Attachment 17

Ginna Station Procedure QA-PES-1

NUCLEAR ASSESSMENT PROCEDURE ROCHESTER GAS & ELECTRIC CORPORATION	PROC. NO. QA-PES-1	REV. 5	PAGE 1 OF 17
	EFFECTIVE DATE: 7/12/01		
	CONTROLLED COPY # 4		
TITLE: EVALUATION OF QUALIFIED SUPPLIERS BY QUALITY ASSURANCE	7/11/2001 Responsible Manager/Date		
	RECORDS CATEGORY		

1.0 Purpose

1.1 The purpose of this procedure is to describe the methods to be used by Quality Assurance (QA) in evaluating a supplier's capability to be considered as a qualified Safety-Related, 10CFR50 Appendix B, (QSL) supplier, or as a qualified Commercial Grade (CGSL) supplier, and the methods to be used for their periodic requalification. This procedure is in accordance with ND-PES, "Control of Procurement Activities".

1.2 Suppliers listed on the Commercial Grade Suppliers List (CGSL) may be used for:

a. Commercial grade items/services to be dedicated for Safety-Related applications (PC-2 procurements) via Method 2 (commercial survey) as described in QA-PES-2.

b. Commercial grade items to be used in Safety-Significant applications (PC-3, Augmented Quality) where evaluation for CGSL listing provides the appropriate added confidence in the suppliers capabilities.

1.3 Unless specifically noted otherwise, all requirements of this procedure apply to suppliers on, or to be added to, the QSL and CGSL.

2.0 Referenced Documents

2.1 IP-RDM-3, Ginna Records

2.2 QA-PES-2, Conducting Commercial Grade Supplier Surveys

2.3 ND-PES, Control of Procurement Activities

2.4 IP-CAP-1, Abnormal Condition Tracking Initiation or Notification (ACTION) Report

3.0 Instructions

3.1 Specific involvement by Quality Assurance in the supplier qualification process is as follows:

a. Perform initial quality assurance evaluations of suppliers of materials, items, services and spare parts.

b. Perform technical evaluations of suppliers of QA services, such as auditing and inspection.

c. Perform annual reviews of the qualification of suppliers of items, materials, services and spare parts.

d. Establish and maintain the Qualified Suppliers List (QSL) and the Commercial Grade Suppliers List (CGSL).

3.2 Initial Qualification Evaluations (QA Program and Organization)

3.2.1 Quality Assurance may be notified of the need for supplier qualification evaluation by formal or informal requests from any of the organizations within the Nuclear Operations Group or other organizations within RG&E which support the Nuclear Operations Group.

a. Requests for supplier qualification should include the specific items/services of interest and, for CG suppliers only, the relevant critical characteristics (CC's) to be verified by means of the survey.

b. Informal requests should be followed-up in writing.

3.2.2 The evaluating Quality Assurance Engineer reviews the available information and extracts the following pertinent information:

a. Supplier's complete name

b. Supplier's complete address

c. Supplier's phone number

d. Individual responsible for Quality Program implementation.

e. Current Quality Assurance Program document

f. Availability of QA Program document to RG&E

3.2.3 The evaluating Quality Assurance Engineer determines the extent of the evaluation that is to be performed on the supplier. This is based on the supplier type and the complexity and importance to safety of the item or service to be procured. For CG suppliers the evaluation is also based on the supplier's ability to maintain processes that adequately control the critical characteristics established by the end user. Evaluation information for qualification of a supplier shall be derived from the following sources when applicable:

a. The supplier's Quality Assurance Program document (e.g., Manual, Program Plan, Topical Report, etc.).

b. A formal audit/survey of the supplier's facility by RG&E, NUPIC (Nuclear Utility Procurement Issues Committee), other utility(ies), or third-party agent.

c. Records of previous purchases and records of reliability, if available, of a supplier's products/services which have been accumulated by RG&E.

d. Communications, both written and verbal, that descriptively attest to the supplier's capabilities and quality program.

e. Nuclear Regulatory Commission (NUREG-0040) inspections performed under the Licensee Contractor and Vendor Inspection program by the Office of Inspection and Enforcement.

f. A currently registered quality system in accordance with the International Standards Organization Quality Standards (ISO-9000), of the appropriate level.

Note 1: If an audit/survey does not serve as a portion of the basis for initial qualification of the supplier, an audit/survey performed by an outside organization shall be obtained, evaluated, and approved or RG&E shall perform an acceptable audit/survey prior to the acceptance of item/service from the supplier. A restriction to this effect shall be placed upon the supplier in the initial qualification document.

Note 2: As a minimum, items a & b above are required for all CGSL suppliers evaluated for PC-2 procurements. CGSL suppliers evaluated exclusively for PC-3 procurements may be based on a minimum of a & f.

Note 3: If RG&E plans to obtain surplus equipment, parts, components or items from another NRC-licensed utility, it is not required that RG&E audit or list the licensee on RG&E's QSL. However, QA shall establish that the licensee has controlled, under their NRC-approved QA Program, the procurement and storage/warehousing of the item(s) intended to be procured by RG&E, and that suitable quality records for the item(s) are available to be submitted to RG&E. The limited scope qualification of the licensee shall be documented on the QA Supplier Evaluation Notification without the checklist attachment. (See paragraph 3.2.9).

3.2.4 When Quality Assurance evaluation of a prospective supplier includes a review of the supplier's quality assurance program, the following instructions should be observed.

3.2.4.1 If not previously received, the evaluating Quality Assurance Engineer should contact the supplier and request a current copy (controlled, if possible) of their quality assurance program document (e.g. manual, program plan, etc.).

3.2.4.2 Upon receipt of the QA Program Document, the evaluating Quality Assurance Engineer shall evaluate the Document in accordance with the applicable QA program requirements for the item or service being procured. For CGSL suppliers this evaluation shall include, and may be limited to, requirements relative to the control of applicable critical characteristics of the items/services.

3.2.4.3 The evaluation of the supplier's QA program document shall be documented on the Supplier Quality Assurance Manual Evaluation Checklist, Figure 1 or equivalent. If a previously accepted supplier QA Program Document is subsequently revised, only the revised portions of the document need to be evaluated and the acceptability of the changes be appropriately documented.

3.2.4.4 If the evaluating QA Engineer determines that the supplier's QA Program Document contains minor discrepancies with those requirements or controls deemed necessary, the QA Engineer shall impose appropriate restrictions on the supplier to preclude the occurrence of conditions adverse to quality.

3.2.4.5 If the evaluating QA Engineer determines that the supplier's QA Program Document contains major deficiencies, qualification of the supplier shall be denied. In this event, the site buyer and the organization requesting the evaluation shall be notified in writing by QA that the supplier cannot be qualified.

3.2.4.6 Following the evaluation, the QA Engineer shall indicate the acceptability of the document in a prominent location on the document, such as the cover sheet or revision status sheet, to include a reference to the checklist when conditions/concerns exist relevant to the acceptance.

3.2.4.7 QA Program Documents will be considered to be acceptable if the Document has been found acceptable as a part of an RG&E, NUPIC, or third party qualifying audit/survey. In such cases, the use of a QAM evaluation checklist will not be required. However, acceptance of the QA Program Document shall be appropriately documented, including the basis for acceptance.

3.2.5 When QA evaluation of a prospective supplier includes a supplier audit/survey, the following instructions shall be observed.

3.2.5.1 If RG&E personnel audit/survey the supplier, the audit/ survey shall be performed in accordance with the applicable procedures.

3.2.5.2 The QA Engineer shall verify the adequacy of the scope of the audit/survey as it pertains to the item or service to be provided by the potential supplier based on input from the RG&E end user. Technical experts may be utilized as needed.

3.2.5.3 If a formal audit/survey conducted by agents acting on behalf of RG&E or from other sources is used as part of the supplier qualification evaluation, the QA Engineer shall document the evaluation of the audit/survey report on the appropriate checklist (Figure 2, 4, or equivalent).

3.2.5.4 Regardless of the source of the audit/survey report, if the evaluating QA Engineer determines that the implementation of the supplier's quality program is deficient, the QA Engineer shall either impose appropriate restrictions upon the supplier or disqualify the supplier from placement on the QSL/CGSL. The site buyer and the organization requesting the evaluation shall be notified by QA in the event of disqualification.

3.2.5.5 If any condition which impacts the operability of installed or accepted equipment at Ginna Station (or renders the equipment status indeterminate) is detected during an evaluation of a supplier, the evaluating QA Engineer shall ensure that an ACTION Report is initiated, per IP-CAP-1.

3.2.5.6 The evaluating QA Engineer shall determine the required frequency of supplier audit/survey. In all cases the supplier shall be audited/surveyed at intervals of no more than 36 months. In the event that a supplier can not be reaudited/resurveyed within the 36 month time period, the supplier shall be disqualified or appropriate restrictions imposed until a satisfactory audit/survey can be completed.

3.2.6 The overall evaluation of the supplier shall be documented by the evaluating QA Engineer on the QA Supplier Evaluation Notification/Checklist, including the Attachment Figure 3. The SEN/checklist shall address the following information as a minimum.

QA Supplier Evaluation Notification/Checklist

a) Supplier's QA Program Document including revision number and/or date.

b) Audit or survey date.

c) Supplier's complete company name.

d) Supplier's address (only the location(s) for which the evaluation/qualification is applicable).

e) Any applicable restrictions.

f) Basis for the qualification scope and restrictions, including any changes thereto.

g) A list of names and titles of individuals authorized to sign QA documents.

h) A listing of relevant critical characteristics for each commercial grade item to be dedicated for safety-related use by RG&E, and a statement regarding adequacy of the supplier's controls for these characteristics.

3.2.6 Cont'd.

QA Supplier Evaluation Notification/Checklist Attachment

i) Impact of any open findings or concerns noted in audit/survey used as basis for supplier approval.

j) Results of any source surveillances performed the last year.

m) A discussion of Nuclear Regulatory Commission inspections conducted at the supplier's facility (if applicable).

l) A discussion of any pertinent items identified by a search of the Operating Experience group's database.

m) A listing of the supplier's ASME certifications and expiration dates (if applicable).

n) The ISO Registration Certificate number, expiration date and Registrar name (or attach a copy of the Certificate) if used as part of the qualification basis.

o) RG&E plans with regard to the next future audit or commercial grade survey.

p) Supplier contact information.

NOTE: Items h & n apply to CGSL supplier's only.

3.2.7 The QA Engineer shall present the completed QA Supplier Evaluation Notification with checklist attachment form to the designated (by the QA Manager) QA Engineer for approval.

3.2.8 The QA Engineer shall notify site buyer that the supplier has been evaluated via a copy of the QA Supplier Evaluation Notification. The completed checklist and a copy of the approved QA Supplier Evaluation Notification with checklist attachment shall be maintained in the Supplier QA file.

3.2.9 Cancelled/Surplus Nuclear Plant Equipment (QSL only)

3.2.9.1 The supplier qualification evaluation for cancelled/ surplus nuclear plant equipment procured through other utilities or agents shall be documented separately for each purchase order. Since this equipment has been previously constructed, completed, and stored only Quality Assurance will participate in the supplier evaluation. A QA Supplier Evaluation Notification shall be completed by Quality Assurance for each subject order.

3.2.9.2 The evaluation of the supplier shall:

a. Conform to the methodologies outlined in this procedure.

b. Shall consider the item's manufacturer and the quality program during the time that the item was fabricated.

c. Shall review the storage history and storage controls for compliance to standard storage and handling practices.

3.2.10 Distributors

3.2.10.1 Distributors of materials and equipment who store, repackage, re-test, mark, tag or otherwise physically handle un-packaged material or equipment shall be evaluated similarly to other suppliers according to paragraph 3.2 above. Distributors who only pass along RG&E's purchase documents to a manufacturer or supplier will not require evaluation or listing on the QSL/CGSL as long as they do not physically handle the unpackaged equipment or material. In the second case the manufacturer or supplier with which the distributor deals shall require evaluation and addition to the QSL for PC-1 purchases and CGSL for PC-2 (CGD Method 2) purchases.

3.3 Initial Technical Qualification Evaluation (QSL only)

3.3.1 For situations in which technical evaluations of quality assurance services are required, the evaluation shall address the capability of the supplier to provide the service to be procured.

3.3.2 In this regard, the technical evaluation considers the following:

a. The supplier's experience and performance

b. Qualifications of personnel

c. Facilities and equipment

3.3.3 Results of the evaluation shall be appropriately documented and included in the QA supplier history file. This evaluation may be included as part of the evaluation described in Section 3.2, in which case separate documentation is not required.

3.4 Review of Qualified Suppliers

3.4.1 Reviews of existing QSL/CGSL suppliers shall be performed by the responsible Quality Assurance Engineer. Each supplier shall be contacted on an annual basis to determine whether any changes have occurred in the supplier's capability, organization, facilities, or quality program. Audits of supplier programs are not to exceed a three year period.

NOTE: A grace period of +90 days may be applied to the frequency for performance of annual supplier evaluations and triennial vendor audits. However, the grace period will not allow the "clock" for a particular activity to be reset forward. However, the clock for an activity is reset backwards by performing the activity early.

3.4.2 Annual supplier evaluations shall be documented on the QA Supplier Evaluation Notification with checklist Attachment, Figure 3, or equivalent.

3.4.2.1 The checklist shall not only contain the information as detailed in Paragraph 3.2.6 but also the following:

a) A list of supplier activity which has occurred since the last evaluation.

b) A discussion of specific deficiencies identified as being attributable to the supplier since the previous evaluation. Include PO#, ACTION Report #/ PER #, Source Surveillance Report # or other pertinent information, as applicable.

c) A discussion of any on-site quality audits/surveys of the supplier by other utilities since the previous evaluation. (when applicable).

3.4.2.1 Cont'd.

d) A discussion of any Nuclear Regulatory Commission inspections at the supplier's facility since the previous evaluation (when applicable).

e) A discussion of any changes in personnel or quality which could impact the supplier qualification.

f) A discussion of any changes in products, services or facilities which could impact the supplier qualification.

3.4.3 As with the initial qualification of a supplier, the review of a new revision of the vendor's QA program document which contains a substantial change in the QA program, shall be documented on the appropriate QAM evaluation checklist.

Note: New revisions will be considered to be acceptable if they meet the same conditions described in Paragraph 3.2.4.7.

3.4.4 Restrictions imposed upon the supplier activities as a result of review activities shall require the Quality Assurance Engineer to assess the impact of the restriction on purchase requisitions in-process and currently open purchase orders relating to the supplier. The Quality Assurance Engineer should consult with appropriate Procurement Engineering personnel to determine the status of any in-process purchase requisitions. The assessment of the restriction's impact should involve the requisition originator (when applicable).

3.4.5 The completed QA Supplier Evaluation Notification and Checklist Attachment shall be maintained in the Supplier QA file.

3.4.6 Audit/survey documents will be reviewed and appropriately documented, as soon as practicable after receipt (see Paragraphs 3.2.4 and 3.2.5). Audits/surveys and manual reviews performed between annual supplier evaluations need not be reported on the Supplier Evaluation Notification Form unless a change in supplier status or a change in restrictions results from the review.

3.5 Qualified Suppliers List/Commercial Grade Suppliers List

3.5.1 The Procurement Quality Assurance team (PQAT) shall maintain an electronic database of all suppliers approved for procurement of items or services utilizing the PC-1 and PC-2 (CGD Method 2 only) processes. Computer data access to the QSL/CGSL database for additions, changes or deletions to this list is limited to the PQAT. All other users are limited to access in the view/display mode only (with the exception of computer system administrators).

3.5.2 The information contained on the QSL/CGSL database shall include:

a) the name of the supplier

b) the specific supplier facility location(s) qualified

c) the approved scope of qualification for item(s) or service(s)

d) the original qualification date (if known)

e) the date of the latest review

f) any restrictions/limitations placed on the supplier. For CGSL suppliers this shall include the critical characteristics which the evaluation has determined to be satisfactorily controlled by the supplier.

g) Supplier's corresponding QSL/CGSL number.

NOTE: Other information may be provided, but is not required.

3.5.3 The QSL/CGSL database shall be updated as changes occur to assure current information is available for use in procurement-related activities.

3.6 Documents requiring approval may be approved by other Procurement QA Engineers in the absence of the designated individual (or in case of such documents prepared by the designated individual). In no case shall a document be prepared and approved by the same Procurement QA Engineer.

4.0 Records

4.1 The responsible QA Engineer shall direct the following completed documents (originals or legible, reproducible copies) to Records Management for retention per Reference 2.1:

- External Quality Assurance Audit Evaluation Checklist (Figure 2)
- Supplier Evaluation Notification form (Figure 3) including Checklist Attachment, when applicable.
- Third Party (External) Audit/Survey Reports.
- Checklist for Evaluation of Commercial Grade Survey Documents (Figure 4)

4.2 Copies (or originals) of all documents prepared in accordance with this procedure (Figure 1, 2, 3 and 4) shall be maintained in the QA Supplier file.

5.0 Attachments

5.1 Figure 1, Checklist for Evaluation of Supplier Quality Assurance Manual

5.2 Figure 2, External Quality Assurance Audit Evaluation Checklist

5.3 Figure 3, QA Supplier Evaluation Notification

5.4 Figure 4, Checklist for Evaluation of Commercial Grade Survey.

ROCHESTER GAS AND ELECTRIC CORPORATION

PROCUREMENT, QUALITY ASSURANCE

ANSI N45.2
CHECKLIST FOR EVALUATION OF SUPPLIER QUALITY ASSURANCE MANUAL

Supplier: _____

Location: _____

_____

_____

Phone Number: _____

Items Supplied: _____

_____

_____

Quality Program Document: _____

_____

Revision Number: _____ Date of Issue: _____

Review Performed by: _____ Date: _____

Consideration for: QSL _____ CGSL _____

Comments: _____

_____

_____

_____

ELEMENT 1: ORGANIZATION

		Yes	No	N/A
1.	Are the lines of authority for quality clearly established and delineated in writing from top management down to the individual worker level? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Does the manual provide sufficient authority and organizational freedom to identify quality problems, recommend or provide solutions, and verify implementation of solutions to personnel and organizations performing quality assurance functions? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 2: QUALITY ASSURANCE PROGRAM

3.	Does the QA Manual provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
4.	Are the provisions made for management to review the status and adequacy of the QA Program at regularly scheduled intervals? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 3: DESIGN CONTROLS

		Yes	No	N/A
1.	Does the QA Manual/Program require adequate controls for design input? _____ _____ _____	☐	☐	☐
	Manual Reference _____			
2.	Are there requirements for the review, approval, release and distribution of design interface documents, including revisions? _____ _____ _____	☐	☐	☐
	Manual Reference _____			
3.	Is the verification and checking process required to be performed by individuals or groups other than those who performed the ordinal design? Are changes handled in the same manner? _____ _____ _____	☐	☐	☐
	Manual Reference _____			

ELEMENT 4: PROCUREMENT DOCUMENT CONTROLS

1.	Is the quality assurance organization required to review purchase orders for sub-tier suppliers prior to award? _____ _____ _____	☐	☐	☐
	Manual Reference _____			
2.	Are sub-tier suppliers required to maintain a quality program and pass on applicable requirements to their sub-tiers? _____ _____ _____	☐	☐	☐
	Manual Reference _____			

ELEMENT 5: INSTRUCTIONS, PROCEDURES AND DRAWINGS

		Yes	No	N/A
1.	Are the activities affecting quality required to be described with documented instructions, procedures and drawings?	☐	☐	☐
	_____ _____ _____ _____	Manual Reference _____		
2.	Are instructions and procedures required to contain appropriate acceptance criteria?	☐	☐	☐
	_____ _____ _____ _____	Manual Reference _____		

ELEMENT 6: DOCUMENT CONTROL

1.	Are documents, including changes, required to be reviewed for adequacy and approved for release by authorized personnel?	☐	☐	☐
	_____ _____ _____ _____	Manual Reference _____		
2.	Are documents, including changes, required to be distributed to the location where the prescribed activity is performed and to the same group that received the original documents?	☐	☐	☐
	_____ _____ _____ _____	Manual Reference _____		

ELEMENT 7: CONTROL OF PURCHASED ITEMS OR SERVICES

		Yes	No	N/A
1.	Are sub-tier suppliers required to be evaluated and selected in accordance with the Quality Assurance/Control Manual or written procedure? _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Does the program provide for surveillance, survey, or audit at sub-tier supplier facilities? _____ _____ _____ Manual Reference _____	☐	☐	☐
3.	Is receiving inspection required to be performed and results documented in in accordance with written procedures? _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 8: INSTRUCTIONS, PROCEDURES AND DRAWINGS

1.	Is necessary identification by heat number, part number, serial number, or other appropriate means required to be maintained on records traceable to the item throughout the manufacturing process? _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Are incorrect or defective material, parts, and components required to be identified and controlled by written procedures? _____ _____ _____ Manual Reference _____	☐	☐	☐

		Yes	No	N/A
3.	Does the supplier provide controls to assure special processes are controlled and accomplished by qualified personnel using qualified procedures?			
	Welding: _____	☐	☐	☐
	NDE: PT__MT__RT__UT__VT__ET____	☐	☐	☐
	Heat Treating: _____	☐	☐	☐
	Plating: _____	☐	☐	☐
	Soldering: _____	☐	☐	☐
	Comments: _____			
	_____	Manual Reference _____		
	_____			

ELEMENT 10: INSPECTIONS

1.	Are inspections required to be performed to verify conformance with the documented instructions, procedures, and drawings used for accomplishing the activity?	☐	☐	☐
	_____			
	_____			
	_____	Manual Reference _____		
	_____			
2.	Are such inspections required to be performed by the individuals other than those who perform the activity being inspected?	☐	☐	☐
	_____			
	_____			
	_____	Manual Reference _____		
	_____			
3.	Does the program require that inspection hold points are indicated on the item identification which is attached to or accompanies the item to be inspected?	☐	☐	☐
	_____			
	_____			
	_____	Manual Reference _____		
	_____			

ELEMENT 11: TEST CONTROLS

		Yes	No	N/A
1.	Are tests required to be performed and documented in accordance with written test procedures? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Are test results required to be documented and valuated to assure that test procedures have been satisfied? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 12: MEASURING AND TEST EQUIPMENT

1.	Are written procedures required to be established for the calibration and controls of inspection and test equipment? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Are manufacturers' recommended practices required to be used in the calibration of measurements and test equipment and is the accuracy of Calibration Equipment required to be traceable to the National Institute of Standards and Technology (NIST)? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 13: HANDLING, STORAGE AND SHIPPING

1.	Are material and equipment handling, shipping, cleaning, and [reservation processes required to be controlled by written procedures? _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 14: INSPECTION, TEST AND OPERATING STATUS

		Yes	No	N/A
1.	Does the program require the identification of the inspection, test and operating status of material and equipment?	☐	☐	☐

_____
_____
_____
_____

Manual Reference _____

ELEMENT 15: NONCONFORMING MATERIALS

1.	Are procedures required for identifying. reporting, segregating, processing, and dispositioning nonconforming items, such as:	☐	☐	☐
	(a) Rejection Forms?	☐	☐	☐
	(b) Identification of discrepant material?	☐	☐	☐
	(c) Segregation from normal production?	☐	☐	☐
	(d) Record maintenance?	☐	☐	☐
	(e) Review of repetitive discrepancies?	☐	☐	☐
	(f) Corrective action?	☐	☐	☐
	(g) Control of scrap material?	☐	☐	☐

_____
_____
_____
_____

Manual Reference _____

2.	Is reinspection required for items that have been repaired or reworked?	☐	☐	☐

_____
_____
_____
_____

Manual Reference _____

ELEMENT 16: CORRECTIVE ACTION

1.	Is a system established to assure the prompt identification and correction of conditions adverse to quality and are these conditions required to be reported to upper management?	☐	☐	☐

_____
_____
_____
_____

Manual Reference _____

ELEMENT 17: QUALITY ASSURANCE RECORDS

		Yes	No	N/A
1.	Are QA records defined and identified? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Does the Quality Assurance Manual require that records be protected from damage by water, fire and other forms of destruction? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
3.	Is the storage requirements a dual or a single facility concept? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐

ELEMENT 18: AUDITS

1.	Are effectiveness audits required at periodic intervals to verify compliance with all aspects of the QA program? _____ _____ _____ _____ Manual Reference _____	☐	☐	☐
2.	Are the following requirements specified in the QA Manual?			
	(a) Audits to be documented?	☐	☐	☐
	(b) Results to be reviewed by management?	☐	☐	☐
	(c) Auditors to be qualified/certified?	☐	☐	☐
	(d) Follow-up of corrective action?	☐	☐	☐
	(e) Re-audit as needed?	☐	☐	☐
	_____ _____ _____ _____ Manual Reference _____			

ROCHESTER GAS AND ELECTRIC CORPORATION

EXTERNAL QUALITY ASSURANCE AUDIT/EVALUATION CHECKLIST
PROCUREMENT, QUALITY ASSURANCE
(Doc. Cat. 5.1.7)

1. Name and address of supplier audited.

   _____
   _____
   _____

   Phone Number: _____

2. Name of utility (company) who performed the audit.

   _____

   Audit Report No: _____

   Date of audit: _____

   Date of report: _____

3. Title and revision of QA Program Document that supplier was audited to:

   _____

   _____

4. Product and/or services audited:

   _____

   _____

   _____

		Yes	No
5.	Is the product/service audited identical or similar to the scope of supplier qualification?	____	____
6.	Does the audit apply to the same facility which will provide the product or service?	____	____
7.	Does the audit report provide sufficient information to show that applicable elements of the supplier's QA program have been developed, documented and effectively implemented?	____	____

EXTERNAL QUALITY ASSURANCE AUDIT/EVALUATION CHECKLIST

		Yes	No
8.	Is the checklist(s) complete, legible and contain signature of the auditor(s	____	____
9.	Have all the findings of the audit been closed? If open, are there any findings that require initiation of an ACTION Report?	____	____
10.	Is each page of the audit report legible and complete with signatures where applicable?	____	____
11.	Does the utility (company) submitting the report consider the supplier to be currently qualified (i.e., are they on the utility's (company's) Approved Suppliers List)?	____	____
12.	Are the Lead Auditor and other team members' certifications/resumes included and current?	____	____

The above information obtained from _____ regarding the supplier qualification was reviewed and is_____ is not_____ considered adequate for RG&E QSL listing. If not considered adequate, please provide reasons below in comment section.

Comments:

Evaluated by: _____

Title: _____ Date: _____

(This form or equivalent.)

ROCHESTER GAS AND ELECTRIC CORPORATION

NUCLEAR ASSESSMENT DEPARTMENT

Date:

Subject: QA Supplier Evaluation Notification (Doc. Cat. 5.1.9)

___QSL	___Initial	___Interim	___Annual	___Disqualify
___CGSL	QA Manual Date_____			Revision No._____
Audit/Survey Date_____		Open/Closed_____		

To: Records Management*

Supplier: QSL# OR CGSL#

ADDRESS:

Status: (List items and services qualified)

Restrictions: (List current restrictions applicable to supplier)

Basis for Status/Restrictions:

Authorized Signatures:

Critical Characteristics:
(Applies only to CGSL Suppliers/PC-2 procurements only)
(List critical characteristics for CGI items and/or services that are to be provided by the CGSL Supplier)

Prepared by:_____
QA Engineer

Approved by:_____
QA Engineer

xc: Site Buyer (For Initial Qualification Only) QA Supplier File*
Receipt Inspection

*Including Attachment

QA Supplier Evaluation Notification Checklist Attachment

Supplier Activity:

A. List supplier purchase order activity in the past year:

B. Discuss specific deficiencies identified as supplier responsible during the past year (Include PO#, PER#/ACTION Report#, Date and Problem/Resolution:

C. If there has been no purchase order activity in past 24 months, discuss why supplier is being maintained on QSL/CGSL listing.

Supplier Evaluation Information:

A. List supplier quality program manual approved by RG&E (Complete QA Program Manual Evaluation):

B. If this is not the latest revision, list revision requested from supplier:

C. Do changes to the revised quality program manual degrade prior commitments?

D. List present RG&E supplier quality audit (or cg survey) approved by RG&E (Include source, date and status of audit/survey and complete QA Audit Evaluation form of CG Survey Evaluation form):

E. Evaluate the impact of open audit findings/survey concerns (to include date finding/concern reported):

F. List any supplier source surveillances conducted during the past year (Include dates and results of surveillances):

G. Have there been any on-site quality audits/surveys of the supplier by other nuclear utilities during the past year? (Who/When)

H. Have there been any Nuclear Regulatory Commission Inspections at the supplier's facility int he past year? (If yes, explain)

QA Supplier Evaluation Notification Checklist Attachment

Supplier Evaluation Information (Continued):

I. Discuss any vendor responsible items identified on the Operational Assessment database.

J. If the supplier is a holder of an ASME certificate(s), list the ASME stamp number(s), date(s) of expiration, and future plans to retain certification:

K. What are RG&E future audit plans?

Supplier Contact Information:

Person Contacted:
Title:
Date/Time:

A. Have there been any changes in products, services or facilities which could impact qualifications? (If yes, explain.)

B. Have there been any changes in personnel or quality involvement which could impact qualifications? (If yes, explain.)

C. Verify authorized personnel data is current.

(this form or equivalent)

ROCHESTER GAS & ELECTRIC
PROCUREMENT, QUALITY ASSURANCE
CHECKLIST FOR EVALUATION OF COMMERCIAL GRADE SURVEY DOCUMENTS
(Doc Cat. 5.1.7)

Supplier: _____
Location: _____
_____
_____
Telephone: _____
Product/Service: _____
CGIEE No: _____ P. O. No:_____
CGI Survey Report No: _____
Date of Survey: _____
Date of Report: _____
Survey performed by: _____
Address: _____
_____

Supplier Quality Program Document Survey was performed to:

_____
_____

Revision No: _____ Date of Issue:_____

Supplier Quality Program Document currently at RG&E:

_____
_____

Revision No: _____ Date of Issue:_____

		YES	NO
1)	Does the product/service surveyed encompass the intended scope of supplier qualification?	____	____
2)	Does the survey apply to the same facility which will provide the product or service? (NOTE: Surveys of distributors must be used in conjunction with surveys of the manufacturer)	____	____
3)	Have all the concerns of the survey been closed? If not, are there any concerns that require initiation of an ACTION Report?	____	____
4)	Is each page of the survey report, including the checklist, legible and complete with signatures where applicable?	____	____
5)	Are the Survey Team Leader and other team members certifications included and current?	____	____
6)	Does the utility (company) providing the report consider the supplier to be currently qualified? (i.e., are they on the utility's C.G.S.L?) Discuss any restrictions in the Comments section.	____	____

(This form or equivalent)

STATUS: (Based on attached completed CGI Survey Evaluation Worksheets)

___ Supplier does **not** have controls adequate for inclusion on the C.G.S.L.

___ Supplier has adequate controls over the following Critical Characteristics:

Critical Characteristics _____ Restrictions (if applicable)

Approval Classification:

_____ CGIEE Specific CGIEE No:_____ Rev. No:_____

OR

_____ Product/Service Specific

Product/Service Description:_____

_____

_____

Comments:

Prepared by: _____ Date: _____
QA Engineer

COMMERCIAL GRADE SURVEY EVALUATION WORKSHEET

Critical Characteristics	Applicable C.G. Control/QAM Section	Objective Evidence: Survey Report Section/References Description/Summary (as applicable)	Results:

Results Key: S-Satisfactory, U-Unsatisfactory, SWR-Satisfactory with restrictions, I-Insufficient data

Attachment 18

RG&E Post Modification Test Plans / Procedures, includes:
PCR 99-004 Rev. 0 Attachment 1, Work and Test Instructions
PCR 99-004 Rev. 1 Attachment 1 Work and Test Instructions
SM-99-004.1 Station Modification Procedure
SM-99-004.2 Station Modification Procedure

ATTACHMENT 2
PCR 99-004
Test Instructions
Testing of Control Room Radiation Monitors R45 and R46

Perform all testing for each section in the order shown here, unless noted otherwise.

1.0 Wiring/Logic/Device Check

NOTE: At the start of testing, the Control Room will be in isolation. R81A and R81B contacts will be overridden to hold the CR isolation system in the isolation condition. This can be performed by opening sliding links or installing jumpers to control circuits described in step 1.1. Put handswitches 1/HS-88V and 1/HS-88W in Active position.

1.1 Disable select control functions of R81A and R81B by taking actions for each contact shown on Attachment 1.

Contact	Open Link\ Install Jumper	Consequences
1	Open CRHB-9 in ABB	Holds damper AKD08 closed
4	Open CRHA-1 in ABB	Holds damper AKD10 closed
6	Open CRHB-5 in ABB	Holds AKD04, AKD01 closed
7	Open CRHA-1 in ABB	Holds damper AKD-05 closed
8	Open CRHA-2 in ABB	Holds damper AKD02 closed
9	Jumper CRHB-6 to CRHB-7	Holds Charcoal Filter Fan on

NOTE: Contact to MCB annunciator E-11 has not been disabled. Therefore, E-11 will clear when the relays are energized, and E-11 will light with a MCB alarm for each test step that simulates a CR isolation (R81A and/or R81B is de-energized). This will confirm actuation of the relays, and will require CR Operators to acknowledge the alarm each time it comes in.

1.2 <u>Normal "Active" Alignment Configuration</u>

- With both trains of Toxic Gas monitoring, and CR radiation monitoring units R-45, R-46 and R36/R37/R38 in their normally energized position with no alarms, verify both R81A and R81B are energized.

Prepared By _____ **Reviewed By** _____

1.3 R-45 & 1/HS-88V Contact Tests

- With hand switch 1/HS-88V in the "Active" position verify the "Green" indicating light for R-45 Active is illuminated and the "Red" indicating light for R-45 Bypass is not illuminated. Verify R81A and R81B are still energized.

- With hand switch 1/HS-88V in the "Bypass" position verify the "Green" indicating light for R-45 Active is not illuminated and the "Red" indicating light for R-45 Bypass is illuminated.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88V in "Bypass" position, push Check Source button on ratemeter R-45 to simulate R-45 alarm and verify that R81A and R81B remain energized. Following test, push Check Source button again to restore to R-45 to normal and place hand switch 1/HS-88V in the "Active" position.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88V in "Active" position, push Check Source button on ratemeter R-45 to simulate R-45 alarm and verify that it results in de-energizing R81A and R81B. Following test, push Check Source button again to restore R-45 to normal, and reset Control Room ventilation by pushing isolation reset push button PB/CRIR. Verify that R81A and R81B re-energize.

1.4 R-46 & 1/HS-88W Contact Tests

- With hand switch 1/HS-88W in the "Active" position verify the "Green" indicating light for R-46 Active is illuminated and the "Red" indicating light for R-46 Bypass is not illuminated.

- With hand switch 1/HS-88W in the "Bypass" position verify the "Green" indicating light for R-46 Active is not illuminated and the "Red" indicating light for R-46 Bypass is illuminated.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88W in "Bypass" position, push Check Source button on ratemeter R-46 to simulate R-46 alarm and verify that R81A and R81B remain energized. Following test, push Check Source button again to restore to R-46 to normal and place hand switch 1/HS-88W in the "Active" position.

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- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88W in "Active" position, push Check Source button on ratemeter R-46 to simulate R-46 alarm and verify that it results in de-energizing R81A and R81B. Following test, push Check Source button again to restore R-46 to normal, and reset Control Room ventilation by pushing isolation reset push button PB/CRIR. Verify that R81A and R81B re-energize.

1.5 Toxic Gas A Train Logic Verification

- With hand switch 1/HS-88E (Turbine Building CREPA Panel) in the "Normal" position, verify the Green indicating light for Train A Chlorine Normal is illuminated and the Red indicating light for Train A Chlorine Bypass is not illuminated.
- With hand switch 1/HS-88E in the "Bypass" position, verify the Green indicating light for Train A Chlorine Normal is not illuminated and the Red indicating light for Train A Chlorine Bypass is illuminated.
- With Control Room Ventilation logic in normal alignment and hand switch 1/HS-88E in Normal position, remove fuses FUCREPA-2/P and N to XI-6850 output contact (simulate Train A High Chlorine Alarm). Verify that R81A de-energizes. Following test, reinstall fuses and reset Control Room Ventilation by pushing isolation reset pushbutton PB/CRIR.

1.6 Toxic Gas B Train Logic Verification

- With hand switch 1/HS-88G (Turbine Building CREPB Panel) in the "Normal" position, verify the Green indicating light for Train B Chlorine Normal is illuminated and the Red indicating light for Train B Chlorine Bypass is not illuminated.
- With hand switch 1/HS-88G in the "Bypass" position, verify the Green indicating light for Train B Chlorine Normal is not illuminated and the Red indicating light for Train B Chlorine Bypass is illuminated.
- With Control Room Ventilation logic in normal alignment and hand switch 1/HS-88G in Normal position, remove fuses FUCREPB-2/P and N to XI-6851 output contact (simulate Train B High Chlorine Alarm). Verify that R81B de-energizes. Following test, reinstall fuses and reset Control Room Ventilation by pushing isolation reset pushbutton PB/CRIR.

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1.7 R36/R37/R38 Logic Test and Bypass Test

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) verify the R36/R37/R38 Override Keyswitch 1/HS-88B in the Normal position. If required, lower High Alarm value to approximately 100 cpm but greater than current R-38 reading. Push the Check Source Button on R-38 to simulate a High Alarm. Verify that relay R81A de-energizes.

- Place the R36/R37/R38 Override Keyswitch 1/HS-88B in Override position. Push PB/CRIR to reset the isolation logic. Verify that R-38 Check Source is still on. Verify that R36/R37/R38 is bypassed by verifying relay R81A is energized. Following test, return setpoint to the as found P-9 value. Return 1/HS-88B to Normal. Push PB/CRIR to reset all logic to normal if required.

1.8 Loss of AC Power Test

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) open sliding link TBR45-3 (A Train power) and verify that R81A and R81B de-energize. Following test close sliding link TBR45-3 and reset Control Room ventilation by pushing isolation reset push button PB/CRIR.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) open sliding link TBR46-3 (B Train power) and verify that R81A and R81B de-energize. Following test close sliding link TBR46-3 and reset Control Room ventilation by pushing isolation reset push button PB/CRIR.

1.9 Manual CR Isolation Test

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push CR Isolation A Train pushbutton PB/CRIA. Verify that R81A and R81B de-energize. Following test, push PB/CRIR to reset.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push CR Isolation B Train pushbutton PB/CRIB. Verify that R81A and R81B de-energize. Following test, push PB/CRIR to reset.

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2.0 Radiation Monitors Test and PPCS Test

This portion of testing will be performed with section 1.0 jumpers and sliding links in the test position to preclude the CR isolation system from changing state during each test. This testing can be performed together as part of the installed Field Calibration of R-45 and R-46. Note background levels displayed by ratemeters before testing to ensure they return to normal when check source removed.

2.1 R-45/RE-45 Response Test

- Remove detector RE-45 from duct adapter. Use Field Calibrator for these units to apply radiation to the detector.
- Verify that R81A and R81B de-energize.
- Remove detector from Field Calibrator. Verify that R-45 and PPCS readings return to normal background level. Clear PPCS alarm.
- Reset logic by pressing PB/CRIR. Verify that R81A and R81B re-energize.

2.2 R-46/RE-46 Response Test

- Remove detector RE-46 from duct adapter. Use Field Calibrator for these units to apply radiation to the detector.
- Verify that R81A and R81B de-energize.
- Remove detector from Field Calibrator. Verify that R-46 and PPCS readings return to normal background level. Clear PPCS alarm.
- Reset logic by pressing PB/CRIR. Verify that R81A and R81B re-energize.

3.0 Final Functional Testing

This testing may be performed independently or incorporated into PT-17.4, or new procedures developed to meet requirements for functional testing of the CR isolation system. The following damper positions (per PT-17.4) will verify isolation has occurred:

AKD10	**Closed**
AKD01	**Closed**
AKD09	**Open**
AKD07	**Open**
AKD05	**Closed**
AKD04	**Closed**
AKD02	**Closed**
AKD08	**Closed**

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3.1 Before restoring logic, push CR manual isolation PB/CRIA to de-energize relays R81A and R81B during restoration.

3.2 Restore logic to operational state by closing sliding links and removing jumper listed in step 1.1. After return to normal is completed, push logic reset PB/CRIR and verify that R81A and R81B energize, and MCB annunciator E-11 clears.

3.3 R-45 Test

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push RE-45 check source button to expose detector to radiation level above setpoint. Verify that all CR Isolation dampers and fans operate as required by PT-17.4 for Control Room Isolation within 60 seconds after ratemeter begins to respond (starts counting up). Verify PPCS point R-45 value matches ratemeter and is in alarm.

- Verify that R-46 ratemeter display remains stable (i.e. no noise induced spike due to R-45 actuation). Reading shall be less than Warning alarm value.

- Remove check source.

- After ratemeter display returns to below alarm and warning setpoint (< 0.15 mR/hr), push reset PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears, PPCS point R-45 returns to background level and alarm clears.

3.4 R-46 Test

- To verify that R81B will perform all isolation functions independent of R81A, place a jumper across terminals TBR46-10 to TBR46-11 in RMS2 (this is across the A Train contact from R-46). This will ensure that when R-46 output contacts open on high alarm, only R81B will drop out and perform isolation functions.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push RE-46 check source button to expose detector to radiation level above setpoint. Verify that all CR Isolation dampers and fans operate as required by PT-17.4 for Control Room Isolation within 60 seconds after ratemeter begins to respond (starts counting up). Verify PPCS point R-46 value matches ratemeter and is in alarm.

- Verify that R-45 ratemeter display remains stable (i.e. no noise induced spike due to R-46 actuation). Reading shall be less than Warning alarm value.

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- Remove Check Source.

- After ratemeter display returns to below alarm and warning setpoint (< 0.15 mR/hr), push reset PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears, PPCS point R-46 returns to background level and alarm clears.

- Remove jumper across TBR46-10 to TBR46-11. Verify CR is not in isolation. If isolation actuate during jumper removal, use PB/CRIR to reset.

3.5 R36/R37/R38 Test

This test will demonstrate operability of existing CR Radiation Monitors.

- Use applicable steps from PT-17.4 to verify operability of R36/R37/R38.
- This test will demonstrate the capability of A train (R81A) to perform isolation functions independent of B train (R81B) since R80B contacts from R36/R37/R38 are only in the A train logic, so only R81A should drop out on a high radiation signal from this monitor. Verify that R81B remains energized after the isolation is initiated.
- Restore CR isolation with PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears.
- System may now be declared Operable.

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ROCHESTER GAS AND ELECTRIC CORPORATION

GINNA STATION

CONTROLLED COPY NUMBER _____

| PROCEDURE NO. SM-99-004.1 REV. NO. 1

CONTROL ROOM RADIATION MONITOR REPLACEMENT

Gary Grams
RESPONSIBLE MANAGER

10-11-01
EFFECTIVE DATE

QA _____ NON-QA _____ CATEGORY 9.1

REVIEWED BY: _____

| THIS PROCEDURE CONTAINS 36 PAGES

SM-99-004.1

Control Room Radiation Monitor Replacement

1. Purpose:

1.1 The scope of this job is to perform the modification of the Control Room Radiation Protection System, PCR 99-004. This procedure is divided into sections as follows:

- Duct Work / Detector Installation
- Conduit and Cable Installation
- Removal and installation of components in Auxiliary Bench Board (ABB).
- Toxic Gas Panel Wiring Changes
- Equipment Installation / Wiring in RMS Racks
- Component Testing
- Logic Testing
- Functional Testing

2. References

2.1 IP-DES-3, GC-76.3, GC-76.9, GC-76.10, FPS-1, M-56.3, M-73.10, EE-29, EE-80, EE-035

2.2 PCR 99-004

3.0 Initial Conditions

3.1 The plant may be in any mode of operation. _____

3.2 Group supervision has verified that applicable reinstatement steps have been marked for independent verification as indicated by the review signature on the work order.

_____

NOTE: During rewiring of the ABB, all controls and indication for Control Room HVAC will be de-energized. The system will remain in isolation throughout that time frame.

3.3 If any parts removed from stock have a conditional release tag attached, fill out the enclosed conditional release form in accordance with A-700, and forward it to Procurement Quality Control. N/A this step if no conditionally released parts were used. _____

3.4 A pre-job briefing has been held with the assigned engineer before starting the job. Personnel suggested to be present during the pre-job brief are: QC, Fire Protection, Welders, Insulators, I&C, Electricians, Operations personnel, RP's and Security. _____

3.5 Materials are available for performing the work. _____

4.0 Notifications

4.1 Notify the Shift Supervisor of the work to be done. _____

4.2 Notify the Training Modification Control Coordinator (Sandy Smith) that work is starting on PCR 99-004. _____

4.3 Notify the Assigned Engineer (Paul Swift) that work is starting. _____

4.4 Notify the System Engineer (Karen Cona and Carm Vitale) that work is starting. _____

4.5 Notify QC that inspections will be required for parts of the job. _____

5.0 Precautions

5.1 Ensure that care is taken to safely address activities involving welding, cutting and grinding.

5.2 Working in the Control Room requires that caution is exercised to minimize the impact on Operations personnel.

5.3 Take care not to bump or jar surrounding equipment when working in the Aux Bench Board and RMS Racks

5.4 Verify by test that equipment is de-energized

5.5 When Control Room ventilation is inoperable, the ventilation system may be placed in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations to log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

6.0 INSTRUCTIONS:

Note 1: Construction Sections of this Modification may be done out of order or concurrently to minimize the installation time.

Note 2: Equivalent parts installed may be differ from Material ID and part numbers specified in this procedure, if approved by Engineering.

6.1 Platform modification work has been completed for this job per drawing SK33013-2779Sh2-1 by Iron Workers.

Assigned Engineer_____

6.2 Installation of Radiation Detectors RE-45 and RE-46

NOTE: Installation of the Radiation Detectors is considered safety related. Torque requirements called out in attachments or vendor manual must be performed using a calibrated torque wrench and documented on GC-76.9.

6.2.1 Request Operations to initiate tracking documentation for taking the Control Room Toxic Gas Monitoring System and Radiation Monitoring System out of service.

Tracking Documentation Initiated _____ SS_____

6.2.2 Request Operations to place the place the Control Room Ventilation System in isolation.

Control Room Ventilation in Isolation_____

6.2.3 Insulators remove insulation on the Control Room Air Intake Duct as needed for installation of the Radiation Detectors. Remove minimum amount of insulation to allow installation of detectors.

_____

6.2.4 Engineering and Craft locate the layout for the detector mounting locations on the Control Room Air Intake Duct, as directed on drawing SK33013-2787-1.

_____

6.2.4.1 Ensure a permit has been issued per A-905 for cutting the duct.

_____

6.2.5 Request Operations to initiate tracking documentation for taking the Control Room Toxic Gas Monitors out of service.

_____

NOTE: Ensure proper FME precautions are taken to preclude foreign materials from entering the duct.

6.2.6 I&C personnel remove the Control Room Toxic Gas Detectors from the Control Room Air Intake Duct. Secure them in a manner to avoid damage.

_____

6.2.7 Welders cut openings in the Control Room Air Intake Duct to accommodate new RE-45 and RE-46 detector mountings, as directed on drawing SK33013-2787-1.

_____

6.2.8 Using the detector mounting flange as a template, machinists drill holes in duct as needed for hardware specified in Attachment 6 of PCR 99-004.

_____

6.2.9 Clean the debris from the duct resulting from cutting the openings and holes. (This step may be performed any time before the system is tested.)

_____

NOTE: The permanent sealant at the Intake Duct/Duct Adapter interface to stop air in-leakage does not have to be SR. Use an appropriate sealant that is acceptable for use in the Turbine Building for these materials.

6.2.10 Install duct mounting flange using hardware (material ID 9112570, 9112758, 9112723,) and sealant (material ID 9191364) per Attachment 6. Record installation on GC-76.9, Exhibit A.

_____

NOTE: DO NOT torque mounting bracket or flange nuts during step 6.2.11. They will be torqued later.

6.2.11 Place detector assembly into duct, attaching to flange per Attachment 6. Make detector connections and tighten per Attachment 6. Reference Attachments 7 and 8 of PCR 99-004 if needed for wiring connections. Record serial number of each detector for each unit and record below.

RE-45 Serial No._____ RE-46 Serial No._____

_____

6.2.12 Insulators repair insulation on duct. As left insulation must not interfere with installed equipment, access to the detectors, or ability to remove detectors from the duct.

_____

6.2.13 I&C personnel re-install the Control Room Toxic Gas Detectors in the Control Room Air Intake Duct.

_____

6.2.14 Restore the Control Room ventilation system, if desired my Operations, by performing appropriate testing. If ventilation system is not to be restored at this time, mark this step N/A.

_____

6.3 Conduit Installation

6.31 Notify Structural Engineering before installation of conduit supports.

_____

NOTE: Size all supports for a future 1 ½" conduit

6.3.2 Install conduit supports mounted on steel members for circuit C5551 (2"), C5552 (2"), and C5557 (1 1/2") on the Control Room side of the superwall, per drawing 33013-2814. Record conduit supports installed on Exhibit B of GC-76.9.

_____

6.3.2 Install conduit supports mounted on the Control Room ceiling for circuit C5551 (2"), C5552 (2"), and C5557 (1 1/2") per drawing 33013-2814. Record conduit supports installed on Exhibit B of GC-76.3, Exhibit A.

_____

6.3.3 Install conduits C5551 (2"), C5552 (2"), and C5557 (1 1/2") per drawing 33013-2814. Record each conduit installed on an Exhibit C of GC-76.9 procedure.

C5551_____

C5552_____

C5557_____

6.3.4 Install new conduit supports for circuit R4522 and R4523 in the Turbine Building. Record installation on Exhibit B of GC-76.9 and M-73.10.

_____

6.3.4.1 Welders install conduit shield as shown on MDCN 2141. _____

6.3.5 Install new 1 1/2" conduit Circuit R4522 from penetration TBP-91-P (third conduit from the top) to Radiation detector RE-45 location in the Turbine Building. Record conduit installation on Exhibit C of GC-76.9.

_____

6.3.6 Paint conduit supports; use GC-76.11 as required. _____

6.3.7 Install new 1 1/2" conduit Circuit R4523 from penetration TBP-91-P (bottom conduit) to Radiation detector RE-46 location in the Turbine Building. Record conduit installation on Exhibit C of GC-76.9.

_____

6.3.8 Install new 1 ½" sealtite conduit Circuit R4522 from penetration TBP-91-P (third conduit from the top) to the Aux Bench Board on the Control Room side of the superwall. Record conduit installation on Exhibit C of GC-76.9.

_____

6.3.9 Install new 1 ½" sealtite conduit Circuit R4523 from penetration TBP-91-P (bottom conduit) to the Aux Bench Board on the Control Room side of the superwall. Record conduit installation on Exhibit C of GC-76.9.

_____

6.4 "A" Train Cable Pulls

NOTE: Circuits C5551, AUO235A, and R4522 will all be pulled through conduit C5551.

6.4.1 Pull cable for Circuit C5551, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on circuit schedule.

_____

6.4.2 Pull cable for Circuit AUO235A, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on circuit schedule. Note that Fire Breach procedure FPS-1 will be used to pull the cable through penetration TBP-91-P, through existing conduit C5529.

_____

6.4.3 Pull cable for Circuit R4522, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule. Note that Fire Breach procedure FPS-1 will be used to pull the cable through penetration TBP-91-P, third conduit from top.

_____

6.4.4 Pull cable for Circuit AU0235B per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule.

_____

6.5 "B" Train Cable Pulls

NOTE: Circuits C5552, AUO239A, and R4523 will all be pulled through conduit C5552.

6.5.1 Pull cable for Circuit C5552, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule.

_____

6.5.2 Pull cable for Circuit AUO239A, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule. Note that Fire Breach procedure FPS-1 will be used to pull the cable through penetration TBP-91-P, through existing conduit C5539.

_____

6.5.3 Pull cable for Circuit R4523, per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule. Note that Fire Breach procedure FPS-1 will be used to pull the cable through penetration TBP-91-P, bottom conduit.

_____

6.5.4 Pull cable for Circuit AU0239B per the circuit schedule on Attachment 5 of PCR 99-004. Record cable cut and pulled on Circuit schedule.

_____

6.6 Test and Termination of Detector Cables

6.6.1 Perform megger and continuity test of detector cables R4522 and R4523. Record on Circuit Schedules on Attachment 5 of PCR 99-004.

R4522_____

R4523_____

NOTE: I&C Technicians read all notes associated with Circuit Schedule R4522 and R4523 page 2 prior to making connections.

6.6.2 I&C install connector on detector end of cable per EE-35. Record on Circuit Schedules on Attachment 5 of PCR 99-004. Use Amphenol connector, Inovision part numbers 92-7005-17A, -12A, and -9A.

R4522_____

R4523_____

6.6.3 I&C perform point-to-point continuity checks to verify wiring is in accordance with Loop Diagram on Attachment 7.

R4522_____

R4523_____

6.6.4 Electricians perform a 1000 VDC hi-pot test for the High Voltage RG59 cable prior to connection.

Hi Pot Test Satisfactory R4522_____

Hi Pot Test Satisfactory R4523_____

6.7 Aux Bench Board Wiring Changes

NOTE 1: Use caution when working in the Aux Bench Board not to bump or jar any adjacent equipment.

NOTE 2: Steps 6.7.1 and 6.7.2 may be marked N/A if the Control Room Ventilation System is already in Isolation.

6.7.1 Request Operations to initiate tracking documentation for taking the Control Room Toxic Gas Monitoring System and Radiation Monitoring System out of service.

Tracking Documentation Initiated _____ SS_____

NOTE: Annunciator E-11 will alarm when Control Room Ventilation is placed in isolation.

6.7.2 Request Operations to place the Control Room Ventilation System in isolation.

Control Room Ventilation in Isolation_____

NOTE: Electricians will assist in placing HOLDs on States Deck slide links.

6.7.3 Request Operations to HOLD the following states deck slide links open in the Aux Bench Board:

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CRHA Terminal 3_____

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

6.7.4 Install a jumper from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7. This will keep the Control Room Charcoal Filter Fan running while R80A is removed and wiring changes are made.

_____

Verified By_____

6.7.5 Request Operations to HOLD the following states deck slide links open in the Aux Bench Board:

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

6.7.5.1 Verify that the Charcoal Filter Fan is running, and that Control Room ventilation dampers are in the Mode "F" positions.

_____

6.7.5.2 Request Operations to HOLD the power to the Control Room Environmental Panels, breaker #11 in panel ACPDPCB07.

_____

6.7.6 Verify by test that R80A relay and all contacts (locator number ZF in the Aux Bench Board) are de-energized.

_____

6.7.7 Remove R80A relay and all wires connected to it from the Aux Bench Board.

_____

6.7.8 Remove Control Room Isolation Reset push button (locator ZA) and all wires connected to it from the Aux Bench Board.

_____

6.7.9 Remove Control Room Manual Recirc push button (locator ZBA) and all wires connected to it from the Aux Bench Board.

_____

CAUTION: Ensure to prevent metal particles from getting into components when drilling

6.7.10 Drill new 4" hole in the Aux Bench Board to accommodate the Fire Mode Selector Switch as shown on drawing SK33013-1735-1.

_____

NOTE: Fire Mode Selector Switch is fed from MCB fuses FUDPMCB04B/VP and /VN. Refer to drawings 21946-542 and 21946-196.

CAUTION: The Fire Mode Selector Switch wiring is energized. Use insulated gloves when moving the switch, and take care not to manipulate the switch.

6.7.11 Move the Fire Mode Selector Switch (locator ZG, EIN 1/HS-88) and Nameplate to the new hole per drawing SK33013-1735-1.

_____

6.7.12 Install the following new devices and labels in the abandoned locations in the top panel of the ABB, as shown on SK33013-1735-1:

PB/CRIR (MID #9215492, 9049764)_____

PB/CRIA (MID #9215492, 9036016)_____

PB/CRIB (MID #9215492, 9036016)_____

6.7.13 Install new relays R81A and R81B (material ID #9083839) inside the ABB panel right section left side in locations shown on Attachment 4 sheet 1. Drill and tap holes in panel side mounting plate. Mount using 10-32 x 3/4" bolts Material ID #5001826). Record relay installation on GC-76.9 Exhibit A.

R81A_____

R81B_____

6.7.14 Install new internal wiring inside the Aux Bench Board using #12 SIS wire (Material ID #9185071) and ring terminals (Material ID #9086919) as shown on drawing SK33013-1860-4. Record ring terminals crimped and wires landed on Exhibit B of GC-76.10 procedure.

_____

6.7.15 Install ring terminals as needed (Material ID #9086919) and land wiring from the following circuits in the Aux Bench Board and record on the circuit schedules:

C5551_____ C5552_____ C5530_____

C5529_____ C5545_____

6.8 Control Room Environmental Panels Wiring Changes (In Turbine Building)

6.8.1 Control Room Environmental Panel "A" Changes

NOTE: Refer to drawing SK33013-2784-1 for changes

6.8.1.1 Remove the following wires in the "A" Panel"

CREA-3 to CREA-4_____	CREA-4 to CREA-5_____
CREB-1 to CREB-3_____	CREC-3 to CREC-4_____
CREB-6 to CREB-11_____	CREB-12 to CREC-1_____
CREB-2 to CREC-2_____	CREC-1 to R80C-1_____
CREC-2 to R80C-2_____	CRED-11 to R80C-11_____
	CRED-12 to R80C-12_____

6.8.1.2 Remove Relay 80C.

6.8.1.3 Move the following jumpers in the "A" Panel and record on Exhibit C of GC-76.10 procedure:

MOVE FROM	**MOVE TO**
CREA-11 to CRED-4	CREA-9 to CRED-4_____
CREA-5 to CRED-3	CREA-3 to CRED-3_____

6.8.1.4 Isolator RY-45 has been bench tested in accordance with M-71.2 and MDCN 2142.

_____

6.8.1.5 Install Isolator RY-45 in the panel per MDCN 2142 by drilling and tapping panel back plate and using 10-32 screws (Material ID #5000994). Record installation on GC-76.9, Exhibit A.

_____

6.8.1.6 Install fuse block FUBA-4 in the panel per MDCN 2142 by drilling and tapping panel back plate and using 10-32 screws (Material ID #5000994). Record installation on GC-76.9, Exhibit A.

_____

6.8.1.7 Install new jumpers in the "A" Panel using #12 SIS wire (Material ID #9185071) and ring terminals (Material ID #9086919). Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CREB-3 to CRED-11_____ CREB-6 to CRED-12_____

CREA-3 to CRED-3_____

6.8.1.8 Install new power jumpers in the "A" Panel per MDCN 2142 using #16 wire (Material ID #9182322) for RY-45. Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CRED-3 to CRED-5_____ CRED-4 to CRED-6_____

CRED-5 to FUBA-4, term. 1_____

CRED-6 to FUBA-4, term. 2_____

FUBA-4 term. 3 to RY-45, term. "A"_____

FUBA-4 term. 4 to RY-45, term. "B"_____

6.8.1.9 Install new signal jumpers in the "A" Panel per MDCN 2142 using #16 TSP (Material ID #9196393) for RY-45. Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CREC-7 to RY-45, term. OUT +_____

CREC-8 to RY-45, term. OUT -_____

(Shield Wire) CREC-9 to RY-45, term. OUT S_____

CREC-10 to RY-45, term. IN +_____

CREC-11 to RY-45, term. IN -_____

(Shield Wire) CREC-12 to RY-45, term. IN S_____

6.8.2 Control Room Environmental Panel "B" Changes

NOTE: Refer to drawing SK33013-2784-1 for changes

6.8.2.1 Remove the following wires in the "B" Panel"

CREE-3 to CREE-4_____	CREE-4 to CREE-5_____
CREE-9 to CREE-10_____	CREE-10 to CREE-11_____
CREF-1 to CREF-3_____	CREF-2 to CREG-2_____
CREF-6 to CREF-7_____	CREF-7 to CREF-10_____
CREF-10 to CREG-1_____	CREG-3 TO CREG-4_____
CREA-9 to CREA-10_____	CREA-10 TO CREA-11_____
CREG-1 to R80E-1_____	CREG-2 TO R80E-2_____
CREH-11 to R80E-11_____	CREH-12 TO R80E-12_____

6.8.2.2 Remove Relay 80E. _____

6.8.2.3 Move the following jumpers in the "B" Panel and record on Exhibit C of GC-76.10 procedure:

MOVE FROM	**MOVE TO**
CREE-5 to CREH-3	CREE-3 to CREH-3_____
CREE-11 to CREH-4	CREE-9 to CREH-4_____

6.8.2.4 Isolator RY-45 has been bench tested in accordance with M-71.2 and MDCN 2142.

_____

6.8.2.5 Install Isolator RY-46 in the panel per MDCN 2142 by drilling and tapping panel back plate and using 10-32 screws (Material ID #5000994). Record installation on GC-76.9, Exhibit A.

_____

6.8.2.6 Install fuse block FUBB-4 in the panel per MDCN 2142 by drilling and tapping panel back plate and using 10-32 screws (Material ID #5000994). Record installation on GC-76.9, Exhibit A.

_____

6.8.2.7 Install new jumpers in the "B" Panel using #12 SIS wire (Material ID #9185071) and ring terminals (Material ID #9086919). Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CREF-3 to CREH-11_____ CREF-6 to CREH-12_____

6.8.2.8 Install new power jumpers in the "B" Panel per MDCN 2142 using #16 wire (Material ID #9182322) for RY-46. Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CREH-3 to CREH-5_____ CREH-4 to CREH-6_____

CREH-5 to FUBB-4, term. 1_____

CREH-6 to FUBB-4, term. 2_____

FUBB-4 term. 3 to RY-46, term. "A"_____

FUBB-4 term. 4 to RY-46, term. "B"_____

6.8.1.9 Install new signal jumpers in the "B" Panel per MDCN 2142 using #16 TSP (Material ID #9196393) for RY-46. Record ring terminals crimped and wires landed on Exhibit C of GC-76.10 procedure.

CREG-7 to RY-46, term. OUT +_____

CREG-8 to RY-46, term. OUT -_____

(Shield Wire) CREG-9 to RY-46, term. OUT S_____

CREG-10 to RY-46, term. IN +_____

CREG-11 to RY-46, term. IN -_____

(Shield Wire) CREG-12 to RY-46, term. IN S_____

6.9 RMS Rack Changes

6.9.1 Install stainless steel plates in RMS-2 rack per drawing 21489-0698, using 10-32 flat head machine screws (Material ID #5001828), countersunk in the plate. Record plates installed on Exhibit B of GC-76.9 procedure.

_____

6.9.2 Install 12 point states decks (Material ID #900606) in RMS-2 rack per drawing 21946-0698 and Appendix 1 of GC-76.9 procedure, using 10-32 machine screws (Material ID #5000994). Record on GC-76.9 Exhibit A.

_____

6.9.3 Install Panduit raceway in RMS racks per drawing 21489-0698. Record on Exhibit C of GC-76.9.

_____

6.9.4 Install switches (Material ID #9035991, 9049746, 9036024) and lights (Material ID #5001863, 9219978, 9217584, 9187570, 5000293) in the blank plate at the top of RMS-2 rack per SK33013-2656-1. Record installation on GC-76.9, Exhibit A.

_____

6.9.5 Install the 948B-1 Rad Monitor chassis (line filters installed, rate meters not installed) in cabinet per drawing 21489-0698, using #8 flat head machine screws. Record on GC-76.9, exhibit A.

_____

6.9.6 Bench testing has been completed by I&C on rate meters per M-71.2 procedure. Attach test results to the work package.

R45_____

R46_____

6.9.7 Record serial numbers of rate meters below:

R45 Rate Meter Serial No._____

R45 Rate Meter Serial No._____ _____

6.9.8 I&C Install rate meters into the rack chassis, using hardware provided by vendor for front panel mounting. Record installation on Exhibit A of GC-76.9 procedure.

_____

6.9.9 Terminate the following circuits that enter RMS-2 rack from outside on TBR45 and TBR46, as shown on drawing SK33013-1618SH1-2. Record on appropriate circuit schedules.

AU0235A_____ C5551_____

AU0239A_____ C5552_____

CAUTION: DO NOT Terminate wires on TB110 in RMS-1 Rack and TB310 in RMS-3 rack at this time. **These terminations are energized 120 volts AC, and will energize the A and B Train of Toxic Gas and Rad Monitoring.** These wires will be terminated when the system is ready to be energized.

6.9.9.1 Ensure a Hot Work Permit has been issued for soldering per A-905.

_____

6.9.9.2 Notify Performance Monitoring prior to soldering in the Control Room, for charcoal filter concerns.

_____

6.9.10 I&C and Electricians Install internal wiring (EXCEPT on TB110 and TB310) in RMS-2 rack as shown on drawing SK33013-1618SH1-2. Use wire (Material ID #9185071) and ring terminals (Material ID #9086919). Record on GC-76.10, Exhibit B. This includes soldering of P1 and P6 connectors, which will also be recorded on GC-76.10, Exhibit B. Vendor assembly instructions for connectors are located in PCR 99-004, Attachment 8. The following connectors and Inovision part numbers are associated:

Connector	Inovision Part No.
P1	87-82-37, 87-81-37S
P2	67-82-14, 67-82-14P
P3	67-82-4, 67-82-4S
P4	30-4
P5	30-92-1
P6	68-23

_____

6.9.11 Install labels on RMS Rack. _____

6.10 **HOLD POINT:** When the installation is complete, prior to testing, notify the Assigned Engineer (Paul Swift) to complete the modification turnover steps up to and including the "Prior to Testing" section.

ASSIGNED ENG. SIGNATURE_____

6.11 Energizing "A" and "B" Train Circuits

6.11.1 Ensure that the R-45 and R-46 switches are in the "Active" position.

R-45_____

R-46_____

CAUTION!! Terminals 4 and 5 of Terminal Decks TB110 and TB310 are energized at 120 volts AC!

6.11.2 Electricians make final connections for "A" train power on TB110 terminals 4 and 5. Record on GC-76,10, Exhibit B.

_____

NOTE: When power is connected, R81A and R81B will energize; Annunciator E11 will clear, but the Control Room will still be in isolation because the dampers are still in their isolation positions.

6.11.3 Electricians make final connections for "B" train power on TB310 terminals 4 and 5. Record on GC-76.10, Exhibit B.

_____

6.12 Start Up and Configuration / Setpoints

NOTE 1: Start-up should only be performed by I&C Technicians familiar with equipment and sections of the Inovision vendor manual "Operations" section.

NOTE 2: Follow Attachment 9 of PCR 99-004 for initial vendor start-up procedure.

6.12.1 I&C Enter set points for Both R-45 and R-46 as follows:

R-45 Warning Setpoint 0.20 mr/hr_____

R-45 Alarm Setpoint 0.25 mr/hr_____

R-46 Warning Setpoint 0.20 mr/hr_____

R-46 Alarm Setpoint 0.25 mr/hr_____

6.12.2 PPCS has been configured by the Computer Group to accept the inputs as shown per the wiring diagrams and circuit schedules. See Attachment 10 for PPCS parameters.

_____

6.13 Calibration

6.13.1 I&C Calibrate the detector and rate meter using approved calibration procedure.

_____

6.13.2 Verify that the PPCS readings for points R-45 and R46 are consistent with the local rate meter readings. Use setpoint tolerances of ± 0.05 mR/hr or 5% of rate meter reading, whichever is greater.

_____

7.0 Testing

7.1 Testing Setup

7.1 Notify Performance Monitoring prior to testing. _____

7.1.1 The Control Room Ventilation dampers are in their isolation positions.

_____

7.1.2 Verify that following Terminal Deck Sliding Links are HELD open:

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CRHA Terminal 3_____

Step 7.1.2 (continued)

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

7.1.3 Verify that the jumper is still in place from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7. This will keep the Control Room Charcoal Filter Fan running during testing.

_____

7.1.4 Verify E11 Annunciator is NOT in alarm. _____

7.2 Normal "Active" Alignment Configuration

7.2.1 With both trains of Toxic Gas Monitoring, and CR radiation monitoring units R-45, R-46, R36/R37/R38 in their normally energized position with no alarms, verify both R81A and R81B relays are energized.

R81A Energized_____

R81B Energized_____

7.3 R-45 & 1/HS-88V Contact Tests

7.3.1 With hand switch 1/HS88V in the "Active" position, verify the following:

Green indicating light for R-45 Active is illuminated_____

Red indicating light for R-45 Bypass is NOT illuminated_____

R81A and R81B are energized_____

7.3.2 With hand switch 1/HS88V in the "Bypass" position, verify the following:

Green indicating light for R-45 Active is NOT illuminated_____

Red indicating light for R-45 Bypass is illuminated_____

R81A and R81B are still energized_____

7.3.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88V in "Bypass" position, push and hold the Check Source button on rate meter R-45 to simulate R-45 alarm and verify that R81A and R81B are still energized.

_____

NOTE: When releasing the Check Source pushbutton, a wait of 60 seconds may be required for the displayed value to indicate ambient conditions.

7.3.4 Release the Check Source button to restore R-45 to normal.

_____

7.3.5 Place hand switch 1/HS-88V in the "Active" position. _____

7.3.6 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88V in "Active" position, push and hold the Check Source button on rate meter R-45 to simulate R-45 alarm and verify that:

R81A and R81B are de-energized_____

Annunciator E-11 Alarms_____

7.3.7 Release the Check Source button to restore R-45 to normal. _____

7.3.8 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.4 R-46 & 1/HS-88W Contact Tests

7.4.1 With hand switch 1/HS-88W in the "Active" position, verify the following:

Green indicating light for R-46 Active is illuminated_____

Red indicating light for R-46 Bypass is NOT illuminated_____

R81A and R81B are energized_____

7.4.2 With hand switch 1/HS88W in the "Bypass" position, verify the following:

Green indicating light for R-46 Active is NOT illuminated_____

Red indicating light for R-46 Bypass is illuminated_____

R81A and R81B are still energized_____

7.4.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88W in "Bypass" position, push and hold the Check Source button on rate meter R-46 to simulate R-46 alarm and verify that R81A and R81B are still energized.

_____

7.4.4 Release the Check Source button to restore R-46 to normal. _____

7.4.5 Place hand switch 1/HS-88W in the "Active" position. _____

7.4.6 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88W in "Active" position, push and hold the Check Source button on rate meter R-46 to simulate R-46 alarm and verify that:

R81A and R81B are de-energized_____

Annunciator E-11 Alarms_____

7.4.7 Release the Check Source button to restore R-46 to normal. _____

7.4.8 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.5 Toxic Gas Train A Logic Verification

7.5.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Normal" position, verify that:

Train A Chlorine Normal Green light is illuminated_____

Train A Chlorine Bypass Red light is NOT illuminated_____

7.5.2 With hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Bypass" position, verify that:

Train A Chlorine Normal Green light is NOT illuminated_____

Train A Chlorine Bypass Red light is illuminated_____

7.5.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Normal" position, remove fuse FUCREPA-2/P to XI-6850 output contact, which simulates Train A High Chlorine Alarm. Verify that:

R81A de-energizes_____

R81B Still Energized_____

Annunciator E-11 Alarms_____

7.5.4 Reinstall fuse FUCREPA-2/P. _____

Verified By_____

7.5.6 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.6 Toxic Gas Train B Logic Verification

7.6.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Normal" position, verify that:

Train B Chlorine Normal Green light is illuminated_____

Train B Chlorine Bypass Red light is NOT illuminated_____

7.6.2 With hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Bypass" position, verify that:

Train B Chlorine Normal Green light is NOT illuminated_____

Train B Chlorine Bypass Red light is illuminated_____

7.6.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Normal" position, remove fuse FUCREPB-2/P to XI-6851 output contact, which simulates Train B High Chlorine Alarm. Verify that:

R81B de-energizes_____

R81A Still Energized_____

Annunciator E-11 Alarms_____

7.6.4 Reinstall fuse FUCREPB-2/P. _____

Verified By_____

7.6.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.7 R36/R37/R38 Logic Test and Bypass Test

7.7.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) verify the R36/R37/R38 Override Key Switch 1/HS-88B in the "Normal" position.

_____

7.7.2 At R38 monitor, record the as found alarm setting.

R38 Alarm Setting_____ _____

7.7.3 If required, lower High Alarm value to approximately 100 cpm but greater than the current R38 setting, and push and hold the Check Source button on R38 to simulate a High Alarm. Verify that:

R81A de-energizes_____

R81B Still Energized_____

Annunciator E-11 Alarms_____

7.7.4 Place the R36/R37/R38 Override Key Switch 1/HS-88B in the "Bypass" position.

_____

7.7.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.7.6 Release the R38 Check Source pushbutton. _____

7.7.7 Return R38 monitor alarm setting to as found value. _____

Verified By_____

7.7.8 Return R36/R37/R38 Override Key Switch 1/HS-88B in the "Normal" position.

_____

7.7.9 If required, reset Control Room ventilation by pushing isolation reset push button PB/CRIR. If not necessary, Mark this step N/A.

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.8 Loss of AC Power Test - A Train

7.8.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) open sliding link TBR45-3 in RMS-3 Rack (A Train Power) and verify that:

R81A de-energizes_____

R81B de-energizes_____

Annunciator E-11 Alarms_____

7.8.2 Close sliding link TBR45-3 in RMS-3 Rack. _____

Verified By_____

7.8.3 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.9 Loss of AC Power Test - B Train

7.9.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) open sliding link TBR46-3 in RMS-3 Rack (B Train Power) and verify that:

R81B de-energizes_____

R81A de-energizes_____

Annunciator E-11 Alarms_____

7.9.2 Close sliding link TBR46-3 in RMS-3 Rack. _____

Verified By_____

7.9.3 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.10 Manual Control Room Isolation Test - A Train

7.10.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push CR Isolation A Train push button PB/CRIA. Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

7.10.2 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.11 Manual Control Room Isolation Test - B Train

7.11.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push CR Isolation B Train push button PB/CRIB. Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

7.11.2 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

NOTE: Note background levels displayed by rate meters before testing to ensure they return to normal when check source is removed.

7.12 R-45/RE-45 Response Test

7.12.1 Remove R-45 from duct adapter and apply radiation to the unit with Field Calibrator. Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

PPCS Alarms_____

7.12.2 Remove detector from Field Calibrator. Verify that R-45 and PPCS readings return to normal background level.

_____

NOTE: QC shall be present to witness torquing of bolts

7.12.3 Reinstall RE-45 and Duct Adaptor Assembly. Torque the Detector Bracket Mounting Hardware and flange nuts to 75 inch pounds maximum. (Per PCR 99-004, attachment 6, sheet 2.) Record installation on Exhibit A of GC-76.9.

_____

7.12.4 Verify PPCS alarm clears. PPCS Alarm Clear_____

7.12.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.13 R-46/RE-46 Response Test

7.13.1 Remove R-46 from duct adapter and apply radiation to the unit with Field Calibrator. Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

PPCS Alarms_____

7.13.2 Remove detector from Field Calibrator. Verify that R-46 and PPCS readings return to normal background level.

_____

NOTE: QC shall be present to witness torquing of bolts

7.13.3 Reinstall RE-46 and Duct Adaptor Assembly. Torque the Decector Bracket Mounting Hardware and flange nuts to 75 inch pounds maximum. (Per PCR 99-004, attachment 6, sheet 2.) Record installation on Exhibit A of GC-76.9.

_____

7.13.4 Verify PPCS alarm clears. PPCS Alarm Clear_____

7.13.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.14 Realignment of Control Room Ventilation System

7.14.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push CR Isolation B Train push button PB/CRIB. (This will prevent damper movement when sliding links are closed.) Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

7.14.2 Request Operations to remove the HOLD and CLOSE the following sliding links:

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CHRA Terminal 3_____

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

7.14.3 Remove the jumper from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7.

_____

Verified By_____

NOTE: When Control Room ventilation is inoperable, the ventilation system may be in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

7.14.4 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.14.5 Verify the following dampers and Charcoal Filter Fan Status as follows:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

7.15 R-45 Test

7.15.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push R-45 Check Source button to expose detector to radiation level above setpoint. Verify the following within 60 seconds after rate meter begins to respond:

AKD10 Closed_____ AKD01 Closed_____

AKD09 Open_____ AKD07 Open _____

AKD05 Closed_____ AKD04 Closed_____

7.15.1 (continued) AKD02 Closed_____ AKD08 Closed_____

Control Room Charcoal Filter Fan ON_____

Annunciator E-11 Alarms_____

PPCS point R45 Alarms_____

PPCS point R-45 value matches rate meter_____

Verify R-46 rate meter remains stable_____

7.15.2 Remove the Check Source from R-45 _____

NOTE: When Control Room ventilation is inoperable, the ventilation system may be in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

7.15.3 When rate meter returns to below alarm and warning set point (< 0.15 mR/hr) push reset button PB/CRIR and verify the following:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

Annunciator E-11 Clear_____

PPCS point R45 Clear_____

7.16 R-46 Test

7.16.1 Place a jumper across terminals TBR46-10 and TBR46-11 in RMS2 rack. This will ensure that when R-46 output contacts open on high alarm, only 81B contacts will drop out and perform isolation function.

_____

7.16.2 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push R-46 Check Source button to expose detector to radiation level above setpoint. Verify the following within 60 seconds after rate meter begins to respond:

AKD10 Closed_____ AKD01 Closed_____

AKD09 Open_____ AKD07 Open _____

AKD05 Closed_____ AKD04 Closed_____

AKD02 Closed_____ AKD08 Closed_____

Control Room Charcoal Filter Fan ON_____

Annunciator E-11 Alarms_____

PPCS point R46 Alarms_____

PPCS point R46 value matches rate meter_____

Verify R-45 rate meter remains stable_____

R81A Remains Energized_____

7.16.3 Remove the Check Source from R-46. _____

NOTE: When Control Room ventilation is inoperable, the ventilation system may be in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

7.16.4 When rate meter returns to below alarm and warning set point (< 0.15 mR/hr) push reset button PB/CRIR and verify the following:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

7.16.4 (continued) Control Room Charcoal Filter Fan OFF_____

Annunciator E-11 Clear_____

PPCS point R46 Clear_____

7.16.5 Remove jumper across TBR46-10 to TBR46-11. _____

Verified By_____

7.16.6 Verify R81A and R81B are energized, and Control Room is NOT in isolation.

_____

7.17 R80B Test

NOTE: This test proves that de-energizing R80B relay causes a Control Room Ventilation Isolation. Procedure PT-17.4 will be performed as Post Modification Testing to verify operability of R36/R37/R38.

7.17.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) open sliding link on terminal deck TBA, terminal 5, located in Splice Box SB-803 in the Turbine Building, just outside the Control Room, and verify the following:

AKD10 Closed_____ AKD01 Closed_____

AKD09 Open_____ AKD07 Open _____

AKD05 Closed_____ AKD04 Closed_____

AKD02 Closed_____ AKD08 Closed_____

Control Room Charcoal Filter Fan ON_____

Annunciator E-11 Alarms_____

R81B Remains Energized_____

7.17.2 Close sliding link on terminal deck TBA, terminal 5, located in Splice Box SB-803.

_____

Verified By_____

NOTE: When Control Room ventilation is inoperable, the ventilation system may be in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

7.17.3 Push reset button PB/CRIR and verify the following:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

Annunciator E-11 Clear_____

R81A and R81B Energized_____

8.0 Post Modification Testing

8.1 Performance Monitoring complete the following test procedures to prove operability:

PT-17.4_____

PT-17.7A_____

PT-17.7B_____

NOTE: THE ASSIGNED ENG. SHALL BE NOTIFIED AND SHALL SIGN STEP 9 AFTER TESTING TO COMPLETE THE REMAINING MODIFICATION TURNOVER STEPS.

9. HOLD POINT: After successful testing the Assigned Engineer Shall complete the remaining Modification Turnover Steps.

ASSIGNED ENGINEER SIGNATURE_____

10. Request Operations clear tracking documentation on the Control Room Ventilation System.

_____

ATTACHMENT 2
PCR 99-004 Revision 1
Test Instructions
Testing of Control Room Radiation Monitors R45 and R46

Perform all testing for each section in the order shown here, unless noted otherwise.

1.0 Wiring/Logic/Device Check

NOTE: At the start of testing, the Control Room will be in isolation. R81A and R81B contacts will be overridden to hold the CR isolation system in the isolation condition. This can be performed by opening sliding links and installing jumpers to control circuits described in step 1.1. Put handswitches 1/HS-88V and 1/HS-88W in Active position.

1.1 Disable the following control functions of R81A and R81B by taking actions for each contact shown on Attachment 1.

Contact	Open Link\ Install Jumper	Consequences
1	Open CRHB-9 in ABB	Holds damper AKD08 closed
4	Open CRHA-1 in ABB	Holds dampers AKD10 and AKD05 closed
6	Open CRHB-5 in ABB	Holds AKD04, AKD01 closed
8	Open CRHA-2 in ABB	Holds damper AKD02 closed
9	Jumper CRHB-6 to CRHB-7	Holds Charcoal Filter Fan on

NOTE: Contact to MCB annunciator E-11 has not been disabled. Therefore, E-11 will clear when the relays are energized, and E-11 will light with a MCB alarm for each test step that simulates a CR isolation (R81A and/or R81B is de-energized). This will require CR Operators to acknowledge the alarm each time it comes in. Visual verification of R81A and R81B status required for each step.

1.2 <u>Normal "Active" Alignment Configuration</u>

- With both trains of Toxic Gas monitoring, and CR radiation monitoring units R-45, R-46 and R36/R37/R38 in their normally energized position with no alarms, verify both R81A and R81B are energized.

Prepared By R Q M Swift Reviewed By Kevin Cave

1.3 R-45 & 1/HS-88V Contact Tests

- With hand switch 1/HS-88V in the "Active" position verify the "Green" indicating light for R-45 Active is illuminated and the "Red" indicating light for R-45 Bypass is not illuminated. Verify R81A and R81B are still energized.

- With hand switch 1/HS-88V in the "Bypass" position verify the "Green" indicating light for R-45 Active is not illuminated and the "Red" indicating light for R-45 Bypass is illuminated.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88V in "Bypass" position, push Check Source button on ratemeter R-45 to simulate R-45 alarm. After ratemeter display exceeds alarm setpoint (0.25 mR), verify that R81A and R81B remain energized. Following test, push Check Source button again to restore R-45 to normal, push ratemeter alarm acknowledge button, and place hand switch 1/HS-88V in the "Active" position.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88V in "Active" position, push Check Source button on ratemeter R-45 to simulate R-45 alarm. After ratemeter display exceeds alarm setpoint (0.25 mR), verify that it results in de-energizing R81A and R81B. Following test, push Check Source button again to restore R-45 to normal, push ratemeter alarm acknowledge button , and reset Control Room ventilation by pushing isolation reset push button PB/CRIR. Verify that R81A and R81B re-energize.

1.4 R-46 & 1/HS-88W Contact Tests

- With hand switch 1/HS-88W in the "Active" position verify the "Green" indicating light for R-46 Active is illuminated and the "Red" indicating light for R-46 Bypass is not illuminated.

- With hand switch 1/HS-88W in the "Bypass" position verify the "Green" indicating light for R-46 Active is not illuminated and the "Red" indicating light for R-46 Bypass is illuminated.

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88W in "Bypass" position, push Check Source button on ratemeter R-46 to simulate R-46 alarm. After ratemeter display exceeds alarm setpoint (0.25 mR), verify that R81A and R81B remain energized. Following test, push Check Source button again to restore R-46 to normal, push ratemeter alarm acknowledge button, and place hand switch 1/HS-88W in the "Active" position.

Prepared By _____ Reveiwed By _____

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) and hand switch 1/HS-88W in "Active" position, push Check Source button on ratemeter R-46 to simulate R-46 alarm. After ratemeter display exceeds alarm setpoint (0.25 mR), verify that it results in de-energizing R81A and R81B. Following test, push Check Source button again to restore R-46 to normal, push ratemeter alarm acknowledge button , and reset Control Room ventilation by pushing isolation reset push button PB/CRIR. Verify that R81A and R81B re-energize.

1.5 **Toxic Gas A Train Logic Verification**

- With hand switch 1/HS-88E (Turbine Building CREPA Panel) in the "Normal" position, verify the Green indicating light for Train A Chlorine Normal is illuminated and the Red indicating light for Train A Chlorine Bypass is not illuminated.
- With hand switch 1/HS-88E in the "Bypass" position, verify the Green indicating light for Train A Chlorine Normal is not illuminated and the Red indicating light for Train A Chlorine Bypass is illuminated.
- With Control Room Ventilation logic in normal alignment and hand switch 1/HS-88E in Normal position, open sliding link CREB-3 to XI-6850 output contact (simulate Train A High Chlorine Alarm). Verify that R81A de-energizes. Following test, close sliding link and reset Control Room Ventilation by pushing isolation reset pushbutton PB/CRIR.

1.6 **Toxic Gas B Train Logic Verification**

- With hand switch 1/HS-88G (Turbine Building CREPB Panel) in the "Normal" position, verify the Green indicating light for Train B Chlorine Normal is illuminated and the Red indicating light for Train B Chlorine Bypass is not illuminated.
- With hand switch 1/HS-88G in the "Bypass" position, verify the Green indicating light for Train B Chlorine Normal is not illuminated and the Red indicating light for Train B Chlorine Bypass is illuminated.
- With Control Room Ventilation logic in normal alignment and hand switch 1/HS-88G in Normal position, open sliding link CREF-3 to XI-6851 output contact (simulate Train B High Chlorine Alarm). Verify that R81B de-energizes. Following test, close sliding link and reset Control Room Ventilation by pushing isolation reset pushbutton PB/CRIR.

Prepared By _____ **Reveiwed By** _____

1.7 **R36/R37/R38 Logic Test and Bypass Test**

- With Control Room Ventilation logic in normal alignment (R81A and R81B energized) verify the R36/R37/R38 Override Keyswitch 1/HS-88B in the Normal position. If required, lower High Alarm value to approximately 100 cpm but greater than current R-38 reading. Push the Check Source Button on R-38 to simulate a High Alarm. Verify that relay R81A de-energizes.

- Place the R36/R37/R38 Override Keyswitch 1/HS-88B in Override position. Push PB/CRIR to reset the isolation logic. Verify that R-38 Check Source is still on. Verify that R36/R37/R38 is bypassed by verifying relay R81A is energized. Following test, return setpoint to the as found P-9 value. Return 1/HS-88B to Normal. Push PB/CRIR to reset all logic to normal if required.

1.8 **Loss of AC Power Test**

1.8.1 **A Train Non-safety Loads**

- Pull Fuses FURMS3/N and P to simulate loss of power to Non-Safety loads.
- Verify power to RY-A is lost. (PPCS point R45, RK-78 points R-29, R-45 and CVHA)
- Verify power to: R-10B, R-13, R-14,
  RY-10B, RY-13, RY-14
  RY-10A, RY-11 and RY-12 is lost.
- Verify power to all other ratemeters, RY-B and recorders in RMS racks is not lost. PPCS Radiation Monitors Group Display can be viewed to confirm radiation monitor operablility, also view point CVHB).
- Re-install fuses FURMS3/N and P to restore power.
- Verify power to RY-A is restored.
- Verify power to: R-10B, R-13, R-14
  RY-10B, RY-13, RY-14
  RY-10A, R-11 and RY-12 is restored.

Prepared By Paul W Swift Reveiwed By Karen Cox

1.8.2 **A Train Safety Related Load R-29**

- Open TB110-4, TB110-5 to simulate loss of power to Safety Related load R-29.
- Verify power to R-29 is lost.
- Verify loss of indication for bypass switch indicating lights 1/HS-88V, 1/HS-88E, 1/HS-88L
- Verify power to XQ-45, XQ-6850/6852 is lost (R81A will drop out and MCB Ann E-11 will annunciate).
- Verify power to: R-10A, R-11, R-12, RK-78 (These are SR but will not loose power with this test.)
  R-10B, R-13, R-14,
  RY-10B, RY-13, RY-14
  RY-10A, RY-11 and RY-12
  RY-A (view point CVHA only) is not lost.
- Close TB110-4, TB110-5 to restore power.
- Verify power to R-29 and Toxic Gas Train A is restored.
- Push CR HVAC Reset pushbutton PB/CRIR.
- Verify CR HVAC restored to normal: E-11 clear, R-45 normal.

1.8.3 **A Train Safety Related Loads R-10A, R-11, R-12, RK-78**

- Pull fuses FURMS4/N and P to simulate loss of power to Safety Related R-10A,
- R-11, R-12 and RK-78.
- Verify power to R-10A, R-11, R-12 and RK-78 is lost.
- Verify power to all other ratemeters, isolators and recorders in RMS racks is not lost. (PPCS Radiation Monitors Group Display can be viewed to confirm radiation monitors operablility, also view point CVHA and CVHB).
- Replace fuses in FURMS4.
- Verify power is restored to R-10A, R-11, R-12 and RK-78.

Prepared By Paul M Swift **Reveiwed By** Karen Cox

1.8.4 **B Train 120 VAC Power Test to Non-Safety Loads**

- Pull Fuses FURMS5/N and P to simulate loss of power to Non-Safety loads.
- Verify power to RK-79 is lost.
- Verify power to RY-B is lost. (PPCS point R46, and RK-79 points R-30, R-46, and CVHB)
- Verify power to all other ratemeters, isolators and recorders in RMS racks is not lost. (PPCS Radiation Monitors Group Display can be viewed to confirm radiation monitor operablility, also view point CVHA).
- Re-install Fuses FURMS5/N and P to restore power.
- Verify power to RK-79 and RY-B is restored.

1.8.5 **B Train Power Test to Safety Related Loads R-30**

- Open TB310-4, TB310-5 to simulate loss of power to loads.
- Verify power to R-30 is lost.
- Verify power to XQ-46, XQ-6851/6853 is lost (R81B will drop out and MCB Ann E-11 will annunciate).
- Verify loss of power to bypass switch indicating lights 1/HS-88W, 1/HS-88G, 1/HS-88M.
- Verify power to RY-B (view point CVHB only) and RK-79 is not lost.
- Close TB310-4, TB310-5 to restore power.
- Verify power to R-30 and R-46 and Toxic Gas Train B is restored.
- Push CR HVAC Reset pushbutton PB/CRIR.
- Verify CR HVAC restored to normal: E-11 clear, R-46 normal.

1.8.6 **A Train Power to Logic**

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) disconnect 120 VAC power connector J3/P3 on rear of R-45 (A Train power) and verify that R81A and R81B de-energize. Following test reconnect cable J3/P3 to restore power to R-45 and reset Control Room ventilation by pushing isolation reset push button PB/CRIR

1.8.7 **B Train Power to Logic**

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) disconnect 120 VAC power connector J3/P3 on rear of R-46 (B Train power) and verify that R81A and R81B de-energize. Following test reconnect cable J3/P3 to restore power to R-46 and reset Control Room ventilation by pushing isolation reset push button PB/CRIR.

Prepared By Paul M Smith **Reveiwed By** Helen Cox

1.9 **Detector Failure Tests**

1.9.1 **A Train Detector Failure Test**

- At detectors at air intake duct, disconnect cable connector from detector RE-45. Wait five minutes for failure delay to actuate. Verify that R-45 Fail Alarm on front panel indicates, and R81A and R81B de-energizes.

- Re-connect cable at air intake duct. Push Alarm Acknowledge on R-45 and verify R-45 Fail alarm has cleared and ratemeter is reading background levels. Reset CR isolation signal by pushing PB/CRIR reset pushbutton. Verify E-11 clears.

1.9.2 **B Train Detector Failure Test**

- At detectors at air intake duct, disconnect cable connector from detector RE-46. Wait five minutes for failure delay to actuate. Verify that R-46 Fail Alarm on front panel indicates, and R81A and R81B de-energizes.

- Re-connect cable at air intake duct. Push Alarm Acknowledge on R-46 and verify R-46 Fail alarm has cleared and ratemeter is reading background levels. Reset CR isolation signal by pushing PB/CRIR reset pushbutton. Verify E-11 clears.

1.10 **Manual CR Isolation Test**

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push CR Isolation A Train pushbutton PB/CRIA. Verify that R81A and R81B de-energize. Following test, push PB/CRIR to reset.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push CR Isolation B Train pushbutton PB/CRIB. Verify that R81A and R81B de-energize. Following test, push PB/CRIR to reset.

2.0 **Radiation Monitors Test and PPCS Test**

This portion of testing will be performed with section 1.0 jumpers and sliding links in the test position to preclude the CR isolation system from changing state during each test. This testing can be performed together as part of the installed Field Calibration of R-45 and R-46. Note background levels displayed by ratemeters before testing to ensure they return to normal when check source removed.

Prepared By _____ Reveiwed By _____

2.1 **R-45/RE-45 Response Test**

- Remove detector RE-45 from duct adapter. Use Field Calibrator for these units to apply radiation to the detector.
- Verify that R81A and R81B de-energize.
- Remove detector from Field Calibrator. Verify that R-45 and PPCS readings return to normal background level. Clear PPCS alarm.
- Reset logic by pressing PB/CRIR. Verify that R81A and R81B re-energize.

2.2 **R-46/RE-46 Response Test**

- Remove detector RE-46 from duct adapter. Use Field Calibrator for these units to apply radiation to the detector.
- Verify that R81A and R81B de-energize.
- Remove detector from Field Calibrator. Verify that R-46 and PPCS readings return to normal background level. Clear PPCS alarm.
- Reset logic by pressing PB/CRIR. Verify that R81A and R81B re-energize.

3.0 **Final Functional Testing**

This testing may be performed independently or incorporated into PT-17.4, or new procedures developed to meet requirements for functional testing of the CR isolation system. The following damper positions (per PT-17.4) will verify isolation has occurred:

AKD10	**Closed**
AKD01	**Closed**
AKD09	**Open**
AKD07	**Open**
AKD05	**Closed**
AKD04	**Closed**
AKD02	**Closed**
AKD08	**Closed**

3.1 Before restoring logic, push CR manual isolation PB/CRIA to de-energize relays R81A and R81B during restoration.

3.2 Restore logic to operational state by closing sliding links and removing jumper listed in step 1.1. After return to normal is completed, push logic reset PB/CRIR and verify that R81A and R81B energize, and MCB annunciator E-11 clears.

Prepared By Paul M Swift **Reveiwed By** Kevin Cox

3.3 R-45 Test

- To verify that R81A will perform all isolation functions independent of R81B, place a jumper across terminals TBR45-10 to TBR45-11 in IC5 (this is across the B Train contact from R-45). This will ensure that when R-45 output contacts open on high alarm, only R81A will drop out and perform isolation functions.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push RE-45 check source button to expose detector to radiation level above setpoint. Verify that all CR Isolation dampers and fans operate as required by PT-17.4 for Control Room Isolation within 60 seconds after ratemeter begins to respond (starts counting up). Verify PPCS point R-45 value matches ratemeter and is in alarm. Verify R81A drops out and R81B remains energized.

- Verify that R-46 ratemeter display remains stable (i.e. no noise induced spike due to R-45 actuation). Reading shall be less than Warning alarm value.

- Remove check source. Push ratemeter alarm acknowledge button

- After ratemeter display returns to below alarm and warning setpoint (< 0.15 mR/hr), push reset PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears, PPCS point R45 returns to background level and alarm clears.

- Remove jumper across TBR45-10 to TBR45-11. Verify CR is not in isolation. If isolation actuate during jumper removal, use PB/CRIR to reset.

3.4 R-46 Test

- To verify that R81B will perform all isolation functions independent of R81A, place a jumper across terminals TBR46-10 to TBR46-11 in RMS2 (this is across the A Train contact from R-46). This will ensure that when R-46 output contacts open on high alarm, only R81B will drop out and perform isolation functions.

- With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) push RE-46 check source button to expose detector to radiation level above setpoint. Verify that all CR Isolation dampers and fans operate as required by PT-17.4 for Control Room Isolation within 60 seconds after ratemeter begins to respond (starts counting up). Verify PPCS point R46 value matches ratemeter and is in alarm.

- Verify that R-45 ratemeter display remains stable (i.e. no noise induced spike due to R-46 actuation). Reading shall be less than Warning alarm value.

- Remove Check Source. Push ratemeter alarm acknowledge button

Prepared By Paul M Swift Reveiwed By Kevin Cole

- After ratemeter display returns to below alarm and warning setpoint (< 0.15 mR/hr), push reset PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears, PPCS point R46 returns to background level and alarm clears.

- Remove jumper across TBR46-10 to TBR46-11. Verify CR is not in isolation. If isolation actuate during jumper removal, use PB/CRIR to reset.

3.5 **R36/R37/R38 Test**

This test will demonstrate operability of existing CR Radiation Monitors.

- Use applicable steps from PT-17.4 to verify operability of R36/R37/R38.
- Restore CR isolation with PB/CRIR. Verify that dampers return to normal (not isolated) position, E-11 clears.
- CR HVAC system may now be declared Operable.

3.6 **Restoration**

3.6.1 Plant vent and Containment vent can be restored to normal by Operations and declared Operable as appropriate for plant conditions.

Prepared By _____ Reveiwed By _____

ROCHESTER GAS AND ELECTRIC CORPORATION

GINNA STATION

CONTROLLED COPY NUMBER _____

PROCEDURE NO. SM-99-004.2 REV. NO. 0

CONTROL ROOM RADIATION MONITOR RELOCATION

RESPONSIBLE MANAGER

9-6-02

EFFECTIVE DATE

QA _____ NON-QA _____ CATEGORY 9.1

REVIEWED BY: _____

THIS PROCEDURE CONTAINS 47 PAGES

SM-99-004.2

Control Room Radiation Monitor Relocation

1 Purpose:

1.1 The scope of this job is to relocate components of the radiation and toxic gas monitoring system in the Control Room, per PCR 99-004 Rev. 1. This procedure is divided into sections as follows:

- Removal and installation of components in Auxiliary Bench Board (ABB).
- Toxic Gas Panel Wiring Changes
- Equipment Installation / Wiring in RMS Racks
- Hardware Installation and Moving in RMS and IC5 Racks
- Component Testing
- A Train 120 VAC Power, RK-79 and PPCS Work
- B Train 120 VAC Power, RK-79 and PPCS Work
- Wiring in RMS and IC5 Racks
- Start Up and Verification of Configuration/Setpoints
- Calibration
- Functional Testing

2 References

2.1 IP-DES-3, GC-76.3, GC-76.9, GC-76.10, EE-29, EE-80, EE-035

2.2 PCR 99-004

3 Initial Conditions

3.1 The plant may be in any mode of operation. _____

3.2 Group supervision has verified that applicable reinstatement steps have been marked for independent verification as indicated by the review signature on the work order.

_____

NOTE: When power for Radiation and Toxic Gas Monitors is de-energized, all controls and indication for Control Room HVAC will be de-energized. The system will remain in isolation throughout that time frame.

3.3 If any parts removed from stock have a conditional release tag attached, fill out the enclosed conditional release form in accordance with A-700, and forward it to Procurement Quality Control. N/A this step if no conditionally released parts were used.

_____

3.4 A pre-job briefing has been held with the assigned engineer before starting the job. Personnel suggested to be present during the pre-job brief are:

Assigned Engineer, QC, I&C, Electricians, Operations personnel, PPCS Computer Group personnel, and RP's.

_____

3.5 Materials are available for performing the work. _____

4 Notifications

4.1 Notify the Shift Supervisor of the work to be done. _____

4.2 Notify the Training Modification Control Coordinator (Sandy Smith) that work is starting on PCR 99-004, Rev 1.

_____

4.3 Notify the Assigned Engineer (Paul Swift) that work is starting.

_____

4.4 Notify the System Engineer (Karen Cona and Carm Vitale) that work is starting.

_____

4.5 Notify QC that inspections will be required for parts of the job.

_____

5 Precautions

5.1 Working in the Control Room requires that caution is exercised to minimize the impact on Operations personnel.

5.2 Take care not to bump or jar surrounding equipment when working in the Aux Bench Board and RMS Racks.

5.3 Verify by test that equipment is de-energized.

5.4 When Control Room ventilation is inoperable, the ventilation system may be placed in Normal line up for a total of 1 hour in 24 hours, per ITS 3.7.9. Operations to log time on Normal line up. Note that normal line up may not be possible due to equipment out of service.

6 INSTRUCTIONS:

Note 1: Construction Sections of this Modification may be done out of order or concurrently to minimize the installation time.

Note 2: Equivalent parts installed may be different from Material ID and part numbers specified in this procedure, if approved by Engineering.

6.1 Aux Benchboard Work Before Isolation

CAUTION: Take care not to disturb existing wiring in the Aux Bench Board.

6.1.1 Punch a 2" and 2 ½" hole through cabinet wall between Aux Bench Board right section and center section as shown on SK33013-2004-1. Use grommets or chase bushings to protect edges.

_____

6.2 Incore Rack 5 (IC5) Work Before Isolation

6.2.1 Remove front plate at top of rack Incore 5 (IC5). _____

6.2.2 Modify the front plate from the top of IC5 by punching holes for lights, switch, and R45 display.

_____

6.2.3 Install stainless steel plates in IC5 rack per drawing 21489-0698, using 10-32 flat head machine screws (Material ID #5001828), countersunk in the plate. Record plates installed on Exhibit B of GC-76.9 procedure.

_____

6.2.4 Install 12 point states deck TBR45 (Material ID #9006061) in IC5 rack per drawing 21946-0698 and Appendix 1 of GC-76.9 procedure, using 10-32 machine screws (Material ID #5001827). Record on GC-76.9 Exhibit A.

_____

6.2.5 Remove the label from existing states deck TBR45 in RMS2 Rack and install it on the new states deck in IC5 Rack.

_____

6.2.6 Re-label the states deck (formerly known as TBR45) as TBR46X.

_____

6.2.7 Install Panduit raceway in RMS racks per drawing 21489-0698. Record on Exhibit C of GC-76.9.

_____

6.2.8 Install the R-45 Rad Monitor chassis (line filters installed, rate meters not installed) in cabinet per drawing 21489-0698, using #8 flat head machine screws. Record on GC-76.9, exhibit A.

_____

6.2.9 Install R-45 switches (Material ID #9035991, 9049746, 9036024) and lights (Material ID #5001863, 9219978, 9217584, 9187570, 5000293) in the blank plate at the top of IC5 rack per SK33013-2656-1. Record installation on GC-76.9, Exhibit A.

_____

6.3 A Train Isolation and Temporary power for Radiation Monitors R-10A, R-11, R-12, and R-29

6.3.1 Operations de-pressurize Containment as necessary before taking radiation monitors out of service.

Operations_____

6.3.2 Performance Monitoring verify that there is sufficient time on the charcoal filters to run the Control Room Ventilation System on Recirc for one week before taking radiation monitors out of service.

Performance Monitoring_____

6.3.3 Operations verify that there should be NO discharge of gaseous effluent from Waste Gas Decay Tanks via Plant Vent, for one week.

Operations_____

6.3.4 Operations verify that there should be NO discharge from the Waste Holdup Tank, for one week.

Operations_____

NOTE: The following jumper installation defeats activation of the Plant Ventilation Isolation Signal.

6.3.5 I&C notify Operations of jumper installation to defeat activation of the Plant Ventilation Isolation Signal.

I&C_____

6.3.6 I&C install a jumper between terminal 12 and 13 on terminal deck FL-2, located in rack RA2 (front).

I&C_____

6.3.7 Request Operations to initiate tracking documentation for taking the following equipment out of service:

Control Room Toxic Gas Monitoring System "A" Train
Radiation Monitor R-10A
Radiation Monitor R-10B
Radiation Monitor R-11
Radiation Monitor R-12
Radiation Monitor R-13
Radiation Monitor R-14
Radiation Monitor R-29
Radiation Monitor R-45
Recorder RK-78

Tracking Documentation Initiated _____ SS_____

6.3.8 Operations to place the "A" train Chlorine monitor switch to the "Bypass" position on the Control Room Environmental Panel.

_____

6.3.9 Request Operations to place the "A" train Ammonia monitor switch to the "Bypass" position on the Control Room Environmental Panel.

_____

6.3.10 Request Operations to place the R-45 monitor switch to the "Bypass" position in the RMS-2 rack.

_____

6.3.11 Notify Operations that HOLDing IBPDPCBE/01 breaker will result in a Containment Vent Isolation signal.

_____

6.3.12 Request Operations to HOLD IBPDPCBE/01 breaker. _____

6.3.13 Verify by test that circuit C2621 is de-energized at terminal block TB110, terminals 1 and 2. Refer to PCR 99-004 rev. 1, Attachment 6, page 1 of 5.

_____

6.3.14 Mark and lift circuit C2621 wires from terminal block TB110, terminals 1 and 2. Record on GC-76.10, Exhibit B.

_____

6.3.15 Remove the following jumpers:
TB110-1 to TB110-4 and TB110-2 to TB110-5. Record on GC-76.10, Exhibit C.

_____

6.3.16 Mark and lift R-29 power wires from terminal block TB110, terminals 4 and 5. Record on GC-76.10, Exhibit B.

_____

6.3.17 Remove jumpers from terminal block TBR12 terminals 3, 4, and 5 to terminal block TBR14 terminals 3, 4, and 5. Record on GC-76.10, Exhibit C.

_____

6.3.18 Remove jumpers from terminal block TBR12 terminals 3, 4, and 5 to Isolator RY-12. Record on GC-76.10, Exhibit C.

_____

6.3.19 Lift wires from terminal block TBR10A to TB110, at TB110. Record on GC-76.10, Exhibit B.

_____

6.3.20 Make temporary connections from circuit C2621 to wiring that feeds R-10A, R-11, R-12 and R-29 as follows by bolting ring terminals together and insulating with tape:

Connect C2621 wire L1, to R-29 wire L1, to R-10A wire L1 _____

Verified By_____

Connect C2621 wire L2, to R-29 wire L2, to R-10A wire L2 _____

Verified By_____

R-10A ground wire and R-29 ground wire to ground _____

Verified By_____

6.3.21 Request Operations to remove HOLD and close breaker IBPDPCBE/01 to energize C2621, R-10A, R-11, R-12, and R-29.

_____

6.3.22 Operations reset CVI, Containment Ventilation. Operations_____

6.3.23 Verify R-10A, R-11, R-12 and the Containment Ventilation Monitor Skid are properly lined up by performing applicable sections of S-14.8, 'OPERATION OF CONTAINMENT VENTILATIONRADIATION MONITORS".

Operations_____

6.3.24 Verify R-10A, R-11 and R-12 function properly by performing applicable sections of PT-17.2, PROCESS RADIATION MONITORS R-11 - R-22 IODINE MONITORS R-10A AND R-10B."

Operations_____

6.3.25 Operations verify operability of R-29 by performing applicable sections of PT-17.1, "AREA RADIATION MONITORS - R1 TO R9 HIGH RANGE AREA MONITORS - R-29, R-30".

Operations_____

6.3.26 Operations clear tracking documentation submitted for radiation monitors R-10A, R-11, R-12 and R-29.

_____

6.4 B Train Monitors and Control Room Ventilation Isolation

6.4.1 Request Operations to initiate tracking documentation for taking the following equipment out of service:

Control Room Toxic Gas Monitoring System "B" Train
Radiation Monitor R-30
Radiation Monitor R-46
Recorder RK-79

Tracking Documentation Initiated _____ SS_____

6.4.2 Notify Operations that annunciator E-11 will alarm when the Control Room Ventilation System is put into recirculation mode.

_____

6.4.3 Request Operations to place the place the Control Room Ventilation System in isolation.

Control Room Ventilation in Isolation_____

6.4.4 Verify that the Charcoal Filter Fan is running, and that Control Room ventilation dampers are in the Mode "F" positions.

_____

6.4.5 Request Operations to HOLD the following breaker # 11 in panel IBPDPCBC. to isolate power to the Control Room Toxic Gas and Radiation Monitors R-30, R-46, and recorder RK-30.

_____

6.4.6 Request Operations to HOLD the following states deck slide links open in the Aux Bench Board: Reference drawing SK21946-0546SH1-1.

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

6.4.6 (continued) Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

CAUTION: Terminals CRHB-6 and CRHB-7 will be ENERGIZED at +65 VDC to ground.

6.4.7 Install a jumper from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7. This will keep the Control Room Charcoal Filter Fan running while R80A is removed and wiring changes are made.

_____

Verified By_____

6.4.8 Request Operations to HOLD the following states deck slide links open in the Aux Bench Board:

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

6.4.9 Request Operations to HOLD the following states deck slide links open in the Main Control Board to disable annunciator E11 power:

Terminal Deck TDY Terminal 9_____

Terminal Deck TDY Terminal 10_____

6.5 Device Removal / Installation in the Auxiliary Bench Board (ABB)

CAUTION: Be careful as components not related to Control Room Ventilation are energized.

6.5.1 Verify by test that all wires and connections on relay R81B are de-energized. (In ABB right section)

_____

6.5.2 Mark or ensure marked wires connected to relay R81B. _____

6.5.3 Remove all wires (both ends) connected to relay R81B and record on attached R81B Relay Jumper Removal Attachment.

_____

6.5.4 Remove relay R81B. _____

6.5.5 In Aux Bench Board right section, install new fuse blocks FUTGA-1 and FUTGA-2, and fuses (Type KTK-R-3) as shown on SK33013-1860-4. Record fuse block installation on GC-76.9, Exhibit A. (Fuse block MID #9169784, fuses #9140085, 8-32 screws #5001830.)

_____

6.5.6 On Aux Bench Board top panel, right section, exchange position of PB/CRIR and PB/CRIA. Refer to SK33013-1735-1, Rev 1.

_____

6.5.7 Fabricate and install mounting plate, R81B, and fuseblocks (FUTGB-1 and FUTGB-2) as instructed on SK-33013-2004-1 in Aux Benchboard Center Section. Record R81B and fuse block installation on GC-76.9, Exhibit A.

_____

6.5.8 Determ circuit C5539 from terminal block CRHD, terminals 9 and 10 in the ABB.

_____

6.5.9 Determ circuit C5545 from terminal block TB03, terminals 10 and 11 in the ABB.

_____

6.5.10 Determ circuit C5552 from terminal block TB03, terminals 10, 11, 12 (and ground for the shield) in the ABB.

_____

6.5.11 Route cables C5539, C5545 and C5552 through smaller hole from Aux Bench Board right section to center sections of ABB.

_____

6.5.12 Reterm circuit C5539 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.13 Reterm circuit C5545 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.14 Reterm circuit C5551 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.15 Reterm circuit C5552 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.16 Install wiring to R81B Relay per drawings SK33013-2004-1, SK21946-0546SH2-1, and SK21946-0546SH1-1. Record on GC-76.10, Exhibit C.

_____

6.5.17 De-term circuit C5530 from terminal deck TB03, terminals 1 and 2 in the ABB.

_____

6.5.18 Re-terminate circuit C5530 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.19 De-term circuit C5529 from terminal deck TB03, terminals 4 and 5 in the ABB.

_____

6.5.20 Re-terminate circuit C5529 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.21 Reterm circuit AU0235 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.22 Reterm circuit AU0239 per circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule.

_____

6.5.23 De-term wire from ZK-1 on the left side of terminal deck TB03, terminal 6, and re-terminate it on the right side of terminal deck TB03, terminal 5 per drawing SK33013-1860-4. Record on GC-76.10, Exhibit C.

_____

6.5.24 Install wiring to fuse blocks FUGA-1 and FUGA-2 in the Aux Bench Board and record on GC-76.10, Exhibit C.

_____

6.5.25 Install wiring to fuse blocks FUGB-1 and FUGB-2 in the Aux Bench Board and record on GC-76.10, Exhibit C.

_____

6.5.26 Remove jumpers CHRD-10 to ZA-3, and CHRD-9 to TB03-12. Record on GC-76.10, Exhibit C.

_____

6.5.27 Verify that all wiring in the Aux Bench Board complies with drawings SK33013-1860-4 rev. 1, SK21946-0546SH1-1 rev. 1, and SK21946-0546SH2-1 rev. 1, and SK33013-2004-1 rev. 0.

_____

6.6 Changes in Toxic Gas Panel CREP A

6.6.1 Remove surge supressors from terminal block CREB terminals 3-4 and 5-6.

_____

6.6.2 Remove wiring from fuseblocks FUCREPA-1, FUCREPA-2, and FUCREPA-3. Record wires removed on GC-76.10, Exhibit C.

_____

6.6.3 Remove existing fuse blocks FUCREPA-2 and FUCREPA-3.

_____

6.6.4 Re-label fuse block FUCREPA-1 as fuse block FUCREPA-4. _____

6.6.5 Install wiring to terminal block CREB per drawing SK33013-2784-1 rev. 1. Record wires installed on GC-76-10, Exhibit C.

_____

6.6.6 Install wiring to fuse block FUCREPA-4 as shown on drawing SK33013-2784-1 rev. 1 and record on GC-76.10, Exhibit C.

_____

6.6.7 Verify that all wiring in the CREP-A complies with drawings SK33013-2784-1 rev. 1.

_____

6.7 Changes in Toxic Gas Panel CREP B

6.7.1 Remove surge supressors from terminal block CREF terminals 3-4 and 5-6. _____

6.7.2 Remove wiring from fuseblocks FUCREPB-1, FUCREPB-2, and FUCREPB-3. Record wires removed on GC-76.10, Exhibit C. _____

6.7.3 Remove existing fuse blocks FUCREPB-2 and FUCREPB-3. _____

6.7.4 Re-label fuse block FUCREPB-1 as fuse block FUCREPB-4. _____

6.7.5 Install wiring to terminal block CREF per drawing SK33013-2784-1 rev. 1. Record wires installed on GC-76-10, Exhibit C. _____

6.7.6 Install wiring to fuse block FUCREPB-4 as shown on drawing SK33013-2784-1 rev. 1 and record on GC-76.10, Exhibit C. _____

6.7.7 Verify that all wiring in the CREP-B complies with drawings SK33013-2784-1 rev. 1. _____

6.8 Hardware Installation and moving in RMS and IC5 Racks

6.8.1 Disconnect all wires connected to ratemeter R-45, bypass switch 1/HS-88V and associated lights in RMS2. The wires with connectors will be used in IC5. _____

6.8.2 Install R-45 in IC5 chassis. Record on GC-76.9 Exhibit A. _____

6.8.3 Install isolator RY-A in IC5 per drawing 21489-0698. Record installation on GC-76.9, Exhibit A. IF new isolator is not available, THEN mark this step N/A. _____

Note: Refer to MDCN 2252 for installation of states deck.

6.8.4 IF new isolator is not available, THEN install new 12 point states deck (Material ID #9006061) in place of isolator, per Appendix 1 of GC-76.9 procedure, using 10-32 machine screws (Material ID #5001827). Record on GC-76.9 Exhibit A. Label new states deck TBRYA. IF new isolator was installed, mark this step N/A.

_____

6.8.5 Install isolator RY-B in RMS2 per drawing 21489-0698. Record installation on GC-76.9, Exhibit A. IF new isolator is not available, THEN mark this step N/A.

_____

6.8.6 IF new isolator is not available, THEN install new 12 point states deck (Material ID #9006061) in place of isolator, per Appendix 1 of GC-76.9 procedure, using 10-32 machine screws (Material ID #5001827). Record on GC-76.9 Exhibit A. Label new states deck TBRYB. IF new isolator was installed, mark this step N/A.

_____

6.8.7 Install new fuse block FURMS5 (material ID 9169784) and fuses in RMS3 rack per drawing 21489-0698. Record installation on GC-76.9, Exhibit A.

_____

6.8.8 Install new fuse block FURMS3 and FURMS4 (material ID 9169784) and fuses in IC5 rack per drawing 21489-0698. Record installation on GC-76.9, Exhibit A.

_____

6.9 A Train 120 volt power, RK-78 and PPCS Work

NOTE: Circuit C2621 will be providing temporary power to R-10A, R-11, R-12, and R-29. Final configuration of this circuit will be performed in section 6.12 of this procedure.

6.9.1 Re-wire TB110 to TBR45 per Attachment 6 sheet 2. Record on GC-76.10, Exhibit C.

_____

6.9.2 Determ circuit B0237 from RK-78, CH11. _____

6.9.3 Re-Terminate Circuit B0237 to RY-A and record on circuit schedule in PCR 99-004 Rev. 1. Record on circuit schedule in PCR 99-004 Rev. 1. IF isolator is not installed, THEN mark this step N.A.

_____

6.9.4 IF isolator is not installed, THEN re-terminate Circuit B0237 to terminal deck TBRYA, terminals 12 (shield), 11 (-), and 10 (+). Record on Circuit Schedule B0237 on MDCN 2252. IF isolator is installed, THEN mark this step N/A.

_____

6.9.5 IF isolator is installed, THEN determ circuit AU0235A from states deck TBR46X in RMS2 Rack. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.9.6 Re-terminate circuit AU0235A on RY-A in IC5 Rack. Record on circuit schedule in PCR 99-004 Rev. 1. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.9.7 Determ R-29 recorder output to RK-78 channel 10 at RK-78. _____

6.9.8 IF Isolator is installed, THEN reterm R-29 recorder output (removed in step 6.9.7) on Isolator RY-A Channel 1, per Attachment 6. Record on GC-76.10, Exhibit C. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.9.9 IF isolator is NOT installed, THEN reterm R-29 recorder output (removed in step 6.9.7) on TBRYA per MDCN 2252. Record on GC-76.10, Exhibit C. IF isolator is installed, THEN mark this step N/A.

_____

6.9.10 Install wiring to TB110, FURMS3 and FURMS4 as shown on Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.9.11 IF Isolator RY-A is installed, THEN install wiring from FURMS3 to RY-A as shown on Attachment 6. Record on GC-76.10, Exhibit C. IF Isolator RY-A is NOT installed, THEN mark this step N/A.

_____

6.9.12 IF Isolator RY-A is NOT installed, THEN install wiring from FURMS3 to terminal block TBRYA as shown on MDCN 2252. Record on GC-76.10, Exhibit C. IF Isolator RY-A is installed, THEN mark this step N/A.

_____

6.9.13 Install wiring from FURMS-4 to RK-78 as shown on Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.9.14 IF Isolator RY-A is installed, THEN install wiring from RY-A channel 1 to RK-78 channel 10. Record on GC-76.10, Exhibit C. IF RY-A is NOT installed THEN mark this step N/A.

_____

6.9.15 IF Isolator RY-A is NOT installed, THEN install wiring from TBRYA to RK-78 channel 10 per MDCN 2252.

_____

6.9.16 IF Isolator RY-A is installed, THEN install wiring from RY-A channel 3 to RK-78 channel 12. Record on GC-76.10, Exhibit C. If Isolator RY-A is NOT installed, THEN mark this step N/A.

_____

6.9.17 IF Isolator RY-A is NOT installed, THEN install wiring from TBRYA to RK-78 channel 12 per MDCN 2252.

_____

6.9.18 IF Isolator RY-A is installed, THEN install wiring from RY-A channel 4 to RK-78 channel 11. Record on GC-76.10, Exhibit C. If Isolator RY-A is NOT installed, THEN mark this step N/A.

_____

6.9.19 IF Isolator RY-A is NOT installed, THEN install wiring from TBRYA to RK-78 channel 11 per MDCN 2252. Record on GC-76.10, Exhibit C. IF Isolator RY-A is installed, THEN mark this step N/A.

_____

6.9.20 Install wiring from RK-78 to fuse block FURMS4 as shown in PCR Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.10 B Train 120 volt power, RK-79 and PPCS Work

6.10.1 IF isolator RY-B is installed, THEN determ circuit schedule AU0239A from terminal block TBR46. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.10.2 IF isolator RY-B is installed, THEN reterm circuit schedule AU0239A on RY-B. Record on circuit schedule in PCR 99-004 Rev. 1. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.10.3 Determ circuit schedule B0247 from RK-79 channel 11. _____

6.10.4 IF isolator RY-B is installed, THEN reterm circuit schedule B0247 on RY-B channel 4. Record on circuit schedule in PCR 99-004 Rev. 1. IF isolator is not installed, mark this step N/A.

_____

6.10.5 IF isolator RY-B is NOT installed, reterm circuit B0247 on TBRYB, terminals 12 (shield), 11 (-), and 10 (+). Record on Circuit Schedule B0247 on MDCN 2252.

_____

6.10.6 Re-wire TB310 to TBR46 per Attachment 6 sheet 5. Record on GC-76.10, Exhibit C.

_____

6.10.7 Determ R-30 recorder output to RK-79 channel 10 at RK-79. _____

6.10.8 IF Isolator is installed, THEN reterm R-30 recorder output (removed in step 6.10.7) on Isolator RY-B Channel 1, per Attachment 6. Record on GC-76.10, Exhibit C. IF isolator is NOT installed, THEN mark this step N/A.

_____

6.10.9 IF isolator is NOT installed, THEN reterm R-30 recorder output (removed in step 6.10.7) on TBRYB per MDCN 2252. Record on GC-76.10, Exhibit C. IF isolator is installed, THEN mark this step N/A.

_____

6.10.10 Install wiring from TB310 to FURMS5 per Attachment 6 page 5. Record on GC-76.10, Exhibit C.

_____

6.10.11 Install wiring from FURMS5 to RK-79 per MDCN 2252. Record on GC-76.10, Exhibit C.

_____

6.10.12 IF Isolator RY-B is installed, THEN install wiring from FURMS5 to RY-B as shown on Attachment 6. Record on GC-76.10, Exhibit C. IF Isolator RY-B is NOT installed, THEN mark this step N/A.

_____

6.10.13 IF Isolator RY-B is NOT installed, THEN install wiring from FURMS5 to terminal block TBRYB as shown on MDCN 2252. Record on GC-76.10, Exhibit C. IF Isolator RY-B is installed, THEN mark this step N/A.

_____

6.10.14 IF Isolator RY-B is installed, THEN install wiring from RY-B channel 1 to RK-79 channel 10. Record on GC-76.10, Exhibit C. IF RY-B is NOT installed THEN mark this step N/A.

_____

6.10.15 IF Isolator RY-B is NOT installed, THEN install wiring from TBRYB to RK-79 channel 10 per MDCN 2252.

_____

6.10.16 IF Isolator RY-B is installed, THEN install wiring from RY-B channel 3 to RK-79 channel 12. Record on GC-76.10, Exhibit C. If Isolator RY-B is NOT installed, THEN mark this step N/A.

_____

6.10.17 IF Isolator RY-B is NOT installed, THEN install wiring from TBRYB to RK-79 channel 12 per MDCN 2252.

_____

6.10.18 IF Isolator RY-B is installed, THEN install wiring from RY-B channel 4 to RK-79 channel 11. Record on GC-76.10, Exhibit C. If Isolator RY-B is NOT installed, THEN mark this step N/A.

_____

6.10.19 IF Isolator RY-B is NOT installed, THEN install wiring from TBRYB to RK-79 channel 11 per MDCN 2252. Record on GC-76.10, Exhibit C. IF Isolator RY-B is installed, THEN mark this step N/A.

_____

6.11 Wiring in RMS and IC5 Racks

NOTE: Refer to drawing SK33013-1618SH1-2

NOTE: A HOT WORK Permit shall be issued for all soldering performed in the Control Room

NOTE: The impact of any soldering performed in the Control Room shall be reviewed regarding Control Room Charcoal Filters

6.11.1 Determ all wires on terminal deck TBR46X. _____

NOTE: Maintain A and B train separation between cables and conductors. Use appropriate panduits or maintain a minimum 6 inch separation for cables that go between A and B trains.

6.11.2 Pull back wiring from conduit C5551 out of the panduit designated A train inside the RMS racks. Move A Train panduit toward the front of the rack, or replaced, to provide a minimum of 6" separation between the B train panduit.

_____

6.11.3 Re-terminate C5551 conductors on TBR45 in IC5 Rack. Record on circuit schedule in PCR 99-004 Rev. 1. Wires can be extended or shortened, as required. Record on circuit schedule in PCR 99-004 Rev. 1.

_____

6.11.4 Remake connectors (include jumpers) J1/P1 to R-45 per new configuration on SK33013-1618SH1-2. Use connector instructions (Attachment 8 of PCR) and same size wire as existing. Reconnect P1 conductors to TBR45. Record on GC-76.10, Exhibit C.

_____

6.11.5 Remake connectors J6/P6 to R-45 per new configuration on SK33013-1618SH1-2. Use connector instructions (Attachment 8 of PCR) and same size wire as existing.

_____

6.11.6 If Isolator RY-A is installed, connect P6 conductors to RY-A channel 2 and 3 per attachment 6 of PCR. Record on GC-76.10, Exhibit C. If RY-A is NOT installed, THEN mark this step N/A.

_____

6.11.7 If Isolator RY-A is NOT installed; connect P6 conductors to TBRYA per MDCN 2252. Record on GC-76.10, Exhibit C. If RY-A is installed, THEN mark this step N/A.

_____

6.11.8 Rework B Train conductors per circuit C5552. Re-use wires that are long enough to reach, other wires can be extended or shortened as required, using appropriate SR terminals. Record on circuit schedule in PCR 99-004 Rev. 1.

_____

6.11.9 Remake connectors (include jumpers) J1/P1 to R-46 per new configuration on SK33013-1618SH1-2. Use connector instructions (Attachment 8 of PCR) and same size wire as existing. Reconnect P1 conductors to TBR46. Record on GC-76.10, Exhibit C.

_____

6.11.10 Remake connectors J6/P6 to R-46 per new configuration on SK33013-1618SH1-2. Use connector instructions (Attachment 8 of PCR) and same size wire as existing.

_____

6.11.11 If Isolator RY-B is installed, connect P6 conductors to RY-B channel 2 and 3 per attachment 6 of PCR. Record on GC-76.10, Exhibit C. If RY-B is NOT installed, THEN mark this step N/A.

_____

6.11.12 If Isolator RY-B is NOT installed, connect P6 conductors to TBRYB per MDCN 2252. Record on GC-76.10, Exhibit C. If RY-B is installed, THEN mark this step N/A.

_____

6.11.13 Install conductors between TBR45 and TBR46 in A Train Panduit as shown on drawing SK33013-1618SH1-2. Record on GC-76.10 Exhibit C.

_____

6.11.14 Install conductors between TBR45 and TBR46 in B Train Panduit as shown on drawing SK 33013-1618SH1-2. Record on GC-76.10 Exhibit C.

_____

6.11.15 Remove jumper TBR45-3 to TBR45-6. Record on GC-76.10, Exhibit C.

_____

6.11.16 Remove jumper TBR46-3 to TBR46-6. Record on GC-76.10, Exhibit C.

_____

6.11.17 Install jumper and wiring on TBR45 to XQ-45, 1/HS-88V, as shown on drawing SK 33013-1618SH1-2. Record on GC-76.10 Exhibit C.

_____

6.11.18 Install jumpers between 1/HS-88V and the indication lights for R-45. Record on GC-76.10 Exhibit C.

_____

6.12 Reconfiguration of power wiring to R-10A, R-11, R-12 and R-29

6.12.1 Operations de-pressurize Containment as necessary before taking radiation monitors out of service.

Operations_____

6.12.2 Request Operations to submit tracking documentation for taking R-10A, R-11, R-12 and R-29 out of service.

_____

6.12.3 Request Operations to HOLD circuit breaker IBPDPCBE/01.

_____

6.12.4 Verify by test that power feeds to R-10A, R-11, R-12 and R-29 are de-energized.

_____

6.12.5 Untape and disconnect circuit C2621 from R-10A and R-29 power feeds.

_____

6.12.6 Land circuit C2621 on terminal deck TB110 as shown in PCR Attachment 6. Record on circuit schedule in PCR 99-004 rev. 1.

_____

6.12.7 Install wiring from TBR10A to fuse block FURMS4 as shown in PCR Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.12.8 Reconnect wiring from R-29 to TB110 as shown on PCR Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.12.9 Install wiring from TBR14 to terminal block TB110 as shown in PCR Attachment 6. Record on GC-76.10, Exhibit C.

_____

6.13 AC Power Restoration

6.13.1 Request Operations to remove HOLD and CLOSE breaker IBPDPCBE/01.

_____

6.13.2 Verify Power to the following A Train loads:

R-10A, R-11, R-12, R-29, R-45, "A" Train Toxic Gas System_____

RY-10A, RY-10B, RY-11, RY-12, RY-13, RY-14_____

RK-78, R-10B, R-13, R-14 _____

Isolator RY-A (N/A if RY-A is NOT installed)_____

6.13.3 Request Operations to remove HOLD and CLOSE breaker IBPDPCBC/11.

_____

6.13.4 Verify Power to the following B Train loads:

R-30, R-46, "B" Train Toxic Gas System_____

RK-79_____

Isolator RY-B (N/A if RY-B is NOT installed)_____

6.14 Start Up and Verification of Configuration / Setpoints

NOTE: Start up should only be performed by I&C Technicians familiar with equipment and sections of the Innovision vendor manual "Operations" section. Follow Attachment 9 for initial vendor start-up instructions.

6.14.1 Enter or verify setpoints for R-45 as follows:

R-45 Warning Setpoint - 0.20 mr/hr_____

R-45 Alarm Setpoint - 0.25 mr/hr_____

6.14.2 Enter or verify setpoints for R-46 as follows:

R-46 Warning Setpoint - 0.20 mr/hr_____

R-46 Alarm Setpoint - 0.25 mr/hr_____

6.14.3 PPCS has been configured to accept the inputs from R-45 and R-46 per Attachment 10 of PCR 99-004 Rev. 1. IF isolators RY-A and RY-B were NOT installed, THEN mark this step N/A.

_____

6.15 Calibration

6.15.1 Verify the following procedures have been changed to include RY-A and RY-B calibrations per the NUS vendor manual for all inputs and outputs shown on PCR 99-004 attachment 6:

CPI-MON-R29/R30_____

CPI-MON-A-53_____

CPI-MON-B-53_____

CPI-MON-R45_____

CPI-MON-R46_____

6.15.2 Calibrate RY-A as per CPI-MON-R29/R30 for R-29 and CPI-MON-A-53 for HMSLCPA. IF Isolator is not installed, mark this step N/A.

_____

6.15.3 Calibrate RY-B per CPI-MON-R29/R30 for R-30 and CPI-MON-A-53 for HMSLCPB. IF Isolator is not installed, mark this step N/A.

_____

6.15.4 Calibrate R-45 per CPI-MON-R45. IF Isolator is NOT installed, mark applicable steps in procedure N/A.

_____

6.15.5 Calibrate R-46 per CPI-MON-R46. IF Isolator is NOT installed, mark applicable steps in procedure N/A.

_____

6.15.6 **HOLD POINT**: When the installation is complete, prior to testing, notify the Assigned Engineer (Paul Swift) to complete the modification turnover steps up to and including the "Prior to Testing" section.

ASSIGNED ENG. SIGNATURE_____

7 Testing

7.1 Testing Setup

7.1.1 Notify Performance Monitoring prior to testing. _____

7.1.2 The Control Room Ventilation dampers are in their isolation positions.

_____

7.1.3 Verify that following Terminal Deck Sliding Links are HELD open:

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CRHA Terminal 3_____

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

7.1.4 Verify that the jumper is still in place from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7. This will keep the Control Room Charcoal Filter Fan running during testing.

_____

7.1.5 Request Operations to remove the HOLD and CLOSE the following states deck slide links open in the Main Control Board to enable annunciator E11 power: (E11 should NOT alarm)

Terminal Deck TDY Terminal 9_____

Verified By_____

Terminal Deck TDY Terminal 10_____

Verified By_____

7.1.6 Verify E11 Annunciator is NOT in alarm. _____

7.2 Normal "Active" Alignment Configuration

7.2.1 With both trains of Toxic Gas Monitoring, and CR radiation monitoring units R-45, R-46, R36/R37/R38 in their normally energized position with no alarms, verify both R81A and R81B relays are energized.

R81A Energized_____

R81B Energized_____

7.3 R-45 & 1/HS-88V Contact Tests

7.3.1 With hand switch 1/HS88V in the "Active" position, verify the following:

Green indicating light for R-45 Active is illuminated_____

Red indicating light for R-45 Bypass is NOT illuminated_____

R81A and R81B are energized_____

7.3.2 With hand switch 1/HS88V in the "Bypass" position, verify the following:

Green indicating light for R-45 Active is NOT illuminated_____

Red indicating light for R-45 Bypass is illuminated_____

R81A and R81B are still energized_____

7.3.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88V in "Bypass" position, push and hold the Check Source button on rate meter R-45 to simulate R-45 alarm and verify that R81A and R81B are still energized.

_____

NOTE: When releasing the Check Source pushbutton, a wait of 60 seconds may be required for the displayed value to indicate ambient conditions.

7.3.4 Release the Check Source button to restore R-45 to normal.

_____

7.3.5 Place hand switch 1/HS-88V in the "Active" position. _____

7.3.6 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88V in "Active" position, push and hold the Check Source button on rate meter R-45 to simulate R-45 alarm and verify that:

R81A and R81B are de-energized_____

Annunciator E-11 Alarms_____

7.3.7 Release the Check Source button to restore R-45 to normal

_____

7.3.8 Push ratemeter alarm acknowledge button. _____

7.3.9 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.4 R-46 & 1/HS-88W Contact Tests

7.4.1 With hand switch 1/HS-88W in the "Active" position, verify the following:

Green indicating light for R-46 Active is illuminated_____

Red indicating light for R-46 Bypass is NOT illuminated_____

R81A and R81B are energized_____

7.4.2 With hand switch 1/HS88W in the "Bypass" position, verify the following:

Green indicating light for R-46 Active is NOT illuminated_____

Red indicating light for R-46 Bypass is illuminated_____

R81A and R81B are still energized_____

7.4.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88W in "Bypass" position, push and hold the Check Source button on rate meter R-46 to simulate R-46 alarm and verify that R81A and R81B are still energized.

_____

NOTE: When releasing the Check Source pushbutton, a wait of 60 seconds may be required for the displayed value to indicate ambient conditions.

7.4.4 Release the Check Source button to restore R-46 to normal. _____

7.4.5 Place hand switch 1/HS-88W in the "Active" position. _____

7.4.6 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88W in "Active" position, push and hold the Check Source button on rate meter R-46 to simulate R-46 alarm and verify that:

R81A and R81B are de-energized_____

Annunciator E-11 Alarms_____

7.4.7 Release the Check Source button to restore R-46 to normal. _____

7.4.8 Push ratemeter alarm acknowledge button. _____

7.4.9 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.5 Toxic Gas Train A Logic Verification

7.5.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Normal" position, verify that:

Train A Chlorine Normal Green light is illuminated_____

Train A Chlorine Bypass Red light is NOT illuminated_____

7.5.2 With hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Bypass" position, verify that:

Train A Chlorine Normal Green light is NOT illuminated_____

Train A Chlorine Bypass Red light is illuminated_____

7.5.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88E (Turbine Building CREP A Panel) in the "Normal" position, open sliding link CREB-3 to XI-6850 output contact to simulate Train A High Chlorine Alarm. Verify that:

R81A de-energizes_____

R81B Still Energized_____

Annunciator E-11 Alarms_____

7.5.4 Close sliding link CREB-3. _____

Verified By_____

7.5.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.6 Toxic Gas Train B Logic Verification

7.6.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Normal" position, verify that:

Train B Chlorine Normal Green light is illuminated_____

Train B Chlorine Bypass Red light is NOT illuminated_____

7.6.2 With hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Bypass" position, verify that:

Train B Chlorine Normal Green light is NOT illuminated_____

Train B Chlorine Bypass Red light is illuminated_____

7.6.3 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) and hand switch 1/HS-88G (Turbine Building CREP B Panel) in the "Normal" position, open sliding link CREF-3 to XI-6851 to simulate Train B High Chlorine Alarm. Verify that:

R81B de-energizes_____

R81A Still Energized_____

Annunciator E-11 Alarms_____

7.6.4 Close sliding link CREF-3. _____

Verified By_____

7.6.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.7 R36/R37/R38 Logic Test and Bypass Test

7.7.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) verify the R36/R37/R38 Override Key Switch 1/HS-88B in the "Normal" position.

_____

7.7.2 At R38 monitor, record the as found alarm setting.

R38 Alarm Setting_____ _____

7.7.3 If required, lower High Alarm value to approximately 100 cpm but greater than the current R38 setting, and push and hold the Check Source button on R38 to simulate a High Alarm. Verify that:

R81A de-energizes_____

R81B Still Energized_____

Annunciator E-11 Alarms_____

7.7.4 Place the R36/R37/R38 Override Key Switch 1/HS-88B in the "Override" position.

_____

7.7.5 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.7.6 Push and hold the Check Source button on R38 to simulate a High Alarm. Verify that:

R81A Still Energized_____

R81B Still Energized_____

Annunciator E-11 Clear_____

7.7.7 Release the R38 Check Source pushbutton. _____

7.7.8 Return R38 monitor alarm setting to as found value. _____

Verified By_____

7.7.9 Return R36/R37/R38 Override Key Switch 1/HS-88B in the "Normal" position.

_____

7.7.10 If required, reset Control Room ventilation by pushing isolation reset push button PB/CRIR. If not necessary, Mark this step N/A.

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.8 Loss of AC Power Test - A Train Non Safety Loads

7.8.1 Pull fuses FURMS3/P and FURMS3/N to simulate loss of power to Non Safety loads. Verify that:

Power to RY-A is lost (N/A if RY-A is not installed)_____

Power to TBRYA-1 and TBRYA-2 is lost (N/A if RY-A is installed)_____

PPCS Points to R45 is lost (N/A if RY-A is not installed)_____

RK-78 points R-29, R-45, and CVHA are lost (N/A if RY-A is not installed)_____

Power to R-10B, R-13, R-14 is lost_____

Power to RY-10B, R-13, RY-14 is lost_____

Power to RY-10A, RY-11, RY-12 is lost_____

Power to all other ratemeters is NOT lost_____

Power to RY-B (or TBRYB, if installed) is NOT lost_____

Power to recorders in RMS racks is NOT lost_____

7.8.2 Install fuses FURMS3/P and FURMS3/N to restore power to Non Safety loads.

_____

Verified By_____

7.8.3 Verify that Power to:

RY-A (or TBRYA-1 and TBRYA-2, if installed) is restored_____

PPCS Points to R45 are restored (N/A if RY-A is not installed)_____

RK-78 points R-29, R-45, and CVHA is restored_____

Power to R-10B, R-13, R-14 is restored_____

Power to RY-10B, RY-13, RY-14 is restored_____

Power to RY-11, RY-12, RY-13 is restored_____

7.9 Loss of AC Power Test - A Train Safety Related Load R-29

7.9.1 Open TB110-4 and TB-110-5 sliding links in RMS1 Rack to simulate loss of power to Safety Related Load R-29. Verify that:

Power to R-29 is lost_____

Switch 1/HS-88V, 1/HS-88E, 1/HS-88L indicating lights are lost_____

Power to XQ-45, XQ-6850/6852 is lost (R81A will drop out)_____

R81B Dropped Out (from R45 loss of power)_____

Annunciator E11 alarms_____

7.9.2 Verify power to the following: RK-78_____

R-10A, R-11, R-12, R-10B, R-13, R-14_____

RY-10A, RY-11, RY-12 RY-10B, RY-13, RY-14_____

RY-A (or TBRYA-1 and TBRYA-2, if installed)_____

7.9.3 Close TB110-4 and TB-110-5 sliding links in RMS1 Rack to restore power to Safety Related Load R-29. Verify that:

Power to R-29 and Toxic Gas Train A is restored_____

7.9.4 Push Control Room HVAC Reset pushbutton PB/CRIR._____

7.9.5 Verify that: Annunciator E11 is clear_____

R-45 is normal_____

R81A and R81B are reset_____

7.10 Loss of AC Power Test - A Train Safety Related Loads R-10A, R-11, R-12, RK-78

7.10.1 Pull fuses FURMS4/N and FURMS4/P to simulate loss of power to Safety Related R-10A, R-11, R-12 and RK-78.

_____

7.10.2 Verify that power is lost to R-10A, R-11, R-12 and RK-78. _____

7.10.3 Verify power to all other ratemeters, isolators, and recorders in RMS racks is not lost.

_____

7.10.4 Replace fuses FURMS4/N and FURMS4/P to restore power to Safety Related R-10A, R-11, R-12 and RK-78.

_____

Verified By_____

7.10.5 Verify power is restored to R-10A, R-11, R-12 and RK-78. _____

7.11 Loss of AC Power Test - B Train Non Safety Loads

7.11.1 Pull fuses FURMS5/N and FURMS5/P to simulate loss of power to Non Safety loads. Verify that:

Power to RY-B (or TBRYB-1 and TBRYB-2, if installed) is lost._____

Power to all other ratemeters, isolators and recorders is NOT lost_____

7.11.2 Install fuses FURMS5/N and FURMS5/P to restore power to Non Safety loads.

_____

Verified By_____

7.11.3 Verify Power to RY-B (or TBRYB-1 and TBRYB-2, if installed) is restored.

_____

7.12 Loss of AC Power Test - B Train Safety Related Load R-30

7.12.1 Open TB310-4 and TB-310-5 sliding links in RMS3 Rack to simulate loss of power to Safety Related Load R-30. Verify that:

Power to R-30 is lost_____

Switch 1/HS-88W, 1/HS-88G, 1/HS-88M indicating lights are lost_____

Power to XQ-46, XQ-6851/6853 is lost (R81B will drop out)_____

R81A Dropped Out (from R45 loss of power)_____

Annunciator E11 alarms_____

7.12.2 Verify power to RY-B (or TBRYB-1 and TBRYB-2, if installed) is NOT lost.

_____

7.12.3 Close TB310-4 and TB-310-5 sliding links in RMS3 Rack to restore power to Safety Related Load R-30. Verify that:

Power to R-30, R-46 and Toxic Gas Train B is restored_____

7.12.4 Push Control Room HVAC Reset pushbutton PB/CRIR. _____

7.12.5 Verify that: Annunciator E11 is clear_____

R-46 is normal_____

R81A and R81B are reset_____

7.13 A Train Power to Logic

7.13.1 With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) disconnect 120 VAC power connector J3/P3 on rear of R-45.

_____

7.13.2 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.13.3 Reconnect 120 VAC power connector J3/P3 on rear of R-45.

_____

Verified By_____

7.13.4 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.13.5 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.14 B Train Power to Logic

7.14.1 With Control Room Ventilation logic in its normal alignment (R81A and R81B energized) disconnect 120 VAC power connector J3/P3 on rear of R-46.

_____

7.14.2 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.14.3 Reconnect 120 VAC power connector J3/P3 on rear of R-46.

_____

Verified By_____

7.14.4 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.14.5 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.15 A Train Detector Failure Test

7.15.1 At detectors at air intake duct, disconnect cable connector from detector RE-45.

_____

7.15.2 After approximately 5 minutes verify that:

R-45 Fail Alarm activates_____

R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.15.3 Reconnect cable at air intake duct. _____

Verified By_____

7.15.4 Push Alarm Acknowledge on R-45 and verify R-45 Fail has cleared and ratemeter is reading background levels.

_____

7.15.5 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.15.6 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.16 B Train Detector Failure Test

7.16.1 At detectors at air intake duct, disconnect cable connector from detector RE-46.

_____

7.16.2 After approximately 5 minutes verify that:

R-46 Fail Alarm activates_____

R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.16.3 Reconnect cable at air intake duct. _____

Verified By_____

7.16.4 Push Alarm Acknowledge on R-46 and verify R-46 Fail has cleared and ratemeter is reading background levels.

_____

7.16.5 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.16.6 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.17 Manual Control Room Isolation Test

7.17.1 With the Control Room Ventilation in normal configuration (R81A and R81B energized) push Control Room Isolation A Train push button PB/CRIA.

_____

7.17.2 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.17.3 Reset by pushing Control Room Ventilation Reset push button PB/CRIR.

_____

7.17.4 Verify that: R81A and R81B energize_____

Annunciator E11 resets_____

7.17.5 With the Control Room Ventilation in normal configuration (R81A and R81B energized) push Control Room Isolation B Train push button PB/CRIB.

_____

7.17.6 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

7.17.7 Reset by pushing Control Room Ventilation Reset push button PB/CRIR.

_____

7.17.8 Verify that: R81A and R81B energize_____

Annunciator E11 resets_____

NOTE: Note background levels displayed by ratemeters before testing to ensure they return to normal when check source is removed.

7.18 R-45/RE-45 Response Test

7.18.1 Record R-45 normal background value. _____

7.18.2 Remove detector RE-45 from duct adapter. Apply radiation using Field Calibrator.

_____

7.18.3 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

PPCS Alarms for R-45 (N/A if Isolator RY-A is NOT installed)_____

7.18.4 Remove detector from Field Calibrator and replace it in duct adapter.

_____

7.18.5 Verify R-45 reading returns to normal background level. _____

7.18.6 Verify PPCS reading returns to normal background level. (N/A if Isolator RY-A is NOT installed).

_____

7.18.7 Clear PPCS alarm. (N/A if Isolator RY-A is NOT installed) _____

7.18.8 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.18.9 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.19 R-46/RE-46 Response Test

7.19.1 Record R-46 normal background value. _____

7.19.2 Remove detector RE-46 from duct adapter. Apply radiation using Field Calibrator.

_____

7.19.3 Verify that: R81A and R81B de-energize_____

Annunciator E11 alarms_____

PPCS Alarms for R-46 (N/A if Isolator RY-B is NOT installed)_____

7.19.4 Remove detector from Field Calibrator and replace it in duct adapter.

_____

7.19.5 Verify R-46 reading returns to normal background level. _____

7.19.6 Verify PPCS reading returns to normal background level. (N/A if Isolator RY-B is NOT installed).

_____

7.19.7 Clear PPCS alarm. (N/A if Isolator RY-B is NOT installed) _____

7.19.8 Reset Control Room HVAC by pushing isolation reset pushbutton PB/CRIR.

_____

7.19.9 Verify that: Annunciator E11 is clear_____

R81A and R81B are reset_____

7.20 Realignment of Control Room Ventilation System

7.20.1 With Control Room Ventilation Logic in normal alignment, (R81A and R81B energized) push CR Isolation B Train push button PB/CRIA. (This will prevent damper movement when sliding links are closed.) Verify that:

R81A and R81B de-energize_____

Annunciator E-11 Alarms_____

7.20.2 Request Operations to remove the HOLD and CLOSE the following sliding links:

Terminal Deck CRHA Terminal 1_____

Terminal Deck CRHA Terminal 2_____

Terminal Deck CRHA Terminal 5_____

Terminal Deck CRHA Terminal 9_____

Terminal Deck CRHB Terminal 2_____

Terminal Deck CRHB Terminal 5_____

Terminal Deck CRHB Terminal 6_____

Terminal Deck CRHB Terminal 7_____

Terminal Deck CRHB Terminal 8_____

Terminal Deck CRHB Terminal 9_____

Terminal Deck CRHB Terminal 10_____

7.20.3 Remove the jumper from the FIELD WIRING side of CRHB-6 to the FIELD WIRING side of CRHB-7.

_____

Verified By_____

7.20.4 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.20.5 Verify the following dampers and Charcoal Filter Fan Status as follows:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

7.21 R81A Functional Test

7.21.1 With the Control Room Ventilation in normal configuration (R81A and R81B energized) de-energize R81A relay by opening states deck sliding link TB03-5, located in the Aux Bench Board right section. This will cause Control Room Ventilation Isolation.

_____

7.21.2 Verity the following:

AKD10 Closed_____ AKD01 Closed_____

AKD09 Open_____ AKD07 Open _____

AKD05 Closed_____ AKD04 Closed_____

AKD02 Closed_____ AKD08 Closed_____

Control Room Charcoal Filter Fan ON_____

Annunciator E-11 Alarms_____

7.21.3 Close states deck sliding link TB03-5, located in the Aux Bench Board right section.

_____

Verified By_____

7.21.4 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.21.5 Verify the following dampers and Charcoal Filter Fan Status as follows:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

Annunciator E-11 Clears_____

7.22 R81B Functional Test

7.22.1 With the Control Room Ventilation in normal configuration (R81A and R81B energized) de-energize R81B relay by opening states deck sliding link CA-3, located in the Aux Bench Board center section. This will cause Control Room Ventilation Isolation.

_____

7.22.2 Verity the following:

AKD10 Closed_____ AKD01 Closed_____

AKD09 Open_____ AKD07 Open _____

AKD05 Closed_____ AKD04 Closed_____

AKD02 Closed_____ AKD08 Closed_____

Control Room Charcoal Filter Fan ON_____

Annunciator E-11 Alarms_____

7.22.3 Close states deck sliding link CA-3, located in the Aux Bench Board center section.

_____

Verified By_____

7.22.4 Reset Control Room ventilation by pushing isolation reset push button PB/CRIR and verify that:

R81A and R81B are energized_____

Annunciator E-11 Clears_____

7.22.5 Verify the following dampers and Charcoal Filter Fan Status as follows:

AKD10 Open_____ AKD01 Open_____

AKD09 Closed_____ AKD07 Closed_____

AKD05 Open_____ AKD04 Open_____

AKD02 Open_____ AKD08 Closed_____

Control Room Charcoal Filter Fan OFF_____

Annunciator E-11 Clears_____

7.23 Verification of Recorders

7.23.1 On recorder RK-78, verify proper indication for:

Containment Hydrogen Monitor A_____

R-45_____

R-29_____

7.23.2 On recorder RK-79, verify proper indication for:

Containment Hydrogen Monitor B_____

R-46_____

R-30_____

8 Post Modification Testing

8.1 Performance Monitoring complete the following test procedures to prove operability:

PT-17.4_____

PT-17.7A_____

PT-17.7B_____

NOTE: THE ASSIGNED ENG. SHALL BE NOTIFIED AND SHALL SIGN STEP 9 AFTER TESTING TO COMPLETE THE REMAINING MODIFICATION TURNOVER STEPS.

9 **HOLD POINT:** After successful testing the Assigned Engineer Shall complete the remaining Modification Turnover Steps

ASSIGNED ENGINEER SIGNATURE_____

10. Request Operations clear tracking documentation on the Control Room Ventilation System.

_____

Attachment 19

Syncor Quality System Procedures
QSP-14-01 Complaint Handling Procedure
QSP-214 Corrective and Preventive Action
QSP-213 Control of Nonconforming Product
QSP-205 Document and Data Control Procedure

INOVISION Radiation Measurements, LLC Quality System Procedure	DOCUMENT NUMBER: **QSP-14-01 Version F** Revision date: 10/10/01
TITLE: **Complaint Handling Procedure**	Page 1 of 4

DCR number: 224	Effective date:

Approved By:	Date
Director of Regulatory/Quality Affairs	
Director of Customer Service	
Director of Manufacturing	
Director of Calibration Lab	

Revision History:

Revision Number	Description	Submitted by
Initial Release		M.J. Nero, J. Brownlee
B	Add clarification of feedback sources and equate complainant with remote premises	J. Brownlee
C	Add reference to CSOP-03-02 and QSP-14-05 to replace use of CSOP-19-01	J. Brownlee
D	Revised to reflect current process and personnel responsibilities, para 6.3 and 6.5.	MJ.Nero
E	Add reference to new complaint log kept to track implementation of corrective/preventive actions pending in section 6.10	J. Brownlee
F	To add information for handling calibration lab complaints	J. Brownlee, C.Grehofsky

1.0 Purpose

1.1 The purpose of this document is to describe the process used to receive, document, review and evaluate complaints received by Inovision Radiation Measurements and the Global Calibration Lab.

2.0 Scope

2.1 The policies, responsibilities and procedures outlined in this procedure apply to the personnel at Inovision who are involved with receiving or resolving complaints and initiating corrective and preventive actions.

3.0 Definition

3.1 *Complaint* means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of an IRM manufactured/marketed device or service.

3.2 *Nonconformance* means the nonfulfillment of a specified requirement.

3.3 *Routine service request* refers to the maintenance, adjustment, or repair of damage or failure resulting from long use, misuse or accident.

3.4 *Unusual conditions that warrant attention* means service requests for rapid wear, unusual problems, unusual maintenance, or development of hazardous conditions.

3.5 *Defect* means the nonfulfillment of an intended usage requirement or reasonable expectation, including one concerned with safety.

3.6 *Corrective action* means action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

3.7 *Preventive action* means action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence.

3.8 *MDR event* is one in which information is obtained that one of our medical devices may have caused or contributed to a death or serious injury; or has malfunctioned and if the malfunction recurs, it is likely to cause or contribute to a death or serious injury. (see 21 CFR part 803)

3.9 *Product feedback* is questions or concerns that are determined to be a misinterpretation, opinion, or suggestion for an enhancement of the product.

3.10 *Quality Review Committee* are those representatives from the management group and others, as appropriate, who convene for the purpose of reviewing those problems whose potential to pose a serious health, safety or business risk needs to be determined; or that suggest a problem trend may be emerging that may affect multiple units of a model or more than one product. This group has the responsibility to determine the root cause of such problems, whenever possible, and to initiate and implement effective corrective and preventive actions, as appropriate.

4.0 Responsibility

4.1 The Directors of Regulatory Affairs/Quality Assurance, Calibration Lab, Customer Services, and Manufacturing, have the responsibility to see that this procedure is followed. The Regulatory Affairs/Quality Assurance department is responsible for administering the complaint handling system and maintaining this procedure. IRM personnel involved with complaint, repair and servicing processes are responsible for following this procedure.

5.0 Applicable Documentation / Records

5.1 QSP-204 Design Control Procedure

5.2 QSP-205 Document and Data Control

5.3 QSP-214 Corrective and Preventive Action

5.4 QSP-216 Control of Quality Records

5.5 QSP-219 Servicing

5.6 CSOP-03-02 Contract/Order/Service Review Checklist

5.7 QSP-14-02 Medical Device Reporting Procedure

5.8 QSP-14-03 Procedure for Product Corrections and Removals

5.9 QSP-14-05 Complaint Initiation form

5.10 QSP-14-07 Calibration Service Complaint Form
5.11 Follow-up Customer Complaint Status log

6.0 Procedure

6.1 When a Sales Representative or Distributor, Customer Service, Calibration Lab, Sales, or other IRM employee is notified by any means of a product problem that is not believed to be due to routine use/service, they are to complete a complaint initiation form. Complaints regarding the performance of a calibration are recorded on the Calibration Service Complaint Form. Notifications that meet the definition of product feedback are not handled as complaints, but are forwarded to product development as input for future consideration. Notifications of product problems through other means- salespeople, reps etc.- are also to be documented with the name of the complainant, specific description of the problem, affected product's model and serial number and any other available information to facilitate follow-up and evaluation. This documentation is given to the Regulatory Affairs/Quality Assurance department.

6.2 The initial evaluation may be changed by information obtained during service, repair, or other activities. Technicians or managers may complete a complaint initiation form and give it to the Regulatory Affairs/ Quality Assurance department whenever it is suspected that a problem no longer meets the definition of routine and warrants more attention. Likewise, problems that were initially felt to be unusual may subsequently end up being documented as routine service once more information is obtained. Such a disposition is to be noted on the complaint record.

6.3 The Product Complaint initiation forms (QSP 14-05) are reviewed for completeness and then forwarded to the Director of Regulatory Affairs for initial review. This review is done to determine if the problem needs to be brought to the attention of the Quality Review Committee, or if it is felt that the problem can be evaluated adequately by certain directors. If an investigation is to be done, the complaint is entered into the Access program for documenting complaints as required. Copies of all initial complaint forms are distributed to the Director of Customer Service, the Manufacturing Manager, Quality Manager, Manufacturing Engineering Supervisor and any other department head that may be affected by the complaint. Complaints that are not felt to warrant investigation are kept in customer dissatisfaction files.

6.4 The Calibration Service Complaints (QSP-14-07) are reviewed and evaluated by the Director of the Calibration Lab. The root cause and corrective/preventive action is recorded on the form. Once complete the reports are forwarded to the Regulatory Affairs/Quality Assurance department if needed for follow-up on any investigations or reports to customers and/or authorities.

6.5 The person(s)or committee assigned to review complaints should have a thorough knowledge of the product line or service in order to make an informed, reasonable decision as to the severity and significance of the complaint and to decide if an investigation is necessary. If it is decided that an investigation is not necessary, a record is made of the rationale used to arrive at this decision and the identity of the individual(s) responsible for making this decision as part of the complaint file. Reviewers may take a problem to the Quality Review Committee for evaluation and investigation at any time.

6.6 When it is determined by the reviewers, that an investigation is warranted, the needed tasks are assigned to the most appropriate area- i.e. the area responsible for the information needed. For example: the Manufacturing engineering or Design engineering department is responsible for investigating design /development related issues and conducting risk analysis when warranted; the Manufacturing group is to handle the manufacturing process. Manufacturing or Document Control may handle document issues; Materials department is to look into component/part and shipping issues; Quality may handle test and inspection issues; customer service is to handle repair and service histories; Calibration Lab is to handle the calibration concerns; and Regulatory is to handle complaint histories and audit-related issues. The Engineering department will be consulted for design changes and items outside the expertise of Manufacturing Engineering. Customer contact and response is normally to be handled by the Customer

Service department or Calibration Lab, however, there may be situations where it is most appropriate for someone from another department to contact the customer to obtain more specifics regarding a problem or to discuss resolution of the problem. The level of investigation should be commensurate with the risk and complexity of the problem. In all cases, the goal should be to determine the root cause of the problem and to identify the most appropriate corrective or preventive action to take.

6.7 If the Quality Review Committee determines that a problem meets the requirements of the MDR regulations of the FDA, or reporting requirements for other authorities, such action is documented in the complaint file and handled according to a separate procedure.

6.8 If the Quality Review Committee determines that a field correction, removal or recall of the product is needed, the action is documented in the complaint file and handled according to a separate procedure.

6.9 Once completed, a written record is kept with the complaint file that includes the name of the device, the date of the complaint, identification and control numbers of the device, the name, address and phone number of the complainant, the nature and details of the complaint, the dates and results of any investigation, any corrective action taken, and any reply to the complainant. If the activities at a remote premise contributed to the complaint, then a copy of the complaint investigation report is sent to them. If no reply is made to the complainant or remote premise because it is not felt to be needed, the record should state this and the reason for not replying.

6.10 Corrective and preventive actions are handled according to the procedures for the specific actions and according to IRM change control and design control procedures, as appropriate

6.11 Complaints are considered open until documentation has been completed that substantiates the disposition of the problem. The complaints are monitored by the Regulatory Affairs /Quality Assurance department to ensure progress is made and that the necessary information is recorded. The Director of Regulatory/Quality Affairs reviews the complaint files for completion and signs the approval for closure with the date. Closed complaints may be reopened if additional information is obtained that requires further review or determination of the disposition. Complaints that are "conditionally closed" pending implementation of corrective/preventive action are tracked on a log to ensure closure.

6.12 Product Complaint investigation records are stored by number and product, and Calibration Service complaints are stored separately. Trending of calibration service complaints is done by the Calibration Director. Trending of product complaints is done by the Regulatory Affairs department on at least a quarterly basis and reported to management as part of the Management Review meeting. Trending is also done in response to particular complaints when needed. Manufacturing history records, engineering change histories and service records may be reviewed looking for particular kinds of information. Calibration, service, production techs, engineering and other personnel may suspect a trend while performing their work- such concerns may be brought to the attention of the Regulatory Affairs department or to the Quality Review Committee for further evaluation.

INOVISION Radiation Measurements, LLC **Quality System Procedure**	DOCUMENT NUMBER: **QSP-214 Version G** Revision date: 10/10/01
TITLE: **Corrective and Preventive Action**	Page 1 of 5

DCR number: 222	Effective date:

Approved By:	Date
Director of Regulatory Affairs/QA	
Engineering Manager	
Finance/MIS Director	
Quality Manager	
Director of Customer Service	
Director of Manufacturing	
Director of Calibration Lab	
Documentation Control Manager	

Revision History:

Revision Number	Description	Submitted by
Initial Release		J. Brownlee
B	Added clarification to preventive action	D. Smith
C	Added CSOP-WI-01 to Applicable documents and added clarification with 6.2.1	L. Guy
D	Add requirements of ISO 13485/ EN 46001 and personnel changes	J. Brownlee
E	Define postmarket surveillance activities currently conducted	J. Brownlee

F	Change procedure approvers to reflect current structure; arrange sections to address the different methods of our corrective/preventive action system; describe various ways used to propose corrective and preventive actions; clarify responsibilities within procedure	J. Brownlee
G	Add statements for ISO 17025 to parts 6.3, 6.4, 6.9, 6.12	J. Brownlee

1.0 Purpose

1.1 This procedure describes the general format for corrective and preventive action at Inovision Radiation Measurements.

2.0 Scope

2.1 This procedure applies to the processing of corrective and preventive actions, including the proper handling of changes, customer complaints, production deviations, nonconformities, Medical Device Reports, recalls, and postmarket surveillance activities.

3.0 Definition

3.1 *Corrective action* is action taken to eliminate or minimize the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

3.2 *Preventive action* is action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence.

3.3 *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. (21CFR 820.3)

4.0 Responsibility

4.1 The Executive, Directors, Managers, and their personnel are responsible for seeing that this procedure is followed and for maintaining it. Personnel throughout the company have the responsibility to follow this procedure and to advise their managers of situations that may need corrective or preventive action.

5.0 Applicable Documentation / Records

5.1 QSP-14-NN Corrective-Preventive Action Procedures
5.2 QSP-201 Management Review Meetings
5.3 QSP-205 Document and Data Control
5.4 QSP-213 Control of Nonconforming Product
5.5 QSP-216 Quality Records
5.6 QSP-217 Quality Audits
5.7 QSP-219 Servicing
5.8 QSP-100, Section 4.14, Quality Assurance Manual, Corrective and Preventive Action
5.9 CSOP-WI-01 Handling Shipping / Receiving Problems

6.0 Procedure

6.1 Existing and potential causes of nonconforming product or other quality problems are detected by analyzing processes, work operations, deviations, waivers and concessions, quality audit reports, service records, complaints, returned product, postmarket surveillance or other feedback sources of quality data. These sources of feedback are documented, evaluated, investigated, interpreted, and collated by the manager or director of the appropriate department or a designee, and communicated to others as needed for action, and/or summarized at the Management Review Meetings. Statistical techniques are used where necessary to detect recurrent quality problems. Preventive actions to eliminate or minimize potential causes of nonconformities are proposed through departmental change control procedures or through corrective/preventive action requests.

6.2 Postmarket surveillance activities are conducted as part of the new product development process approximately one year after market introduction. In addition, information on new and existing products is obtained at sales and technical shows and discussed at staff meetings and management review meetings. Users of IRM products may also be periodically consulted for feedback and technical expertise for corrective and preventive actions. The suitability of current products in relation to market needs is considered during annual business and strategic planning sessions.

6.3 Corrective Action

6.3.1 Action(s) needed to correct a problem may be proposed on form QSP-17-100 or on the complaint forms, complaint records, deviations, engineering change notifications, departmental reports or Quality Plans. Corrective action requests may be initiated by IRM personnel, or by outside auditors or customers. The requested action is forwarded to the appropriate department manager for review and consideration. A determination of the steps necessary to implement the action and the effect it may have on other activities must be made. The corrective action taken is to be appropriate to the magnitude of the problem and commensurate with the risks encountered as determined through cause and risk analysis. More serious or recurrent problems, which are taken to a Quality Review Meeting, may have the appropriate corrective action decided by the group rather than by an individual. The corrective action selected should be the action most likely to eliminate the problem and to prevent recurrence. If the proposed action is adopted, the Regulatory/Quality Department and Document Control Department follow the corrective action requests until action has reportedly been implemented. Verification that the corrective action has been implemented and is effective is made before it is considered closed.

6.4 Preventive Action

6.4.1 As part of a continuous improvement philosophy, actions needed to prevent a problem can be proposed on QSP-17-100, in an engineering change notification, in the Quality Plan or other reports. IRM Personnel, outside auditors, or customers may initiate the Preventive Action requests. The requested action is forwarded to the appropriate department manager for review and consideration. A determination of the steps necessary to implement the action and the effect it may have on other activities must be made. If the preventive action is accepted, plans are developed, implemented and

monitored to reduce the likelihood of the occurrence of the potential nonconformance or to take advantage of the opportunities for improvement. If the proposal is adopted, the Regulatory/Quality or Document Control Department follows Preventive Action requests until action has reportedly been implemented. Verification that the Preventive Action has been implemented and is effective is made before it is considered closed.

6.5 Changes to the documented procedures resulting from corrective and preventive action are controlled, documented and recorded according to the document and data control procedures in the affected areas.

6.6 Nonconformities found during incoming inspection or during production activities are documented, and investigated to identify the underlying root cause and to determine if the problem is related to the product, process or quality system.

6.7 Customer problems which are not related to the performance of the product are monitored by Customer Service and trended with the RA/QA Department.

6.8 Customer complaints relating to product performance are initially received and reviewed by the person receiving the complaint to determine if the problem is a need for routine service or an unusual condition warranting further evaluation. If it is felt to need further attention, because it suggests a trend or involves a risk to the user or company, a complaint report is initiated. The Regulatory Affairs/Documentation Coordinator then follows complaint reports until some resolution has been found. If a corrective action is not taken or an investigation is not conducted, the reason is recorded on the complaint record. Complaint reports are maintained and trended by the Regulatory Affairs/Documentation Coordinator. Service reports are also monitored to look for unusual conditions warranting attention.

6.9 Customer complaints relating to calibration service are handled separately, unless they present a serious health or business risk, or suggest a trend. The calibration service complaints are recorded on QSO 14-07. The Calibration Director or Calibration Services Manager will investigate the complaint. The investigation will determine the root cause of the problem. Corrective actions will be implemented, as needed. Preventive actions regarding needed improvements and potential sources of nonconformance will be implemented and recorded on the calibration service complaint form. The Calibration Director will monitor the corrective and preventive actions. The QA department will keep corrective and preventive action records.

6.10 Complaints are copied to the appropriate members of the Management Group for review and evaluation and to determine the appropriate action to take. In some cases, the cause of the reported problem may be obvious and a formal investigation is not needed, or the complaint is isolated with no apparent cause or trend, and a repair is made or a replacement is sent. The Director of Customer Service or the Director of the Calibration Lab may make such determinations, consulting other Management members as needed; however, other members of the organization may also provide relevant information. Investigations are conducted and documented when the cause of the problem is not apparent or the product is failing to meet its performance claims. Information obtained and subsequent action taken is reported to the Regulatory Affairs/Quality Assurance department and summarized on the complaint record. The record of action taken may be documented as a service, calibration, engineering change, and process change or field correction activity. When the investigation determines that the activities at remote premises played a part in the complaint, the Regulatory

Affairs/Documentation Coordinator sends a copy of the report to those premises. The remote premises may be the complainants in the case of complaints coming from other divisions of Inovision.

6.10 Complaints or quality problems that may present a serious health or business risk, or suggest a trend are specifically presented to members of the Management Group for consideration at a Quality Review Meeting. These Quality Review Meetings are generally scheduled as needed by the Regulatory Affairs Department, but may be convened by any member of the Management Group when felt to be necessary. Other personnel with expertise in the area to be discussed are included in these discussions. Needed investigative activities are identified and the appropriate individuals initiate these actions and report back to the group on their findings. The corrective and preventive action felt to be most appropriate is then decided and documented by the group.

6.11 When the cause of a product or quality problem is identified, an analysis of its possible effect (including any effects on other products) is done, and subsequent corrective action is initiated.

6.12 If it is determined in a Quality Review Meeting that a nonconformity may affect multiple instruments and/or it poses a serious health risk, customers are contacted and a notification, field correction, recall, removal and/or replacement is initiated. These activities are handled according to the regulatory requirements of the countries in which the affected product(s) has been distributed and/or according to the standards to which our facility operates. A plan is developed to suit the individual circumstances of the situation, taking into account the number of products, units and the hazard involved. If the situation poses a health risk and/or necessitates a recall, and the product is a medical device or otherwise regulated (such as by the NRC), the FDA district office, NRC and/or other national regulatory authorities are notified as appropriate. The notifications are done according to the procedures in the applicable regulations or standards through the Regulatory Affairs Department.

6.13 Complaints that allege that a medical product malfunction has occurred and that this malfunction has caused or contributed to, or could cause, a death or serious injury, must be handled according to the Medical Device Reporting procedures found at 21 CFR 803 and those of applicable foreign regulatory authorities.

6.14 For items subject to regulation by the Nuclear Regulatory Commission or the Atomic Energy Act of 1954, a defect or nonconformance is deemed to exist if anyone obtains information reasonably indicating that a basic component, licensed activity or a portion of the facility has a defect or failure that could be associated with a substantial safety hazard.

6.15 The effectiveness of corrective and preventive actions is reviewed at Management Review meetings.

INOVISION Radiation Measurements, LLC **Quality System Procedure**	DOCUMENT NUMBER: **QSP-205 Version G** Revision date: 10/9/01
TITLE: **Document and Data Control Procedure**	Page 1 of 4

DCR number: 214	Effective date:

Approved By:	Date
Director of Regulatory/Quality Affairs	
Director of Manufacturing	
Document Control Manager	
Director of the Calibration Lab	

Revision History:

Revision Number	Description	Submitted by
A	Initial Release	J. Brownlee
B	Make reference to applicable documentation more general	Mary Jo Nero
C	Additional requirements for EN46001/ ISO13485 and personnel changes	J. Brownlee
D	Revised to reflect responsibility changes	J. Brownlee
E	Revised to reflect issuing of documents for production use	J. Brownlee
F	Updated to reflect movement of additional procedures to Document Control Dept. and to reflect current practices.	J. Brownlee, M.J.Nero
G	Update to reflect movement of Engineering and Customer Service procedure masters to control of Document Center	J. Brownlee

1.0 Purpose

1.1 To describe the procedures for handling document and data control at Inovision Radiation Measurements (IRM).

2.0 Scope

2.1 This procedure applies to the documents and data, which are required and maintained as a part of IRM's Quality System, including to the extent applicable, documents of external origin such

as standards and customer drawings. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

3.0 Definition

3.1 *Controlled documents:* Documents and data that prescribe activities affecting quality, such as instructions, procedures, and drawings, including changes to those documents. Controlled documents have restricted access, are approved prior to issue, are identified by an assigned number and version or revision level, and are maintained and controlled by designated personnel. The control ensures that invalid, down-level and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

3.2 *Uncontrolled documents:* Documents and data that are not part of the required Quality System, and that are used for reference only and are not recorded for future traceability.

4.0 Responsibility

4.1 The Directors of Manufacturing and Regulatory/Quality Affairs and the Document Control Manager are responsible for seeing that this procedure is followed and for maintaining it. IRM personnel who create, store, issue, control or use such documents and data are responsible for following this procedure and the applicable procedures referenced in this procedure.

5.0 Applicable Documentation / Records

5.0 QSP-103 Document /Quality Record Matrix

5.1 MOP-05-NN Manufacturing Operating Procedures for Document Control

5.2 QSP-05-NN Quality System Procedures' Document and Change Control Procedures

6.0 Procedure

6.1 Documentation areas of IRM:

- The Quality System Manual and Procedures (QSP), Device Master Records (including product structures, drawings, work packets), Engineering Operating Procedures and Change Notices(ECN), Test Procedures (TP), Calibration Procedures, Customer Service Operating Procedures, deviations, label masters, instruction manuals, and data sheets are controlled by the Document Center/Control Department. This area also assists in keeping records of advertising pieces, catalogs and price lists.
- The Manufacturing area controls the Manufacturing Operating Procedures (MOP), some historic Manufacturing Change Orders, routers and assembly instructions
- Each department controlling masters of documents has a procedure in place that specifies how to request a change to an existing document or to submit a new document for review and approval. Each department also has document formats, which may be used or modified to meet the purposes of the author and/or users.
- Each of these areas has its respective procedures reviewed and approved by its manager, or by a team of reviewers and approvers if the document applies to more than one functional area. Documents are not issued for use until they have been approved in writing, whether they are the first version or a subsequent revision of the original document.

6.2 An index of standard operating procedures for each document area is maintained and indicates the document number, title and latest version or revision level. Changes to these lists must also

be reviewed prior to issue for use. Other documents, such as drawings, test procedures etc. are maintained by latest version in the AS400 or other electronic system.

6.3 Documents that are approved by just one person may carry that signature on every page of the document. Documents that are approved by more than one person have a cover page that indicates the dates and signatures of the approvers, and the effective date of the document. Documents in each of the areas will eventually carry a header or footer, where practical, that indicates the number of the document, its revision level and pagination. Such changes, including going to the new Inovision name and procedure formats, will be done when the document is revised for other reasons. Document changes are reviewed and approved by the same function that performed the original review and approval or by personnel with the proper expertise. The approving individuals have the appropriate information available on which to base their approval.

6.4 The masters of the approved documents are stored in each area's Master File(s), and are maintained and controlled by the area's document control clerk or other designated person. The documents have restricted access to ensure that the current, approved documents are issued. Each area also maintains a Master Historical or Archive File for storing obsolete or down-level documents for reference. Down-level or obsolete documents may be needed for conducting repairs or service or for completion of an in-process work order, but issue and use of these documents for such purposes, must be approved by the area's manager. For medical devices, at least one copy of the obsolete document is maintained for at least the lifetime of the medical device, to ensure that the specifications to which it was manufactured are available. This "lifetime" period has been defined by IRM for medical devices as 7 years.

6.5 Working copies of procedures, drawings, forms etc. are produced directly from the approved masters, and are kept current with the Masters. The current working copies are made available to personnel who carry out the activities described in the document. Electronic copies of calibration procedures are located on the Documentation Drive. They are kept current by the Document Control Dept. These files are read-only and can only be changed by the Documentation Manager or designee. Approved hard copy master files are always created before changes are made to the Documentation Drive.

6.6 Master copies that are produced from electronic files are maintained in a protected subdirectory, which precludes unauthorized access. Only the files associated with the active approved versions are stored on the approved directory- documents undergoing revision are in a separate subdirectory.

6.7 External documents, such as customer drawings, standards, articles or other publications referred to in IRM documents are kept on file in the respective document area or by the manager in the department where they are used. The current versions are maintained as needed, and down-level or obsolete versions are kept in the Historical or Archive file for reference when needed, or otherwise marked as obsolete.

6.8 Each document control area handling masters has a change control procedure in place to ensure that a record of changes is maintained and that changes are controlled. The record includes the document changed, a brief description of the change, identification of other affected documents (if applicable), the signature of the approving individual (s), the approval date and the effective date, if different from the approval date. Approved changes are communicated to the appropriate personnel in a timely manner, consistent with the effective date.

6.9 Proposed changes which could affect the finished product's performance or intended use, or that could affect the process by which the product is made or tested, must be reviewed to determine:

- if the change is altering the design and should be under design control requirements,
- if a validation of the new process is needed,
- if revalidation of an existing process is needed for this product,
- if a Regulatory submission is needed for the change, and
- what verifications will be needed for this change.

6.10 Device Master Records, Quality System Procedures, departmental operating procedures and other master documents are retained for an unlimited period of time as specified in QSP-103, but for at least 7 years, which is the lifetime period defined for IRM's medical devices. Other documents needed for historical data, legal and /or knowledge preservation are retained according to QSP-103.

INOVISION Radiation Measurements, LLC **Quality System Procedure**	DOCUMENT NUMBER: **QSP-213 Version E** Revision date: 10/10/01
TITLE: **Control of Nonconforming Product**	Page 1 of 5

DCR number:	Effective date:

Approved By:	Date
Director of Regulatory Affairs/QA	
Quality Manager	
Manufacturing Engineering Supervisor	
Director of Manufacturing	
Director of Customer Service	
Materials Manager	
Purchasing Manager	
Systems Manager	
Director of Calibration Lab	

Revision History:

Revision Number	Description	Submitted by
Initial Release		J. Brownlee
B	More clearly define use of hold and reject tags, put items in more logical order, reflect new management responsibilities	E. Telepak
C	Add requirements for EN46001/ ISO 13485 and personnel changes, reference new NCR report form and procedure	J. Brownlee

D	Update titles of approvers, clarify who is contacted regarding dispositions on NCR reports in 6.6 and 6.7	J. Brownlee, Z.Giatis, J. Hildebran, D. Smith
E	Add requirements and discussion of handling nonconforming services for ISO 17025 in section 7.1	J. Brownlee,C. Grehofsky

1.0 Purpose

1.1 This procedure describes the control of nonconforming product and services at Inovision.

2.0 Scope

2.1 This procedure applies to the identification, documentation, evaluation, segregation and disposition of suspect and nonconforming product or product that has had nonconforming work done to it and the proper notification to affected departments and/or clients.

3.0 Definition

3.1 *Nonconformance* means the nonfulfillment of a specified requirement.

3.2 *Deviation* means a variance from the established and approved procedure or instruction.

4.0 Responsibility

4.1 The Directors of the Calibration Lab, Manufacturing, Customer Service and Regulatory Affairs/QA, and the Managers of Quality, Materials, Purchasing and Systems, and the Manufacturing Engineering Supervisor have the responsibility to see that this procedure is followed and to maintain it. Personnel throughout the organization have the responsibility to notify their managers when they become aware of information that suggests a material or product may be nonconforming, and to follow this procedure.

5.0 Applicable Documentation / Records

5.1 MOP-13-NN Manufacturing Operating Procedures for Nonconforming Product

5.2 QSP-13-NN Procedures for Nonconforming Product

5.3 MOP-04-06 Manufacturing Deviation Control Procedure

5.4 MOP-06-23 Materials Processing for Deviations, Engineering Change Orders

5.5 QF- 1116 Nonconformance report form

5.6 QSP-212 Inspection, Test and Operating Status

5.7 QSP-214 Corrective and Preventive Action

5.8 QSP-100, Section 4.13 Quality Assurance Manual, Control of Nonconforming Product

6.0 Procedure

6.1 Incoming, in-process or finished materials, components and products that do not meet their specified requirements are documented, evaluated, and investigated, if necessary.

6.2 A nonconformance does not immediately indicate a product failure, but must be evaluated to determine the disposition of the material. Specified requirements in purchase orders, Device Master Records and work instructions may be set tighter than the performance claims in the product's labeling and manuals to allow for expected changes during the anticipated life of the

product. Nonconformances and deviations from established specifications or instructions require special judgement by the appropriate personnel.

6.3 Deviations from work instructions, test or calibration procedures or drawings that can be foreseen are to be proposed to Manufacturing Engineering or to the Director of the Calibration Lab through the deviation process and approved before implementation, so that the impact of the deviation on the finished product can be considered by personnel with the expertise to make such an assessment. If the deviation occurred during production or testing/calibration and could not be foreseen, it too must be reported to the manager or director for consideration of corrective actions and their effects before the product can move to the final stage in processing. Deviations are described, evaluated and their disposition documented by the reviewing individuals from Production, Manufacturing Engineering, and/or the Calibration Lab and the record is kept as a part of the instrument's production or service history. Changes or deviations that are needed urgently are handled according to QSP 13-03.

6.4 Nonconforming material or product is segregated from regular inventory and its nonconforming status is identified on the unit's accompanying paperwork or by means of a tag.

6.4.1 Incoming materials that are nonconforming are kept segregated and handled with a nonconformance report.

6.4.2 If an accepted incoming material is later found to be unacceptable at the point of use, it is identified, segregated and tagged with a Reject material tag, and processed per QSP 13-01.

6.4.3 If a product is being processed with an unreleased material (see QSP210), urgent change/deviation as per QSP 13-03, or needs to be pulled from production or inventory in order to investigate a potential nonconformity, it is tagged "hold"(per QSP 13-02) and/or moved to a separate holding area pending further disposition. This action may be initiated by anyone who becomes aware of a potential nonconformity by notifying the Director of Manufacturing, the Director of the Calibration Lab, the Manufacturing Engineering Supervisor, Quality Manager or Director of Regulatory Affairs/QA.

6.5 The Quality Manager and/or Regulatory/Quality Engineer reviews nonconforming materials and products in a preliminary review process. If the nonconforming material or product was purchased, the Purchasing Manager is involved in the disposition of the material. If the purchased material is to be discarded (scrapped) or returned to the vendor or manufacturer, this decision is documented on the nonconformance report and the action is initiated by the Quality Department or Purchasing Department. Nonconforming product or services that involve the calibration of an item are reviewed with the Director of the Cal Lab.

6.6 If the Quality Manager and/ or Regulatory/Quality Engineer or other reviewers feel that the nonconforming material or product can be reworked, repaired or may be able to be used-as- is, then it is documented on the Nonconformance Report (NCR). A determination must be made as to the adverse effect, if any, the rework, repair or use-as-is disposition might have on the product and this is to be included on the report. The Director of Manufacturing, the Manufacturing Engineering Supervisor, Director of the Calibration Lab or other personnel with the expertise needed, may be consulted when appropriate to determine root causes of the

nonconformance and the appropriate corrective action. When involved in the disposition, they are to sign in the engineering section of the report. The disposition is documented and authorized on the NCR, and the corrective action is initiated by the appropriate managers. Rework and repair activities are conducted according to authorized and approved procedures or documents, and reinspection and retest activities are performed to determine if the material meets its specified requirements. Such activities are recorded on the NCR.(see QSP-13-06)

6.7 The disposition of material or product that does not meet its specified requirements, even after rework, and needs to be repaired or used-as- is must be documented on an NCR. The NCR is then dispositioned either by the QA Manager or Regulatory/Quality Engineer and/ or by any other personnel with the needed expertise. The root cause of the nonconformance and the effectiveness of the corrective action must be considered, including the impact that such action might have on the performance of the finished material or product. The reviewers that take part in the decision must sign the NCR in the appropriate block, if provided. The repair or use-as-is decision must also be recorded on a deviation and a copy of the dispositioned NCR attached. The deviation is reviewed as described in 6.3. If the product is not usable or its nonconformance could effect form, fit or function, it may be scrapped or returned to the supplier by documenting it on the NCR. If conflicts arise regarding the appropriate action to take, they are resolved by the Quality Manager, Cal Lab Quality Manager, and/or the Director of Regulatory Affairs/QA. Nonconforming product accepted by concession through a deviation must still meet regulatory requirements and the record must contain the name of the person authorizing the concession.

6.8 Where required by contract, the proposed use of product, which does not conform to specified requirements, must be reported for waiver or concession to the customer or the customer's representative. The description of the nonconformity that has been accepted must be recorded to denote the actual condition. Written authorization to use or release the material or product must be obtained from the customer or their representative.

6.9 Products that do not meet the performance claims stated in their labeling are not released, and products within their warranty, that are alleged to not meet their performance claims are evaluated and if necessary, serviced and restored to proper function before return to the customer.

6.10 Nonconforming medical devices, regulated by the FDA or other national authorities, may not be offered or distributed by concession to the customer if they do not meet the performance claims stated in their labeling or other regulatory requirements.

6.11 Nonconformance evaluations, investigations into their causes, corrective and preventive actions, and review decisions are documented and kept in the history records.

7.0 Procedure-Calibration or Service Testing Nonconformance

7.1 Whenever any aspect of the calibration work or service testing does not conform to its own procedures or the agreed requirements of the client, the following procedures will be followed:

7.1.1 The Calibration Director or the Calibration Services Manager are responsible for the management of all nonconforming work in the calibration laboratory. They have the authority to halt work and withhold calibrations reports, as necessary. If a calibration technician or customer service representative suspects nonconforming work has been

performed, it is his/her responsibility to bring the matter to the attention of the Calibration Director or the Calibration Services Manager and to halt work or hold shipment until resolution has occurred.

7.1.2 When any nonconforming work has been presented, an evaluation of the significance of the nonconforming work will be performed by the Calibration Director or the Calibration Services Manager.

7.1.3 Corrective actions will be taken immediately by the Calibration Services Manager or the Calibration Director, and documented through the Inovision Corrective and Preventive Action program on form QSP 17-100.

7.1.4 If the nonconformance resolution requires customer notification, a customer service representative will notify the customer. If the nonconformance resolution requires rework, a customer service representative will notify the customer and oversee the return of the instrument.

7.1.5 Only the Calibration Services Manager or the Calibration Director can authorize the resumption of work.