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J. Phillip Bayne
Executive Vice President
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October 19, 1983
IPN-83-87

Director of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Attention: Mr. Steven A. Varga, Chief
Operating Reactors Branch No. 1
Division of Licensing

Subject: Indian Point 3 Nuclear Power Plant
Docket No. 50-286
Quality Assurance Program Review

Dear Sir:

Your letter of August 18, 1983 served to summarize the August 12, 1983 conference call regarding the Quality Assurance Program at Indian Point 3. For the reasons delineated in our letter dated January 11, 1983 (IPN-83-1), the Authority has held all revisions to the Quality Assurance Program in abeyance. As indicated in your August 18, 1983 letter, this ongoing issue has been satisfactorily resolved. The Attachment to this letter provides the Authority's responses to the questions presented in Enclosure I to your September 23, 1980 letter, pertaining to the Quality Assurance program for Indian Point 3.

Pursuant to 10 CFR 50.54(a) the Authority has submitted a description of the Quality Assurance program to the NRC Region I Office via letter dated June 10, 1983 (IPN-83-57). Several of the responses to your questions necessitate revisions to portions of this Quality Assurance Program description. The revisions to the Quality Assurance Program description will be incorporated, as appropriate, into the FSAR during the 1984 annual FSAR update.

Should you or your staff have any questions regarding this matter, please contact Mr. P. Kokolakis of my staff.

Very truly yours,

G. M. Wilverding

for J. P. Bayne
Executive Vice President
Nuclear Generation

A001 Add: Walter Haass
1/1

cc: attached

cc: Dr. Thomas E. Murley
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P. O. Box 66
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*59. Question

The response to Request 1 is not acceptable under present review guidelines. It is the staff position that all items including programmatic requirements (e.g., emergency plan, security, meteorology, etc.) affecting safety that can be derived from the General Design Criteria of 10 CFR Part 50 Appendix A and other pertinent regulations shall be under the control of PASNY's 10 CFR Part 50 Appendix B quality assurance program. These items include those that can be identified from Regulatory Guide 1.29 (positions 1 through 4) plus spare and replacement parts, and consumables and expendables needed for the various activities performed in connection with those items. The current "Q-list" (Table 17.2.2-3 in the FSAR) should be expanded to meet this staff position. (See item A of Enclosure 2.)

Response

The current "Q-list", which is provided by the Authority's quality assurance procedure entitled "Quality Assurance Scope", identifies the safety related and non-safety related structures, systems and components at Indian Point 3 subject to the Authority's Quality Assurance Program. It is the Authority's policy to revise this "Q-list" as necessary to maintain its currentness. The "Q-list" was revised in July 1983 to include the control room ventilation system, the fuel building emergency exhaust system, and the meteorological tower.

The non-safety related structures, systems and components to which the Quality Assurance Program is applied include: the additional low level radiation waste storage tanks, the condensate polishing plant, the Branch Technical Position 9.5.1 fire protection systems affecting safety related systems, the meteorological monitoring program and packaging for transport and the tranportation of radioactive materials.

The Authority is taking an active role in industry groups addressing the topic of "equipment important to safety".

*Responses to Questions 1-58 have been transmitted previously.

60. Question

The response to Request 5 is not adequate. Paragraph (a) states that "independent inspections are performed by QA on selected modes of plant operation, maintenance, and modification activities" without identifying the specific QA individuals or groups responsible for this function and what criteria are utilized to determine the "selected modes" on which inspection will be performed. Paragraph (a) also identifies the operating organization as being responsible for performing tech spec surveillance and verification activities. Page 17.2-14 of the FSAR (#16) identifies the Authority's QA Department as being responsible for providing surveillance or inspection of plant activities while page 17.2-32 of the FSAR identifies the operating organization as being responsible for performing QC inspections at the plant. From the above descriptions, it is difficult to determine what group is responsible for performing a particular surveillance or inspection. Therefore, it is requested that you clearly identify the designated QA individuals or groups and operating organization individuals or groups responsible for performing the particular inspection and surveillance function. Also, describe the criteria to be used to determine the "selected modes" to be applied to independent inspection.

Paragraph (c) of the response to Request 5 does not clearly describe the extent independent evaluation and verification of documented inspections and surveillance results will be performed. Clarify your intent in this regard.

Response

(a) Inspection activities of physical work such as plant modification, maintenance activities and material/equipment receipt are performed by quality control personnel reporting to Superintendent of the Plant QA staff.

"Selected modes" of plant operations was intended to refer to the Technical Specifications requirements such as shutdown, startup and refueling operations as performed by the Operations Department. Technical Specification surveillance tests are performed by the Plant Technical Services, I&C or Operations Department as scheduled. These activities are subjected to audits and QA surveillance on a periodic basis by the Plant QA staff to verify compliance with the Technical Specifications.

(c) Independent evaluation of components or systems are performed in accordance with administrative procedures and documented by Plant Technical Services. These evaluations, including testing, are performed on components or systems which have been subjected to modification or rework that could impact Tech Spec requirements. These evaluations are subject to QA audit as described in item a.

Inspection operations performed by QC personnel as described in item (a) are performed in accordance with Administrative and QA procedures, and the documented results reviewed for adequacy and completeness by the QC Supervisor/designee prior to incorporation in the plant record system.

61. Question

The response to Request 9 whereby the onsite QA organization only attends staff meetings on an as needed basis or during refueling or other outages is not adequate. It is our position that the QA organization, both onsite and offsite, should be actively involved in all quality-related aspects of the operation of a nuclear power plant. (See item C of Enclosure 2.)

Response

The QA Superintendent (on-site) or his designee attends and participates in staff management meetings including those associated with planning the daily work schedules for Operations, Maintenance, In-Service Inspection, Testing and Modifications, to provide QA/QC input as necessary and thus keep current of plant activities so that QA/QC actions can be properly identified and planned.

To clarify this item the Authority will revise the last paragraph of 17.2.1.4, in the QA Program to reflect this current practice:

> "To remain cognizant of plant activities, the QA Superintendent, or his designated representative, attends and participates in plant staff meetings. The plant Quality Assurance Superintendent and Quality Control Supervisor have the authority to initiate stop work orders through the Resident Manager or other appropriate authorized personnel when such work is not being performed in accordance with approved drawings, specifications, procedures or regulatory requirements. Various Departments of the Authority assist the Vice President-Quality Assurance in the overall Quality Assurance Program. Assistance from other Authority Departments is available to the Quality Assurance Staff whenever necessary."

62. Question

a. The response to Request 10 is not adequate. It is an NRC staff position that the qualifications and experience of the Director of Quality Assurance (offsite) be at least equal to those of the individual responsible for managing the onsite QA program as described in Section 4.4.5 of ANSI/ANS 3.1-1978, "Selection and Training of Nuclear Power Plant Personnel." In lieu of the above, we would accept a commitment to the education and experience described in the following Section 4.4.5 of ANS 3.1-1979:

> EDUCATION: Bachelor Degree in Engineering or related science.
>
> EXPERIENCE: Four (4) years experience in the field of quality assurance, or equivalent number of years of nuclear plant experience in a supervisory position preferably at an operating nuclear plant or a combination of the two. At least one (1) year of this four years experience shall be nuclear power plant experience in the implementation of the quality assurance program. Six (6) months of the one year experience shall be obtained within a quality assurance organization.

b. Expand your responses to requests 7 and 8 to address the qualification requirements of the QA personnel (see item C of Enclosure 2).

Provide a description to satisfy the above positions.

Response

a) In response to this item, the Authority will revise Appendix 17.2-9, of the QA Program as attached. This will clarify the Authority's position on qualification and experience requirements for the position of Director of Quality Assurance which is equivalent to the requirements imposed on the individual managing the onsite QA program.

b) The subject Appendix of item a) also includes the qualification and experience requirements of other QA personnel such as Managers, Engineers, the QA Superintendent and the QA Supervisor.

APPENDIX 17.2-9
QA PERSONNEL QUALIFICATION

Qualification requirements have been established for activities requiring various levels of proficiency and training for personnel on an individual basis. Personnel assigned to perform Quality Assurance activities will have qualifications that are commensurate with the responsibilities with which they are charged. Quality Assurance personnel will have demonstrated their ability to perform competently in those areas for which they will be held responsible. Qualifications of personnel performing QA functions shall be determined from the following data:

Education

A. A degree in engineering or a related field of study.

B. Where a college degree has not been obtained, two years of experience in the paragraph "Experience Requirements - Area" below, will be acceptable in lieu of each year of college level education. This requirement is based on a four-year accredited curriculum.

Experience Requirements - Area

A. Design
B. Construction
C. Operation
D. Quality Assurance
E. Nuclear

Experience Requirements - Years

The required number of years of experience, listed hereinafter, shall be the sum of all the years in any or all of the areas listed in the Experience paragraph above, plus a degree in engineering or a related field of study.

Position - HQ	Experience Years
Vice President - Quality Assurance	10*
Director of QA	7*
QA Manager	7
QA Engineers	5

Position - Plant	Experience Years
QA Superintendent	7*
QA Supervisor	5
QA Engineers	5
QC Supervisor	5

*At least one year of this experience shall nuclear power plant experience in the implementation of the QA program, within the QA organization.

Plant QC personnel shall be certified based on the experience and education requirements as defined in the Authority's position on Regulatory Guide 1.58 (Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel) as accepted by the NRC and ANSI N45.2.6 as referenced in Appendix 17.2-6, (Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants). The Authority does not believe that a high school diploma or equivalent should be mandatory as indicated by Regulatory Position C.6 of Regulatory Guide 1.58. The Authority believes that an individual's technical training, experience and performance capability are the more significant parameters for establishing personnel qualifications. The experience level certification shall be commensurate with the activity to be performed.

63. Question

The response to Request 12 needs further clarification. Specifically describe your controls for documenting and maintaining as-built conditions on drawings and specifications. Describe the extent as-built drawings and specifications identify nonconformance dispositioned "accept as is."

Response

The procedure that describes the controls for documenting and maintaining as buit conditions on drawings and specifications is Administrative Procedure No. 12, Modifications. It requires that the drawings and specifications shall be up-dated based on design information and as built condition by the design organization. The drawing update task is presently being performed on a system basis.

The as-built drawings and specifications document the existing plant condition with respect to equipment installation. These items are not used to disposition nonconformances as "accept as is".

To clarify the Authority's program, we propose to revise paragraph 17.2.3.6, of the QA Program, in accordance with the following text.

17.2.3.6 Design Change Control

Procedures are established to assure that design changes, including as-built information generated during plant modification activities are appropriately documented, and submitted for review and approval by design organization prior to incorporation in the plant record documents.

64. Question

The respone to Request 16 is not adequate. The matrix included in Request 16 indicates examples where the QA organization does not review or concur in all procedures and documents that affect safety and quality. It is the staff's position that qualified individuals in the QA organization, either onsite or offsite, shall be responsible for performing reviews of all documents affecting safety and quality, including changes thereto, and for indicating approval. (See item D of Enclosure 2.)

Response

The following revised Matrix, reflecting the current Administrative/Departmental Procedures, is submitted in response to this question.

In all cases procedures are reviewed by the department requiring these procedures, by persons other than the preparer. They are approved by the department and in the case of plant procedures by the Resident Manager after Plant Operating Review Committee (PORC) review.

Because of the technical nature of many of these documents, the Authority considers that they should be prepared and reviewed/approved by technical personnel and that the current review cycle is sufficient to meet the requirements of Criteria V of 10CFR50, Appendix B.

Procedure	Preparation	Review/Concurrence	Approval	Issuance
Operating	O	O, P	O, RM	O
Plant Administrative	D	D, QA, P	RM	RM
Maintenance	M	M, QA, P	M, RM, QA	M
Modification	TS	TS, QA, P	TS, QA, RM, SP	TS
Calibration	D	D, P	D	D
Surveillance Test	TS	TS, P	TS, RM	TS
Test	TS	TS, P	TS, RM	TS
Fuel Handling	O	O, P, QA	O, RM, QA	O
Inservice Inspection	C	N, C, TS, QA, P	C, QA, RM	TS
Emergency	RE	RE, QA, P	RE, RM	RE
Security	S	S, P	S, RM	S
Health Physics	RE	RE, P	RE, RM	RE
Chemistry	RE	RE, P	RE, RM	RE
Other Documents				
Work Authorizations	D	O, QA	O	O
Drawing Packages	C	E, C, TS, QA	C/TS	TS
Specifications	C	E, C, TS, QA	C/TS	E, TS
Procurement Documents	PU	D, QA, RM	RM/SP	PU
Nonconformance Reports NCA's	QA	D	QA	QA
Deficiency Report (DCAR's)	QA	D	QA	QA
Procurement Documents (HQ)	C/CA	C, CA, QA, E, N	C/CA	CA

Legend

O	=	Operations
M	=	Maintenance
TS	=	Technical Services
IC	=	Instrument & Control
RE	=	Radiological & Environmental
QA	=	Quality Assurance
P	=	Plant Operations Review Committee
SRC	=	Safety Review Committee
RM	=	Resident Manager
D	=	Applicable Dept. (Plant)
C	=	Contractor
N	=	Nuclear Operations (HQ)
S	=	Security
E	=	Engineering
PU	=	Purchasing (Plant)
CA	=	Contract Administration (HQ)
SP	=	Superintendent of Power

65. Question

The response to Request 19 is not adequate in that you have not addressed the QA organization's involvement in the review, concurrence, and control of vendor's nonconformances dispositioned "use as is" or "repair". It is a staff position that you should specifically describe the QA organization's involvement in these activities.

Response

The Authority's QA program requires that major contractor/major vendors nonconformances with a disposition of "use as is" or "repair" be reviewed by qualified personnel to assure that the Authority concurs in the vendor's disposition. This review may require technical or quality personnel or both based on the nature of the reported condition. To clarify the intent of the program the Authority will add the following text to the third paragraph of Section 17.2.15.1 of the QA Program.

> "The description of nonconformance identified as "use as is" or "repair" are reviewed for acceptability by quality assurance and/or cognizant technical personnel."

Additionally, the fourth paragraph of Section 17.2.15.1 of the QA Program will be revised as follows:

> "Measures have been established in the program to assure that nonconformance data related to work performed at Contractor/major vendor's facilities, relative to "use as is" or "repair" dispositions are reflected in the inspection records and forwarded to the plant to be retained as part of the plant records following a review for acceptability by quality assurance and/or cognizant technical personnel."

66. Question

The response to Request 22 requires clarification in that the response states QA reviews and concurs with AP17, "Calibration of Measuring and Test Equipment" whereby the response/matrix of procedures in Request 16 does not show any QA involvement for calibration procedures. Please correct this discrepancy or explain in equivalent detail.

Response

Our response to Request 22 was correct. To clarify this item, it should be noted that AP-17 is an administrative procedure which describes the controls applied for implementing the plant calibration program. This and other administrative procedures which implement program requirements are subject to a review by QA. The individual equipment calibration instructions, generated by the cognizant departments, are subject to the review process described in the response to item 64.

67. Question

The responses to Requests 23 and 56 identify the operations organization as being responsible for the status of nonconforming, inoperative, or malfunctioning structures, systems, and components without describing the QA organization's involvement. It is our position that the QA organization be involved as a minimum, in the review and concurrence for the application and removal of status indicators such as tags, stamps, shop traveller, etc.

Response

Non-conforming materials, items and components are controlled in accordance with Quality Assurance Procedure QAP 15.2 which includes provisions for segregation and identification. The QC group is responsible for applying the appropriate "hold" or "reject" tags pending final disposition of the items. QAP 15.2 is applicable to items undergoing receipt inspection as well as any items which are removed from a plant system.

The status of item operability is controlled by the plant Surveillance Test Program as delineated in the Technical Specifications. The Operations groups identify random component failures. The licensed operators are charged with the responsibility of determining and identifying the operability status of plant systems and components. The QA department's involvement in this activity includes reviews by audit of surveillance test records, amd witnessing operability tests and related administrative controls.

68. Question

The response to Request 27 is not adequate. It is a staff position that you commit to comply with the following NRC regulatory guides for future operational activities including maintenance and modification:

a) Regulatory Guide 1.29, Rev. 3, "Seismic Design Classification."

b) Regulatory Guide 1.33, Rev. 2, "Quality Assurance Program Requirements (Operation)" (endorses N18.7).

c) Regulatory Guide 1.38, Rev. 2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants" (endorses N45.2.2).

d) Regulatory Guide 1.39, Rev. 2, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3).

e) Regulatory Guide 1.64, Rev. 2, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11).

f) Regulatory Guide 1.88, Rev. 2, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9).

g) Regulatory Guide 1.94, Rev. 1, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants" (endorses N45.2.5).

h) Regulatory Guide 1.116, Rev. 0-R, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8).

i) Regulatory Guide 1.123, Rev. 1, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13).

j) Regulatory Guide 1.144, (January 1979), "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12)

Should you elect to take any exceptions to the above regulatory guides or the ANSI standards they endorse, please identify the specific sections to which you take exception and provide your alternative approach with equivalent supporting detail for evaluation.

Response

a) Regulatory Guide 1.29, Rev. 3, "Seismic Design Classification"

Regulatory Guide 1.29, Rev. 3 provides a seismic design classification system for identifying those plant features that should be designed to withstand the effects of the Safe Shutdown Earthquake (SSE). This guide is to be used in the evaluation of submittals for operating license or construction permit applications. The design basis for Indian Point 3 at the operating license stage did not address Regulatory Guide 1.29. The criteria for seismic classification at Indian Point 3 are delineated in Chapter 16.1 of the FSAR.

All components, systems and structures classified as seismic class I were designed to withstand the SSE. All seismic class II components were designed to withstand the Operating Basis Earthquake (OBE). It has been found that the loading combinations and stress limits involving the OBE will govern the design of seismic class II piping systems with respect to seismic criteria. In those cases where it was shown that the loading combinations involving the SSE governed, the adjacent seismic class II piping and supports were designed to the seismic class I criteria.

Equipment classified as seismic class I or II fulfill the criteria for safety related equipment, as delineated in Regulatory Guide 1.26, Rev. 2. All equipment at Indian Point 3 identified as seismic class I or II are regarded as safety related equipment and are identified as such on drawings and process and instrumentation diagrams.

b) Regulatory Guide 1.33, Rev. 2, "Quality Assurance Program Requirements (Operation)" (endorses N18.7).

Appendix 17.2B of the FSAR dated July 1982 states that the Quality Assurance requirements for the operation of Indian Point 3 comply with Regulatory Guide 1.33, November 1972. The numerous requirements of ANSI N18.7 - 1971, as endorsed by Regulatory Guide 1.33 (November 1972), require a great number of procedures to control the quality assurance program for the entire operation of Indian Point 3. The preparation and implementation of the procedures necessary to assure compliance with Regulatory Guide 1.33 (November 1972) were very time consuming and manpower intensive. There exists many interfaces between the procedures governing the quality assurance program for the various aspects of Indian Point 3 operation.

Revision 2 to Regulatory Guide 1.33 serves to endorse a later version of ANSI N18.7. While the revisions included in N18.7 - 1976 are not extensive, the interfacing between the governing procedures necessitates a large work effort to be expended on revising these procedures. The Authority feels that the increased level of safety afforded by ANSI N18.7 - 1976 does not justify the manpower necessary to comply with Regulatory Guide 1.33, Rev. 2.

c) Regulatory Guide 1.38, Rev. 2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-cooled Nuclear Power Plants" (endorses N45.2.2).

Appendix 17.2 B of the FSAR dated July 1982 states that the quality assurance requirements for packaging, shipping, receiving, storage and handling comply with Regulatory Guide 1.38 (March 1973) with the following exceptions:

a. Regulatory Position C.3 - Tapes, dessicants and dessicant bags do not contain the following as a basic and essential chemical constituent: lead, zinc, copper, mercury, cadmium and other low melting point metals, their alloys, and/or compounds.

b. As prescribed in ANSI N45.2.2-1972 maximum levels of water leachable chlorides, total halogens, and sulfur and their compounds are imposed upon tapes.

c. Dessicants and dessicant bags contain nonhalogenated and nonsulfur bearing materials.

d) Regulatory Guide 1.39, Rev. 2, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3).

Appendix 17.2 B of the FSAR dated July 1982 states that the housekeeping program complies with Regulatory Guide 1.39, which endorsed ANSI N45.2.3-1973. Regulatory Guide 1.39, Rev. 1 provided clarification of the "should/shall" items appearing in the original issuance. Additionally Rev. 1 requires the utilization of ANSI N45.2.3-1973 in conjuction with Regulatory Guide 1.120 in addressing the concern of fire protection and prevention. Revision 2 did not provide any substantive changes from the previous issuance.

e) Regulatory Guide 1.64, Rev. 2, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11).

Appendix 17.2 B of the FSAR dated July 1982 states that the Quality Assurance requirements for the design or design change resulting in modification of Indian Point 3 comply with Regulatory Guide 1.64, October 1973. The only substantive change posed by Revision 2 is the constraints placed on the use of the originator's supervisor for design verification. The Authority employs the superior of the responsible engineer for the design verification provided the superior is the only available technically qualified individual. Hence the Authority complies with Regulatory Guide 1.64, Rev. 2.

f) Regulatory Guide 1.88, Rev. 2, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9)

As stated in Appendix 17.2 B of the FSAR dated July 1982 the collection, storage and maintenance of Nuclear Power Plant Quality Assurance records conforms with Regulatory Guide 1.88, Rev. 2.

g) Regulatory Guide 1.94, Rev. 1, "Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel during the Construction Phase of Nuclear Power Plants" (endorses N45.2.5).

During the operational phase of Indian Point 3, the Authority has not installed structural steel and structural concrete to a great extent. The installation of a condensate polisher and a radwaste vault were the only major modifications requiring the installation of structural steel and structural concrete during the operational phase. The quality assurance requirements which were utilized for these modifications, are provided by Regulatory Guide 1.143, "Design Guidance For Radioactive Waste Management Systems, Structures and Components installed in Light-Water-Coded Nuclear Power Plants". The quality assurance requirements provided by Regulatory Guide 1.143 meet the intent of Regulatory Guide 1.94.

The Authority's method of installing structural steel and structural concrete assure that the intent of Regulatory guide 1.94 will be fulfilled for future applicable modifications.

h) Regulatory Guide 1.116, Rev. O-R, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8).

Regulatory Guide 1.116 Rev. O-R endorses N45.2.8-1975 with three clarifications as delineated in Paragraph C, Regulatory Position. This Regulatory Guide provides no substantive changes from the program requirements imposed during the initial plant construction or start-up phases. The program requirements were performed in accordance with the draft N45.2.8 standard included in WASH 1284 and 1309.

The application of N45.2.8-1975 to the operational phase of the plant is limited due to the intent of the standard and the limited number of modification activities that would be subject to specific standard requirements. However, Administrative Procedure AP-12, "Modifications," which provides direction for proposed changes, tests or experiments as well as other program requirements, meets the intent of the Regulatory Guide.

i) Regulatory Guide 1.123, Rev. 1, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13).

This Regulatory Guide endorses ANSI N45.2.13-1976 with six clarifications as delineated in Paragraph C, Regulatory Position. The Authority's QA Program, as defined in the current QA Program Description meets the intent of this Regulatory Guide.

Section 17.2.4, of the QA Program, defines the general requirements of the overall program which are implemented by a series of Quality Assurance and Contract Administration Procedures. These procedures provide for the control of the procurement process when performed by the Authority or by an agent/consultant to the Authority.

The following procedures provide guidance and direction to assure that the intent of Regulatory Guide 1.123 is satisfactorily achieved.

.Quality Assurance Procedures

QAP 4.1	Procurement Document Review
QAP 7.1	Vendor Selection and Evaluation
QAP 7.2	Monitoring of External AE Organizations Delegated Procurement Activities by the Authority
QAP 7.3	Receiving Inspection
QAP 7.4	Vendor Evaluation
QAP 7.7	Contractor/Vendor Surveillance Inspection
QAP 15.2	Control of Nonconforming Material, Parts and Components
QAP 16.3	Corrective Action Control-Headquarters

.Contract Administration Procedures

CAP 4.1	Review of AE Procurement Documents
CAP 4.3	Review of Authority Procurement Documents
CAP 4.4	Processing of Authority Procurement Documents
CAP 4.5	Preparation and Processing of Change ORders
CAP 7.1	Bid Evaluation and Vendor Selection

j) Regulatory Guide 1.144, (Jan 1979), "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12)

This Regulatory Guide endorses ANSI N45.2.12-1979 with several clarifications as delineated in Paragraph C, Regulatory Position. The significant positions concern operational phase audit related to RG 1.33 (ANSI N18.7) and scheduling requirements for external audits of supplier/contractors.

The QA audit procedures specifically addresses the internal audit which are performed in accordance with the requirements defined in Section 6 of the Technical Specifications and a Safety Review Committee procedure, SRCP-18.1, where the function is delegated to QA. The scheduling requirements for external audits as defined in the Regulatory Guide are defined in the QA procedures, and require the generation of a specific audit schedule. The program essentially meets the requirements of the standard.

69. Question

The response to Request 28 is not adequate in that Section 13.2.1.2 appears to describe provisions for retraining and requalification of personnel that does not include a need to be aware of design changes or modifications affecting the performance of their duties. Please revise your response and clarify the above.

Response

Section 12.2.2.1 of our July, 1982, FSAR deals with retraining. It states in part:

> In addition, the retraining program will include those items applicable to their (referring to any individual whose job responsibility requires) position in the following areas of interest:
>
> a) Familiarization with plant operating experience (Licensee Event Reports)
> b) Modifications and design changes
> c) Revisions to procedures and indoctrination to new procedures including administrative controls and procedures affecting organization responsibilities, security, access control rules for visitors, contractors and temporary personnel and other related subjects.

70. Question

The response to Request 29 is incomplete. Your description implies that design control activities have been assigned to PASNY's major contractors and architect-engineers. A description has not been provided to assure that errors and deficiencies in approved design documents, including design methods (e.g., computer codes) for items that could affect safety, are documented and corrected. Revised your response to include such controls.

Response

The response to this item, item 73 and item 77 are closely related and, while a response to 73 and 77 have been provided separately, we propose to clarify the last paragarph of 17.2.3.4, of the QA Program to include the following text.

> "Errors and deficiencies in the design and the design process, including the use of computer codes that could adversely affect safety-related structures, systems and components identified during design review in accordance with approved procedures, are documented, and corrective action is taken to correct the deficiency and preclude repetition.

71. Question

The response to Request 30 does not provide sufficient information for our review. Please re-review our request and respond accordingly.

Request 30

For design verification activities, provide a statement that the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

Response

The Authority's design verification program is described in Engineering Department and site modification procedures which require that the activity be performed by individuals or groups other than those who performed the design. The procedures contain provisions to define the responsibilities of the verifier, the scope of the verification including input requirements, area and features to be reviewed and the reporting methods and review cycle.

To clarify the Authority's position, the third paragraph of 17.2.3.4, of the QA Program will be revised, in accordance with the following text.

> "The individuals or groups who perform design verification or checking are other than those who perform the original design. Design verification activities are performed in accordance with approved procedures that define the responsibilities of the verifier, the scope, areas and features to be verified including pertinent conditions and reporting documentation requirements."

72. Question

The response to Request 31 requires additional information. Although the response to NRC Question 421.2 was acceptable with the information provided by PASNY in the August 9, 1977 submittal, present guidelines require further description. For example, if a design change altered the original configuration and functioning of a safety relief system, this could constitute a major design change and therefore require equipment qualification under the most adverse conditions as determined by the analysis. Independent design review in itself would not assure the equipment or system would necessarily perform the intended function. Therefore, it is our position that when the design verification method is by test, the following provisions are included:

a) Procedures provide criteria that specify when verification should be by test.

b) Prototype, component, or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreverisble.

c) Testing is performed under conditions that simulate the most adverse conditions as determined by analysis.

Response

In response to this item the Authority will revise the Note in Section 17.2.3.4 of the QA Program to read as follows:

NOTE: The qualification test of a prototype unit under adverse design conditions would not be practical or realistic when verifying the adequacy of a design change or modification to an existing system of an operating plant. Design changes will constitute the majority of engineering work when an operating plant is involved. In such case the Authority will depend on an independent review to assure the necessary adequacy verification.

However, if analysis determines that testing is the only acceptable method of verification, the testing shall be performed under conditions that simulate the most adverse operational conditions. This testing, to the maximum extent possible, shall be performed prior to installation.

73. Question

Clarify your response to Request 32 whereby procedures are established to assure PASNY verifies that computer codes are certified and specified for a particular use.

Response

Computer codes used in the Authority's design process are subjected to a review and approval process in accordance with Engineering Department procedures. This process assures that appropriate documentation is available such as a program summary defining the particular code use, a user's and programmer's manual, program source information, test data and results and validation information.

To clarify the Authority's program requirements, we proposed to add the following sentence to the first paragraph of Section 17.2.3.3 in the QA Program.

> "Computer programs used in the design process shall be reviewed and approved prior to initial use in accordance with Engineering Department procedures"

74. Question

The response to Request 34 needs additional clarification and information. Special processes, as addressed in Criterion IX of Appendix B to 10 CFR 50, are generally those processes where assurance of quality cannot be determined by direct inspection of the inprocess activity or product but rather through more stringent control of the process itself. Examples of special processes other than noted in the response to Request 29 are chemical cleaning, cadwelding, protective coatings, concrete placement, hydrostatic testing, etc. Therefore, it is our position that your describe the criteria for determing what special processes are and provide as complete a listing as possible of special processes.

Response

To futher describe processes subject to special process controls, we propose to revise the second paragraph of Section 17.2.9.1 in the QA Program. This revision will include criteria to identify special processes and to expand the present process listing in accordance with the following text.

> "A special process is defined as a unique manufacturing, inspection or test process where the assessment of quality by direct inspection of the process or product is disadvantageous or impractical after the operation is complete. Processes of this nature require the application of effective controls on the process as described later in this Section. Special processes include, but are not limited to, welding, cadwelding, studwelding, heat treating, nondestructive examination, protective coating application, concrete placement, and chemical cleaning."

Hydrostatic testing is completed in accordance with applicable codes and standards.

75. Question

The response to Request 35 is not clear. Clarify whether all inspections associated with normal operations (e.g., routine maintenance, surveillance, and tests) are performed by the QA organization and identify the specific QA department responsible for performing the various inspections for the above areas. Also describe provisions which assure that the qualifications of inspection personnel will be reviewed for adequacy prior to initiating inspections of items affecting safety and quality.

Response

The QA Program, appears to adequately address this issue. To clarify any possible misunderstanding, the Authority will delete the last paragraph of Section 17.2.10.1, of the QA Program, to reflect the fact that the operating organization does not perform any Quality Control inspections at IP-3. Only Quality Control personnel conduct Quality Control inspections at IP-3.

The paragraph to be deleted reads:

> "The operating organization will perform inspections at the plant in accordance with approved written procedures which conform to the requirements of the Authority's Operation Quality Assurance Program."

76. Question

The responses to Requests 33 and 43 do not provide sufficient information to determine that the principal contractor's QA program will be reviewed and approved by the QA organization prior to initiation of activities. Clarify your response and provide a description to include the above information.

Response

The Authority's FSAR, Section 17.2.2, dated July 1983 contains the information, which responses to this item. The referenced Appendix 17.2A is stated below. This approval process is performed by QA prior to the initiation of work.

APPENDIX 17.2A

ARCHITECT-ENGINEER

The Authority may delegate to Architect-Engineers quality affecting activities for modifications and/or additional facilities or services. Any work so delegated shall be in accordance with an approved Quality Assurance Program and implementing procedures as may be required for the performance of such tasks.

Additionally, paragraph 17.2.7.2 of the QA Program, outlines the program requirements for QA to assess a supplier's capability to provide an acceptable product or service prior to the award of a procurement order or contract.

77. Question

The response to Request 45 is not adequate. The reference to Response 29 does not address provisions which assure that drawings and specifications receive a documented check to verify dimensional accuracy and completeness. Revise your response to include such controls.

Response

The Authority's program to assure that dimensional accuracy and completeness of drawings and specification is described in a series of Engineering Department and Plant Administrative Procedures appropriate to the document type. The procedure for drawing review includes in-process reviews by engineering and design personnel as well as a final supervisory review and approval. Results are documented on a review form or check print as appropriate to the procedural requirements. Sketches, generated by plant technical personnel as part of a modification activity, are checked by an individual other than the originator prior to a review and approval by the cognizant engineer. This activity is documented on the sketch prior to transmittal to the engineering/design organization for incorporation in the plant drawings.

The review process for specification is similar to that imposed on drawings including an interdiscipline review. The procedure controlling this activity contains review sheets for identifying comments and contains review guidance in the form of checklists.

All identified deficiencies are corrected prior to document issue.

To clarify the Authority's program requirements, see the proposed QA Program change included in the response to item 70.

78. Question

Clarify in the response to Request 46 whether the review of drawings and specification are performed by the QA organization and whether the results of this review are documented.

Response

The Authority's response to item 77 describes the program requirements for the review of drawings and specifications which are performed in accordance with approved procedure that include QA personnel in the review cycle. These reviews are performed to assure that the documents contain the necessary quality requirement such as inspection and acceptance criteria and that the documents have been appropriately processed in accordance with Authority procedures.

To clarify the Authority's program requirements, we propose to revise the second paragraph of 17.2.3.3, of the QA Program, in accordance with the following text.

> "Design documents are reviewed by technical and quality personnel to assure that design characteristics can be controlled, inspected and tested; and inspection and tests criteria are identified. The review also assures that documents have been prepared reviewed and approved in accordance with approved procedures. Review results are appropriately documented."

79. Question

The response to Request 47 requires clarification. Our request asked whether the QA organization participates in the verification of suppliers' activities. Your response states that the "QA organization establishes the need for verification of suppliers' activities and "Authority personnel conduct inspections/audits." It is our position that the QA organization participate in the verification of the supplier's performance during fabrication, inspection, testing, and shipment of materials, equipment and components. Please revise your description to accommodate the above position.

Response

It is Authority practice to verify the acceptability of supplier activities using the QA organization to perform inspections and surveillance of these activities as appropriate to the nature of the procurement. Additionally, technical personnel from engineering or operations are included in this effort when deemed necessary to accomplish specific tasks. To clarify the Authority's program requirements, we propose to revise the first paragraph of 17.2.7.3, in the QA Program, as shown in the following text.

17.2.7.3 SOURCE AND VENDOR EVALUATIONS

Based upon complexity of purchased items and supplier performance history, source inspections or audits of vendors shall be performed as necessary to assure that the required quality of the purchased items is obtained. Surveillance of suppliers' fabrication, inspection, testing, and shipment of materials, equipment and components will be planned, performed and reported in accordance with written procedures which assure conformance to the purchase order requirements. Source inspections, surveillances or audits of supplier activities shall be performed by qualified personnel from quality assurance, engineering and/or operations as determined necessary during the procurement phase.

80. Question

The response to Request 50 does not describe how suppliers' certificates of conformance are evaluated and whether the results of this evaluation are documented. Please revise your description to accommodate the above request.

Response

Suppliers' certificates of conformance are evaluated by quality assurance or technical personnel by various methods based on the nature of the procurement and documented in reports appropriate to the method employed. For example, if a principal contractor has delegated procurement responsibility, the contractor performs the primary verification which is then audited to assure conformance and documented in the audit report. Authority procurements, based on the nature of the item or component, may be subject to source inspection or to a receiving inspection which would evaluate the adequacy of the certificate of conformance and provide a documented report. When determined necessary, independent inspections or tests may be performed to verify conformance.

To clarify the Authority's position, we propose to revise the second paragraph of 17.2.7.3 of the QA Program as shown in the following text.

> "Suppliers' certificates of conformance are periodically evaluated by audits, source or receiving inspection activities, independent inspections, or tests to assure their validity. Results of these evaluations are documented in appropriate reports."

81. Question

Clarify in your response to Request 53 whether the QA organization is responsible for performing daily, planned, and unscheduled audits and surveillances.

Response

In addition to the planned and periodic audits included in the Authority's audit program, the program also includes requirements for surveillance audits. These audits are conducted routinely on an unscheduled basis by plant QA personnel for surveillance of day-to-day activities or other unique activities or processes when designated by QA supervision.

Surveillance reports are issued to affected Authority management for review, information and action, as necessary. If a deficiency is identified, during a surveillance audit, a Nonconformance and Corrective Action Report is attached and issued with the surveillance report.

To clarify the is requirement, we propose to revise the first paragraph of 17.2.18.1, of the QA Program, to include the following text.

17.2.18.1 GENERAL DESCRIPTION

The Authority's Quality Assurance Program includes a comprehensive system of planned and periodic audits to be carried out by the Authority Quality Assurance organization to verify compliance with all aspects of the program. This audit system provides data for a continuing evaluation of the effectiveness of the program. In addition, surveillance audits are conducted routinely on an unscheduled basis of ongoing or day-to-day activities to verify satisfactory completion of the activity.

82. Question

The response to Request 54 is not adequate in that QA involvement has not been specified. It is our position that the QA organization, as a minimum, evaluate and verify the completeness of inspection and test activities affecting safety and document the results.

Response

Inspections and test of certain work associated with plant maintenance or modifications, are identified as Quality Control "hold or witness points" in work procedures or steplists in accordance with Quality Assurance Procedure, QAP 10.1. QC inspectors evaluate results by comparing them to the acceptance criteria specified in the applicable drawing, specification or other requirement document. Documenting and controlling completeness of the required inspection actions is accomplished by signing off the "hold or witness point" on the work procedure or steplist and/or preparing a Quality Control Inspection Record.

83. Question

The responses to our series of questions are documented separately from Chapter 17.2.2 of the FSAR. Incorporate or reference all responses to these QA questions, including the positions in Enclosure 2, in Section 17.2.2 of the FSAR to provide a unified QA program description.

Response

Pursuant to 10 CFR 50.54(a) the Authority has submitted a description of the Quality Assurance program to the NRC Region I Office via letter dated June 10, 1983 (IPN-83-57). Several of the responses to your questions necessitate revisions to portions of this Quality Assurance Program description. The revisions to the Quality Assurance Program description will be incorporated, as appropriate, into the FSAR during the 1984 annual FSAR update.