Proposed Regulatory Treatment of 10 CFR 50.55(e)

Summary:

Title 10 of the *Code of Federal Regulations* (10 CFR) 50.55(e) requires holders of construction permits, manufacturing licenses, and combined licenses (COL) prior to the Section 52.103(g) finding and their contractors to evaluate deviations and failures to comply and to report to the Nuclear Regulatory Commission (NRC) those deviations, that on the basis of an evaluation, are determined to constitute a substantial safety hazard (defect); failures to comply that are associated with a substantial safety hazard; and significant programmatic breakdowns in the 10 CFR 50 Appendix B quality assurance program that could have led to the production of a defect. Specifically, the rule states in part,

> "(e)(3) *Procedures*. Each individual, corporation, partnership, or other entity holding a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR part 52 must adopt appropriate procedures to—
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> (i) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (e)(3)(ii) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.
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> (ii) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in paragraph (e)(4)(v) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.
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> (iii) Ensure that a director or responsible officer of the holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR Part 52 is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (e)(3)(i) or (e)(3)(ii) of this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity—
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> (A) Fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission, relating to a substantial safety hazard;
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> (B) Contains a defect; or
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> (C) Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of appendix B to 10 CFR Part 50 which could have produced a defect in a basic component. These breakdowns in the quality

assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture."

Per the NRC's draft regulatory basis document, *Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance,"* December 2012, Revision 0, NRC staff states, "The requirements of 10 CFR 50.55(e) are largely redundant with Part 21." Indeed, 10 CFR 50.55(e) requirements are nearly identical with the requirements of 10 CFR Part 21 with the exception of the third reporting clause, 10 CFR 50.55(e)(3)(iii)(C), related to significant breakdowns in the quality assurance program.

Also, under 10 CFR Part 21, all entities that are required to meet the requirements of Part 21 are required to report the existence of defects and failures to comply associated with a substantial safety hazard directly to the NRC while under 10 CFR 50.55(e), only the holder of the construction permit, including a COL holder prior to the Section 52.103(g) finding, is required to notify the NRC of reportable conditions.

Part 21 applies to applicants for Early Site Permits and COLs and remains in effect during the construction and operations phases of a combined license,[1] but 10 CFR 50.55(e) applies to COL holders from the issuance of the license until the 10 CFR 52.103(g) determination by the NRC.[2] Thus, the responsible entities and applicable time periods addressed by Part 21 fully encompass those in 10 CFR 50.55(e).

This paper provides the basis for concluding that the safety benefits provided by 10 CFR 50.55(e) no longer justify the regulatory costs of implementing the essentially duplicative rule. The paper discusses the following observations which lead to this conclusion:

- The requirements of 10 CFR 50.55(e) and 10 CFR Part 21 are essentially identical.
- The significant break down in the quality assurance program clause of 10 CFR 50.55(e) is ambiguous requiring licensees to devote an inordinate amount of time and resources to associated activities, and diverting licensee and vendor resources from more important nuclear safety issues with no commensurate increase in the protection of public health and safety.
- The increased level and effectiveness of NRC oversight during construction make the significant break down in the quality assurance program clause of 10 CFR 50.55(e) unnecessary.
- The underlying purpose of 10 CFR 50.55(e) is fully achieved through the implementation of 10 CFR Part 21 and other regulatory processes. Therefore, 10 CFR 50.55(e) should be deleted and can be deleted without any reduction to the health and safety of the public.

[1] 10 CFR 21.2(a)
[2] 10 CFR 50.55

Discussion:

10 CFR 50.55(e) History:

Section 50.55(e) of 10 CFR was promulgated in 1972.[3] According to the Commission statements of consideration, 10 CFR 50.55(e) was promulgated because the Atomic Energy Commission (AEC) determined that 10 CFR 50, Appendix B, Criterion XVI, required significant issues to be reported to the AEC:

> "Among other requirements in the Commission's "Quality Assurance Criteria for Nuclear Power Plants," Appendix B to 10 CFR Part 50, Criterion XVI "Corrective Action" requires that significant conditions adverse to quality be reported to appropriate levels of licensee management. The following amendment to section 50.55 of 10 CFR Part 50 requires the holder of a construction permit for a nuclear power plant to report the more important of these deficiencies to the Commission."[4]

The original 1972 10 CFR 50.55(e) rule required that four categories of deficiencies be promptly reported to the Commission. Specifically, the rule stated in part.

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i. "A significant breakdown in any portion of the quality assurance program conducted in accordance with the requirements of Appendix B, or

ii. A significant deficiency in final design as approved and released for construction such that the design does not conform to the criteria and bases stated in the safety analysis report or construction permit, or

iii. A significant deficiency in construction of or significant damage to a structure, system, or component which will require extensive evaluation, extensive redesign, or extensive repair to meet the criteria and bases stated in the safety analysis report or construction permit or to otherwise establish the adequacy of the structure, system, or component to perform its intended safety function, or

iv. A significant deviation from performance specifications which will require extensive evaluation, extensive redesign, or extensive repair to establish the adequacy of a structure, system, or component to meet the criteria and bases stated in the safety analysis report or construction permit or to otherwise establish the adequacy of the structure, system, or component to perform its intended safety function."

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Following the issuance of 10 CFR Part 21 in 1977, nuclear plants under construction were required to meet the reporting requirements of both 10 CFR 50.55(e) and Part 21. The NRC noted that many issues were reported twice – once under 10 CFR 50.55(e) and again under Part 21.[5] Based on this observation, the NRC revised 10 CFR 50.55(e) and Part 21 in 1991 in an effort to eliminate duplicate reporting. Although 10 CFR 50.55(e) was further revised in 2007 to incorporate Part 52 into the rule, the basic requirements of the rule have remained unchanged since 1991.

[3] 37 FR 06459 March 30, 1972
[4] 37 FR 06460 March 30, 1972
[5] 56 FR 36082 July 31, 1991

Similarity in Basic Requirements of 10 CFR Part 21 and 10 CFR 50.55(e):

Section 50.55(e) of 10 CFR requirements are nearly identical with the requirements of 10 CFR Part 21 with the exception of the third reporting clause, 10 CFR 50.55(e)(3)(iii)(C), related to significant breakdowns in the quality assurance program. Both Part 21 and 10 CFR 50.55(e) require that deviations and failures to comply be evaluated and if the deviation rises to the level of a defect or if the failure to comply is determined to be associated with a substantial safety hazard, the condition be reported to the NRC. Part 21 contains a set of definitions that are to be used when implementing the regulation and 10 CFR 50.55(e) relies on the Part 21 definitions when implementing 10 CFR 50.55(e). Both regulations contain identical time lines for performing evaluations, and if necessary, making reports to the NRC. The method by which these reports are to be made to the NRC is identical, and the required content of the reports is essentially identical. Furthermore, both Part 21 and 10 CFR 50.55(e) require that the provisions be imposed on suppliers through purchase documents as appropriate.

The primary difference between the regulations is that 10 CFR 50.55(e) requires that that significant programmatic breakdowns in the quality assurance program that could produce a defect be reported to the NRC. As described later in this paper, the same level of NRC oversight on this issue is achieved through other regulatory processes. Other differences between the regulations include the required reporting entity. The reporting entity for Part 21 is any entity to which the regulation applies while for 10 CFR 50.55(e) only the holder of the construction permit or combined license makes the report. Thus, Part 21 has the benefit of direct responsibility and accountability for reports. Inconsequential differences exist in the records retention requirements and minor differences exist in the details of the reporting requirements. 10 CFR 50.55(e) requires an additional five years of record retention for completed evaluations of deviations and failures to comply because construction is expected to take approximately ten years. Reports made under 10 CFR 50.55(e) are to include information related to reactors manufactured under Part 52 if applicable and Part 21 requires notification of to whom an early site permit was transferred if applicable.

Part 21 applies to applicants for Early Site Permits and Combined Licenses and remains in effect during the construction and operations phases of a combined license.[6] Section 50.55(e) of 10 CFR applies from the issuance of a combined license or a construction permit through the 10 CFR 52.103(g) finding for plants constructed under Part 52 or the issuance of an operating license for plants constructed under 10 CFR Part 50.[7]

Nuclear safety will be preserved when 10 CFR 50.55(e) is deleted because: Part 21 and 10 CFR 50.55(e) are similar, important issues related to nuclear safety would continue to be reported to the NRC, and Part 21 requirements are imposed during the period in which 10 CFR 50.55(e) requirements are imposed.

The significant break down in the quality assurance program clause of 10 CFR 50.55(e) is ambiguous:

Section 50.55(e)(3)(iii)(C) of 10 CFR requires that if the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity, “undergoes

[6] 10 CFR 21.2(a)
[7] 10 CFR 50.55

any significant breakdown in any portion of the quality assurance program conducted under the requirements of appendix B to 10 CFR Part 50 which could have produced a defect in a basic component," the condition be reported to the NRC, "whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture." Conversely, the statements of consideration for the 1991[8] amendments to Part 21 and 10 CFR 50.55(e) noted the following:

> "Such breakdowns in the quality assurance programs may not actually result in a defect being created in a basic component. However, such breakdowns may be severe enough or extensive enough to indicate that the overall program is deficient to the extent that the program itself represents a defect. In such cases, these programmatic breakdowns are reportable as defects because they could clearly have produced substantial safety hazards."

Implementation of the requirement to report such programmatic deficiencies is difficult because of the use of the term defect. Part 21 contains a specific definition of defect (also applicable to 10 CFR 50.55(e)), and the above statement appears to expand the definition of "defect." Furthermore, NUREG-0302 Rev. 1, page 7, contains the following statement in regards to quality assurance programs:

> "How does Part 21 interact with an approved Quality Assurance Program which is the established mechanism to control defects and deviations?
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> Response:
> A quality assurance program, for example, in accordance with Appendix B to Part 50, should be the mechanism whereby assurance is provided that deviations and non-compliances do not occur and, where they do occur, they are detected and properly dispositioned…"

As a result of this apparent ambiguity in the regulatory guidance, implementation of the quality assurance clause of 10 CFR 50.55(e) is complicated by the above conflicting statements in regards to "defect." Even though NRC licensees and other affected entities have invested significant resources in developing and implementing processes that are intended to meet the requirements of 10 CFR 50.55(e), the NRC continues to identify apparent non-compliances with implementation of the regulation. In our view, it is the responsibility of the NRC to correct this confusion created by the agency's own regulatory guidance.

Even if one adopts the language from the original regulation which required the reporting of significant programmatic breakdowns in the quality assurance program, the degree of breakdown that represents a reportable condition is difficult to ascertain. This is because of the complexity of the quality assurance program which involves 18 separate, but overlapping criteria that are designed to work in conjunction with each other to prevent the creation of or detect defects. Given the NRC's desire that trivial matters not be reported,[9] NRC licensees and other affected entities continue to find it very difficult to find a set of conditions that should be reported under the regulation. Furthermore, as described in the next section of this paper, the same level of NRC oversight on this issue is achieved through other regulatory processes.

[8] 56 FR 36082 July 31, 1991
[9] 37 FR 06459 March 30, 1972

Recent inspection activities have established that construction inspectors consider the most significant reportability attribute of significant QA program breakdowns to be "could have produced a defect in a basic component," with particular emphasis on "did" the breakdown produce a defect. If the breakdown produces a defect, that is clearly a reportable condition under both Part 21 and 50.55(e). If it did not produce an identifiable defect, the safety significance is substantially reduced. Also, the QA breakdown at that point would have been identified and appropriate corrective actions (including work stoppages, as necessary) invoked to prevent in the creation of any defects. Therefore, the attempt to resolve the hypothetical criterion of "could have produced a defect" is not needed.

The NRC has recognized this confusion and difficulty associated with implementation of the rule. As noted in the NRC's draft regulatory basis document, *Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance,"* December 2012, Revision 0, the requirements of 10 CFR 50.55(e) need not be applied to suppliers of basic components. An excerpt is provided below for clarification:

> "…The requirements of 10 CFR 50.55(e) are largely redundant with Part 21. The existence of two near-identical reporting regulations can cause confusion. The NRC staff has noted that combined operating license applicants, licensees, and their vendors have been challenged by the applicability of 10 CFR 50.55(e) through the supply chain. Specifically, the staff has noted that the regulations and associated Statements of Consideration are unclear as to when vendors are required to report significant breakdowns in any portion of the QA program that could have produced a defect in a basic component.
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> A combined licensee recently invoked 10 CFR 50.55(e) upon its engineering procurement and construction contractor. That contractor, in turn, invoked the requirements upon the nuclear steam supply company and its other suppliers. NRC vendor inspectors have noted during inspections that the requirements of 10 CFR 50.55(e) need not apply to vendors for regulatory compliance. However, those vendors still may be under contractual obligations. The inspectors have noted that suppliers of new reactor basic components should have requirements equal to those of suppliers to operating reactors. The staff has noted that the requirements of Part 21should capture defects and failures to comply for vendors to meet the intent of Section 206 of the Energy Reorganization Act…"

The burden of complying with the rule outweighs any regulatory safety benefit of the rule because of the above identified difficulties in providing for effective implementation of the rule and the significant resources devoted to this effort.

Increased level and effectiveness of NRC oversight during construction reduces the need for 10 CFR 50.55(e):

In the statements for consideration[10] for the original issuance of 10 CFR 50.55(e), the AEC responded to several comments regarding the necessity of the rule itself. One commenter had observed, "…the rule itself is unnecessary, since existing quality assurance programs require maintenance of records of the deficiencies and these are available to the Commission."

[10] 37 FR 06459 March 30, 1972

With respect to that comment, the AEC responded, "the Commission believes that the rule is necessary, so that the AEC staff will have prompt notification of the deficiency and timely information on which to base an evaluation of the potential safety consequences of the deficiency and determine if further regulatory action is required…"

Based on the above, the rule is intended to inform the NRC of deficiencies in support of NRC needs to evaluate issues and take appropriate regulatory action. However, the requirements of Part 21 satisfy three of the four reporting criteria of the original 10 CFR 50.55(e). Therefore, the remaining underlying purpose of 10 CFR 50.55(e) is to inform the NRC of significant programmatic breakdowns in construction quality assurance programs so that the NRC can take appropriate regulatory action.

The NRC currently is using the Construction Reactor Oversight Process (cROP) as a systematic process for oversight of construction programs. The program is described in Inspection Manual Chapter (IMC) 2506, *Construction Reactor Oversight Process General Guidance and Basis Document*. The current oversight program resulted from assessment of the effectiveness of the NRC's construction oversight processes documented in NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress," issued May 1984.

Consequently, the NRC revised its construction oversight process and developed the Construction Inspection Program (CIP). The CIP has four phases. The first and second phases support a licensing decision for an early site permit (ESP) and the COL application. Inspections are initially performed to confirm the accuracy of data submitted to the NRC in support of safety evaluations for an ESP and COL. The third and fourth phases support construction activities and the preparations for operation. Prior to and during plant construction, off-site inspections will be conducted to review vendor activities and licensee oversight of these activities. During plant construction, on-site inspections will focus on verifying satisfactory completion of inspections, tests, analyses, and acceptance criteria (ITAAC), as specified in the final safety analysis report (FSAR), and also on inspecting programs for operational readiness and transition to power operations.

An important element of the CIP is the use of construction resident inspectors (CRI). The number of CRIs will depend on the amount and type of safety-related construction work going on at the site. Projects that proceed more quickly and have numerous safety-related construction activities ongoing simultaneously will warrant more CRIs than projects that proceed more slowly with few simultaneous safety-related activities.

The baseline inspection program within the CIP consists of ITAAC inspections and construction and operational program inspections. The construction program inspections (IMC 2504) include six areas for inspection as part of the construction baseline inspection program including Quality Assurance (QA) Program during Construction and Reporting of Defects. *Note that while the reporting of defects section refers to failure to comply associated with a substantial safety hazard and defects, both of these sections are silent on significant breakdowns in the quality assurance program.*

As further described in IMC 2505, "The baseline inspection program is the lowest level of required NRC inspections at each facility and is implemented at a given frequency stated in the respective [inspection procedures] IPs…As set forth in both IMC 2503 and

IMC 2504, the observation of construction activities will also include monitoring the implementation of the QA program by the licensee and its contractors to evaluate the ability to find and appropriately characterize and resolve any occurrences of conditions adverse to quality."

To systematically analyze NRC inspection data and assess licensee performance, the NRC developed the cROP which is outlined in the NRC's "Oversight Process Assessment Program Pilot Guidance and Implementation Plan."[11]

The construction assessment program within cROP (IMC 2506-12) integrates various information sources relevant to licensee safety performance, enabling NRC staff to "make objective conclusions regarding their significance, take actions based on these conclusions in a predictable manner, and effectively communicate these results to the licensees and to the public.

The following key principles were identified as having a direct effect on the assessment program design:

- Inspection results will be the input to the assessment program.
- Inspection results will have established thresholds.
- Crossing inspection thresholds will result in the NRC considering a range of actions as defined in the Construction Action Matrix.

A review system was developed that provides continuous, quarterly, mid-cycle, and end-of-cycle (annual) reviews of licensee performance data (inspection results)." This continuous oversight with numerous interactions provides NRC an ongoing window to the health of licensee quality programs.

Consequently, because of the increased level of NRC oversight, access to licensee's corrective action information, and the cROP, the NRC is completely and effectively informed of significant quality assurance issues and has the means to promptly evaluate the significance of the issue and take appropriate regulatory action. Moreover, if a quality assurance program breakdown results in a defect, the defect would be reported under Part 21. As a result, the underlying purpose of the rule is already achieved and the rule should be deleted. Furthermore, since the underlying purpose of the rule is already achieved, deletion of the rule will not result in any commensurate reduction in nuclear safety.

Conclusion:

As described above, 10 CFR 50.55(e) and Part 21 are nearly identical; the existing rule is ambiguous and difficult to implement resulting in inappropriate levels of resources devoted to its implementation which diverts licensee and vendor resources from more important nuclear safety issues; and the underlying purpose of 10 CFR 50.55(e) is achieved through the implementation of 10 CFR Part 21 and other regulatory processes. Therefore, 10 CFR 50.55(e) should be deleted as part of the Part 21 rulemaking, and this can be done without any reduction to the health and safety of the public.

[11] Accession Number ML112700583