PUR-1 Digital I&C Upgrade

Quality Assurance Program

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Organization

The project organizational structure is listed in Table 1 below. The team consists of groups from Mirion Technologies (main vendor), Scientech (subcontractor), and Purdue University (the facility). Each group has personnel involved in the completion of the project. This table is not comprehensive but represents the main personnel involved. The PUR-1 staff role is primarily one of providing requirements and verifying compliance with those requirements.

Table 1: PUR-1 Digital I&C Project Team

Name	Organization/Title	Location
Ben Schlottke	Mirion Project Manager	Munich, Germany
Ewald Liebhart	Mirion Director Development	Munich, Germany
Hans-Georg Wurtscheid	Mirion Development/ technical draftsman	Munich, Germany
Peter Kandziora	Mirion Test Manager	Munich, Germany
Roy Ray	Mirion Technical Engineer U.S.A.	Atlanta, GA
Bart Humble	Scientech Plant Performance Division Manager	Idaho Falls, ID
Laura Kinghorn	Scientech Project Manager	Idaho Falls, ID
Robert Ammon	Scientech Project Engineer	Idaho Falls, ID
DJ Bramlette	Scientech Lead System Engineer	Idaho Falls, ID
Clive Townsend	PUR-1 Project Manager	West Lafayette, IN
David Storz	PUR-1 System Technician	West Lafayette, IN
Robert Bean	PUR-1 Independent Reviewer	West Lafayette, IN

Purdue personnel will be responsible for final signature of completion of satisfactory work as well as the final equipment installation. They are additionally responsible for verification of compliance with all Technical Specifications, facility licensing, and other regulator interfacing.

Design Control

All design documents and system plans shall be developed by the vendor and approved by Purdue personnel. Purdue personnel will provide a list of I&C Technical Specifications relevant to the facility as well as the current Operations and Characteristics Manual (OCM). The operability of systems should be mimicked as nearly practicable while the implementation of technology may differ greatly from the original design.

Design Requirements

The basis for the design of the new reactor shall be fundamentally based around a reproduction of the system functionality of the current I&C. All design bases present in the PUR-1 Technical Specifications (TS), PUR-1 Safety Analysis Report (SAR), other facility documents, as well as commonly accepted codes and standards shall be followed.

Design Process

The design process will be principally managed according to vendor internal documentation and the Mirion and Scientech facilities. Where practical, PUR-1 staff will be invited to witness system development, Factory Acceptance Testing (FAT), aid in final system staging, and perform the majority of the final installation.

The final delivered I&C system shall contain detailed drawings (hard copies as well as digital versions) which explicitly list all system components, cable locations, system functionality, interface screens, and relation to the currently built facility.

Design Verification

Independent design review shall be used to verify the adequacy of design by internal company reviewers (applicable to Scientech and Mirion Technologies) as well as by Purdue personnel. Design reviews will be documented at the beginning of each delivered document with those personnel who performed the review. Factory Acceptance, Site Acceptance, and integral testing shall be performed and documented.

Mirion and Scientech shall identify and document the particular design verification method or methods used and provide summaries to PUR-1 staff. Design verification shall be performed by competent individuals or groups other than those who performed the design, but who may be from the same organization. Integral testing shall be performed prior to reliance upon the newly designed system.

The FAT and SAT formal test plans shall include appropriate acceptance criteria and shall demonstrate the adequacy of performance under conditions that simulate the design conditions. Test results shall be documented and evaluated by PUR-1 staff or their designees to assure that test requirements have been met.

Design Documents and Records

Design documents and records, which provide evidence that the design and design verification processes were performed, shall be collected, stored, and maintained for the lifetime of the installed I&C system. They shall be kept and protected at a level commensurate with their importance and reproducability.

Commercial Grade Items

The use of commercial grade equipment in safety-related applications shall be reviewed to assure that this equipment can adequately perform its intended function by the vendor. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

Change Control

Modifications to facility structures, systems, components, or computer codes shall be based on a defined "as exists" design. Changes to verified designs shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analysis for the structures, system, component, or computer code are still valid. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure should be reviewed and modified as necessary.

Procurement Document Control

Procurement documents shall contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchases. The procurement documents at all procurement levels shall identify the documentation required to be submitted for informing, review, or approval by the purchaser. At each level of a procurement, the procurement documents shall provide for access to the supplier's plant facilities and records, for inspection or audit by the purchasers, the designated representative, or other parties authorized by the purchaser. These may or may not be retained by PUR-1 staff. The procurement documents shall include purchaser's requirements for reporting and approving disposition of supplier nonconformance associated with the items or services being procured. The procurement documents for safety-related items should prohibit the supply of substandard or counterfeit parts and materials.

Procedures, Instructions and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

Document control

The preparation, issue, and change of documents which specify requirements that affect quality, or prescribe activities affecting quality, shall be controlled to assure that correct documents are used. The document control system shall be documented, and provide for

- Identification of documents to be controlled and their specified distribution
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
- Review of documents for adequacy, completeness, and correctness prior to approval and issuance.

Major changes to controlled documents shall be reviewed and approved by the same organizations, that performed the original review and approval, unless there are other organizations which are specifically designated.

Control of Purchased Items and Services

The procurement of items and serviced shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services for acceptance upon delivery or completion. Mirion Technologies and Scientech shall have internal procedures to guarantee adequate protection of acquired equipment.

Supplier Selection

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents.

Work Control

The purchaser shall establish measures to control the supplier's performance as appropriate.

Verification Activities

The supplier shall be responsible for the quality of the product and shall verify and provide evidence of that quality. Supplier-generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria. Based on the complexity of the product and importance to safety, the purchaser shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, audits, or review of the supplier's nonconformances, dispositions, waivers, and corrective actions.

Item or Service Acceptance

The purchaser shall establish a system to provide assurances that purchased items and services conform to procurement specifications. Purchase methods used to accept an item or related service from a supplier shall be a supplier Certificate of Conformance, source verifications, receiving inspection, post-installation test, or a combination thereof. Receiving inspections shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configurations, identification, and cleanliness, and to determine any shipping damage, fraud, or counterfeit.

Identification and Control of Items

When specified by codes, standards, or specifications that include specific identification or traceability requirements, the item identification and control process shall be capable of providing identification and traceability control. Items' identification shall be maintained from the initial receipt or fabrication of the items up to and including installation and use. Where physical identification of the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification marking shall be applied through the use of materials and methods which provide clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when the item is subdivided, and shall not be obliterated or hidden by surface treatment or coatings unless substitute means are provided. Where specified, items having limited calendar or operating life shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

Control of Special Processes

Special processes include any in which the results are highly dependent on the control of the process or the skill of the personnel. These are also those processes in which the specified quality cannot be readily determined by inspection or nondestructive testing of the product. Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. It is the responsibility of the organization performing the special processes to adhere to the approved procedures and processes. The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions that control the process. Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment associated with special processes.

Inspections

Inspections to verify conformance of an item or activity to requirements shall be planned, documents, and performed. The inspection program shall apply to procurement construction, modification, maintenance and experiment fabrication. Inspection of items in-process or under construction shall be performed for work activities where product quality cannot be determined by inspection of the completed product. The final

inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. Completed items shall be inspected for completeness, markings, calibrations, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. Associated quality records shall be examined for adequacy and completeness. Only items that have passed the required inspections and tests shall be used, installed, or operated. Measuring and Test Equipment (M&TE) used to perform inspections shall be identified in inspection documentation for traceability of inspection results.

Inspection results shall be documented. Acceptance of items shall be documented and approved by authorized personnel. Inspections shall be performed by persons other than those who performed the work being inspected but they may be from the same organization. Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. The need for formal training shall be determined, and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspections. Records of inspection personnel's qualification shall be established and maintained by PUR-1.

Test Control

Formal testing shall be required to verify conformance of designated structures, systems, or components to specified requirements, and demonstrate satisfactory performance for service or to collect data in support of design or fabrication. Testing shall include prototype qualification tests, proof tests prior to installation, and functional tests. Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied. Computer programs used for operational control shall be tested in accordance with an approved verification and validation plan, and shall demonstrate required performance over the range of operation of the controlled function or process.

Control of Measuring and Test Equipment (M&TE)

Tools, gauges, instruments, and other M&TE used for activities affecting quality shall be controlled, and calibrated or adjusted, at specified periods to maintain accuracy within specified limits. Out-of-calibration devices shall be tagged or segregated, and not used until they have been recalibrated. Records shall be maintained of calibration data traceable to individual piece of M&TE. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

Handling, Storage and Shipping

Handling, storage, and shipping of items shall be in accordance with work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures for condition the activity.

Inspection, Test and Operating Status

The status of inspection and test activities shall be identified on the items or in documents traceable to the items, in order to assure that required inspections and tests are performed, and to assure that items which have not passed the required inspections and tests are not inadvertently installed or operated.

Control of Nonconforming Items and Services

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Controls on nonconforming items shall provide for identification, documentation, evaluation, segregation

from like conforming items when practical, and disposition of nonconformities. Nonconforming conditions shall be evaluated for further reporting to appropriate regulatory agencies. Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items proposed and approved, in accordance with documented procedures.

The disposition (use as-is, reject, repair, or rework) of nonconforming items shall be identified and documented. Technical justification for the acceptability of a nonconforming item dispositioned "repair" or "use as-is" shall be documented. Nonconformance to design requirements of items dispositioned as "use as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. The as built records shall reflect the accepted deviation. Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.

Corrective Actions

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. The corrective actions shall be in accordance with the design requirements unless those requirements were faulty. In the case of a significant condition adverse to quality, the cause of the condition shall be investigated and corrective action taken to preclude recurrence. Corrective actions needed during the testing phase will be documented and resolved as Test Exception Reports (TERs) in accordance with this QA plan and the vendor procedures.

Quality Records

Records for the system will be maintained by PUR-1 in a manner consistent with the importance of the equipment. The records system will be available to all Purdue personnel both digitally and physically. Physical copies of safety-related information will be kept in the designated record vault at the facility. In addition to operation manuals, inspection and test results, quality assurance reviews, quality assurance procedures, and engineering reviews will be maintained.

Some records shall be maintained at the PUR-1 for the life of the particular item while it is installed or stored for future use. Such records shall be classified in accordance with the following

- those which would be of value in demonstrating capability for safe operation
- those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item
- those which would be of value in determining the cause or results of an accident or malfunction of a safety related item
- those which provide required baseline data for in-service inspections
- those which would be of value in planning for facility decommissioning

Other records shall be retained for a shorter period as determined by the PUR-1 Facility Director or Reactor Supervisor. The records shall be stored in the records vault or other safe location. Records maintained by a supplier shall be accessible and available to PUR-1 personnel.

Assessments

PUR-1 personnel, or a designated representative, shall conduct periodic assessments of quality-affecting activities during design, construction or modification to evaluate the effectiveness of the as-implemented quality program. Assessments shall be performed in accordance with written procedures or checklists. Assessment results shall be documented, and should be reviewed by management personnel who have

responsibility for the area assessed. Conditions requiring prompt corrective action shall be reported immediately to the Facility Director or Level 1.

Management of the assessed organization or activity shall investigate adverse findings, scheduled corrective action (including measures to prevent recurrence), and notify the appropriate assessing organization in writing of action taken or planned. The adequacy of the responses shall be evaluated by the assessing organization. Assessment records included assessment plans, reports, written replies, and the record of completion or corrective actions. Personnel selected for assessment assignments shall have experience or training commensurate with the scope, complexity or special nature of the activities to be assess. The assessor shall have the capability to communicate effectively, both in writing and orally.

Experimental Equipment

PUR-1 personnel shall maintain control of design, fabrication, installation, and medication of any experimental equipment to the extent that these impact safety related items.