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8/8/85

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USNRC

10 CFR 50.55(e)

Issue Date: 4/1/80

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Guidance - 10 CFR 50.55(e), Construction Deficiency Reporting

1. PURPOSE

Deficiency reporting based on the requirements of Part 50.55(e) is designed to provide the NRC staff with prompt notification and timely information of deficiencies encountered during construction of nuclear power plants. The intent of the Rule is to provide a basis for evaluation on the part of the NRC with respect to potential safety consequences of deficiencies and the need for further action by NRC.

2. DISCUSSION - GENERAL

The conditions of construction permits are contained in 10 CFR 50.55. Subpart 10 CFR 50.55(e) imposes a reporting requirement on construction permit (CP) holders to report each deficiency found in design and construction which if it were to have remain uncorrected could have adversely affected the safety of operations of the nuclear facility at any time throughout the expected lifetime of the plant. Reporting is limited to deficiencies which meet certain other requirements as discussed below.

3. RESTATEMENT OF THE REGULATION

The entire subsection of 10 CFR 50.55(e) is included here for convenience.

50.55(e)(1) If the permit is for construction of a nuclear power plant, the holder of the permit shall notify the Commission of each deficiency found in design and construction, which, were it to have remained uncorrected, could have affected adversely the safety of operations of the nuclear power plant at any time throughout the expected lifetime of the plant, and which represents:

- (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

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- 2 -

- (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.
- (2) The holder of a construction permit shall within 24 hours notify the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office of each reportable deficiency.
- (3) The holder of a construction permit shall also submit a written report on a reportable deficiency within thirty (30) days to the appropriate NRC Regional Office shown in Appendix D of Part 20 of this chapter. Copies of such report shall be sent to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The report shall include a description of the deficiency, an analysis of the safety implications and the corrective action taken, and sufficient information to permit analysis and evaluation of the deficiency and of the corrective action. If sufficient information is not available for a definitive report to be submitted within 30 days, an interim report containing all available information shall be filed, together with a statement as to when a complete report will be filed.
- (4) Remedial action may be taken both prior to and after notification of the Division of Inspection and Enforcement subject to the risk of subsequent disapproval of such action by the Commission.

4. APPLICABILITY

Subsection 10 CFR 50.55(e) applies to the CP holder and his contractors. The CP holder is responsible for reporting each deficiency in accordance with the criteria and requirements of 10 CFR 50.55(e). The regulation applies to design and construction and encompasses all of the activities inherent in design and construction even though they may be performed by agents, contractors, subcontractors or consultants. The CP holder must establish and implement a system that assures all reportable deficiencies are identified and reported and the reporting requirement must be imposed on his agents, contractors and subcontractors.

- 3 -

5. CRITERIA FOR REPORTING

a. Deficiency

- (1) must have been identified, i.e., found
- (2) related to activities conducted as authorized by a construction permit holder (design, construction or modification)
- (3) could adversely affect the safe operation of a facility if it were not corrected, i.e., it is significant
- (4) significant deficiency relates to one or more of the following:
 - (a) breakdown in QA program
 - (b) design released for construction
 - (c) damage to a structure, system or component
 - (d) construction of a structure, system, or component
 - (e) deviation from performance specifications

b. Timeliness

- (1) Initial report - within 24 hours
- (2) Written report - within 30 days (initial or final)
- (3) Supplemental written report(s) as necessary to provide all information.

c. Reporting Organization

The CP holder is responsible for implementing instructions which will provide for licensee reporting of all reportable deficiencies identified by organizations authorized by him to conduct construction phase activities.

6. CLARIFICATION OF 50.55(e) PHRASES

a. Could adversely affect

If a deficiency meets all the criteria and it could affect adversely safe operations of the facility, it is reportable. "Could" does not imply that it would absolutely adversely affect safe operations. It implies a probability that safe operations may be adversely affected if the proper conditions existed. "At any time" means that all service and accident conditions of operation must be considered.

- 4 -

The fact that a deficiency is obvious and could not possibly go uncorrected and therefore could not adversely affect safe operation does not negate the requirement to formally report the deficiency if it meets the criteria of 50.55(e).

b. Significance

To be reportable under 10 CFR 50.55(e) a deficiency must be significant. Significant is interpreted as having an effect or likely to have an effect on, or influence, the safe operation of the facility in an adverse manner.

Although "significant" is not defined in 50.55(e), it is not the intent that trivia be reported. Significance primarily pertains to operational safety and not to the cost of the corrective action. However, as indicated below, the cost to repair or redesign provides an indicator of the term "extensive." Trivial situations such as cosmetic defects are not reportable.

The test of significance includes but is not limited to safety related items/activities as discussed below.

- (1) It is important to note that the regulation does not specifically state that 50.55(e) applies only to safety related structures, systems and components although this may be inferred from the wording.

The 50.55(e) requirement applies to any structure, system or component (SSCs) if it contains a deficiency which were it to have remained uncorrected could have affected adversely the safety of operation of the facility. This includes those SSCs that; even if not classified as safety related, could cause or contribute to the degradation of integral plant safety as a result of an adverse interaction with safety related SSCs. Primary examples of this are undesirable conditions or failures in a nonsafety system, structure, or component which could impact or degrade safety systems or a safety function.

The inspector must use caution in applying 50.55(e) to nonsafety SSCs and must satisfy himself that the licensee has considered the interactions that a deficiency in a nonsafety SSC could create.

- (2) If a deficiency involves inadequate management reviews, it may be significant.

- 5 -

c. Extensive

An item is reportable if it requires extensive evaluation to determine if it is adequate to perform its intended safety function or will not impair the accomplishment of a safety function through adverse interaction.

Extensive means the expenditure of resources (time, manpower, money) to a degree disproportionate with the original design, test or construction expenditure. The inspector should use caution - this requires judgement and experience. For example, the lack of extensive evaluation may be used as a justification for not reporting. But it also may indicate an inadequate evaluation due to expense involved or a failure to consider interactions and therefore should be considered suspect.

Redesign may appear to be not extensive; the inspector should verify that all interactions and interfaces have been considered and that sufficient design margin is available.

d. Significant Breakdown in Quality Assurance

A breakdown in the QA program related to any criteria in 10 CFR 50, Appendix B, may be a reportable deficiency depending upon its significance. This applies to those design and construction activities affecting the safety of plant operations, including activities such as design verification, inspection, and auditing. For example, QA program breakdown may result from an improper identification system for safety related materials. More specifically, the implementing procedures may be incomplete or otherwise inadequate, or the execution of adequate procedures may be incomplete, improper or completely ignored. In the latter case, not following established procedures to assure that specified quality related requirements are met, for example, may constitute a breakdown in the QA program that is reportable.

Similarly, an inadequate record keeping system that makes it impossible on a broad scale to determine whether quality requirements have been met, is another example. In such a case extensive evaluation and testing may be required to establish that applicable requirements have been met.

Conversely, occasional, incomplete or otherwise inadequate records that do not indicate a significant breakdown in the QA program nor an unsafe condition are not considered reportable. For example, if during site construction, delivery times (from mixing to placing) of a few of many truckloads of concrete are not recorded as required, and it can be shown by other records that requirements important to safety have been met, the matter would not be reportable. These other records may be related concrete truck trip tickets, batch plant records or acceptable test results of concrete samples representing concrete from these trucks. The lack of complete records in this example would not lead to unsafe plant operation, nor would it constitute a significant breakdown in the QA Program.

- 6 -

e. Notification and Reporting

(1) Notification - Reportable Deficiency

10 CFR 50.55(e)(2) specifies that the CP holder shall notify the appropriate NRC Regional Office within 24 hours of each reportable deficiency. Notification means: (a) telephone report; (b) telegraphic report; and (c) verbal report

to the NRC Regional Office after becoming aware of a reportable deficiency, excluding holiday or weekend elapsed times. A notification to a NRC representative present at the CP holder's facilities does not satisfy the regulation.

The threshold for notification (not reporting) is considered to be within 24 hours after licensee (CP holder) becomes aware of the reportable deficiency (or potentially reportable deficiency as clarified below). Aware of the deficiency means that any cognizant licensee individual has knowledge of the deficiency as a result of:

- (d) observation of condition
- (e) a formal submittal by any organization involved in the design, construction, evaluations or inspection of the facility
- (f) an informal report, or allegation, by any organization or person.

(2) Notification - Potentially Reportable Deficiency

All of the reportability criteria of 50.55(e) may not be satisfied when a deficiency is initially discovered. It is not always possible for the licensee to decide promptly during an evaluation whether the identified deficiency is reportable. However, in most cases, significance can be partially satisfied, or sound judgement will indicate potential significance. In these cases, it should be considered that the deficiency is a potentially reportable deficiency, and the Regional Office should be notified. The CP holder should specify that it is a potentially reportable deficiency.

The following IE position has been established to alleviate the apparent conflict between prompt notification and necessary evaluation time for those cases where an extended period of time could lapse in completing a adequate evaluation of the identified deficiency:

Notification by telephone to the Regional Office within 24 hours after a cognizant licensee individual becomes aware of a potentially reportable deficiency is considered acceptable. A potentially reportable deficiency is considered to exist

- 7 -

when: (1) an initial prompt review of available information indicates that the problem could be significant (i.e. - partial significance is established) but, for various reasons, additional time is required to complete the evaluation; and (2) the deficiency may be considered significant, but neither a prompt review or full evaluation can be completed within 14 days due to lack of specific information.

For example, an extensive evaluation period may exist when the licensee cannot determine without testing and analysis whether the physical properties relative to the material used for a section of reactor coolant piping were met, the licensee should promptly notify the Regional Office of this matter. If the results of the above analysis indicates that the material is not acceptable, extensive evaluation and/or rework may be required. If this is the case, it is clearly a reportable deficiency. Conversely, if the analysis in the above example confirms acceptability of the material, the licensee should document these results in his records and notify the Regional Office that this deficiency was determined not to be significant based on the results of further analysis or investigation. Consequently, some matters which require notification may not, subsequently, require a written report.

In summary, the intent is to require a prompt notification in cases where a potentially reportable deficiency has been identified but the formal evaluation required to confirm whether the item is reportable can not be completed immediately.

(3) Interim Report

The CP holder may meet the 30 day written report requirement by submitting an interim report in lieu of the complete report if sufficient information is not available for a definitive report. The interim report should specify:

- (a) the potential problem and reference the notification
- (b) approach to resolution of the problem
- (c) status of proposed resolution
- (d) reasons why a final report will be delayed
- (e) projected completion of corrective action and submittal date of the complete report.

- 8 -

(4) Complete Report

The regulation requires that the CP holder submit a written report to the appropriate Regional office within 30 days after initial notification. If an interim report is submitted the final report shall be due on the date committed in the interim report. The complete report shall contain:

- (a) description of the deficiency
- (b) analysis of the safety implications. This should include an identification of interfacing systems and possible interactions.
- (c) corrective actions taken. Corrective actions should be sufficient to correct the deficiency and prevent future identical or similar occurrences. To prevent future occurrences the causes of the deficiency must be fully explored and identified.
- (d) sufficient information to permit analysis and evaluation of the deficiency and of the corrective action.

7. ENFORCEMENT

If a CP holder is aware of a reportable deficiency and it can be shown by objective evidence that he has not met the time reporting requirements, then he is in noncompliance with the reporting requirement of 50.55(e) and enforcement action should be taken.

The licensee should be encouraged to discuss "reportability" with the responsible IE inspector whenever he has a question or doubt regarding this matter. It is appropriate for the inspector to indicate his views on whether a particular matter is reportable, but the licensee should understand that the ultimate responsibility remains with the licensee, and the inspector's judgement may change during a future inspection wherein he has an opportunity to fully review the circumstances associated with the matter.

Another aspect of this Regulation related to reportability determination pertains to judgement--judgement used by the licensee in determining whether a matter is reportable. The licensee has to make a judgement based on his (or others) evaluation/analysis. If the licensee decides, on the basis of the above, that a matter is not reportable, he may have satisfied the intent of this part of the Regulation. However, the inspector can exercise his option and challenge the licensee's decision of nonreportability. A challenge may be valid if:

- . the evaluation is clearly faulty by way of omission of facts
- . engineering or other calculations are in error

- 9 -

- the evaluation is not supported by adequate records
- the evaluation has not considered interactions
- past IE experience (including that of the inspector) provide a basis as precedent for reportability
- the licensee has established a trend or pattern of habitually evaluating deficiencies as non-reportable
- evaluation is performed by a person(s) or organization without expertise in the subject.

The inspector has the right and the responsibility to examine the technical validity of the licensee evaluation and if an inappropriate or unsupported decision of nonreportability has been made by the licensee, enforcement action should be considered. Regional management should review and, when valid, determine the appropriate enforcement action to take. If there is evidence that superficial evaluations are being made to procedurally satisfy or bypass NRC requirements, strong escalated enforcement action should be considered. (MC-0800 will be changed, accordingly)

8. RELATION TO APP. B REQUIREMENTS

10 CFR 50, Appendix B, requires procedures to be established and records maintained to handle required actions relative to resolution of identified deficiencies. Procedures and records (as in (1) and (2) below) are required to assure prompt notification and adequate reporting under 50.55(e). Means to do this should be an integral part of each licensee's QA program.

(1) Implementing Procedures

Although the specific requirements of 50.55(e) are few (notify, evaluate, report), implementing procedures to assure that these requirements are met should be established by the CP holder. For example, some means (such as procedures or instructions) are required to assure that deficiencies found in design and construction activities delegated by the licensee to others are handled properly and reported in a timely manner to the CP holder. The procedures should assure that the evaluation of the significance of the deficiency to the safety of plant operations is performed by a person(s) with adequate expertise in the subject and that adequate management review is provided.

(2) Records

The licensee should maintain records to demonstrate that adequate evaluation/analysis of all deficiencies was made regarding the impact on safe operations. It is appropriate for the IE inspector to inform the licensee that without such records the appropriate licensee management cannot establish whether such evaluations were made or whether the NRC requirements associated with this activity were overlooked.

- 10 -

9. RELATIONSHIP TO 10 CFR 21 REPORTING

Reporting of Defects and Noncompliances (10 CFR 21) imposes a reporting requirement on licensees and permit holders to immediately notify the Commission of defects, in basic components or the facility which could create a substantial safety hazard. There are certain situations which can result in duplicate reporting of the same defect under 50.55(e) and Part 21 requirements. Guidance that duplicate reporting is not the intent of the NRC regulations has been promulgated via NUREG-0302, Rev. 1 and in correspondence supplied to the Atomic Industrial Forum. This guidance is reproduced below:

(1) NUREG-0302 Rev. 1 Guidance

- Q. Must items reported as Significant Deficiencies (under 50.55(e)) or Reportable Occurrences (under 50.36) also be reported as required in 10 CFR 21?
- A. Duplicate reporting is not required. Care should be exercised, however, to assure "that the Commission has been adequately informed" (§21.21b) and the information specified in §21.21(b)(3) is provided should the reporting party's evaluation show that a notification is required.
- Q. How do we determine when to report a "problem" under the provisions of 50.55(e) vs the provisions of Part 21?
- A. §50.55(e) requires initial reporting in 24 hours of the time licensee or his agent first identifies a significant deficiency. A followup report is required in 30 days. If evaluation requires substantial time to complete, interim report(s) are acceptable.
- §21.21(b)(1) requires reporting within two days of when the director or responsible officer obtains information reasonably indicating a failure to comply or a defect with a written report required within five days.
- In all cases, the exercise of reasonable judgement is expected in reporting potentially reportable problems to avoid the severe penalties, which could be imposed should the problem turn out to be reportable.
- Q. 10 CFR 50.55(e), Conditions of Construction Permits, requires that the holder of a permit notify the Commission of certain designs and construction deficiencies which are also the subject of 10 CFR 21. Why has not 10 CFR 50.55(e) been deleted?

- 11 -

- A. §50.55(e) requires reporting that would not be reported under Part 21. For example, 1) significant damage to a basic component following delivery to the site is reportable under 50.55(e) and not under Part 21; and 2) a significant break down in quality assurance is reportable under 50.55(e) and not under Part 21.
- Q. Is the determination of a "defect" based on the same criteria as provided in Part 50.55(e) and/or the requirements for technical specifications for operating plants?
- A. No. In the case of the permit holder, however, a defect reportable under Part 21 would also be reportable under 10 CFR 50.55(e). In the case of the licensee some items could be reportable under Part 21 that are not reportable as LER.
- Q. For possible problems noted under 10 CFR 50.55(e) we report to the Commission "possible significant deficiencies." Will we be allowed to report "possible defects and noncompliances" under the requirements of 10 CFR Part 21?
- A. Yes, a report may be made during the evaluation before the conclusion is reached that the deviation is a defect. A report is not required, however, until 2 days after the responsible officer or director is informed of the conclusion reached as a result of the evaluation.
- Q. It appears to us that there will be more reports filed with the Commission under the requirements of 10 CFR Part 21 than under 10 CFR 50.55(e). Does the Commission have this same belief?
- A. No. The majority of items subject to reporting under 50.55(e) would not fit the definition in Part 21 for a "defect" involving a "substantial safety hazard." For those cases where both 50.55(e) and Part 21 reporting requirements may apply, it is expected that permit holders will report only under 50.55(e) as long as they include the information required by Part 21 to adequately inform the Commission.
- (2) Supplemental Guidance Supplied to Atomic Industrial Forum on Q/A 15 and 16 Under 21.21(b)(1) of NUREG 0302, Rev. 1

The regions are authorized to use the enclosed staff positions on 10 CFR Part 21 in communications with licensees. These positions were prepared in response to inquiries from AIF and supplement those of NUREG 0302, Rev. 1. In particular, until pertinent reporting regulations are amended, the staff position response to AIF should be used in answering licensee questions on how and when 50.55(e) reporting may be used in lieu of dual reporting under both 50.55(e) and Part 21.

- 12 -

When a combined 50.55(e)/Part 21 event is reported by a licensee to the regional office by telephone, the region should use §50.55(e)(3) and §21.21(b)(3) information requirements for guidance to assure that the Commission is "adequately informed." Where an event is reported under 50.55(e) and it is (subsequently) established that the event is also reportable under Part 21 the licensee should be informed that it is acceptable for the licensee to provide the information required under §21.21(b)(3) via a supplement to the initial 50.55(e) report. (From N. Moseley to Reg. Director memo of 5/8/79 forwarding 4/26/78 letter sent to AIF)

It is the staff's position that the licensee is not required to report under Part 21 an occurrence that falls within the scope of either Part 21 or 50.55(e) or Reg. Guide 1.16 if that occurrence is reported in accordance with 50.55(e) or Reg. Guide 1.16 requirements. In such cases, it is also the staff's position that the time requirements (oral, 24 hours under 50.55(e) and R.G. 1.16) of the reporting method used would be controlling and, for the licensee, the Part 21 reporting times would not be applicable. (Does not change prior staff position relative to information (21.21(b)(3)) requirements)

However, a director or responsible officer of a non-licensee organization upon receiving information of a reportable defect would be subject to Part 21 reporting time requirements unless he has actual knowledge the Commission has been adequately informed. Therefore, in those cases where a non-licensee has provided the licensee, or licensees (i.e., the defect is generic in nature) with the reportable information and that information is in fact reported by the licensee(s), the non-licensee is not required to duplicate the reporting.

In this instance it is also the staff's position that the non-licensee must have actual knowledge that the reporting was executed prior to expiration of applicable Part 21 reporting time requirements before he would be relieved of reporting the defect.

It should also be noted that non-licensees are not relieved of reporting until the Commission is "adequately informed." Your attention is specifically directed to §21.21(b)(3)(vi). If licensee 50.55(e) report(s) do not adequately address the generic applicability, i.e., information on all such components, which the non-licensee may be uniquely qualified to provide, the Part 21 reporting responsibility would remain with the non-licensee for providing that part of the unreported information.

The reverse is not true because Section 50.55(e) does not have a provision like that included under §21.21(b) (last sentence) to relieve the licensee of reporting under 50.55(e) where he had actual knowledge that the Commission has been adequately informed via a Part 21 report. However, the staff has stated that where

- 13 -

the Part 21 report includes all information required for 50.55(e) reporting it would be acceptable for the licensee's 50.55(e) report to simply reference the previously submitted Part 21 report.

(3) Additional Guidance - Information Notice 79-30

Recent IE experience (i.e., enforcement issued to S&W, B&W and 5 Region II licensees) clarifies - "The staff position permitting alternate reporting via 50.55(e) or LER of a defect was intended to avoid duplicate reporting of the same event. The use of alternate reporting methods by a licensee does not relieve him from assuring compliance with 10 CFR Part 21. Therefore, each licensee must maintain a system which will assure compliance with all requirements of 10 CFR Part 21 and, in particular, in cases where the deficiency being reported under an alternate method is also a 'defect', to assure that all information required under Part 21 is forwarded to the NRC via the initial or a followup written report."

10. 10 CFR 50.55(e) EVENT FLOW DIAGRAMS

The flow diagram on the following pages illustrate the sequence of steps and considerations relative to determining whether an identified construction deficiency is reportable.

Figure 1 is a duplication of the guidance previously made available to licensees via NUREG-0302, Rev. 1.

Figure 2, incorporates the IE position for assuring prompt reporting of reportable and potentially reportable deficiencies.

- 14 -

FIGURE 1

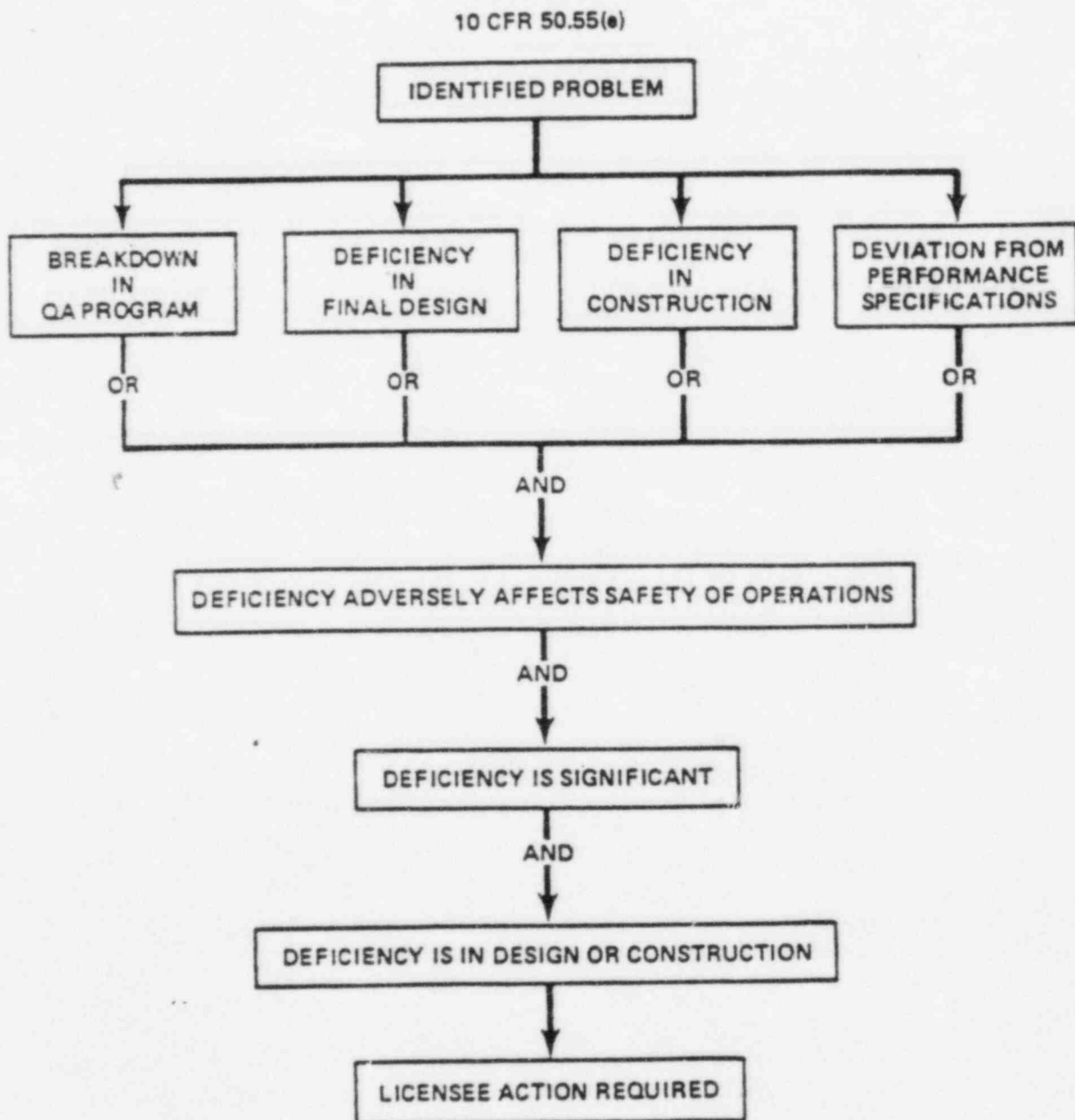


FIGURE 2

10 CFR 50.55(e) - IE POSITION

