections should examine higher-risk plant operations and areas where historical problems have been encountered (Attachment 1).

RESPONSE

We agree and the procedures were enhanced to incorporate this approach to inspection. The emphasis of the inspection program is on safety and focuses on the most significant activities.

COMMENT 8

Inspectors who focus on instances such as operators failing to strictly follow procedures, missing a report filing deadline by a few days, or failing to update a procedure with minor changes are not profitably expending NRC resources (Attachment 1).

RESPONSE

Since it is our intent to focus inspection on higher-risk areas, and since in many instances the IROFS and management measures are dependant on human performance through implementation of procedures, the NRC believes that assuring that operators follow procedures

is, in fact, one element in determining if a facility is operating safely. In addition, meeting other regulatory requirements, such as those in implementing proper surveys, bioassays, effluent monitoring, etc. is dependant on plant staff following procedures. The NRC's Enforcement Policy recognizes that there is a range of safety impacts from failing to follow procedures, and provides guidance on how to categorize the findings based on actual and potential safety and security impact.

COMMENT 9

Unless the NRC identifies some major, safety-significant deficiency in a license that it previously approved, there should be no need to periodically review, for example, the NCS calculations that underlie NRC-approved plant operations (Attachment 1).

RESPONSE

We intend to focus on plant changes, recognizing that observations of operations could cause inspectors to review safety analyses of existing operations. We all should recognize that the ISA summary reviews and vertical slice reviews of actual ISAs as part of the ISA summary approval did not review all calculations that support ISA conclusions.

COMMENT 10

75-80% of inspection resources be spent on risk-significant aspects of plant operations and 20-25% on compliance with prescriptive requirements (Attachment 1).

RESPONSE

The NRC is responsible to assure that plants are operating safely and securely. The ratio of resources used to review safety or security is dependant on actual plant operations. In addition, the NRC is responsible to assure that licensees meet all regulatory requirements, and certain of those you classify as "prescriptive" are significant with respect to protecting public health and safety and will receive NRC inspection to perhaps a greater degree that the 20-25% you suggests (e.g. worker dose control, effluent control, transportation, etc.).

COMMENT 11

Inspections should eliminate duplication between programmatic and technical aspects of inspections by concurrent, rather than separate, examination of IROFS and their supporting management measures (Attachment 1).

RESPONSE

The re-drafted procedures take a more integrated review of IROFs and supporting management measures.

COMMENT 12

Consolidate inspections of management measure into an IP (maintenance, configuration control, etc.) (Attachment 1).

RESPONSE

The re-drafted procedures take a more integrated review of IROFs and supporting management measures.

COMMENT 13

Add an IROFS IP to ensure IROFS are installed and supportive management measures are in place (Attachment 1).

RESPONSE

The re-drafted procedures take a more integrated review of IROFs and supporting management measures.

COMMENT 14

Consolidate into one IP “compliance-based” inspections of analytical procedures and/or calculations (Attachment 1).

RESPONSE

The procedures contain risk-informed and performance-based aspects as well as “compliance based” aspects. Procedures were consolidated where we believed it would be effective and efficient.

COMMENT 15

Merge Nuclear Criticality Safety Program (IP 8801X) and Nuclear Criticality Safety Evaluations and Analyses (IP 88025) (Attachment 1).

RESPONSE

Procedures are kept separate for tracking and assigning hours to inspection activities.

COMMENT 16

Merge Operational Safety (IP 88020), management measures, and Maintenance (IP 88025) (Attachment 1).

RESPONSE

The re-drafted procedures take a more integrated review of IROFs and supporting management measures.

COMMENT 17

Inspections of various safety disciplines may be better conducted in three categories, analytical, programmatic, and operational (Attachment 1).

RESPONSE

Our current approach, for the most part, is to focus on operational performance, then where there are issues, delve into programmatic and analytical structure. One key exception would be plant change review where we would review all three aspects of selected plant changes.

COMMENT 18

The draft risk-based IP remain highly compliance focused (Attachment 1).

RESPONSE

Without greater detail pointing out which procedures you are addressing, we are unable to comment on this concern.

COMMENT 19

Incorporate a new inspection philosophy that focuses less on “mining” of a licensee’s problem identification system to simply chalk up violations, and more on an approach that addresses the effectiveness of a licensee’s problem identification and corrective action program (Attachment 2).

RESPONSE

It is our expectation that inspectors do not “mine” a licensee’s problem identification system. The guidance in IMC 610 is clear regarding audit and assessment findings - that they need not be discussed, with IMC 610 giving examples where it is appropriate to discuss the items.

COMMENT 20

ISA should be the primary focus of risk-informed inspection, including IROFS (equipment or procedures), underlying analyses (consequence evaluations, PHAs, NCSEs, set point determinations) (Attachment 2).

RESPONSE

The ISA is the focus for certain inspection areas (operational safety, NCS, plant changes, etc.)

COMMENT 21

Programs and methodologies - In doing inspections of the PI&R system, inspectors should focus on evaluating programs and not waste time looking at the “problem” (Attachment 2).

RESPONSE

The revised procedures should have the inspectors focus on the effectiveness of the PI & R system.

COMMENT 22

Inspection should include examination of low-consequence accidents, Part 20, safety audits (except IROFS), Part 70.24 CAAS (Attachment 2).

RESPONSE

The revised procedures include this.

COMMENT 23.a

Inconsistent acknowledgment of Part 70, Subpart H changes and terminology.

RESPONSE

Terminology is consistent with part 70.

COMMENT 24.a

Generally no parallel structure between *Inspection Requirements* and *Inspection Guidance*.

RESPONSE

There is parallel structure in the revised procedures.

COMMENT 24.b

IPs should use terms that are consistent with industry standards (Attachment 2).

RESPONSE

The revised procedures are consistent with NRC regulations and applicable industry standards.

COMMENT 25

Inconsistent terminology pervades many procedures (regulatee, licensee, IROFS, SSCS) (Attachment 2).

RESPONSE

The revised procedures use consistent terminology.

COMMENT 26

Industry would encourage the NRC to not again attempt to revive the performance indicator approach for licensee assessment. NRC-industry effort to develop performance indicators was unsuccessful due to pronounced differences amongst individual facilities. (Attachment 2).

RESPONSE

We plan to interact with stakeholders as we consider such an approach.

83822 Radiation Protection

No comments to respond to.

880XX Plant Safety Modifications**GENERAL COMMENT 27**

The IP seems to primarily focus on the licensee's configuration management system, but also extends into functioning of the §70.72 facility change process and baseline design criteria. (No inspection guidance is, however, offered for compliance with §70.64, and this suggests that this objective (§01.04) could easily be omitted from the IP.). By combining these three regulatory requirements, the IP becomes rather cluttered and confusing. The NRC should consider drafting separate IPs for the configuration management system and for the facility change process.

Several statements are far too broad (e.g. §02.02(a) which directs the inspector to review the ISA and ISA Summary – an exercise that would take weeks to accomplish). The IP should direct the inspectors to focus on changes to the plant's design and operations since the last inspection; this important direction is missing in some sections (e.g. §02.02(a), but present elsewhere (e.g. §03.04(b)(3)), and should be stated throughout the IP. Regrettably, some old terminology persists (e.g. references to SSCs) and some sections (§03.02©)) are unacceptably prescriptive and too similar to reactor inspection terminology. These must all be corrected (Attachment 2).

RESPONSE

The procedure was revised to incorporate many of the general and specific comments. Most significantly, the configuration management and control section was removed and placed in a separate procedure. The configuration management and control program will be reviewed in detail from a programmatic point of view if the plant modification program review determines there are problems. The procedure was revised to align more with Part 70 with equivalent looks for Part 40 and 76 licensee and certificate holders.

COMMENT 28

01.02: Delete reference to “structures, systems and components (SCCs)” in this and many following sections (e.g. §03.02(a), §03.02b(3), §03.02c(2)(e), §03.04a(1)). Replace with the IROFS terminology (Attachment 2).

RESPONSE

The acronym SCCs was removed.

COMMENT 29

01.04: There are no requirements or guidance for application of §70.64. Delete this objective (Attachment 2).

RESPONSE

The application of 70.64 has been added to 02.02/03.02.

COMMENT 30

02.01: The suggestion that a licensee transmit voluminous information to Headquarters prior to an inspection must be stricken. The NRC should contact the licensee prior to the inspection and identify which documents are requested for review at the facility. A major principle of the Part 70 revisions was to keep all safety analysis documentation (i.e. ISA, NCSEs) at the licensed facility for NRC review. Delete the second sentence. Also, the Requirements should state that plant modifications made since the previous inspection will be examined (Attachment 2).

RESPONSE

Clarification was added to this section which states: The team leader should make appropriate arrangements with the licensee or certificate holder staff in advance of the inspection to have relevant documents available for review as part of inspection preparation. Depending on the amount of material needed for preparation, the team leader should obtain the material as part of an inspection preparation trip to the site or by requesting the licensee or certificate holder transmit it for in-office review. If neither of these approaches are feasible, the on site time of the team should be expanded to include time to review information related to the selected modifications while on site.

COMMENT 31

02.02(a): “Summary” in the term “ISA Summary” should be consistently capitalized. This sentence is far too broad. The inspectors should only consider changes to the facility since the prior inspection and examine whether such changes have been properly analyzed and recorded (Attachment 2).

RESPONSE

Summary has been capitalized. "The selections should be made from those made since the last Permanent Plant Modifications inspection." has been added to 02.01.

COMMENT 32

02.02(c)(2): Addition of "designed" prior to "implemented" may be helpful (Attachment 2).

RESPONSE

We agree. Comments inserted in procedure.

COMMENT 33

02.02d(1): Although no timeframe is presented for updating of such documents, a debate on what constitutes a "reasonable period of time" may be inevitable. Should greater clarity be provided to the inspector? Replace "applications" by "amendments" in the third line (Attachment 2).

RESPONSE

We agree. The section now reads: Determine whether design and licensing documents have either been updated or are in the process of being updated to reflect the modifications in accordance with the licensee's or certificate holder's requirements. Examples of design documents which could be affected by modifications are: license amendments, ISAs, ISA Summary, IROFS lists, drawings, supporting calculations and analyses, plant equipment lists, and vendor manuals.

COMMENT 34

03.01: The sentence "...the elections should be based on the risk-significance of the modifications..." is excellent and should be included in every IP. Insert a comma after "inspectors" (Attachment 2).

RESPONSE

A comma was inserted.

COMMENT 35

03.01(d): Capitalize "Summary" (Attachment 2).

RESPONSE

Summary was capitalized.

COMMENT 36

03.02: Inspections must be made against the regulations and license commitments, and not against guidance. Although the last sentence of §03.02(a) correctly cautions the reader to not rely on NUREG-1520 or NUREG-1513, there is a significant danger that these two documents will be considered to be the standard against which the inspection will be conducted. In the “NOTE” make reference to IROFS (Attachment 2).

RESPONSE

See the response to the first comment.

COMMENT 37

03.02(b): For consistency of terminology with §02.02(b), the title of this section should read “Testing Review.” In point (3), make reference to IROFS (Attachment 2).

RESPONSE

“Test Review” was changed to “Testing Review.” IROFS have been referenced.

COMMENT 38

03.02(c): This section is compliance-based rather than performance-based and requires modification. It appears to have been lifted from a reactor IP, for many reactor terms and requirements are employed. In 3(e) the implication is that IROFS must be seismically qualified. There is no regulatory requirements for this. Delete (e). Section 3(g) only applies to GDPs, but not fuel cycle facilities. Clarify this discrepancy and limit the applicability of 3(g). The requirement of section 3(h) is unnecessary and so broadly stated that literally days or weeks would be required to ensure that the fire protection systems are installed per design. This is inappropriate guidance to meet the §02.02©) requirement. Revise. The guidance in section 3(d) that “adequate physical separation/electrical isolation exists for redundant trains of safety-related equipment” may pertain to redundant systems for double contingency and prevention of common failure service issues such as shared battery power supplies. If not, this sentence could direct the inspector deeply into common mode failure analysis without much useful guidance. Clarification is needed (Attachment 2).

RESPONSE

This section has been revised to read:

System Condition and Capability Review

1. Through observations of work in progress and/or discussions with operators, engineering staff, and staff making the modifications, determine the adequacy of work controls and interface with operations.

2. Based on risk, select a sampling of IROFS and other safety controls changed or added as a result of the modifications, and determine through walkdowns, reviews, and discussions with licensee staff, determine whether:
 - (a) the installed IROFS and controls are consistent with the applicable process and instrumentation diagrams (P&IDs) and engineering drawings,
 - (b) equipment and instrumentation elevations, including the adequate sloping for piping and instrument tubing, support the design function of the IROFS and safety controls,
 - (c) protection defined in the ISA is provided for equipment located in areas susceptible to fire, chemical corrosion, high energy line breaks, adverse temperature, or other environmental concerns,
 - (d) physical separation/electrical isolation exists for redundant IROFS or safety controls as specified in the ISA or other safety analyses,
 - (e) structural support equipment is installed properly, and
 - (f) fire protection systems are installed per design.

COMMENT 39

03.02(c)(4): Inspection of management measures is already being addressed in other IPs. The redundancy of repeating this inspection in IP880XX must be deleted (Attachment 2).

RESPONSE

This procedure reviews the implementation of the measures whereas IP88005's review is management orientated. This section has been enhanced to read: Select a sample of higher-risk IROFS and determine whether management measures as specified in the ISA and other safety analyses were adequately implemented, including revisions to procedures for normal operations, alarm response, and emergency conditions, training for any changes in operation, maintenance, surveillance, and procedures, and pre-fire plans have been changed where appropriate.

COMMENT 40

03.03(d)(4): Why is fire safety identified for special examination? Why not nuclear criticality safety issues? Why not other safety programs? This focus is inappropriate (Attachment 2).

RESPONSE

This section was broadened to read: Document Update Review. Determine whether revisions were necessary for the ISA Summary or other applicable design basis documents, and if so, that any such revisions are adequate.

COMMENT 41

03.03: For consistency with 02.03 terminology, this section should be entitled "Identification and Resolution of Problems" (Attachment 2).

RESPONSE

02.03/03.03 were changed to read: Problem Identification and Resolution.

COMMENT 42

03.04(a)(1)(b): Correct the English expression by replacing “between” by “among” (The former word is used to compare two objects, the latter word is used to compare more than two objects.) (Attachment 2).

RESPONSE

We agree. “Between” was replaced with “among.”

COMMENT 43

03.04(a)(1)(c)(6): Make reference to IROFS (Attachment 2).

RESPONSE

This section on configuration management was removed from this procedure and placed in a new procedure for configuration management. The comment will be addressed in the new procedure.

COMMENT 44

03.04(a)(1)(c)(9)¶2: Replace “between” by “among” (see earlier English grammar note) (Attachment 2).

RESPONSE

We agree. “Between” was replaced with “among.”

COMMENT 45

03.04(a)(5): Insert the word “be” at the end of the first line so as to read “...should be trained on and be familiar with the ...” (Attachment 2).

RESPONSE

This section on configuration management was removed from this procedure and placed in a new procedure for configuration management. The comment will be addressed in the new procedure.

COMMENT 46

03.04(b)(3): This is excellent guidance by directing the inspector's attention to "...analyses established since the last inspection..." This is an underlying theme of industry's comments – that inspections should not always re-invent the wheel, but focus their attention on plant changes implemented since the previous inspection (Attachment 2).

RESPONSE

No response required.

88005 Management Organization and Controls**COMMENT 47**

01.06: There is no specific requirement for the licensee to have a QA program. There is no QA regulatory requirement for Part 70 licensees (e.g. "whether components manufactured at vendor facilities are inspected at the vendor shops and/or upon receipt", and "sign-offs attesting to overall conformance to the requirements for component design, testing and installation") and has no regulatory basis. These reactor requirements should be deleted from 88005 (Attachment 2).

RESPONSE

The QA review section is adequately addressed in 03.06. We routinely review QA for items such as cylinder valves, shipping containers, etc.

COMMENT 48

02.02(b): There is a continual omission of other safety programs in the IP. Why does not chemical safety warrant any consideration (Attachment 2).

RESPONSE

Chemical safety was considered part of the plant safety program, however, we inserted chemical safety in several places for clarity.

COMMENT 49

03.02(b)(2) 2nd Paragraph: Inspection of the configuration management system should be relegated to a separate management measure IP (Attachment 2).

RESPONSE

We will keep it in one management inspection procedure for now. Configuration management was separated from IP880XX, *Plant Safety Modifications*, however, and placed in a new procedure IP 880XX(A), *Configuration Management Programmatic Review*. IP880XX was renamed *Permanent Plant Modifications*.

COMMENT 50

03.02(c)(1) 1st Paragraph: This action will have been performed as an update of the ISA and ISA Summary when evaluating facility changes (Attachment 2).

RESPONSE

This part of the inspection involves much more than ISA issues.

COMMENT 51

03.04: The title of this section should conform to 02.04 (Attachment 2).

RESPONSE

We agree. The title was changed.

COMMENT 52

03.04(a) Paragraph 1: Change shiftly to shift (Attachment 2).

RESPONSE

We agree. The word was changed.

COMMENT 53

03.04(b): The title of this section should conform to 02.04(b) (Attachment 2).

RESPONSE

We agree. The title was changed.

COMMENT 54

03.04(b)(2): For consistency throughout the IP (e.g. with the subsequent 03.04(b)(1), add the words "if require" or "if appropriate" after NRC. Not all events will have to be reported to the NRC - use the graded approach consideration (Attachment 2).

RESPONSE

It says it in the first paragraph.

COMMENT 55

03.04(b) 1st Paragraph: There is no regulatory requirement to evaluate root and contributing causes as might be required for a power reactor. Revise (Attachment 2).

RESPONSE

Root cause is an important part of corrective action. Section 02.04/03.04 was enhanced to provide additional detail for the inspector's review of problem identification and resolution and incident investigations. Root cause and the extent of condition reviews and corrective actions should be sufficient to prevent reoccurrence of any violations of NRC requirements.

COMMENT 56

03.04(b)(5) on page 9: There is no requirement that every incident be reported or analyzed within 30 days. Application of the graded approach negates the IP claim. Revise (Attachment 2).

RESPONSE

Wording changed accordingly.

COMMENT 57

03.06: See earlier comments on the inapplicability of a reactor QA program to fuel cycle licensees (Attachment 2).

RESPONSE

The qualifying wording regarding QA is sufficient.

88010 Operator Training/Retraining**GENERAL COMMENT 58**

There is very poor correspondence between the Inspection Requirements (02) and the Inspection Guidance (03) sections of the IP and it is not clear how the two are linked (Attachment 2).

RESPONSE

Section 03 provides additional guidance to the 02 requirements section. The type of guidance provided will vary as the needs and subject matter require. Sometimes there is no additional guidance provided as the requirement stands by itself. Sometimes additional information is inserted of a general informative nature, and other times the guidance is very specific to the requirement. The inspectors have reviewed these procedures and feel their purpose is served by the present guidance.

COMMENT 59

There is no guidance offered in IP 88010 to meet the 02.02(a) inspection requirement (training of individuals to perform IROFS administrative functions) , or how the graded approach would function in their training (Attachment 2).

RESPONSE

We are inspecting the licensee to ensure that training is provided to operators. We do not prescribe the specific details of the training to be provided by the licensee.

COMMENT 60

02.02(b): Nuclear criticality safety is covered in IP 88015 and should be deleted from 88010 (Attachment 2).

RESPONSE

The region's inspectors review the criticality safety training for all employees in 88010 to assure it was adequately performed. The criticality safety training reviewed in 88015 (old proc no.) is for the professional criticality safety staff, not the general employees.

COMMENT 61

03.01(a)(3): Expectations that an operator should be required "...to the extent within the workers' control to observe Commission regulations and licenses..." seems to be far too high-level (Attachment 2).

RESPONSE

Wording changed for clarity.

COMMENT 62

03.01(4): The expectation that an operator would know all Commission regulations and license conditions is unreasonable (Attachment 2).

RESPONSE

The wording was changed for clarity.

COMMENT 63

03.01(b) and 03.02: Confusing use of "licensee" and "regulatee" (Attachment 2).

RESPONSE

Regulatee changed to Licensee or Certificate Holder.

COMMENT 64

03.03(e): This section states that “...refresher training should be provided at least every two years, or as specified in the facility license or certificate...” Considering the annual GET training, quarterly criticality safety training (which many licensees are including in Integrated Safety Refresher training), and the biennial review, adequate training should already be available (Attachment 2).

RESPONSE

Training will be inspected according to license or certificate requirements. If there are no requirements, it will be expected to be provided at the frequency to assure staff perform tasks safely and as required by procedures.

COMMENT 65

03.05: What is specified in the first sentence is not appropriate for managers and supervisors. Revise. The meaning of the last sentence is unclear. In such an event, workers shall stop the process and notify their supervisors (Attachment 2).

RESPONSE

We do not understand the comment, but minor wording change was made.

8801X - NCS Program

NCS inspection procedures have been extensively rewritten and restructured to align Requirements and Guidance sections, to eliminate unnecessary prescription and to make the language clearer. In addition, Subpart H language has been incorporated where applicable. The following specific comments were addressed.

Inspection Procedure Titles**COMMENT 66**

NRC should consider merging of the two nuclear criticality safety IPs, Nuclear Criticality Safety Program [IP8801X] and Nuclear Criticality Safety Evaluations and Analyses [IP8801Y]

RESPONSE

Procedures are kept separate for tracking and assigning hours to inspection activities.

COMMENT 67

01.01: There are many individuals identified as “NCS specialists,” “NCSF staff,” “NCS analysts,” “NCS senior reviewers,” “NCS engineers,” etc. Are these all one-in-the same? Consistency in personnel classifications would be useful.

RESPONSE

We agree. The titles were made consistent.

COMMENT 68

01.01(c): Use of the word “each” could be an onerous problem, especially if “equivalent” process changes have no effect on safety as determined through the ISA analysis

RESPONSE

We agree. The wording was clarified.

COMMENT 69

01.01(f): Start this clause with a verb: “Assure that NCS staff...”

RESPONSE

We agree. The wording was changed.

COMMENT 70

01.01(h): “NCS procedure violations” is far too broad. Procedure violations are inevitable and will occur. Inspectors should focus on safety-significant violations and recurring violations as possibly indicative of training deficiencies. Focusing on trivial procedure violations should not be the purpose of an inspection.

RESPONSE

NRC expects licensees to track correction of procedure violations. See also our previous comment on procedural adherence.

COMMENT 71

02.01(c): The last sentence of this section should be relocated to 02.01(b)

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 72

02.02(a): Why should the licensee’s engineers necessarily be involved in the documents’ preparation? They should only provide reviews of even sophisticated operations and engineering procedures that may have been written by others, including contractors.

RESPONSE

This text was moved to guidance section.

COMMENT 73

02.02(c): Similar concern with the all-encompassing “all” terminology (see 01.01©) above).. To what does “all information” pertain? Elaborate.

RESPONSE

We agree. Use of “all” has been limited in the procedures.

COMMENT 74

02.03(d) and 03(e): Engineered or geometric controls should be preferred, when practicable. Use of administrative controls is clearly acceptable for certain situations (e.g., large margin, low likelihoods, low risk, etc.). Justification for use of administrative controls should not be required; the adequacy of the designated administrative controls need only be demonstrated.

RESPONSE

We agree. We clarified the wording.

COMMENT 75

02.04(a)(1): “...report all detected violations of written NCS...: the inspector should again be directed to focus on safety-significant violations. Same comment applies to the final sentence in this section (1).

RESPONSE

The inspector should assure that the licensee programs evaluate and correct violations of NRC requirements.

COMMENT 76

02.04(a)(2): “...individuals having unescorted access...” this probably means employees. Use simpler language?

RESPONSE

It means individuals with unescorted access. Many license employees do not have this access and some with access are not employees.

COMMENT: 77

02.04(a)(3): Is there really a need for a management representative to inspect areas where SNM is handled? Surely this work should be delegated to a technical expert engaged by the licensee. This section also erroneously states that annual inspections are required. This “requirement” is not found in any regulation or license commitment. The frequency should be risk-informed. Areas such as laundries may not need to be inspected on an annual basis. Which management representative are required – certainly not supervisors? What about their qualifications (see 04.04(b)).?

RESPONSE

Management is responsible for the safe operation of the facility. Although any particular licensee might not specify management review of operations at any particular area of the plant, management is responsible for safe operations and this includes review of actual operations. Certain reviews are delegated to technical staff, but management reviews are routinely done. This section was rewritten.

COMMENT 78

02.04(b)(1) and (2) : This section is titled “Audit Program,” but the description of activities describe more of an “NCS program appraisal” rather than an audit. Audits are geared to compliance with requirements, but both paragraphs focus on demonstrating that the licensee is evaluating program adequacy. Sections (1) and (2) should be reversed to first ensure that an audit program is in place (current section (2)) and that it operates (current section (1)). After making this switch, delete the last two sentences from the (new) section (1), as it simply (and unnecessarily) repeats what is said in the new Section (2). One should also insert the word “any” in the phrase “...corrective actions for any safety-significant violations of written requirements...”, so as not to pre-judge that there actually will be any violations. Most licensees do not use the term “teams.” Correct this terminology error.

RESPONSE

Requirements and Guidance sections have been completely restructured which, in this case, resulted in elimination of the term “teams.”

COMMENT 79

02.04(c): This step appears to be establishing expectations that require NCS staff to conduct a “formal” review (i.e., concurrence) with proposed corrective actions is unnecessary. Corrective actions for a criticality limit violation will be either a correction to an inadequate NCS analysis/control, or a renewed commitment by plant managers that the existing limit will be complied with. In the first case, the corrective actions will be the responsibility of the NCS staff and in the second, the corrective actions will be the responsibility of the fissile material operations management. Regardless, NCS will be involved, but in the second case cited, it will be in a consultation role. Suggest replacing “NCS staff” with the term “appropriate management.”

RESPONSE

This section has been rewritten to better define the audit program inspection requirements.

COMMENT 80

02.05(a): Replace "...control systems identified in safety analyses..." by "IROFS."

RESPONSE

Subpart H language added. "Control systems" is a separate concept which remains applicable.

COMMENT 81

03.01: This section does not provide any guidance in the areas of "NCS guidance" or "independence," both of which are included in the "Inspection Requirements" section. Again, there must be one-to-one correspondence between items in the Inspection and Requirements section of each Inspection procedure chapter.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 82

03.01(a): The English expression in both sentences is very poor. For example, a program does not in itself develop procedures.

RESPONSE

We agree. The wording was changed.

COMMENT 83

03.01(a)-(d): This section of guidance does not parallel the corresponding requirements section. Guidance should be provided for each of the items listed in the requirements section.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 84

03.01(c): This section requires that individuals performing independent reviews of evaluations have "...at least two years experience doing NCS evaluations and at least one year of experience at the company's facility..." This requirement does not exist in the regulations or in operating licenses. The amount of time in a position is not a good measure of competency or ability. The basis for this frequency seems to be highly arbitrary. The requirement should be

that the licensee has a program with performance objectives that must be met before allowing second party review. This inspection item limits the ability of licensees to use contract engineers for performing some evaluations that are inherently simple. For example, evaluations of fissile material storage in single planar arrays or shelves are not very different from facility to facility. The use of contractors to perform and review these types of evaluations should not be precluded by this inspection procedure. Replace “company’s” by “licensee’s” for a facility need not strictly be operated by this type of business entity.

RESPONSE

We agree. The wording was clarified.

COMMENT 85

03.01(c) and (d): These are both sub-bullets for staff qualifications. Relocate.

RESPONSE

We agree and relocated them.

COMMENT 86

03.02(a)-(e): This section does not parallel the corresponding requirements section (Administrative and Operating Procedures). The guidance portion needs to provide **guidance for each of the items listed in the requirements section of this procedure.**

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 87

03.02(b): Poor English expression. Also, incorporate the term “IROFS.”

RESPONSE

Requirements and Guidance sections have been completely restructured. Subpart H language has been incorporated.

COMMENT 88

03.02(b): Make reference to ISAs here.

RESPONSE

Subpart H language has been incorporated into the procedures.

COMMENT 89

03.02(c): Item (4) leads the inspector to expect a particular organizational structure and reporting system. This inspection guidance should be more performance oriented. For example, requiring that the NCS staff evaluate abnormal events and report their evaluation to plant management is a very prescriptive requirement. A licensee could well have a program in which key plant management personnel are directly involved in the review of all abnormal events and who approve anticipated and actual corrective actions.

RESPONSE

This guidance is pertinent and not intended to be prescriptive. Guidance has been relocated to 03.02(b).

COMMENT 90

03.02(e): The second sentence has no meaning, and should be deleted. The final sentence should be relocated to 03.01(a) where this specific information would be useful.

RESPONSE

We agree. The procedure was revised to incorporate the comment.

COMMENT 91

03.03(a): This section does not parallel the corresponding requirements section. The guidance portion for Administrative and Operating Procedures needs to provide guidance for each of the items listed in the requirements section of this procedure.

RESPONSE

Requirements and Guidance sections have been completely restructured. NRC does not agree that all requirements need guidance.

COMMENT 92

03.04(a)-(h): This section is not parallel with the corresponding requirements section. The guidance portion for Administrative and Operating Procedures needs to provide guidance for each of the items listed in the requirements section of this procedure

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 93

03.04(a): The content of this section appears identical to that of 02.04a(2). Delete?

RESPONSE

We agree. It was deleted.

COMMENT 94

03.04(b): The last sentence of paragraph (b) should be relocated to paragraph (c). Also, the last sentence of paragraph (c) should be placed in paragraph (b), as it addresses the adequacy of IROFS.

RESPONSE

We agree. Subpart H language has been incorporated into the procedures.

COMMENT 95

03.04(c): The draft guidance leads the inspector to expect an activity at a frequency that is not required by regulation or by license requirements. The frequency of licensee inspections should be based on a “risk-informed performance-based” approach that considers safety importance. Many operations do not need a weekly or daily inspection. Some operations are not even performed weekly. Specific timeframes should not be specified. What is specified in the license or certificate will define the inspection frequency. The statement “Operational inspections should be performed on a daily or weekly basis by staff familiar with the operations” is unclear regarding who specifically is expected to perform this inspection and what their qualifications would have to be. What are operational inspections (must they be documented)? Should ensure this is not meant to be NCS staff.

RESPONSE

We agree. Specific timeframes have been deleted.

COMMENT 96

03.04(h): Establishing expectations that require NCS staff to conduct a review (implied “formal” review and concurrence) with proposed corrective actions is unnecessary. How does one “confirm their adequacy?” This guidance is unnecessarily restrictive. Explain.

RESPONSE

This section has been rewritten. There is a clear expectation that regulatees conduct program audits and that the results of the audits are made available to plant management who have program responsibility.

COMMENT 97

03.05(b) and (c): “controls” and “NCS control systems” should refer to IROFS. The inspector should make comparisons of operations against what is stated in the ISA.

RESPONSE

The term "IROFS" has been inserted where appropriate.

Procedure 8801Y – NCS Safety Evaluations and Analyses**COMMENT 98**

A merging of IP8801X and 8801Y should be considered.

RESPONSE

Addressed previously.

COMMENT 99

01.01(a): One would normally assume that if a licensee meets regulatory requirements and license conditions, adequate criticality safety is provided. The last portion of this sentence implies, however, that this is not the case. This section should be deleted. (See IP83833, page 4, last paragraph, for an example of a good way to capture this type of objective).

RESPONSE

We agree. The section was deleted.

COMMENT 100

01.01(c): This section leads the inspector to expect that all criticality scenarios are identified and listed in the NCS evaluations. In reality, one can not possibly identify "all" scenarios. The regulatory requirement requires the licensee to just identify bounding scenarios. For example, a licensee may not identify all the possible mechanisms that could cause flooding and still have adequate protection against flooding. Use IROFS here.

RESPONSE

We agree. The wording was clarified.

COMMENT 101

02.03(d): This section suggests that any time an administrative control is used, the evaluation should include a written explanation as to why an engineered control was not used. This is neither required by regulation nor by the operating licenses of most licensees.

RESPONSE

We agree. The wording was clarified.

COMMENT 102

02.03(e): This section goes far beyond regulatory requirements by requiring “control systems” (presumably IROFS) for each accidental criticality pathway. This is incorrect. The guidance should direct the inspector to determine, where possible, that the double contingency principle is met, and where not possible, that sufficient diversity and redundancy is present so that it takes two unlikely independent and concurrent failures before accidental criticality is possible.

RESPONSE

The focus of the inspection requirement is that the inspector needs to determine whether the licensee’s or certificate holder’s actions assure that subcriticality is assured.

COMMENT 103

02.05(a): The first sentence of this section is largely a repeat of §02.03e and isn’t really related to sub-critical margin. The discussion of double contingency (DC) leads the inspector to expect that DC is always provided, when, in fact NUREG 1520 guidance specifically allows sufficient redundancy and diversity so long as it takes two unlikely independent and concurrent failures before accidental nuclear criticality is possible. Also, the last sentence leads the inspector to expect that each time an administrative control is used, a written justification for not having an engineered control present must be available in the evaluation. This is neither required by regulation nor by the operating licenses of most licensees. Subcritical Margin and the establishment of this margin is a license commitment and the inspection should focus on checking for compliance with this commitment to establish and use the appropriate sub-critical margin when calculating the allowed upper sub-critical limit.

RESPONSE

This section has been revised.

COMMENT 104

03.01: The definition of “favorable geometry” is confusing. Recommend substituting: “a system whose dimensions and shape are such that a nuclear criticality event can not occur with any material that can credibly be inside the equipment.” For example, a single 9-inch diameter tank constitutes favorable geometry in a facility that does not possess material enriched to more than 5 wt.% U.

RESPONSE

The definition given is common and is only intended for inspection purposes.

COMMENT 105

03.02(a)-(f): This section does not parallel the corresponding Requirements section. The guidance portion for Administrative and Operating Procedures needs to provide guidance for each of the items listed in the requirements section of this procedure. The procedure would be

improved if those items supporting “appropriate limits and controls,” “Adequate Safety Margin,” and “Limits and Controls Make Sense for ease of Operation” were grouped as sub-bullets under these main headings.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 106

03.02(d): The second sentence in this section should be deleted. This section runs counter to the “risk-informed, performance-based” regulation that the NRC is trying to implement. It leads the inspector to believe that he or she should pay closer attention to areas where more protection is provided than to those where less protection is provided to prevent an accident sequence. What exactly is a “pseudo control?” The inspector should be referred to the ISA Summary for a definition of unlikely.

RESPONSE

A definition of “pseudo control” has been added for clarity.

COMMENT 107

03.03(a)-(s): This section does not parallel the corresponding Requirements section. The guidance portion for Administrative and Operating Procedures needs to provide guidance for each of the items listed in the Requirements section of this procedure. The IP would be improved if those items supporting items (a)-(g) of the Requirements section were grouped as sub-bullets under the same main headings as listed in the requirements section.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 108

03.03(b): This paragraph leads the inspector to expect that one can identify all possible normal and abnormal states of a process. In actual practice, this cannot be done. The apparent focus on considering NCS in the event of an earthquake, tornado or flood seems misplaced. An inadvertent criticality should be of secondary consideration in the event of a major natural phenomenon.

RESPONSE

As discussed above, use of the term “all” has been limited.

COMMENT 109

03.03(d): This paragraph leads the inspector to expect that two “control systems” are present for each accident pathway. Rather than cause confusion by using “control systems” please consider using “independent barriers” for each potential accident pathway. The guidance seems to place undue emphasis on the number of controls (“...two NCS control systems...as barriers,” “...two independent controls are shown to be operative...”) versus two unlikely, concurrent and independent changes in process conditions. The overriding principle is that the operation shall be determined to be subcritical for all normal and credible abnormal conditions. The emphasis should be on maintaining subcriticality, as opposed to counting contingencies and IROFS.

RESPONSE

This is pertinent guidance and has been reworded for clarity.

COMMENT 110

03.03(e): The second to last sentence leads the inspector to expect that each time an administrative control is used, a written justification for not having an engineered control present must be available in the evaluation. This is neither required by regulation nor by the operating licenses of most licensees.

RESPONSE

This is pertinent guidance and has been reworded for clarity.

COMMENT 111

03.03(j), (k) and (n): Each establishes “safety limits” for certain parameters. Rather than list these in the procedure, the inspector should be directed to the licensee’s operating license. Some of the ‘safety margins’ listed may not be consistent with existing operating licenses.

RESPONSE

This section has been completely restructured.

COMMENT 112

03.03(l), (o), and (p): These items lead the inspector to expect certain controlled parameters are controlled by IROFS, while others are not. This is inconsistent and confusing. Why would one expect that density, for example, must be controlled by an IROFS, but enrichment control neutron absorption, and mass are not?

RESPONSE

This section has been completely restructured.

COMMENT 113

03.04(a): This section does not provide guidance on meeting some of the items listed in the corresponding Requirements section (e.g. determining that NCS limits for controlled parameters are discussed with operating management and that operating management has agreed to and are implementing the limits and controls). This section also fails to provide any guidance on assuring that the reviews confirm that initial analyses and assumptions were realistic.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 114

03.05(a): This section touches on several issues that are not directly related to sub-critical margin. For example, start up conditions for new or revised processes and the establishment of multiple levels of system controls within a facility are extraneous. This section should be re-written to provide guidance that corresponds to a re-written §02.05. Additionally, this section leads the inspector to believe that a licensee will have a multi-tier control scheme which is neither required by regulation nor by operating licenses.

RESPONSE

Requirements and Guidance sections have been completely restructured.

COMMENT 115

03.06(a): This section does not provide guidance on meeting some of the items listed in the corresponding requirements section.

RESPONSE

Requirements and Guidance sections have been completely restructured.

Procedure 8801Z – Criticality Alarm Systems**COMMENT 116**

02.01(a): The last sentence that directs that areas containing any amount of fissile material must be monitored is incorrect. It would not, however, apply to areas containing less than 750 grams of U235. Correct to be consistent with the regulations.

RESPONSE

We agree. The wording was clarified.

COMMENT 117

02.01(b): The description of system design feature requirements is inconsistent between this section and 02.04(a). The System Requirements in 02.01(b) states that "...electronic logic requires that one detector be in the alarm mode before sounding the alarm..." . However, 02.04(a) states "Verify by observation, discussion, and document review that system design features include....that electronic logic requires that two detectors be in the alarm mode before sounding the alarm...". These requirements are contradictory. In addition, the construction of these sentences requires technical editing to clarify their intent.

RESPONSE

We agree. The wording was clarified.

COMMENT 118

02.05(a): The statement: "...fissile material areas or processes are covered by at least two detectors as demonstrated by sufficiently bounding and conservative assumptions and calculations..." implies that calculations are needed to determine alarm coverage in all cases. Operations in areas that are limited to rooms of dimensions less than 100 feet and lacking any significant shielding materials are obviously covered by an alarm cluster anywhere in the room without the need for explicit calculations. Suggest deleting the phrase "and calculations."

RESPONSE

The text appropriately directs the inspector to look at supporting calculations.

COMMENT 119

03.01(c): The statement: "A criticality monitoring system shall be maintained in all areas where special nuclear materials is handled, used or stored except at the Gaseous Diffusion Plants where a criticality monitoring system must be maintained in all areas of the facility" should be re-worded to state: "A criticality monitoring system shall be maintained in areas of the facility as required by the facility's license or certificate."

RESPONSE

We agree. The wording was clarified.

COMMENT 120

03.02(c) through (d): The content of these sections is unnecessarily specific and prescriptive. Inspections should be conducted in accordance with each licensee's design basis. Suggest that these steps be deleted.

RESPONSE

The procedure has been extensively revised to remove prescription.

COMMENT 121

03.02(c), (d) and (e): These three guidance items are unnecessarily prescriptive. Modify.

RESPONSE

The procedure has been extensively revised to remove prescription.

COMMENT 122

03.02(g): Most facilities do not have the ability to reset the criticality alarm from a location outside areas that require evacuation. There are also no requirements for this capability.

RESPONSE

This refers to the EOC which licensees are required to maintain.

COMMENT 123

03.03(a): The word “immediately” in the Inspection Objective is inconsistent with **the word “promptly” in this section.**

RESPONSE

We agree. The wording was clarified.

COMMENT 124

03.03(b): The sentence at the end of this section regarding the set-point of the detectors is too specific and should be left to each licensee’s license or certificate. Similarly, in 03.03©) the “one-half second” response time is too specific and should be left to each licensee’s license or certificate. Finally, the entire section 03.05 on Sensitivity should be deleted and left to what is specified in each licensee’s license or certificate.

RESPONSE

The procedure has been extensively revised to remove prescription.

COMMENT 125

03.04(e) and (f): Should accommodate the fact that the components of the alarm system will be designed and maintained as described in a licensee’s license or certificate. The ability of the components to withstand damage in case of fire, explosion, corrosive atmosphere, earthquake or other extreme conditions will be necessitated by the specific accident analysis performed for that operation or area. Design and installation of the system should (not shall) be such as to resist earthquake damage. This is consistent with the ANSI standard (ANSI/ANS-8.3).

RESPONSE

The procedure has been extensively revised to remove prescription.

COMMENT 126

03.05(c): Should not the unit be “mrad/h” rather than rad/h?

RESPONSE

It is indeed rad/h but has been eliminated as prescriptive and, apparently, confusing.

88020 Operational Safety**GENERAL COMMENT 127**

This should be the most important IP for the NRC. Regrettably, most of IP 88020 is redundant, duplicates what is presented in other IPs, and seems to be more compliance-based than risk-informed (e.g. focus on housekeeping, following procedures). Industry recommends that IP 88020 be significantly revised to strongly focus on the verification and validation of established safety programs (Attachment 2).

RESPONSE

The procedure has been extensively revised based on comments received. The major changes were:

- removed minor internal duplication within the procedure, especially regarding operating procedure implementation
- clarified that reviews of training, management measures, ongoing mods, maintenance and surveillance, etc. are implementation of these as part of operations, not a programmatic look
- addressed control room observations
- addressed operator work-arounds
- addressed operations review on all operating shifts
- addressed attending the plan-of-the-day meeting

The comment regarding redundancy may be explained as follows. IP 88005, *Management Organization and Controls*, IP 88010, *Operator Training/Retraining*, and IP 88025, *Maintenance and Surveillance of Safety Controls* are programmatic orientated inspection procedures. IP 88020 is operationally orientated and reviews the implementation and understanding in the field by the operating personnel. The procedure was reviewed for redundancies and some minor instances were removed.

Specific comments are addressed below:

COMMENT 128

01.03: This inspection activity (focus on IROFS) duplicates the effort of IP88005 (Attachment 2).

RESPONSE

See redundancy explanation above.

COMMENT 129

02.01(b)(3): The terms Safety Limit and Limiting Condition for Operation (LCO) are used in this IP in a manner consistent with the regulations in 10 CFR 50.36. Fuel cycle facilities are generally licensed under 10 CFR 70 and there are no regulatory requirements for LCOs. There may be safety limits (lower case), but the language in the inspection procedure may need to be revised to remove suggestions that there is any requirement for LCOs and focus on process safety limits identified in the ISA Summary and any license conditions imposed on facility operation. Revise (Attachment 2).

RESPONSE

The term LCO is used at some fuel cycle facilities and so the terminology will remain. The inspectors encounter a variety of terms at the various fuel cycle facilities and employ them from our procedures as appropriate to the licensee or certificate holder.

COMMENT 130

02.02(a): The statement to base the inspection on "...plant activities..." is inconsistent with the guidance elsewhere in the IP that directs inspectors' attention to safety-significant operations. Revise (Attachment 2).

RESPONSE

The selections of activities to be reviewed by the inspectors will be focused on safety-significant operations. The inspectors will also inspect regulatory requirements and operations beyond those in 70.61

COMMENT 131

02.02(b): This duplicates what is performed in the management measure IP88005. Revise. Add the term IROFS when speaking of safety controls, for these were designated as part of the ISA effort and are associated with higher-risk operations (Attachment 2).

RESPONSE

See response to General Comment above. Clarification of terms has been added to the procedure.

COMMENT 132

02.02(c)(4): This duplicates what is performed in the training IP88010. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 133

02.03(d): This duplicates what is performed in the training IP88010. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 134

02.03(e): This duplicates what is performed in the incident reporting section of IP88005. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 135

02.04: This duplicates what is performed in the corrective action section of IP88005. Revise (Attachment 2).

RESPONSE

This section has been revised to avoid overlapping review. Also, see response to General Comment above.

COMMENT 136

03.01(a)(4): the term "...infrequently performed tests or evolutions (IPTEs)..." is an undefined term for fuel cycle licensees. Add a definition for clarity (Attachment 2).

RESPONSE

The acronym has been deleted but the self-explanatory phrase has been retained.

COMMENT 137

03.01(b)(1)¶1 and 2: This duplicates what is performed in the operator training IP88010. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 138

03.01(b)(2): This duplicates what is performed in the facility change process IP880XX. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 139

03.01(b)(3): See identical comment for §02.01(b)(3) above regarding the use of the terms Safety Limit and Limiting Condition for Operation (LCO) (Attachment 2).

RESPONSE

See response to comment above.

COMMENT 140

03.02: For consistency with §02 terminology, the title of this section should read “Observe Implementation of ISA, IROFS, SAR and NCSEs” (Attachment 2).

RESPONSE

We agree. The title was changed.

COMMENT 141

03.02(b)¶1: This duplicates what is performed in the management measure section of IP88005. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 142

03.02(c)¶1: Add the term IROFS to the list of safety controls (Attachment 2).

RESPONSE

Comment accepted.

COMMENT 143

03.02(d): This duplicates what is performed in the maintenance IP88005 (sic IP88025). Revise (Attachment 2).

RESPONSE

We agree. This section was deleted.

COMMENT 144

03.03(b): This duplicates what is performed in the operator training IP88010. Revise (Attachment 2).

RESPONSE

See response to General Comment above.

COMMENT 145

03.04(a): This duplicates what is performed in the Corrective Action Program section of IP88005. Revise (Attachment 2).

RESPONSE

This section has been revised to avoid overlapping review. Also, see response to General Comment above.

88025 Maintenance and Surveillance of Safety Controls**COMMENT 146 SUMMARY**

As discussed at the Atlanta workshop, IP88025 requires major revisions and the NRC has agreed to prepare such revisions. The industry will await issuance of the revised IP before spending more time commenting on their appropriateness. IP88025 is so flawed and inapplicable to fuel cycle facilities that editorial and technical corrections will be insufficient to remedy the draft IP's deficiencies. The authors who will draft the replacement IP should first acquire a sound understanding of the Subpart H requirements before attempting to draft the IP. A complete re-write is in order (Attachment 2).

RESPONSE

IP 88025 submitted for your review was a compilation and revision of the inspection procedures used for the fuel cycle inspection and chemical safety inspection program at fuel cycle facilities for the past several years. Based on your comments at the Atlanta workshop, the procedure has been rewritten. See the RESPONSE to COMMENT 127 above for a clarification of the maintenance and surveillance sections in IP 88020 and 88025.

88035 Radioactive Waste Management**COMMENT 147**

02.02, paragraph 1: Suggest addition of the following words at the end of the text: "...Appendix G to 10 CFR Part 20], if any, since the prior IP88035 inspection." (Attachment 2).

RESPONSE

We agree. The wording was changed.

88045 Environmental Protection and Effluent Control**COMMENT 148**

01.01: Replace "report" by "reporting" to improve the English expression (Attachment 2).

RESPONSE

We agree. The wording was changed.

COMMENT 149

01.02: The intention in this section is clear, but the English expression should be improved to better convey the intent of this objective (Attachment 2).

RESPONSE

We agree. Section rewritten.

COMMENT 150

01.03: This objective seems redundant for the inspection. Delete (Attachment 2).

RESPONSE

We agree. It was deleted.

COMMENT 151

02 and 03: There is lacking a correspondence between the inspection Requirements of 02.01, 02.02 and 02.03 and corresponding Guidance. (In contrast, good alignment exists between the requirements and guidance for topics introduced in 02.04 and 02.05.) Such better alignment will assist an inspector in addressing specific topics (Attachment 2).

RESPONSE

03 provides additional guidance to the 02 requirements section. The type of guidance provided will vary as the needs and subject matter require. Sometimes there is no additional guidance provided as the requirement stands by itself. Sometimes additional information is inserted of a general informative nature, and other times the guidance is very specific to the requirement. The inspectors have reviewed these procedures and feel their purpose is served by the present guidance.

COMMENT 152

03.01, line 5: Changes to the program may be implemented to maintain, but not necessarily “enhance” its effectiveness. Recommend revising to read: “...that the changes have maintained, or enhanced, the program...” (Attachment 2).

RESPONSE

We agree. Wording inserted.

COMMENT 153

03.02 paragraph 4: Last line, insert a comma after “sample” so as to read: “...magnitude different from a licensee sample, yet both could...” (Attachment 2).

RESPONSE

We agree. The comma was inserted.

COMMENT 154

03.03, page 5: Insert a period and create a new sentence so as to read: “...and counting and evaluation of results. Discuss...” (Attachment 2).

RESPONSE

We agree. The wording was changed.

COMMENT 155

03.03(a) paragraph 5 (base on page 5): It is quite unreasonable to expect an operator to be conversant with how the set points are established (Attachment 2).

RESPONSE

The sentence said “operator/technicians.” We added the word “responsible” to read “responsible operator/technicians.”

COMMENT 156

03.03(b) paragraph 3, last sentence: This is totally incorrect. Biasing to the right of zero will indicate that releases are occurring, when none are, in fact, happening. The author(s) of this IP should consult NCRP Report #58, §7.1.3 for an explanation of how these negative numbers are to be handled. See also NUREG-1575, §2.3.5, section 1 for further guidance (Attachment 2).

RESPONSE

Following review, we have rewritten the section.

COMMENT 157

03.04 and 03.05: For consistency with the requirements of 02, the title of this section should be “Radioactive Liquid/Airborne Effluents” (Attachment 2).

RESPONSE

We agree. The title was changed.

COMMENT 158

03.06, line 8: Suggest addition of a couple of words so as to read: “...associated tasks (sic tasks) and through interviews with employees...” (Attachment 2).

RESPONSE

We agree. The wording was changed.

88050 Emergency Preparedness**COMMENT 159**

Section 02.01(a): For clarity and to emphasize that the IP88050 inspections are to be conducted against regulations and license commitments, recommend changing “NRC requirements” – which could erroneously be interpreted to include various guidance documents to read “regulations” (Attachment 2).

RESPONSE

No change deemed necessary. NRC inspector training emphasizes that NUREGs and Regulatory Guides are not considered requirements. It should be clearly understood that guidance documents are exactly that "guidance."

COMMENT 160

Section 02.01(a) and (e): These two requirements appear to be very similar. Consolidate? (Attachment 2)

RESPONSE

Items (a) and (e) address two different categories of change. Item (a) is specific to human/equipment resources, and item (e) deals with the site physical and operational changes. The fact that both items deal with site changes could be the grounds for consolidation.

SUGGESTION

If consolidated, consider the following statement as a replacement "Determine if changes made to facilities, equipment, organization, agreement letters, emergency response training, etc. since the last inspection meet license commitments and NRC requirements."

COMMENT 161

Section 02.01(e): Insert commas as follows: "...and, if so, the regulate has..." (Attachment 2).

RESPONSE

We agree. Revised statement would read "Determine whether the licensee/certificatee has evaluated any significant facility additions and/or modifications for their impacts on the emergency preparedness program and, if so, has made appropriate revisions to the Plan."

COMMENT 162

Section 02.02(a)(1) for consistency in terminology, insert "Emergency" before the word "Plan" (Attachment 2).

RESPONSE

We agree. Revised statement would read "Determine whether the implementing procedures have been reviewed and approved as specified in the Emergency Plan."

COMMENT 163

Section 02.02(c): The second sentence is incorrect. Most fuel cycle facilities do not have the ability to silence a criticality alarm from an external plant location. There are no regulatory requirements to silence an alarm from an external location. Revise this inspection requirement so as to not create new, and unjustified, licensee expectations (Attachment 2).

RESPONSE

The statement “external plant location” may have created confusion. In this context, the term “external location” is defined as a location remote to the area(s) to be evacuated. Therefore, with the exception of gaseous diffusion plants, fuel facilities do have the capability to manually silence the criticality alarms from a location remote to the area(s) of potential criticality accidents.

COMMENT 164

Section 02.02(d): This requirement demands that postings be made, which may not be applicable to all licensees. Appropriate postings or other means (e.g. training, procedures) should be in place to convey the restrictions (Attachment 2).

RESPONSE

We agree. Revised statement would read “Determine whether for areas in which firefighting restrictions exist because of criticality safety concerns, appropriate postings, training, and or procedures are in place that clearly and concisely portray such restrictions.

COMMENT 165

Section 02.02(d): This requirement is far too broad. Changes to the Emergency Plan need only be coordinated with off-site agencies if they impact the services to be provided by the off-site agencies. Many changes to the Emergency Plan may never affect the off-site services. Insert some words to clarify this requirement: “...determine whether any changes to the emergency preparedness program that may impact the services to be provided by off-site support groups and agencies have been properly coordinated with them...” (Attachment 2).

RESPONSE

The reference was incorrect. This comment appears to be specific to Section 02.01(d). We agree. The revised statement would read “Determine whether any changes to the emergency preparedness program, involving offsite response organizations expected to respond, have been properly coordinated with the appropriate offsite support organization(s).”

COMMENT 166

Section 02.04(e): The IP exhibits many grammatical errors that require attention. There are many double negatives and examples of confusing sentence structure that must be corrected. For example, §02.04(e) is very convoluted: “...Determine whether by random selection, the

agencies for which agreements are in effect are periodically contacted by the regulatee for training and taking part in drills or otherwise reviewing the plans in the agreements so that the agencies are familiar with their respective roles in emergency responses..." (Attachment 2) .

RESPONSE

The reference in the NEI letter incorrectly refers to 2.04(e). The correct reference should be 2.04 (b). The sentence was restructured for clarity.

COMMENT 167

Section 02.05(a): Are all licensees bound by the requirement of quarterly communication checks? If not, then modify to agree with license conditions or commitments (Attachment 2).

RESPONSE

No change deemed necessary.

COMMENT 168

Section 02.05(d): For consistency with the rest of the IP, revise this requirement to read "...past operational events since the last IP88050 inspection that required..." (Attachment 2).

RESPONSE

No change deemed necessary. The inspector(s) performing the audit recognizes that the inspection encompasses the activity since the last audit of this program area.

COMMENT 169

Section 02.06(a): Correct the English in the last sentence ("...survey instruments, which is operational and within calibrated."). It is unintelligible (Attachment 2).

RESPONSE

We agree. The operational readiness of survey instruments would be determined based on the equipment responding to a source check and appropriate calibration in accordance with the calibration procedure requirements.

SUGGESTION

Verify that the kits contain the appropriate quantity of dosimeters and survey instruments, and the equipment was operational and calibrated.

COMMENT 170

Section 03.00: In the first line of "General Guidance" remove the "s" from "describes" (Attachment 2).

RESPONSE

We agree. The word was changed.

COMMENT 171

Section 03.01: All of the requested investigations are contained in the ISA. The inspector should be directed to examine changes in the ISA that would have been made in support of the changes. With respect to hazardous materials, NRC jurisdiction only applies to hazardous chemicals produced from licensed material. Modify to be consistent with 10 CFR 70.64(a)(5) (Attachment 2).

RESPONSE

No change deemed necessary. This section provides guidance for reviewing global Plan changes. The inspector's consultation with NRC regional and/or headquarters experts would include if necessary the hazard analysis review.

COMMENT 172

Section 03.02(a): This guidance seems to be unnecessary and rather trivial in terms of importance as an inspection component (Attachment 2).

RESPONSE

No change deemed necessary. This guidance was provided solely for the benefit of the inspectors performing the assessment to ensure consistency in how the program review is done.

COMMENT 173

Section 03.02(c): Place a period after "locations" (Attachment 2).

RESPONSE

The correction was made.

COMMENT 174

Section 03.02(e): This section is confusing and unclear as to its intent. The inspector should be directed to examine the ISA where all of the suggested analyses will already have been completed. Re-write. With respect to hazardous materials, NRC jurisdiction only applies to hazardous chemicals produced from licensed material. Modify to be consistent with 10 CFR 70.64(a)(5) (Attachment 2).

RESPONSE

No change deemed necessary. This guidance was provided solely for the benefit of the NRC inspectors.

COMMENT 175

Section 03.02: In the Controlled Reentry paragraph, delete the guidance about the control of criticality alarms at external plant areas. [See comment above for §02.02(c)]. The meaning of the phrase “recovery from a limit violation” is unclear. To what does this refer? Clarification needed (Attachment 2).

RESPONSE

Comments regarding the Controlled Reentry paragraph are addressed above in Section 02.02(c).

COMMENT 176

Section 03.04: Last sentence should read the inspector should simply consult the ISA (Attachment 2).

RESPONSE

No change deemed necessary.

COMMENT 177

Section 03.05: For consistency with the language used in §02.05, the title of this guidance section should read: “Tests, Drills and Exercises” (Attachment 2).

RESPONSE

Comments accepted and section will be revised to state “Tests, Drills and Exercises.”

88051 Evaluation of Exercises and Drills**COMMENT 178**

Section 01.02: Delete the word “simulated” for the procedures also apply to real events (Attachment 2).

RESPONSE

We recognize the procedures could be used during actual events. However, no change is deemed necessary. The Plan implementation evaluation is based on observations resulting from simulated emergencies which contain numerous artificialities. The results from the simulated events are used to make enhancements to the Plan and procedures for use in responding to actual emergencies.

COMMENT 179

Section 02.02: Recommend one instance where the risk-informed nature of Part 70 regulations could be considered, and that is to focus inspectors on the most risk-significant emergency events. In the second sentence insert words so as to read: "...Determine whether the exercise will use the most risk-significant accident scenarios postulated in the ISA for the site..." (Attachment 2).

RESPONSE

No change is deemed necessary. If the Emergency Plan was written in accordance with 10 CFR 70.22, Regulatory Guide 3.67, and guidance contained in Chapter 8 of NUREG-1520, each type of accident identified in the ISA Summary for which protective actions may be needed should be described in the Emergency Plan. Therefore, the most risk significant accident scenarios postulated in the ISA summary should also be the accident scenarios postulated as the most probable for the specific site.

COMMENT 180

Section 02.06(e): All other items in this section start with nouns. Delete the words "decide the" (Attachment 2).

RESPONSE

We agree. The words were deleted.

SUGGESTION

Change "Decide the appropriate protective action recommendations" to "Protective recommendations."

COMMENT 181

Section 03.03(d): Believe "IC" should read "ICP" (Attachment 2).

RESPONSE

We agree. The change was inserted.

COMMENT 182

Section 03.04(c): The last phrase added to this item (c) does not constitute a sentence. Re-write in a manner that parallels the second sentence in §03.05(b) (Attachment 2).

RESPONSE

No change is necessary.

COMMENT 183

Section 03.05(d): Replace “between” with “among.” The former word addresses comparison on two items; the latter word addresses comparison amongst more than two items (Attachment 2).

RESPONSE

We agree. The change was made.

COMMENT 184

Section 03.09(e): Suggest inserting the word “member” after “Team” for clarity (Attachment 2).

RESPONSE

This guidance is understood by inspection staff and therefore no change is deemed necessary.

Procedure Changes

Category I and III Fuel Cycle Facilities except Fuel Assembly Only Facility:

880AA *Event Followup* - New procedure

880BB *Radiation Protection* - Replaces 83822. Minor changes. Places use in MC 2600 only. 83822 will remain in MC 2800.

880XX *Configuration Management Programmatic Review* - New procedure. Incorporates the configuration management review from 88020 and 88063. To be used as needed if identified for review during an 88020 inspection.

88005 *Management Organization and Controls* - Management section from 88020, 88058, 88059, 88065, 88066 added, and implementing Part 70.62 management measures

88010 *Operator Training/Retraining* - Added training sections from 88015, 88020 and 88061.

88020 *Operational Safety* - Transferred sections on management, training, maintenance and surveillance, configuration control and design change, and emergency preparedness to those specific procedures.

Added requirements from 88056, 88057, 88058, 88059.

Added requirements for the implementation of Part 70.

88025 *Maintenance and Surveillance of Safety Controls* - Added maintenance and surveillance testing from 88015, 88020, 88060 and 88062, and additional safety considerations required by new Part 70.

88035 *Radioactive Waste Management*; and 88045 *Environmental Protection* - Procedure requirements for 88035 and 88045 were rearranged.

84850 *Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61* and 84900 *Low-Level Radioactive Waste Storage*; were deleted from MC 2600 and incorporated into 88035 and 88045.

88050 *Emergency Preparedness*, 88051 *Evaluation of Exercises and Drills* -

The inspection effort previously in 88050 was separated out and placed in a new procedure 88051. 88064 and sections of 88015 and 88020 were incorporated into 88050 to reduce duplicate inspection efforts

88054 *Fire Protection (Triennial)*. Not completed.

88055 *Fire Protection (Annual)*.

88056-66 These former chemical safety procedures were deleted: Process Safety Information, Hazard Identification & Assessment, Standard Operating Procedures, Site-wide Safety Procedures, Detection and Monitoring, Training, Maintenance & Inspection, Management of Change, Emergency Procedures, Incident Investigation, Audit and Inspection. The contents were distributed to 88005, 88010, 88020, 88025, 88050, and some to 880XX.

8801X *NCS Program* - Derived from previous IP 88015

8801Y *Safety Evaluations and Analyses* - Derived from previous IP 88015

8801Z *Criticality Alarm Systems* - Some information from previous IP 88015 but essentially is completely new.