



UNITED STATES  
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MEMORANDUM TO: Suzanne Black, Chief  
Quality Assurance and Maintenance Branch  
Division of Reactor Controls and Human Factors

FROM: Larry L. Campbell  
Quality Assurance and Safety Assessment Section

*Larry L. Campbell*

SUBJECT: TRIP REPORT - SEPTEMBER 6-7, 1995, ASSESSMENT OF THE PALO VERDE NUCLEAR GENERATING STATION GRADED QUALITY ASSURANCE PROGRAM FOR COMMERCIAL GRADE ITEM DEDICATION

This trip report provides the results of the assessment of graded quality assurance (QA) program applied to the commercial grade item (CGI) dedication process. The assessment was conducted on September 6-7, 1995, at the Palo Verde Nuclear Generating Station (PVNGS). The NRC assessment team (the team) performed the assessment to review PVNGS's program for the procurement and dedication of CGIs used in safety-related low-risk-significant system applications consistent with the requirements of Appendix B to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR) and also to determine the extent to which the licensee had implemented the NRC comments to the Nuclear Energy Institute (NEI) performance-based graded quality assurance guidance document, "Draft Pilot Project Guideline for Implementation of a Graded, Performance-Based Approach to Quality." The process used to classify structures, systems, and components as low-risk-significant was not within the scope of the team's review. During the assessment, the team held discussions with the PVNGS procurement engineering staff and at the conclusion of the assessment discussed preliminary observations with PVNGS staff as identified in the appendix of the attached report. The attached report provides details to support the conclusions summarized in the following paragraphs.

The team concluded that PVNGS has made a significant, and conservative, effort to establish a graded QA process for procurement and CGI dedication activities. This conservative approach was evident in the limited scope of the graded procurement activities and the issuance of only four purchase orders for CGIs to be dedicated for use in low-risk-significant applications.

However, based on a review of PVNGS' QA program and implementing procedures for grading the procurement process and several low-risk-significant CGI dedication packages, the team concluded that the following 4 areas required improvement.

1. The present procedural guidance for performing low-risk-significant procurement and CGI dedication activities needed improvement. Based on a discussion with the PVNGS procurement engineering staff and review of the completed CGI dedication packages, the team considered the lack of prescriptive text on the use of the grading criteria to be a weakness in the PVNGS safety-related low-risk-significant CGI dedication program.



PVNGS procurement engineering informed the team that they were aware of several of the inconsistencies and errors in Procedure No. 87DP-OMC09, "Item Procurement Specification (IPS) Requirements," dated May 30, 1995. The PVNGS staff further stated that following PVNGS's receipt and evaluation of the NRC assessment trip report, a revision to this procedure would be issued to address, as appropriate, identified NRC concerns and self-identified concerns that may not have been discussed in the trip report.

2. One QA program element which the NRC staff has consistently considered to be necessary for a graded QA process was appropriate consideration of feedback information. Feedback information can be derived from numerous sources, such as (1) in-plant component failure data, (2) adverse trend reports, (3) corrective action information, (4) industry assessments, (5) INPO and NRC generic communications, and 6) manufacturers' recommendations and notices. The team discussed the letter from J. Milhoan, NRC, to W. Rasin, NEI, dated June 15, 1994, which articulated the staff's expectation with regard to reassessing QA controls and safety significance based on new information and operational experience.

From discussions with PVNGS procurement engineering staff, the team determined that PVNGS had not yet incorporated the requisite feedback sources into its new graded QA program. The team found that the program did not require that information about in-plant nonconformance report trends and component and part failures be transmitted to procurement engineering staff so that they could assess the need to adjust the specified quality controls for verification of critical characteristics. The team learned that during a recent PVNGS procurement audit, the licensee had identified the need for an appropriate mechanism to adjust graded quality controls based on plant experience of dedicated CGIs.

Although the team viewed the lack of corrective action feedback as a weakness, PVNGS's decision to refrain from changing its program until after the NRC and PVNGS Nuclear Assurance reviews were completed did not result in any safety concerns. The team concluded that the self-identified audit findings reflected a strength, regarding the audit comprehensiveness, good constructive criticism, and attention to detail in the examining of the different elements of the graded QA program.

3. The team also discussed with PVNGS procurement engineering the finding that the process for confirming that dedicated CGIs would perform their intended safety function appeared to be inconsistent with the intent of the revised 10 CFR 21 rule published in the Federal Register on September 8, 1995, and NRC Generic Letter (GL) 91-05, "Licensee Commercial Grade Procurement and Dedication Programs," dated April 9, 1991. The revised rule and the GL defined dedication as the process whereby reasonable assurance is provided that a commercial grade item used as a basic component will perform its intended safety function. After reviewing several CGI dedication packages for low-risk-significant applications, the team determined that for most dedications, PVNGS

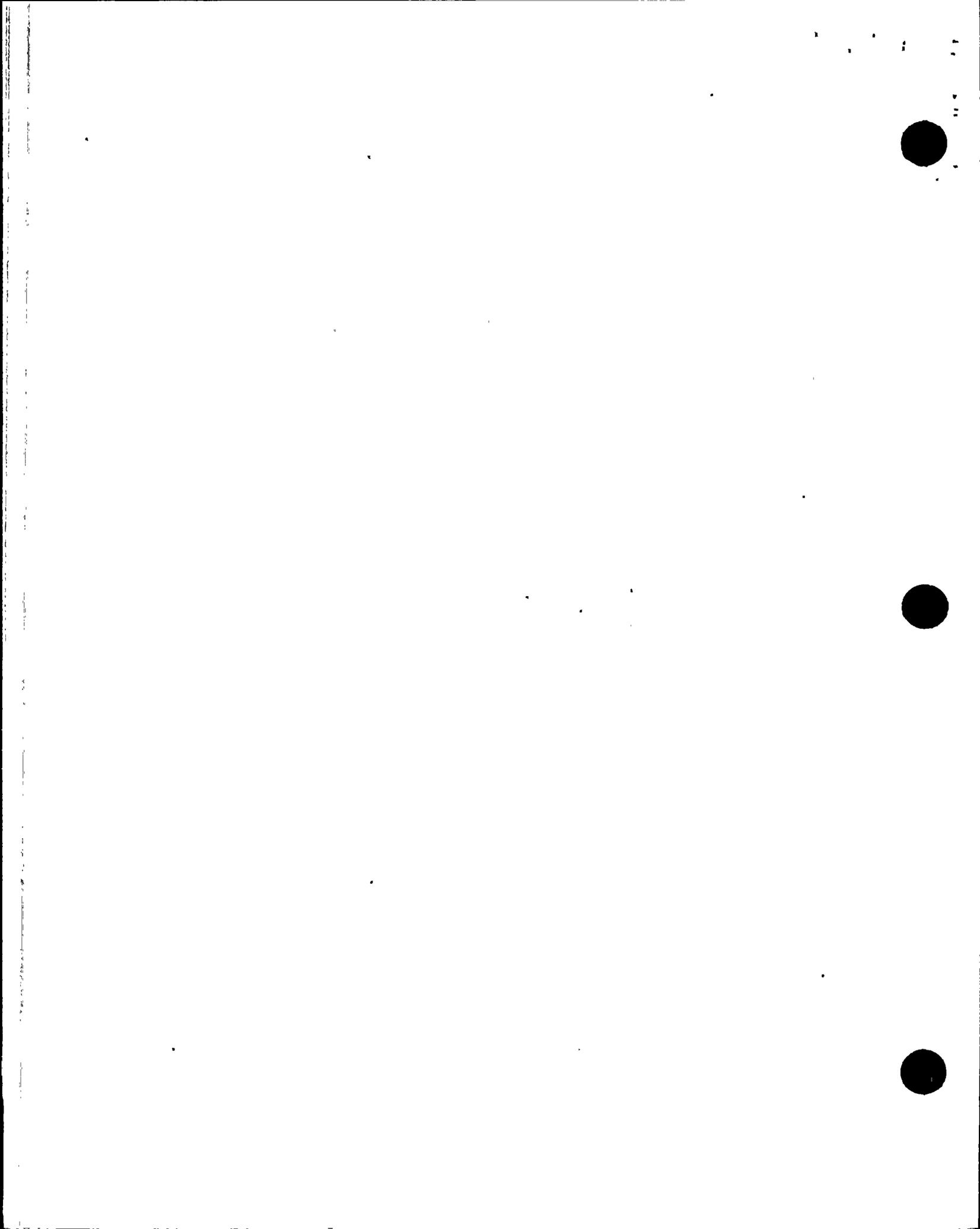


apparently relies on visual verifications performed during receipt inspection. This visual verification generally, requires the verification only of part number and external configuration checks, and involves little, if any, functional testing. The identification of critical characteristics and verification methods do not appear sufficient to provide reasonable assurance that complex items, as well as some simple items, will perform their intended safety function. The team recommend that PVNGS reevaluate the practice of generally excluding functional testing, including normal post-installation testing, from the dedication process.

4. The team concluded that additional provisions are warranted to ensure the equivalency of dedicated items with components that were originally seismically qualified by test or analysis. A manufacturer could have revised its manufacturing processes or design thereby affecting the physical characteristics of the CGI being dedicated in a manner that its seismic qualification would be indeterminate. The team noted that there are several options available for obtaining confirmation that the manufacturer has made no manufacturing or design changes affecting the CGI's seismic qualification. The NRC assessment team noted that PVNGS is responsible for assessing any identified manufacturing or design changes to determine their impact on the seismic qualification of the equipment.

In conclusion, the NRC assessment team and PVNGS agreed that further interaction would be scheduled to continue the review of PVNGS's progress in implementing graded QA requirements for procurement and dedication of CGIs used in safety-related low-risk-significant applications.

Attachments: As stated



TRIP REPORT DETAIL DISCUSSION  
ASSESSMENT OF THE PVNGS GRADED QA REQUIREMENTS  
FOR  
PROCUREMENT AND CGI DEDICATION

I. PVNGS PROCEDURE ON GRADED QA FOR COMMERCIAL GRADE ITEM DEDICATION

The Palo Verde Nuclear Generation Station (PVNGS) quality assurance program and Procedure No. 87DP-OMC09, "Item Procurement Specification (IPS) Requirements," with an effective date of May 30, 1995, provide requirements for graded quality assurance (QA) for the procurement and dedication of commercial grade items (CGIs) used in low-safety-significant systems. Section 3.2.9, "Graded QA," and Section 3.3.6, "Requirements for Safety Related Low Risk Significant (P06)," of this procedure were recently revised to provide specific requirements for the procurement and dedication of safety-related low-risk-significant items. This procurement procedure refers to PVNGS Procedure No. 87DP-OMC37, "Commercial Grade Dedication Requirements," with an effective date of November 11, 1993, which describes dedication activities in greater detail.

PVNGS has assigned the classification Category P06 for the procurement and dedication of CGIs used in safety-related low-risk-significant applications. To be Category P06, an item has to meet the following requirements:

- a. the item is to be installed in a system, structure, or component identified by the expert panel as being safety related low-risk-significant,
- b. the item meets the definition of a commercial grade item as defined in Part 21 of Title 10 of the Code of Federal Regulations (10 CFR Part 21),
- c. the item is equivalent to what was seismically qualified, and
- d. the item is not:
  - safety-related ASME Section III item (Category P02),
  - a part and/or component identified as quality augmented Category (P04), such as non-safety-related items installed in the fire protection and radioactive waste management systems,
  - environmentally qualified,
  - a type A commodity, such as cable, heat shrink, lugs, packing, piping, insulation, or weld rod,
  - a molded case circuit breaker, or
  - a Category P05, non-quality-related item.

The NRC assessment team (the team) reviewed Procedure No. 87DP-OMC09, evaluated its implementation by reviewing selected low-safety-significant CGI dedication packages (see Section VI of this trip report), and discussed the use of this procedure with PVNGS procurement engineering staff. The team's review of PVNGS Procedure No. 87DP-OMC09 identified the following concerns:



a. Section 17.2.2.3 of the PVNGS Updated Safety Analyses Report and Section 3.2.9 of Procedure No. 87DP-OMC09 require that the following criteria be used in grading quality assurance requirements for the dedication of CGIs:

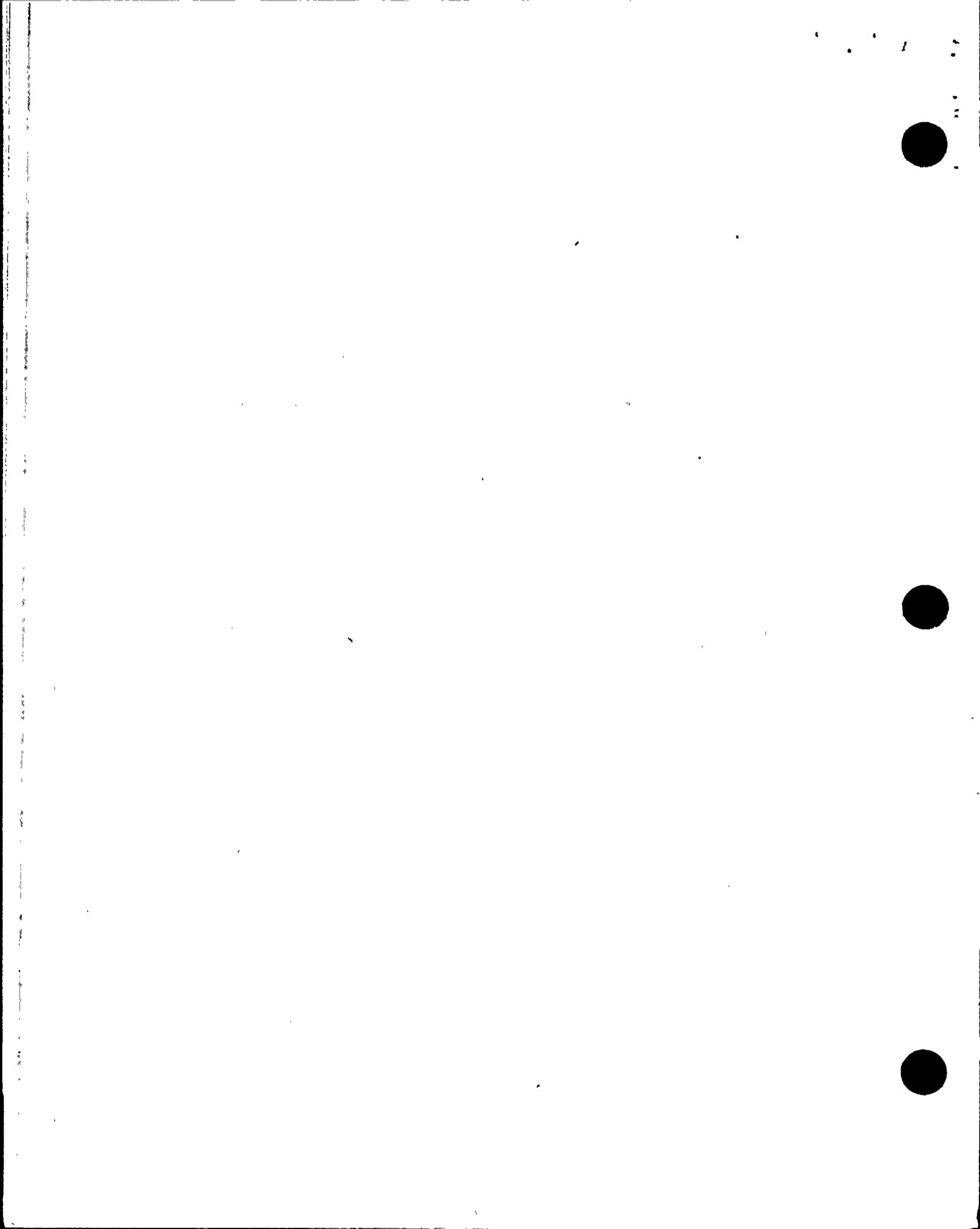
1. the effect of a malfunction or failure of the item on nuclear safety or plant operation;
2. the design and fabrication complexity or uniqueness of the item;
3. the need for special controls, surveillance, or monitoring of processes, equipment, and operational activities;
4. the degree to which functionality can be demonstrated by inspection or test; and
5. the quality history and degree of standardization of the item.

Although PVNGS procurement engineering had developed a flow chart describing the above process, neither the flow chart nor the text of Procedures No. 87DP-OMC09 and No. 87DP-OMC37 contained prescriptive guidance for applying the five criteria to the CGI dedication process for adjusting critical characteristic verification activities. The team found that the grading criteria were consistent with the criteria in the appendix to ANSI N45.2.13, "Quality Assurance for the Control of Procurement of Items and Services for Nuclear Power Plants," Revision 1. However, the ANSI N45.2.13 appendix contained additional guidance that would be appropriate for consistently applying the five criteria for graded procurement and CGI dedication activities.

Several item procurement specifications (IPSS) packages, reviewed by the team reflected the lack of guidance on the use of the grading criteria. For example, the team found that the third criterion was incorrectly interpreted by PVNGS as not being applicable for procurement. Although the third criterion specified that the need for special controls, surveillance, or monitoring process, equipment and operational activities is a factor for grading quality controls, the IPS evaluations generically stated that the criterion is not applicable for the procurement process and will not be considered during the development of the dedication plan. The appendix to ANSI N45.2.13 provides a detailed discussion on this criterion and clearly indicates that it is applicable to the procurement process. It appears that this incorrect statement was made because prescriptive guidance on the use or intent of this criterion was not addressed procedurally.

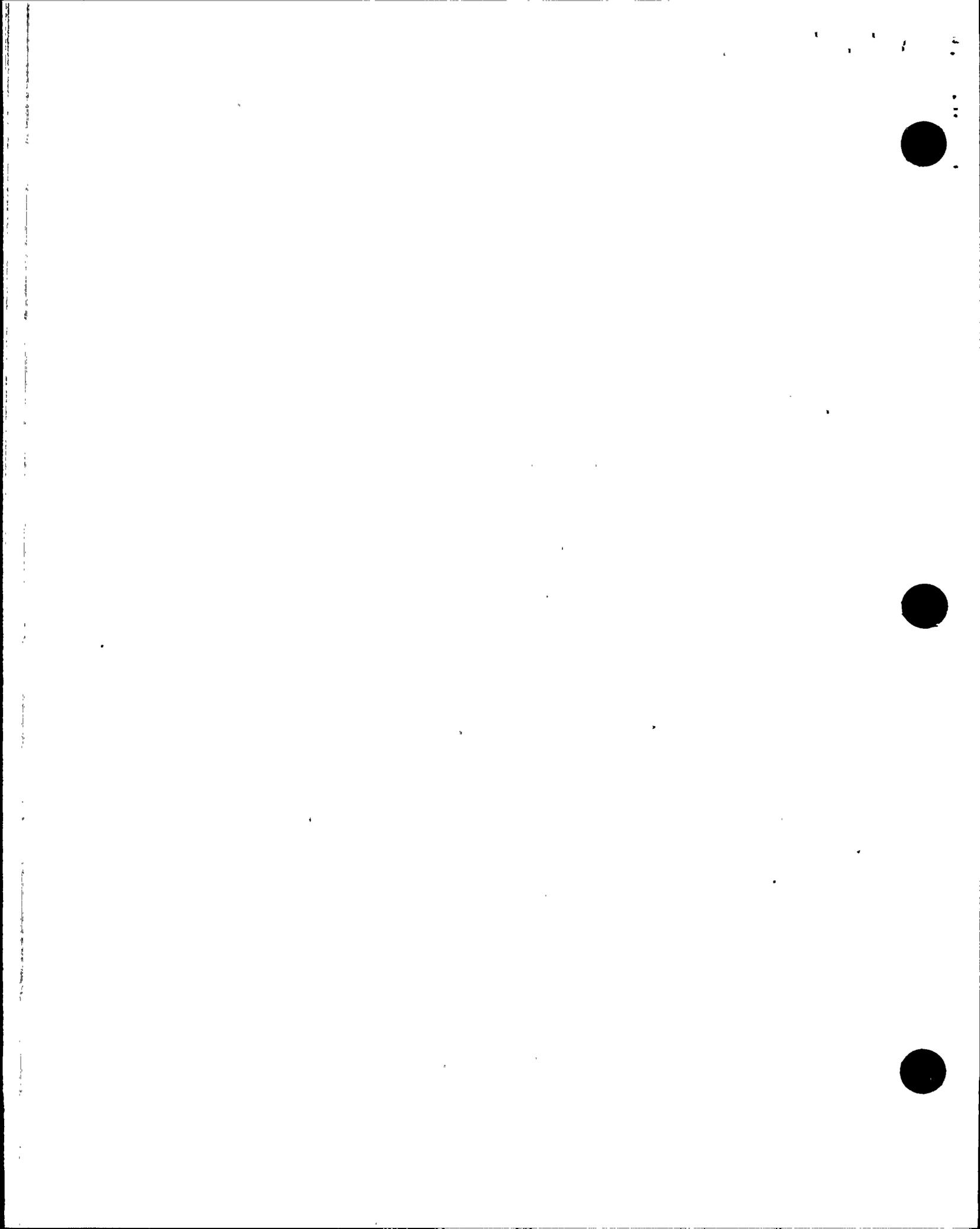
Based on discussion with the PVNGS procurement engineering staff and review of the completed CGI dedication packages, the team considered the lack of prescriptive text on the use of the criteria to be a weakness in the PVNGS safety-related low-risk-significant CGI dedication program.

b. The team determined that neither the PVNGS Quality Assurance Plan (QAP) nor the implementing procedure for safety-related low-risk-significant CGI dedications required corrective action programs to be in place for performing an effective root cause analysis of low-risk-significant failures that could have resulted from inadequate procurement and CGI dedication activities. The team found that there was no established



program requiring feedback of in-plant component and part failures to the procurement engineering group. Further, there were no existing provisions to require corrective actions to minimize the potential for repetitive failures. (Section II of this trip report provides further discussion on this item.)

- c. Although the PVNGS procurement engineering group was performing a history search of certain databases, such as the Institute of Nuclear Power Operations (INPO), Nuclear Power Reliability Data System (NPRDS), and NRC information notices, bulletins, and generic letters, there were no requirements or guidance in Procedure No. 87DP-OMC09 for performing this type of industry search.
- d. Section 3.3.6.5, "P06-Dedication Plan," states, in part, that the CGI's attributes to be verified as part of the dedication process "are typically those which may be verified through visual examination (i.e., part number, configuration, etc.)." The team expressed concern that this statement, as written, could be misleading. The intent of the dedication process, from the NRC staff's perspective, is to verify that the CGI, once dedicated, will perform its intended function. Because Section 3.3.6 emphasizes visual examination for verifying critical characteristics (identified by PVNGS as attributes), the need to perform other examinations and tests to verify that the dedicated CGI will perform its intended function has been de-emphasized. Section IV of this trip report further discusses the verification of attributes during the CGI dedication process that provide reasonable assurance that the dedicated CGI will perform its intended function.
- e. Section 3.3.6.4, "P06-Receiving Inspection Requirements," states, in part, that the acceptance and dedication of a CGI is outlined in Procedure No. 87DP-OMC37, "Commercial Grade Dedication Requirements," and that the implementation and documentation of the dedication process has been stipulated in Procedure No. 87DP-OMC37. It appeared to the team that the requirements contained in the PVNGS CGI dedication procedure were only being followed in selected areas and that the PVNGS procedure controlling safety-related low-risk-significant CGI dedication activities contained inconsistencies such as the following:
  - The Item Type Technical Evaluation (required for safety-related high-risk-significant CGI dedications by Procedure No. 87DP-OMC37) is not required by Procedure No. 87DP-OMC09 for low risk significant CGI dedications, but is still a requirement of Procedure No. 87DP-OC37 for other CGI dedications.
  - Procedure No. 87DP-OMC09 contains inconsistent requirements regarding the use of Category P06 for the dedication of CGIs used in environmentally qualified (EQ) applications. Dedication of EQ equipment is presently excluded from the P06 process.



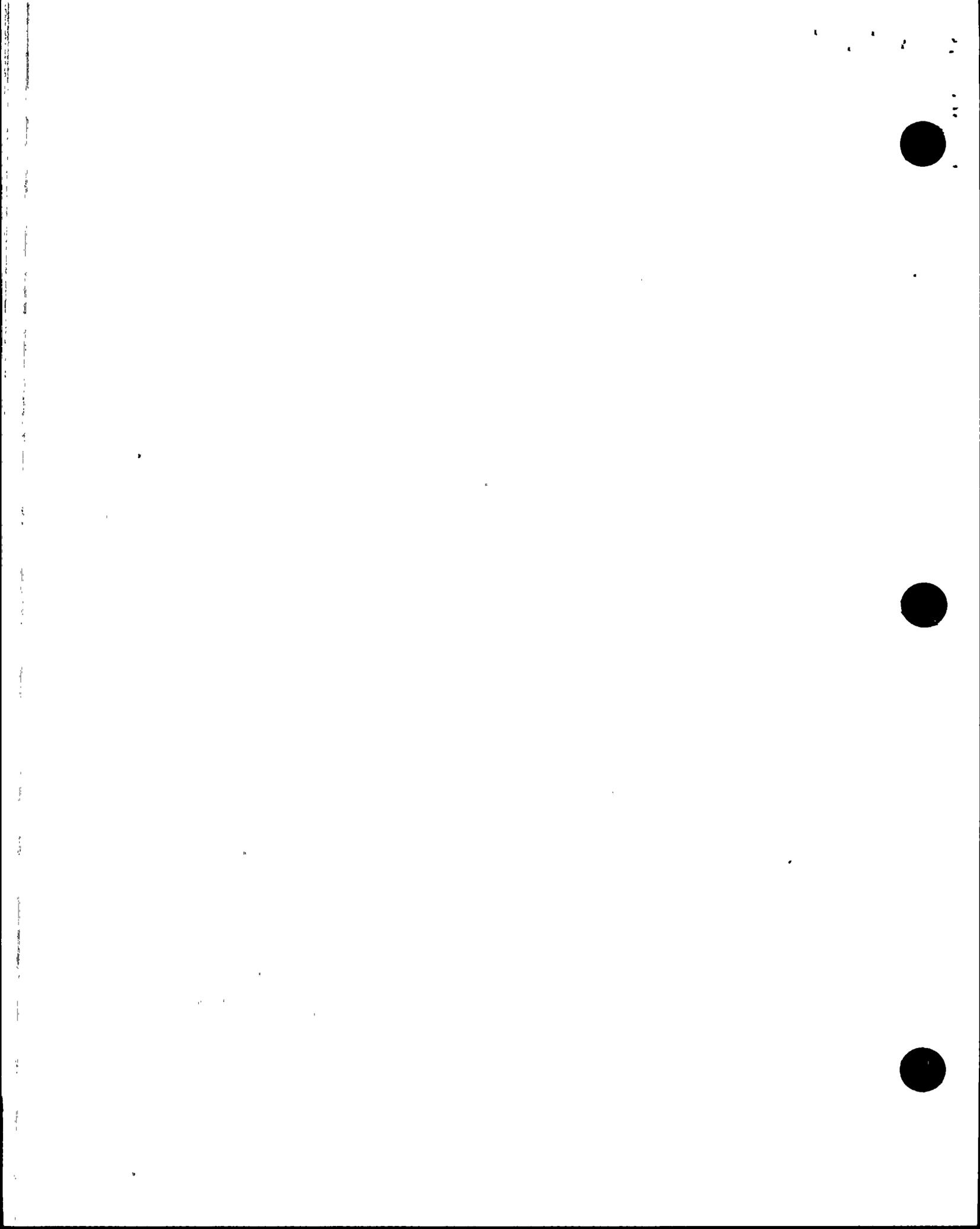
- The team discussed the use of PVNGS's CGI definition. The team noted that certain CGIs, such as the high-voltage printed circuit boards used in the radiation monitoring system, were being dedicated by PVNGS, but did not meet the definition of a CGI contained in Procedure No. 87DP-OMC09. The team mentioned that the recently issued revision to 10 CFR Part 21, issued in the Federal Register (60 FR 48369) and effective October 19, 1995, changed the definition of a CGI and now permits PVNGS to classify items such as the circuit boards as CGIs. The NRC assessment team found that PVNGS was not meeting its procedure requirements for classifying items as CGIs and suggested that PVNGS consider revising the CGI definitions in Procedures No. 87DP-OMC37 and No. 87DP-OMC09 to be consistent with the new 10 CFR Part 21 CGI definition.
- f. Procedure No. 87DP-OMC09 provides no guidance on how to determine if the CGI being dedicated is equivalent to what was originally seismically qualified. (This item is further discussed in Section III of this trip report.)

The team concluded that the present procedural guidance for performing low-risk-significant procurement and CGI dedication activities needed improvement. PVNGS procurement engineering informed the NRC assessment team that they were aware of several of the inconsistencies and errors in Procedure No. 87DP-OMC09. The PVNGS staff further stated that following PVNGS's receipt and evaluation of the NRC assessment trip report, a revision to this procedure would be issued to address, as appropriate, identified NRC concerns and self-identified concerns that may not have been discussed in the trip report.

## II. CORRECTIVE ACTION FEEDBACK LOOP

One quality assurance (QA) program element which the NRC staff has consistently considered to be necessary for a graded QA procurement process was appropriate consideration of feedback information. Feedback information can be derived from numerous sources, such as (1) in-plant component failure data, (2) adverse trend reports, (3) corrective action information, (4) industry assessments, (5) INPO and NRC generic communications, and (6) manufacturers' recommendations and notices. The team and PVNGS procurement engineering staff discussed the letter from J. Milhoan, NRC, to W. Rasin, NEI, dated June 15, 1994, which articulated the staff's expectation with regard to reassessing QA controls and safety significance based on new information and operational experience.

From these discussions, the team determined that PVNGS had not yet incorporated all of the requisite feedback sources into its new graded QA program. It was the team's understanding that PVNGS performed an initial search of databases, such as those containing INPO and NRC generic communications, using them as its main feedback information source. The team found that the licensee did not require in-plant nonconformance report trends



and component and part failures to be fed back to the procurement engineering staff so that they could assess the need to adjust the specified quality controls for identifying and verifying critical characteristics.

The team was provided with a PVNGS internal audit report, No. 95-007, "Procurement and Material Control," and an associated PVNGS Condition Report/Disposition Request (CRDR), CRDR No. 95Q184, dated April 25, 1995. The team reviewed the audit report and associated documents and found that it identified several concerns in the graded quality assurance program for procurement and commercial grade dedication activities. In that audit, which was conducted March 28 through April 14, 1995, the team noted that one PVNGS audit finding was that component and part failure information was not being consistently fed back to PVNGS procurement engineering staff. As a result of the audit, several CRDRs were written to control the findings and the associated corrective action.

One CRDR, No. 95Q184, contained concerns regarding examples of inconsistent graded QA program implementation in procurement and dedication activities. One CRDR concern stated that there was not a consistent feedback mechanism to provide component and part failure information to procurement engineering so that appropriate corrective actions could be taken to minimize the possibility of repetitive failures. The CRDR indicated that PVNGS Procedure No. 70DP-OEE01, "Equipment Root Cause of Failure," required an equipment root cause of failure analysis (ERCFA) only when the failure involved a critical system. The CRDR went on to say that many low-risk systems would therefore not require an ERCFA and that even when an ERCFA is performed, feedback to procurement engineering is not mandated by the procedure. As the PVNGS requirement basis of this deviation, CRDR No. 95Q184 quoted the January 31, 1995, NRC letter, stating "NRC comments to the NEI draft document on Graded Quality Assurance...indicate that corrective action programs that perform an in-depth root cause analysis of low-risk-significant SSCs and institute the requisite corrective actions to minimize the potential for repetitive failures are required."

Although Palo Verde's CRDR No. 95Q184 indicated that the corrective action was supposed to be completed by June 30, 1995, the team found that the corrective action had not been implemented. When procurement engineering staff was asked about the lack of corrective action, they told the team that they wanted to have the benefit of the team's assessment report before changing the program, which was audited in April and May 1995. Although the team viewed the lack of corrective action as a weakness, PVNGS' decision to refrain from changing its program until after the NRC and PVNGS Nuclear Assurance reviews were completed did not result in any safety concerns. The team concluded that the self-identified audit findings reflected a strength. Examining the different sections of the graded QA program, the audit was detailed and comprehensive, and the criticisms were very constructive.



### III. SEISMIC QUALIFICATION

General Design Criterion 2, "Design Bases for Protection Against Natural Phenomena," of Appendix A to 10 CFR 50 requires that nuclear power plant structures, systems, and components (SSCs) important to safety be designed to withstand the effects of earthquakes without loss of capability to perform their intended safety functions.

Appendix A, "Seismic and Geologic Siting Criteria for Nuclear Power Plants," to 10 CFR Part 100 requires that all nuclear power plants be designed so that, if a safe-shutdown earthquake (SSE) occurs, certain SSCs remain functional. These plant features are those necessary to ensure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe-shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in 10 CFR Part 100.

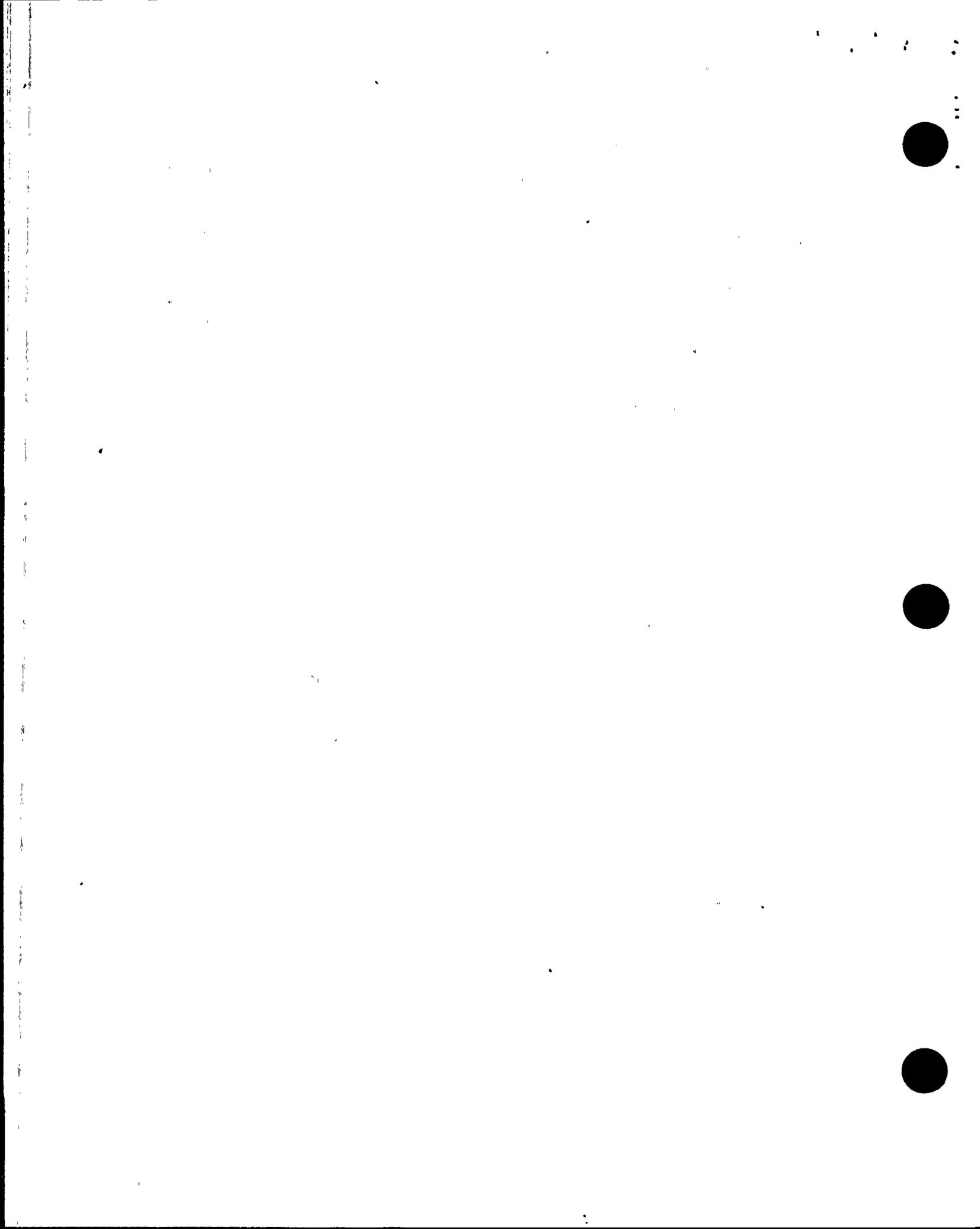
Criterion III, "Design Control", of Appendix B to 10 CFR Part 50 requires, in part, that design control measures, provide for verifying the adequacy of design such as by the performance of a suitable testing program. Where a test program is used to verify the adequacy of a specific design feature (e.g., ability of plant equipment to perform its intended safety function(s) "during and after the time it is subjected to the forces resulting from one SSE preceded by a number of operating basis earthquakes (OBEs)"<sup>1</sup>), the program is required to include suitable qualification testing of a prototype unit under the most adverse design conditions. Criterion III also provides for acceptable calculation and/or analyses in lieu of testing to demonstrate seismic qualification of equipment.

Regulatory Guide (RG) 1.29, "Seismic Design Classification," describes an acceptable method for identifying and classifying those nuclear power plant features that should be designed to withstand the effects of the SSE (Seismic Category I). Included in this category are Class 1E (i.e., safety-related electrical and electronic) systems, including auxiliary systems for the onsite electric power distribution system.

IEEE Standard 344, "IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations," dated January 31, 1975, was conditionally endorsed by the NRC via RG 1.100. RG 1.100 states the staff's position that conformance with the requirements and recommendations specified in IEEE 344-1975 for conducting seismic qualification testing of Class 1E equipment, when such qualification is performed in conjunction with the guidance in RG 1.89, provides adequate basis for complying with the design verification requirements of Criterion III of Appendix B to 10 CFR Part 50.

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<sup>1</sup>RG 1.100, "Seismic Qualification of Electric Equipment for Nuclear Power Plants," Revision 1 (August 1977).



Licenses have traditionally relied on a combination of testing and/or analyses to demonstrate seismic qualification of original plant equipment. For replacement items, licenses typically rely on the original equipment manufacturer (OEM), provided that the OEM is adequately maintained in the licensee's approved suppliers list, to maintain the qualified status via traceability to an original seismic calculation or test report which established the seismic imperviousness of a given prototype, including internal piece-parts.

In June 1988, the Electric Power Research Institute (EPRI) published EPRI NP-5652 (Project Q101-7), "Guideline for the Utilization of Commercial Graded Items in Nuclear Safety Related Application (NCIG-07)." EPRI NP-5652 was conditionally endorsed by the NRC via Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989.

EPRI NP-5652, Section F.1.3, "Seismic Qualification," states, in part, "The purchaser should *reasonably assure* [our emphasis] that the commercial grade items will not adversely affect the original seismic qualification of the parent component in which they are intended for installation." It adds that for simple metallic items reasonable assurance can typically be achieved by verifying three critical characteristics (part number, material, and dimensions). For complex items, however, "modifications made to internal piece-parts may result in a redistribution of mass. Changes in assembly or type of materials should also be considered for complex items. These modifications could all adversely affect the way in which the item reacts during a seismic event. *Therefore, the verification of design controls, modifications to internal part characteristics, and assembly procedures should be considered if maintaining seismic qualification is an issue*" [our emphasis]. However, EPRI NP-5652 does not elaborate on what would constitute acceptable methods for considering such design controls, modifications, and assembly procedures.

In February 1993, EPRI published EPRI NP-7484 (Project Q101-29), "Guideline for the Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants." EPRI NP-7484 has not been endorsed by the NRC. This document provides the industry's perspective on the processes needed to (1) provide reasonable assurance that replacement items will meet seismic performance requirements necessary to maintain the seismic design basis of commercial nuclear power plants, (2) determine when a seismic technical evaluation of replacement items (STERI) is necessary as part of the procurement process for spare and replacement items, and (3) establish supplier program requirements necessary to maintain continued seismic adequacy for spare and replacement items.

In discussing procurement requirements for "potentially seismic sensitive items," it was noted that EPRI NP-7484, Page 3-47, states, in part, that certain design, material, manufacture, or other configuration characteristics (dependent on the type of item and the plant licensing basis requirements) are essential for the required seismic adequacy to be maintained. In those instances where the licensee itself performs the STERI evaluation (as the team



believes is the case with PVNGS), EPRI NP-7484 provides that such essential characteristics necessary to support assumptions of seismic adequacy in the STERI be translated accordingly into the procurement documents.

The only methods allowed by EPRI NP-7484 for verifying that the procurement requirements have been met is procurement from (1) an approved Appendix B supplier with adequate configuration controls, (2) an Appendix B supplier with supplementary source verification or augmented receipt inspection requirements, or (3) a commercial grade supplier as described in EPRI NP-5652.

Before the assessment visit, PVNGS staff informed some members of the team that PVNGS practices in the area of seismic qualification verification were in agreement with the guidance provided in EPRI NP-7484.

During the visit, however, the team was informed that verification of part or model number and a visual configuration check alone constitutes reasonable assurance that P06 items (as defined above), including complex items as described in EPRI NP-5652, remain seismically qualified or will not adversely impact the original seismic qualification of the parent component in which they are intended for installation and that acceptable verification methods (as identified in EPRI NP-7484) to establish that the procurement requirements have been met are not necessary.

The team agrees that there may be instances where, for less complex, seismically insensitive, commercial grade items, part or model number and visual configuration checks alone, may achieve reasonable assurance that the item(s) will remain impervious to a postulated design basis event (DBE) or will not adversely affect the original seismic qualification of the parent component in which they are intended for installation. Relevant procedural guidance at PVNGS, however, remains silent on (1) how verification of design controls, modifications to internal part characteristics, and assembly procedures should be considered when the commercial grade items are complex and seismically sensitive and (2) how specific design, material, manufacture, or other configuration characteristics essential for the required seismic adequacy, should be identified, evaluated, and maintained during the procurement process.

The team concluded that additional provisions are warranted to ensure the equivalency of dedicated items with components that were originally seismically qualified by tests or analysis. A manufacturer could have revised its manufacturing processes or design thereby affecting the physical characteristics of the CGI being dedicated in a manner that its seismic qualification would be indeterminate. The team noted that there are several options available for obtaining confirmation that the manufacturer has made no manufacturing or design changes affecting the CGI's seismic qualification. The NRC assessment team noted that PVNGS remains responsible for assessing any identified manufacturing or design changes to determine their impact on the seismic qualification of the equipment.



#### IV. PERFORMANCE TESTING

PVNGS informed the team that it was implementing the guidance contained in the EPRI NP-5652 guideline for the dedication of low-risk-significant components. The EPRI document addresses the performance of augmented receipt inspection testing and post-installation tests, where appropriate, as part of the dedication process. The team discussed with the PVNGS procurement engineering the process utilized to confirm that dedicated CGIs would perform their intended safety function and noted that this process appeared to be inconsistent with the intent of the revised 10 CFR Part 21 rule effective on October 19, 1995, and NRC Generic Letter (GL) 91-05, "Licensee Commercial Grade Procurement and Dedication Programs," dated April 9, 1991. The team also noted that the revised rule and GL define dedication as the process whereby reasonable assurance is provided that a dedicated commercial grade item, used as a basic component, will perform its intended safety function.

The team noted that PVNGS Procedure No. 87DP-OMC09, Section 3.3.6.5 specified that P06 item dedication plans should assess the five grading criteria and specify "only those verification attributes necessary to provide a level of assurance appropriate to the low risk significance of the item. These attributes are typically those which may be verified through visual examinations (i.e., part number, configuration, etc.)."

The team observed that PVNGS Procedure No. 87DP-OMC37 specifies a wide range of item performance characteristics for typical critical design attributes (CDAs) and critical verification attributes (CVAs). The procedure specifies that an item type technical evaluation (ITTE) is performed which would first determine the safety function associated with the item to be dedicated. For items considered to be simple, the procedure states that the CDAs which are necessary to support the identified safety functions tend to be physical properties related to material and dimensions, whereas for complex items the CDAs tend to have performance-related characteristics. The ITTE would then identify CVAs that provide reasonable assurance that the requisite CDAs are present in the item received. The procedure defines CVAs for simple items as primarily physical properties and the CVAs for complex items as primarily performance characteristics. However, the procedure controlling PVNGS' CGI dedication process for low-risk-significant applications does not require the preparation of an ITTE.

The team examined a sample of P06 item procurement specification change notices (IPSCNs) that document the evaluation of the item with respect to the five grading criteria and specify the associated CVA verification techniques and acceptance criteria. It was noted that in some cases (see Section VI of this report) the CGI would be dedicated based on a part number and configuration check. Questioning PVNGS procurement engineering about the performance of testing during receipt or following installation, the team found out that even though the dedication process did not require a functional test, a routine post-installation test (PIT) was still typically being done to ensure item operability. The PVNGS' basis for dedicating certain CGIs was based on a more limited set of verification attributes (which may not have



adequately verified item functionality). However, following the limited dedication, the items were considered basic components. In several examples, PVNGS did not specify the PIT to be part of the CGI dedication process.

Based on the review of several CGI dedication packages for low-risk-significant applications, the team determined that for most dedications, PVNGS relies on verifications performed during receipt inspections which, generally, require the verification only of part number and external configuration checks and very little, if any, functional testing. The dedication activities do not appear to be sufficient to provide reasonable assurance that complex items, as well as some simple items, will perform their intended safety function. The team considered PVNGS's practice of generally excluding functional testing, including normal PIT, from the dedication process to be a weakness.

#### V. PVNGS CRITERIA FOR GRADED QUALITY ASSURANCE

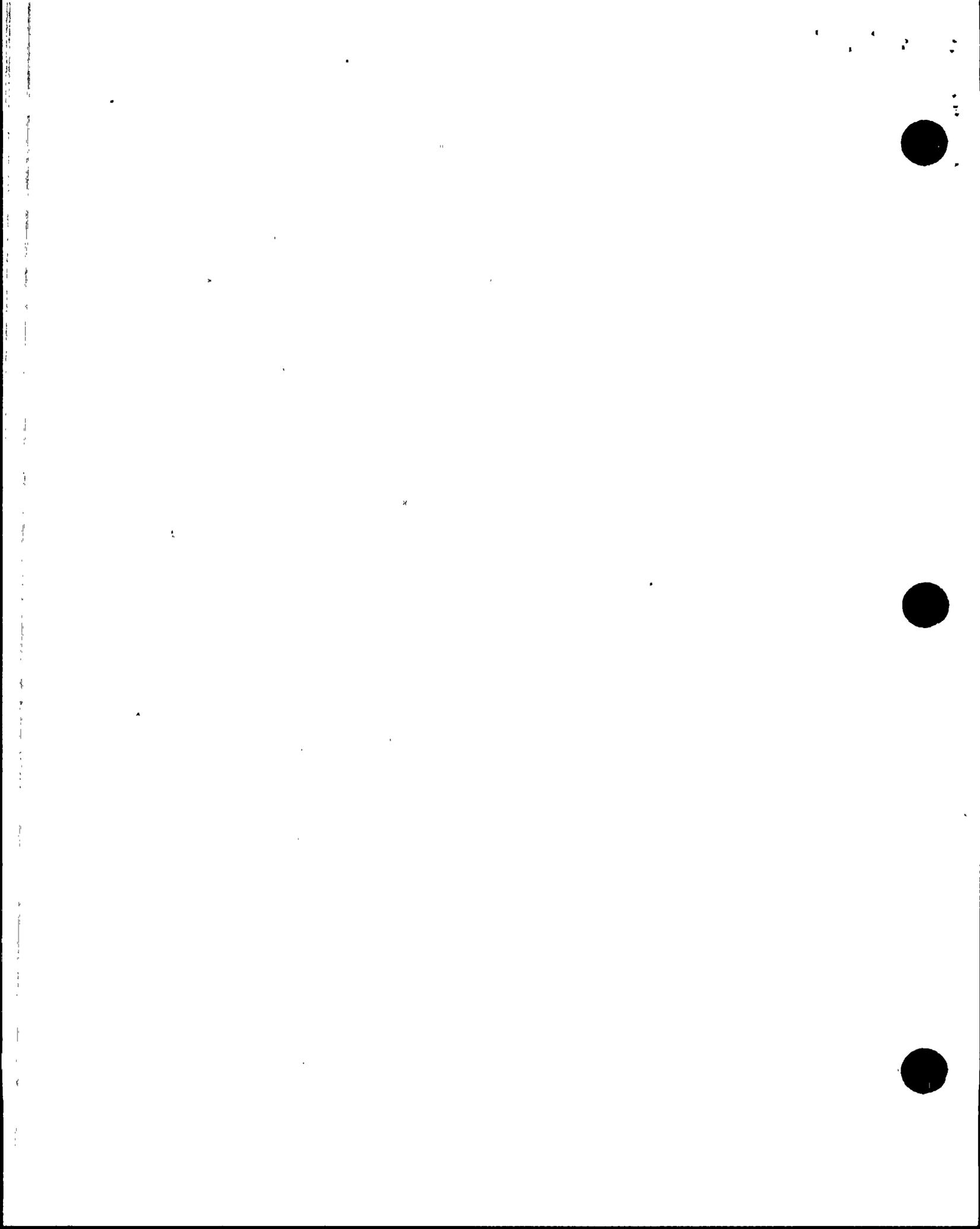
Section 17.2.2.3, "Graded Approach," of the PVNGS Updated Safety Analysis Report (UFSAR) provides that the following criteria be considered in implementing the grading of quality assurance requirements:

1. the effect of a malfunction or failure of the item on nuclear safety or plant operation,
2. the design and fabrication complexity or uniqueness of the item,
3. the need for special controls, surveillance or monitoring of processes, equipment, and operational activities,
4. the degree to which functionality can be demonstrated by inspection or test, and
5. the quality history and degree of standardization of the item.

Section 17.2.2.3 continues by stating, in part, that:

The extent to which the requirements of this Plan apply to activities shall be based as a minimum on Operating License conditions and other plans previously approved by the NRC, other regulatory commitments as may have been made associated with activities, the text of this Plan, the Unit's Technical Specifications, and Appendix 17.2B of this Plan. Such other plans or regulatory commitments include, but are not limited to, those associated with emergency planning, physical plant security, safeguard contingency planning, radiological controls, radiological environmental controls, fire protection, inservice inspection, inservice testing, licensed operator qualification and requalification, process control, offsite dose calculation, shift technical advisor training, environmental qualification of equipment, security guard training and qualification, etc.

When the graded approach is utilized, the justification and basis for grading shall be documented and retrievable. Application of the graded approach shall be accomplished in accordance with procedures concurred with by the Nuclear Assurance organization. These procedures shall clearly identify how the justification and



basis for grading shall be documented and maintained. Grading of Plan requirements applicable to items shall be the responsibility of the Vice President, Engineering. Grading of Plan requirements applicable to activities shall be the responsibility of the organization responsible for performing the activity.

The team discussed the use of the five criteria for grading procurement and CGI dedication activities with PVNGS procurement and QA. The team noted that Section 5.2.13, "Procurement and Materials," of ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operations)," Revision 2, dated February 1978, states, in part:

The Appendix to ANSI N45.2.13, "Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants," is particularly useful in determining the procurement quality assurance requirements depending on the complexity or safety of the item.

The appendix to ANSI N45.2.13 provides the five criteria being used by PVNGS for its graded QA requirements for procurement and CGI dedication. The team agreed that the five criteria, if properly applied, should provide an adequate basis for grading procurement and CGI dedication activities. However, as previously discussed in this trip report, additional guidance on the use of these criteria needs to be provided in the procedures controlling P06 procurement activities in order to meet existing regulatory requirements.

The team briefly discussed the use of the five criteria for activities other than procurement and noted that such use would require specific guidance for applying the criteria to the activity being performed and that there may be need to modify or add criteria for non-procurement related activities. The team also noted that additional guidance for graded quality was provided in ANSI N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities," Section 2, "Quality Assurance Program. "

## VI. Dedication Package Number and Description

The team reviewed several low-risk-significant CGI dedication packages to determine if PVNGS had developed and implemented the necessary procedural controls for graded procurement and CGI dedication activities to ensure that the CGI, once dedicated, would perform its intended safety function. The following examples are items that PVNGS had either purchased or intended to purchase at a future date, using graded QA to control the procurement and dedication process.

1. Item Procurement Specification (IPS) No. K020-002, Revision 00, with IPS Change Notice (IPSCN) No. IPSCN(GC) No. 0069, dated September 1, 1995, described the graded dedication plan for a 3/8 inch vacuum relief valve for use in the Radiation Monitoring (SQ) system. The SQ system is listed in Engineering Study No. 13-NS-B28 as a low-risk-significant

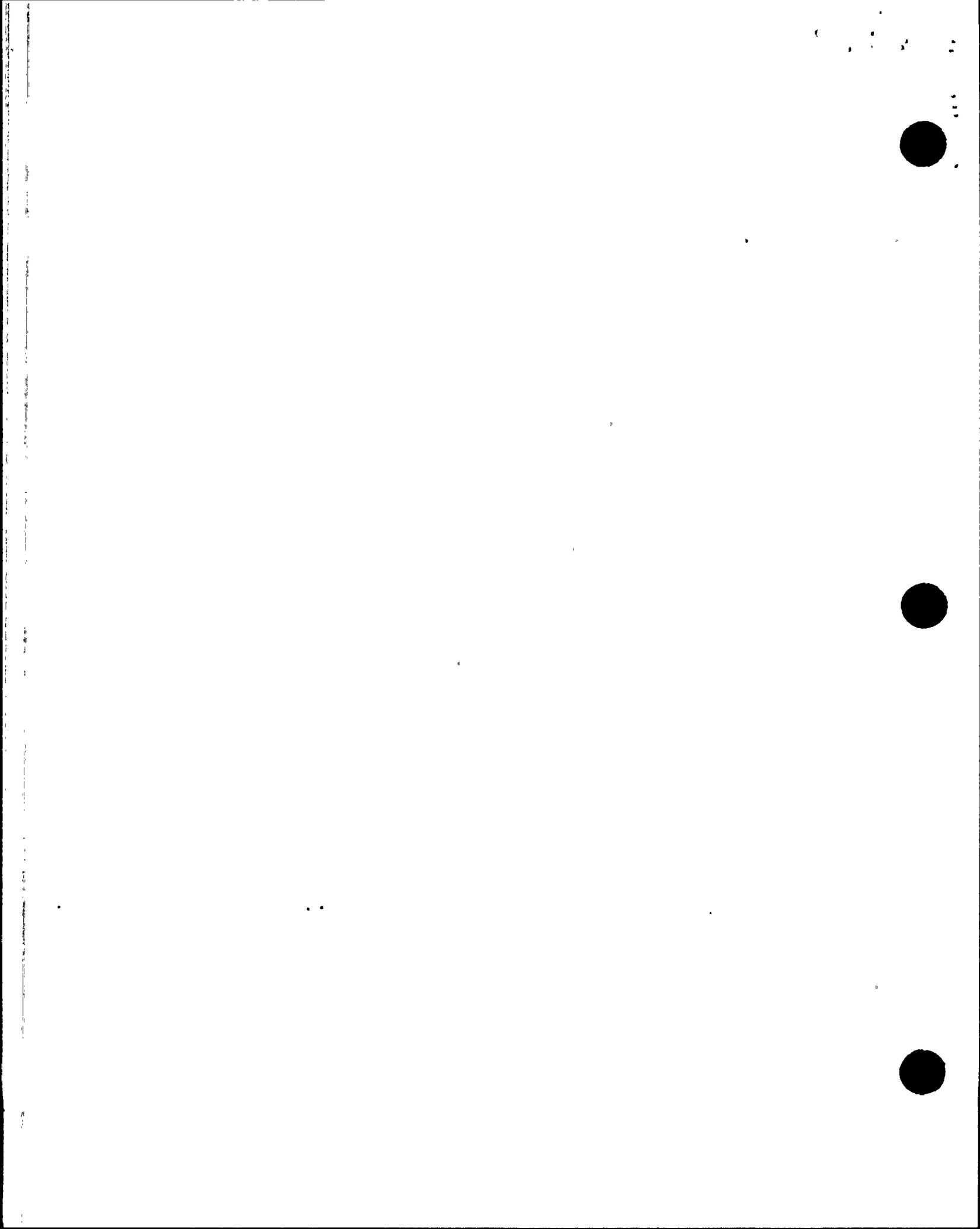


system. The valve is installed on the suction side of a pump and prevents cavitation when a vacuum forms on the pump's suction side.

The critical characteristics verified by visual examination were part number and general configuration. Additionally, during receiving inspection, instructions required the inspector to actuate the stem by compressing the spring attached to the plunger. The instructions also noted that a frozen or binding stem during this actuation would be considered a failure. All verification activities were performed by certified quality control inspectors.

The team provided the following comments on the vacuum relief valve dedication activities to PVNGS procurement engineering personnel.

- One of the five criteria to be considered in grading QA requirements for dedicating CGIs in safety-related low-risk-significant applications is "the need for special controls, surveillance, or monitoring of processes, equipment, and operational activities." The IPS states that this criterion did not relate to the procurement process and that, as such, it [would] not be considered during the development of the dedication plan. This statement was apparently due to the licensee's failure to address the criterion procedurally. The appendix to ANSI N45.2.13 provides a detailed discussion on this criterion and clearly indicates that it relates to the procurement process.
- The IPS states, in part, that PVNGS has a trending program in process in place to verify performance of the parts within the SQ system; however as discussed in Section II of this trip report, the team found that there was no established program requiring feedback of in-plant nonconformance report trends and component and part failures to the procurement engineering group. The IPS also stated, in part, that based on the manufacturing process, design, and QA history, the material, physical properties and performance verification attributes would not be verified.
- The performance of the CGI dedication verification activities included very minimal verification that the relief valve would function properly. The process of manually compressing the spring attached to the plunger demonstrates that the stem is not frozen and that stem binding is not present. The dedication activities did not provide objective evidence that the vacuum relief valve would perform its intended function. Although testing was not part of the CGI dedication process, following the setting and installation of the valve, a PIT was performed to verify that the valve functioned properly.



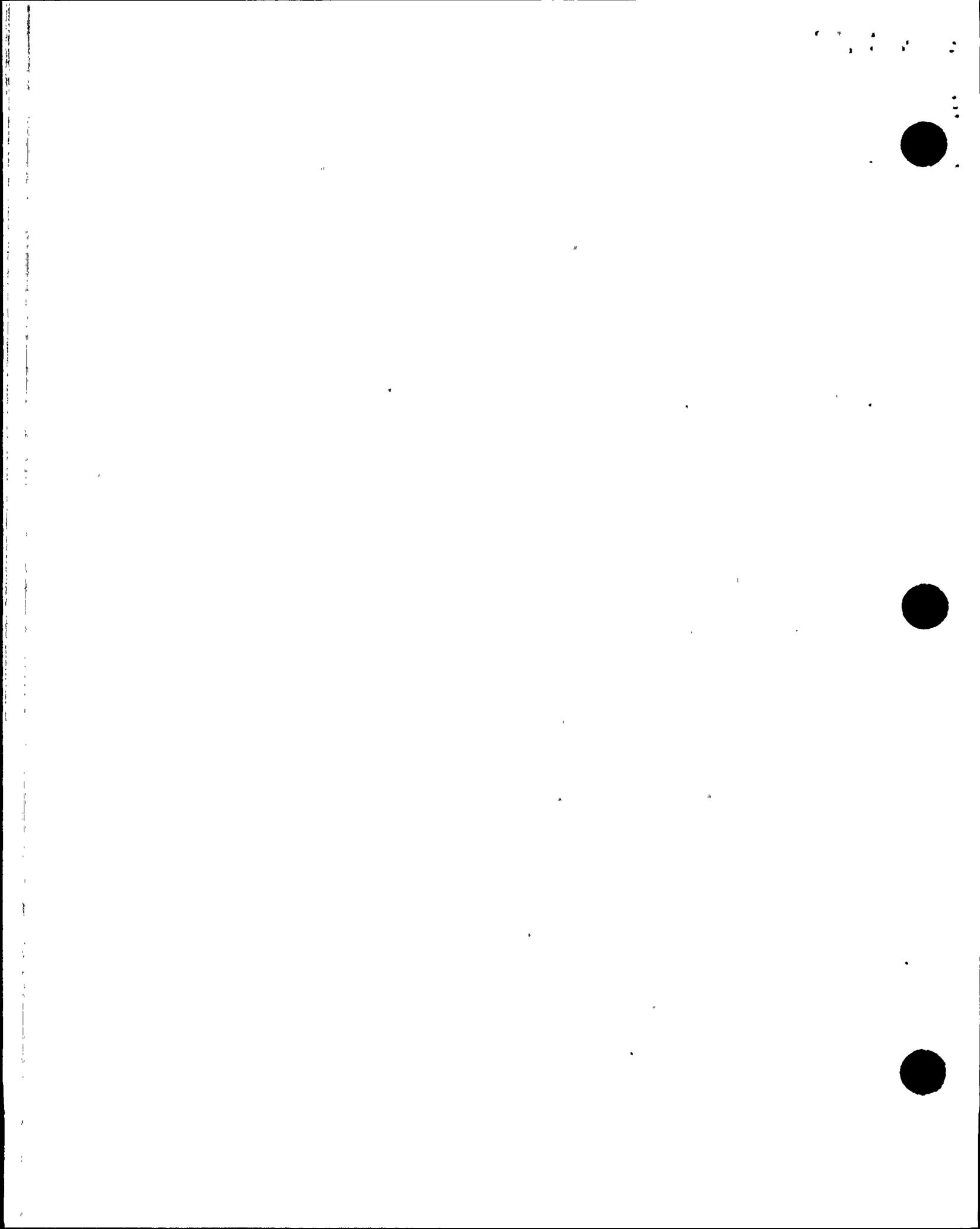
PVNGS procurement engineering informed the team that for a similar vacuum relief valve installed in safety-related high-risk-significant applications, additional CGI dedication activities such as the following would be performed:

- The spring constant for the spring providing the opposing force to the stem (moderates the action of the valve) would be verified.
  - A functional test would be performed.
2. IPS No. R411-006, Revision 00, with IPSCN(GC) No. 0026, dated August 25, 1995, including IPSCN No. R411-006-00-0024 described the dedication plan for an S-R Products Electro-Thermo Link (ETL) Fusible link. The PVNGS stock number for this item is component/item (C/I) No. 4543-000046. The ETL is used exclusively in the PVNGS Fire Damper (HJ) system. The HJ system was listed in Engineering Study No. 13-NS-B28 as a low-risk-significant system. The team understands that PVNGS has not procured any C/I No. 4543-000046 ETL fusible links under its new graded QA program. The IPSCN's discussion of PVNGS QAP Criterion 2, "The design and fabrication complexity or uniqueness of the item," stated:

The Fusible link is a simple device manufactured with large production runs by standardized manufacturing processes. The assembly consists of two overlapping metal plates joined by a low melting point alloy. As the assembly is heated the alloy melts and the fusible link pulls apart creating an electrical or mechanical corrective action. The metal strips are cut to size and the alloy is applied by a series of machinery. The fusible link has no moving parts. The standardized manufacturing process and simple design provide a high level of homogeneity in the end product. The manufacturing process for a fusible link is a standardized process of a simple design which serves to prevent the introduction of sporadic errors.

The narrative under "Criteria Evaluation" stated that "ETL fusible links have numerous CVAs dealing with materials, physical properties, configuration and performance (functionality) which verify the ability of the part to perform its safety functions to open and maintain structural integrity... the material, physical property and performance verification attributes will not be verified because these did not surface as problem areas during the quality history review. Another factor in not verifying these attributes is the standardized manufacturing process and simplistic design...." Therefore, PVNGS' commercial grade dedication plan identified that general configuration (S03), part number (I07), and verification of the presence of an Underwriters Laboratory, Incorporated (UL) stamp (I05) were the CVAs which would be verified. The IPSCN discussion of PVNGS QAP Criterion 4, "The degree to which functionality can be demonstrated by inspection or test," stated:

Receipt inspections demonstrate functionality to a



small degree whereas destructive testing performed during receipt inspections verify functionality to high degree. The safety functions of a Fusible link are to open (CF02) and maintain structural integrity (CF08)... Performance testing using a calibrated oven could be utilized during the receiving process which would verify the required critical verification attributes (e.g., alloy's material of construction, acceptable performance, etc.) to ensure functionality. ETL fusible links do not require special tests or inspection to ensure they satisfy the required safety function.

The team requested PVNGS procurement engineering to check an ETL fusible link out of the warehouse for the NRC team to look at. The team saw that the ETL did not seem to be merely an "assembly consisting of two overlapping metal plates joined by a low melting point alloy." Instead, the ETL resembled a fusible link which had an electrical heater unit integrated into the formed links with two electrical wires coming out of a potting type compound at the end of the heater device. The manufacturer's sheet which was with the ETL indicated that the wires would be connected into an associated circuit for remotely energizing the heater and melting the alloy between the links and heater device. The ETL provides a redundant release vehicle for the safety-related fire damper. That is, the heater is designed to react to an electrical impulse, such as from a smoke detector or other type of remote alarm. The ETL also reacts to local heat sources, just as a standard fusible link does. The manufacturer's instructions for installing the ETL stated that it was designed to replace standard UL-listed fusible links of less than 40 pound ratings. The manufacturer's sheet stated that the ETL is designed to react to an electrical impulse of 0.2 amperes over a short period at a voltage range of 6-30 VAC or DC low voltage, National Electric Code Class 2. The manufacturer's sheet also contained two cautionary notes: "(1) If the electrical resistance range is not within 10-30 ohms, remove the ETL and return it to your supplier, (2) Warranty is voided if ETL links are used in monitored systems with more than an absolutely limited 1-milliampere maximum input constant current."

It appeared to the team that PVNGS' narrative regarding the design and fabrication complexity or uniqueness of the item undersimplified the description of the ETL, whereas the narrative description resembled that of a standard fusible link and not that of an ETL. The narrative, contained in the package, also did not address potential human intervention in the handling of the electrical heater device and associated wires, connections and potting. The team also noted that the PVNGS rationale for its choice of CVAs did not address either of the two cautionary notes found on the manufacturer's installation sheet and also did not address the notes regarding specific applications. Consequently, the team did not agree with the PVNGS conclusion that the "ETL fusible links do not require special tests or inspection to ensure they satisfy the required safety function." The team expected that, as a minimum, PVNGS would have its receipt inspection verify the ohmic



value of a representative sample of the ETLs. The team queried fire protection personnel who actually replace the ETLs periodically and the team found that the associated nuclear administrative and technical manuals that specify fire damper functional tests require the ohmic value of the ETL heater device to be within the 10-30 ohm range. Therefore, even though the graded QA dedication process and rationale for grading the procurement requirements for this device appeared inadequate, 100 percent of the ETL devices used in safety-related low-risk-significant applications appear to be subjected to a PIT.

3. IPS No. R411-005, with IPSCN(GC) No. 0019, dated September 1, 1995, described the graded dedication plan for a blade seal for use in the control building heating, ventilation, and air conditioning (HVAC) system (system HJ). The blade seal is installed in a 14-inch bubbletight damper. The HJ system has been designated a low-risk-significant system at PVNGS. The safety function of the item is to maintain pressure integrity.

With regards to the critical characteristics, when PVNGS receives the item from the vendor, PVNGS' practice is to verify general configuration by a visual check. When the blade seal is fabricated by PVNGS personnel, the verification includes traceability of the sheet material (procured as P01). The team was informed that the general configuration check would be done by quality control inspectors. The IPSCN acknowledged that receipt inspections demonstrate functionality to a small degree and that a bench test could be performed to verify material and physical property verification attributes.

The team has the following comments on the blade seal dedication for a low-risk-significant application:

- The complete elimination of material testing parameters for blade seals obtained from the vendor would lead to the potential installation of blade seal material that does not conform to the requisite hardness and compression requirements to ensure adequate sealing of the damper. PVNGS could use a sampling approach to verify these parameters and satisfy QAP criterion 4. Thus, QAP grading Criterion 4 could be fulfilled based on using a sampling approach to ensure proper material characteristics.
- The IPS stated that the grading criterion on the need for special controls, surveillance, or monitoring is not related to the procurement process. ANSI N45.2.13 provides additional detail that correlates this QAP criterion to the procurement environment.
- A quality history search performed as part of the IPSCN identified no problems with this type of blade seal.



- The performance of in-plant leakage checks on the HVAC system and the periodic replacement of the blade seals would provide additional assurance that the items, and the HJ system, would perform their safety function.
- The fabrication of the seals by PVNGS site personnel should include the necessary actions to verify material traceability.

In order to determine the dedication requirements for a similar seal used in a safety-related high-risk-significant application, the team examined IPS No. R411-005, IPSCN No. 0016, dated March 14, 1995, which described the dedication plan for Ruskin blade seals. The verification included compression set, durometer hardness, thickness, width, inside diameter, and configuration. The team also reviewed Ruskin vendor technical Manual No. VTM-R411-0001 for the Ruskin dampers. The bubbletight dampers are butterfly-type of dampers with silicone seals. The manual specifies that when replacing the blade seal, that a leak test should be performed. The blade seals are to be replaced at 5 year intervals. The manual specifies that the seals should have a hardness of 60 +/- 1 durometer (in contrast to IPS No. R411-005, with IPSCN 0016, which specified 60 +/- 5 durometer) and tensile strength of 1140 psi minimum. The team also noted that non-metallic gaskets parameters such as marking, part number, configuration, thickness, and material properties such as compressibility are normally verified for gaskets used in safety-related high-risk-significant applications.

4. IPS No. K020-002, Revision 00, with IPSCN(GC) No. 0067, dated September 2, 1995, provided a change to the dedication plan provided in IPSCN No. K020-002-00-0055 for an Amalgamated Services Incorporated (ASI), High-Voltage Printed Circuit Board (high voltage PC board), PVNGS C/I No. 4401-001958. The high-voltage PC board is used exclusively in the PVNGS SQ system for powering the radiation detectors such as GM tubes, beta and gamma scintillators, and ion chambers. The SQ system was listed in Engineering Study No. 13-NS-B28 as a low-risk-significant system. The team understands that PVNGS has not procured any C/I No. 4401-001958 high-voltage PC boards under its new graded QA program. Under QAP Criterion 2, "The design and fabrication complexity or uniqueness of the item," the IPSCN stated:

The PC board is a relatively complex device consisting of various discrete components and is utilized throughout the nuclear industry. The discrete [individual high-voltage PC board] components are utilized in many different PC board configurations throughout other industries. These boards and associated discrete components are manufactured with large production runs by standardized manufacturing processes. The PC boards are assembled utilizing an auto insertion process for placing the discrete components on the board and a solderwave process for permanently attaching the components. Discrete



components are placed in the insertion chutes by workers who may or may not place them in the chutes in the correct orientation.

Under QAP Criterion 4, "the degree to which functionality can be demonstrated by inspection or test," the IPSCN stated that, "the safety functions for this PC board are to maintain circuit integrity (CF20) and to provide signal (CF24)... Testing could be utilized during the receiving process which would verify the required critical verification attributes to ensure functionality. The PC boards do not require special tests or inspection to ensure they satisfy the required safety functions." Additionally, the IPS change notice "criteria evaluation" narrative stated that, "The quality history did not indicate a problem with the PC boards. Therefore, at this point in time, it is concluded that this type of PC board is being manufactured correctly. However, homogeneity is difficult to achieve with a manufacturing process which involves human intervention. Therefore, a simple performance (functional) test will be completed during receiving activities to verify that all connections are intact and the PC board meets the manufacturer's specification sheet and that a visual general configuration and part number verification be performed."

The IPS sheet stated that "the PC board has numerous CVAs dealing with materials, physical properties, configuration and performance (functionality) which verify the ability of the part to perform its safety functions of maintaining circuit integrity and providing a signal." Based on this discussion, PVNGS decided that the material and physical property verification attributes would not be verified; instead, general configuration (S03), part number (I07), and acceptable performance (P43) would be verified to ensure that the correct part was received and that errors had not occurred during the production process.

At the PVNGS site Electronics Rework Facility, the team watched a demonstration of a simulated "acceptable performance (P43)" receiving test of the high-voltage PC board (Test # FTA-062). The team observed that the simulated test was a test which applied a variable voltage input to the card and monitored the PC card output. Although the procurement engineering staff stated that the high-voltage PC board assembly, C/I No. 4401-001958CI, would not meet the definition of a CGI, the IPSCN stated that "this printed circuit board [assembly] is considered a commercial grade item by virtue of the fact that it is made up of individual discrete components which are:

- not a nuclear unique design,
- used in many non-nuclear applications, and
- may be ordered from the supplier/manufacturer by specifications stipulated in the manufacturer's published product description [commercial grade items]."

The team questioned this characterization of the high-voltage PC board in the IPSCN since it conflicts with the definition contained in Section 21.3(a) of 10 CFR Part 21 and statements provided in the IPSCN.

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Specifically, this PC board appeared to be nuclear unique and it did not appear that it would be used in many non-nuclear applications.

During discussions with PVNGS procurement engineering staff on September 20, 1995, (subsequent to the NRC plant visit) the team discussed the PC board "safety functions," that were included in the IPSCN, specifically the circuit integrity (CF20) and signal (CF24). During this discussion the cognizant procurement engineer informed the team that the wrong safety-function code was used. The procurement engineer stated that since the device was a high-voltage PC board, the CF24, "Transform/Supply Energy," should have been used. The PVNGS engineer also stated that during a recent discussion with the high-voltage PC board manufacturer, PVNGS received contradictory information regarding the automated manufacturing process. The manufacturer stated to the PVNGS Engineer that:

- The high voltage PC cards were not assembled utilizing an auto insertion process for placing the discrete components in the PC board locations.
- A solderwave process for permanently attaching the components to the PC boards was not used.

The team expressed concern about the lack of attention to detail in this dedication package, the differing process control information received from the manufacturer, and the fact that the high-voltage PC board assembly did not meet PVNGS's procedural definition of a CGI, but the IPSCN indicated that it could be procured as a CGI.

5. IPS No. G080-191, Revision 00, with IPSCN(GC) No. 0003, dated August 27, 1995, described the dedication plan for an electrical contact block for use in Class 1E 480 Volt Motor Control Centers (identified as the PH system at PVNGS). The PH system is listed in Engineering Study No. 13-NS-B28 and categorized as low-risk-significant.

The identification of the contact block's critical verification attributes was based on an evaluation of the five criteria found the PVNGS QAP. The evaluation in the IPSCN concluded that the safety functions of a contact block (any) were to maintain circuit integrity and to change state and that "utilizing receipt inspections (visual) to ensure functionality for the contact block [was] not an acceptable method." The IPSCN added that performance testing could be completed during the receipt inspection process to verify the critical verification attributes (e.g., insulation resistance, continuity, etc.) required to ensure functionality. This portion of the IPSCN evaluation, however, concluded that "contact blocks [did] not require special (sic) tests or inspection to ensure they satisfy the required safety function. "That is, Class 1E contact blocks categorized as low-risk-significant at PVNGS can be de dedicated (i.e., found suitable for safety-related applications) without having to ensure their functionality. The team concluded that "special" in this context, meant

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performance testing that could be completed during the receiving process to verify the critical verification attributes required to ensure functionality.

Except for a brief discussion of the contact block's fasteners, the IPSCN evaluation did not address seismic requirements. (See Section III of this report for a detailed discussion of seismic qualification requirements for procurement.)

Finally, the IPSCN evaluation arrived at the unsubstantiated conclusion that verification of general configuration and part number, in and of themselves, confirmed that the contact block's material, physical properties, and performance (insulation resistance, contact rating and resistance, etc.) are acceptable.

6. IPS No. L045-001, with IPSCN(GC) No. 0007, described the dedication plan for capacitors for use in a low-risk-significant system waste gas ventilation monitor. The IPSCN acknowledged that receipt inspections demonstrate functionality to a small degree whereas in-service inspections demonstrate functionality to a high degree. The IPSCN stated that the capacitors have numerous CVAs that need to be verified to ensure their ability to perform their safety function. The IPSCN specified that the low-risk-significant dedication for the capacitor would be limited to part number and configuration verifications.

The team had the following observations on the IPSCN:

- The part number verification was designated in the IPSCN as CRB-28-074. A review of the attached vendor drawings indicted that the capacitor is actually Lambda part CBR-28-074. The team pointed out this discrepancy to PVNGS procurement staff.
- The IPSCN evaluated grading QAP Criterion 3 on the need for special controls, surveillance, and monitoring and stated that the criterion was not appropriate to the procurement process. As discussed in Section I of this report, this criteria can be applicable to procurement activities.
- The performance only of visual verifications of the capacitor part number and configuration means that testing for a number of relevant critical verification attributes are not performed that are normally performed for safety-related high-risk-significant capacitor dedication. As discussed in Section IV of this report, if these types of verifications are not performed, at least on a sampling basis, the dedication process can not give a reasonable assurance of the capacitor's ability to function.

The team reviewed Material Engineering Evaluation (MEE) No. 01007) that documented the commercial grade item technical evaluation for capacitors used in safety-related high-risk-significant applications. The evaluation concluded that for electrolytic capacitors, the following CVAs should be checked: weight, configuration and dimensions,



capacitance, capacitance tolerance, current leakage, working voltage, equivalent series resistance, industry markings, end connection, and dimensions for acceptable fit. For non-electrolytic capacitors, the dielectric strength at rated voltage would be verified in lieu of current leakage and equivalent series resistance. The MEE refers to utilizing applicable MIL-Specifications for performing the capacitor testing.



APPENDIX  
PERSONS CONTACTED  
SEPTEMBER 6-7, 1995

PVGNS:

M. Armenta\*  
A. Krainik\*  
S. Garrett\*  
J. Johnston  
M. Heider\*  
D. Kissinger  
D. Lamontage\*  
D. Leech\*

D. McGinil  
P. McGreedy  
T. Rudolph  
C Rogers\*

Organization

Nuclear Materials Management & Budgets  
Nuclear Regulatory Affairs  
Nuclear Materials Management & Budgets  
Instrumentation & Controls  
Nuclear Materials Management & Budgets  
Nuclear Assurance  
Nuclear Regulatory Affairs  
Nuclear Assurance

Nuclear Materials Management & Budgets  
Instrumentation & Controls  
Fire Protection  
Nuclear Regulatory Affairs

ENERGY CORPORATION INC.

J. Brown\*

Licensing Department

US NRC:

L. Campbell\*  
R. Gramm\*  
K. Johnston\*  
J. Peralta\*  
J. Petrosino\*

NRR  
NRR  
Senior Resident Inspector  
NRR  
NRR

\* Indicates attendance at exit meeting on September 7, 1995

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