

PROJECT NO.: K20.00271.PA
SPECIFICATION NO: 17021
FOR: PROGRAMMABLE LOGIC CONTROLLERS

KITECH
INCHON, SOUTH KOREA
cGMP BIOPHARM CONTRACT MANUFACTURING
FACILITY

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Issue:	For Approval	Final Issue	General Revision
Revision:	A	0	1
Date:	06/17/02	12/20/02	7/31/03
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SECTION 17021
SPECIFICATION FOR
PROGRAMMABLE LOGIC CONTROLLERS

PART 1 GENERAL

1.01 GENERAL REQUIREMENTS

- A. This specification defines the requirements and guidelines for programmable logic controller (PLC) systems. Design guidelines, conventions and practices to be used in configuring the PLC based systems are included to ensure consistency in documentation for validation packages.
- B. The internal wiring of the controller is to be fixed, with the logic functions to be performed in a given application programmed into its memory. The controller shall be supplied with a CPU, input/output scanner, outputs, memory, power supply, and all power and interface cables required to function as a ready-to-operate system.
- C. All areas of questions or noncompliance shall be submitted to the Buyer for review and resolution or approval.

1.02 SUMMARY

- A. This specification ensures that control systems supplied are developed according to Current Good Manufacturing Practice Regulations (cGMPs) in Title 21 Code of the Federal Regulations (CFR) made substantive law by Section 501 of the Food, Drug and Cosmetic Act which will permit validation. With Buyer's prior concurrence, the use of the Supplier's standard control systems shall be permitted. Where compliance with this specification causes a deviation from that normally supplied in the standard package, the deviation(s) shall be stated in the proposal.
- B. The purpose of this specification is to:
 - 1. Ensure that control systems provided by equipment suppliers conform to the design philosophy of the plant.
 - 2. Reduce the number of different control system manufacturers and type of control systems in the plant.
 - 3. Ensure that information on control system items is readily available to all of the Buyer's design departments.
 - 4. Establish a minimum acceptable control system quality level.
 - 5. Ensure that all PLCs supplied can be validated according to current Good Manufacturing Practices (cGMPs) in Title 21 Code of the Federal Regulations 9CFR) made substantive law by Section 501 of the Food, Drug and Cosmetic Act.

C. Terminology

1. PLC: Programmable Logic Controller. This refers to a programmable controllers central processing unit alone or to a system, including the processor, racks, and I/O cards.
2. I/O: Input / Output. Input designates information sent to the processor from connected field devices; output designates information being sent to connected field devices from the processor. The information referred to may be binary (on / off signals), analog, or encoded serial or parallel data.
3. Data Highway: A Supplier specific data communication link used to allow data transfer between 2 or more PLCs or other intelligent devices.
4. Scan Time: Time required to read all inputs, execute the control program, and update local and remote I/O. For the purpose of this specification, Scan Time refers to the maximum overall scan time.

D. Suppliers are not expected to reveal trade secrets except under properly executed secrecy agreements between appropriate parties.

E. The Supplier shall permit the Buyer to audit the system development process to ensure that the requirements described above are being met. The Supplier shall release to the Buyer all information required for an FDA inspection.

F. Work Included:

1. The Supplier shall furnish all of the following:
 - a. CPU
 - b. Input/Output Scanner
 - c. Inputs
 - d. Outputs
 - e. Memory
 - f. Power Supply
 - g. Power Cables
 - h. Interface Cables
 - i. PLC Enclosure
 - j. Mounting and Wiring
 - k. Documentation
2. The Supplier shall perform all programming and testing to insure proper performance of all items provided as part of the PLC. All components shall be properly tagged, supplied with test certificates, and supplied with all documentation required to establish material conformance.
3. The acceptance of the Supplier's drawings by the Buyer does not in any way relieve the Supplier of design responsibility. Drawing acceptance by Buyer is authorization to proceed with manufacturing only; it is neither an approval of the Supplier's design nor acknowledgement of the design as meeting all specified requirements.

- G. Work Not Included:
 - 1. Facility communication cabling.
 - 2. One source of UPS power.

1.03 RELATED DOCUMENTS

- A. Reference Specifications:

- 1. 16000 – General Provisions for Electrical Work
 - 2. 16001 – Electrical Requirements for Packaged Equipment
 - 3. 16120 – Conductors and Cables
 - 4. 16264 – Uninterruptible Power Supplies

- B. References: The publications listed form a part of this specification. Each publication shall be the latest revision and addendum in effect on the date this specification is issued for construction unless noted otherwise. Except as modified by the requirements specified herein or the details of the drawings, Work included in this specification shall conform to the applicable provisions of these publications:

- 1. ANSI (American National Standards Institute)
 - 2. ASME (American Society of Mechanical Engineers)
 - 3. ASTM (American Society for Testing and Materials)
 - 4. FCC (Federal Communications Commission)
 - 5. FDA (Food and Drug Administration)
 - 6. FM (Factory Mutual Engineering Corporation)
 - 7. GAMP (Good Automated Manufacturing Practice)
 - 8. cGMP (Current Good Manufacturing Practice)
 - 9. ICEA (Insulated Cable Engineers Association)
 - 10. IEC (International Electromechanical Commission)
 - 11. IEEE (Institute of Electrical and Electronics Engineers)
 - 12. ISA (The Instrumentation Systems and Automation Society)
 - 13. NEMA (National Electrical Manufacturers Association)

14. NIST (National Institute of Standards Technology)
15. NFPA (National Fire Protection Associations)
16. OSHA (Occupational Safety and Health Administration)
17. SAMA (Scientific Apparatus Makers Association)
18. UL (Underwriters' Laboratories)

C. Attachments:

1. Not Applicable

1.04 SUBMITTALS

- A. The Supplier shall provide complete operating instruction manuals pertaining to the following:
 1. System specifications
 2. Electrical power requirements
 3. Application considerations
 4. Assembly and installation procedures
 5. Power-up procedures
 6. Troubleshooting procedures
 7. Programming procedures
 8. Explanation of internal fault diagnostics
 9. Shut-down procedures
 10. Recommended spare parts list
- B. Panel and PLC Cabinet Drawings - Drawings of local control panels and PLC Cabinets shall include front and rear layout as well as typical cross sections with dimensions. Supplier shall also furnish recommended layout of remote supervisory control panel instruments, if applicable.
- C. Annotated Ladder Logic Diagrams – All documentation and control systems programming shall be in Korean. PLC Control Systems shall be supplied with annotated ladder logic diagrams.
- D. Manufacturer's Prints - All suppliers of control systems, whether supplied directly to Supplier or indirectly, shall be required to furnish documents covering specifications, wiring, recommended spare parts lists, and instructions for maintenance and operations.
- E. Wiring Drawings - Schematic and/or loop diagrams are required for all devices within the PLC. Logic diagrams and elementary wiring diagrams are required for all control systems. Electrical terminal arrangement drawings are required for all electrical devices whether or not they are wired by Supplier.

- F. Junction Box Drawings - Drawings of all junction boxes shall include layout, dimensions, mounting and labeled terminations.
- G. Calculations - Supplier shall furnish sizing calculations control systems components such as processor loading, power supply, etc. for Buyer's review during the design phase of the order.
- H. Certifications - Supplier shall provide all certifications necessary to support any test requirement that may be specified in the mechanical equipment general specifications such as seismic, chemical, and physical.
- I. The Supplier shall provide a list of field sales and support personnel. The supplier shall also provide a field service department with experienced technicians in the Incheon, Korea area who are capable of providing telephone and/or on-line service, on-site service, and adequate spare parts.
- J. Each device and component used shall be entered into a bill of material. The bill of material shall include the device description, device manufacturer, model number and all other pertinent information.
- K. All drawing deliverables except loop diagrams shall be submitted on full-size drawings. All deliverables shall also be electronically submitted on CD-ROM.

1.05 QUALITY ASSURANCE

- A. In order to support validation of the PLC based control system a Quality Assurance and Quality Control Plan must be put in place and the proper documentation furnished. This quality assurance plan will ensure that the PLC configuration follows a structured development and audit methodology. The Supplier must include the quality plan and the required validation documentation within the submittals.
- B. Inspections
 - 1. After the installation of the instruments and tubing is complete, the Seller shall visually check each component for conformance to the drawings, specification, and manufacturer's recommendations.
 - 2. All materials and workmanship shall be subject to inspection and examination by the Buyer. Any defective material, defective workmanship, and instruments installed inaccessibly or in violation of OSHA or cGMP guidelines shall be replaced, reworked, or relocated to the satisfaction of the Buyer at no additional cost.
 - 3. All test procedures shall be submitted to Engineers for approval. The Supplier shall notify, in writing, the Engineer 2 weeks prior to the start of these tests so that the Engineer and/or Owner may be present to witness these tests.

C. Testing

1. Device Check

- a. Supplier shall test the contact configuration on all auxiliary relays having convertible contacts and verify conformance with the N/O and N/C positions shown on the elementary diagrams.
- b. Supplier shall determine the contact configuration on all control and instrument switches, synchronizing switches, selector switches, and pushbuttons, and verify conformance with switch contact diagrams. Supplier shall verify that each contact operates in each switch position as indicated on the switch contact diagrams, and that all switches with spring return action do return to the intended positions freely and without binding.
- c. Supplier shall check all devices to ensure complete conformance with the equipment list.
- d. Nonconformances shall be corrected.

2. Wiring Check

- a. Supplier shall perform a point-to-point check with wiring diagrams, check for correct wire and terminal block markings, and verify that all connections are correct and tight. All wiring terminations shall be connected to the specific device terminals as shown on the approved diagrams. Supplier shall make an electrical continuity test on each conductor.
- b. Nonconformances shall be corrected.

3. System and Performance Testing

- a. These activities are to be included within the Factory Acceptance Testing (FAT) executed by the Supplier at their facility and should consider the following:
 - i PLC software programming is functioning within design parameters in accordance with Supplier's operational requirements and Engineers' procurement specifications.
 - ii Operator Interface Station and programmed graphics, display and controls are functioning within design parameter in accordance with Supplier's operational requirements and Engineers' procurement specifications.
 - iii Instruments are functioning individually within design parameters.
 - iv Instrument loops are functioning within design parameters.
 - v Loop alarm or control output signals are within design parameters.
- b. If all components of a loop are not available for testing, their functions shall be simulated so that as realistic a test as possible is performed.
- c. Supplier shall be responsible to protect all devices from exposure to overvoltage or other hazards during testing. A test procedure shall be submitted to Engineers

prior to testing for approval. The test procedure shall contain the acceptance criteria for each test performed.

- d. Supplier shall notify Engineers of any defective equipment supplied to them for mounting by other vendors as soon as individual defects are discovered.
4. All test equipment required for this work shall be furnished and retained by Seller. Test equipment for use with the Buyer furnished control system shall be the Buyer's responsibility.
5. After approval by the Buyer, Seller shall use his approved software test plan for test execution. Test shall be witnessed by the Buyer prior to acceptance of the control package. Seller to give Buyer a minimum of ten (10) days advance written notice of test.

1.06 DELIVERY, STORAGE, HANDLING

- A. The electrical equipment shall be designed to withstand storage and transportation temperatures within the range of minus 25 to 55 degrees C and up to 65 degrees C for short periods not exceeding 24 hours. Suitable means shall be provided to prevent damage from excessive moisture, vibration, stress, and mechanical shock during shipment.
- B. The front of each panel shall be covered with plastic that can remain in place during installation. Crating, skids and any additional bracing required shall be provided to protect against damage to structure, finish and components during transit and handling. Supplier shall remove and properly pack all plug-in instruments and devices that cannot be properly secured for transit and handling to prevent damage.

PART 2 PRODUCTS

2.01 GENERAL

- A. Supplier shall design, fabricate, and deliver a complete PLC system with hardware and software including, but not limited, to the following:
 1. CPUs (Central Processing Units)
 2. I/O systems
 3. Operator Interface Stations
 4. Special interconnecting cable
 5. Power Supply
 6. Chassis

7. Enclosures and termination cabinets shall be pre-wired. If Supplier's equipment is shipped in sections, provisions should be made to have interface wiring connected at one end and the other end coiled and labeled for termination's to be performed in the field.
8. Programming software, including sequencing, graphic and textual operator displays, data acquisition and on-line diagnostics.
9. Documentation

B. Supplier shall offer the following additional services:

1. On site testing and startup
2. Operator and maintenance training
3. Maintenance service contracts

- C. All devices provided by the Supplier shall use industry standard power supplies, and shall generate industry standard signals.
- D. All Supplier furnished electrical instruments installed in a hazardous area shall be designed for operation according to the applicable electrical area classification.
- E. All conductors shall be identified at each termination point using "Brady" wire marking system or approved equal.
- F. All major assemblies and sub-assemblies, modules, and devices shall be identified using permanent labels or markings each of which indicated the manufacturer's catalog number, product manufacturing date code and certifications.

2.02 DESIGN REQUIREMENTS

A. Design Criteria

1. The system shall be designed for 0.98 availability through selection of reliable components, conservatively applied in accordance with the manufactures specifications, through serviceable equipment arrangement, detailed system diagnostics and through quality workmanship in assembly. Complicated and costly redundant or fault tolerant configurations shall be employed only with Owner's approval.
2. All systems shall be applied and assembled in accordance with the component manufacturer's recommendation. This shall include recommended techniques for power separation and surge and noise suppression.

3. In all cases the “fail safe state” is the state that is assumed when power is removed from a device. Upset conditions that require a process unit shutdown will drive all devices within that unit to their fail-safe state.
4. All hardware-generated alarms will be wired normally closed, alarm on **open**. Software generated alarms will be alarm on **true**.
5. Emergency stop circuits shall be hardwired and controlled by a magnetic relay.
6. Separate inputs and outputs shall be used for each device. All parallel or series wired circuit applications will be subject to Owner's approval. Pilot lights for indicating the status of an input device need not be connected to an output module.
7. The scan time of the PLC program shall be sufficiently fast to support the performance requirements specified in the Supplier's Functional Specification. Under no circumstances shall the overall scan time exceed 120 msec.
8. Alarm handling shall be defined by the Supplier within their Functional Specification, but should include both audible and visual alarms. Audible alarms shall be silenced with operator acknowledgment. Visual alarms shall remain on as long as conditions exist. An alarm report shall be printed to show all alarm conditions. The report shall record and print the following key alarm parameters:
 - a. Time activated
 - b. Type activated
 - c. Time acknowledged
 - d. Time corrected
9. Batch ID No's must be able to be entered and printed out on all records and reports associated with a process run.
10. Logon/password access shall be required at the Operator Interface Station, with each logon/password assigned an authorization level to limit system access and privileges. Typical authorization levels may include; Operator, Technician, Chemist, Supervisor, Maintenance or Manager.
11. Graphic standards and graphic layouts shall be Supplier's standard, contingent upon approval of the Owner.

B. Basic Materials and Methods

1. Central Processing Unit
 - a. The central processing unit shall have sufficient instructions to perform all data manipulation, arithmetic functions (+, -, x, /, =), function block operations, and binary logic. The central processing unit shall support Relay Ladder Logic. The

use of Relay Ladder Logic is recommended. Other graphical languages or textural languages may also be utilized for PLC programming provided the requirements of IEC 61131-3, "Programming Languages" (formally IEC 1131-3) are met.

- b. All software shall be retained during power outage through the use of battery backed up RAM or EPROM. Wherever batteries are used, lithium batteries shall be utilized and the processor programmed for low battery alarming.

2. Power Supply

- a. Supplier shall furnish all power supplies and line filtering equipment required for the operation of the PLC system. No special provisions for clean power will be furnished by Owner. Each individual equipment unit of the PLC system shall be capable of operating from an input power source of 220 VAC +/- 10 percent, 60 Hz +/- 2 percent, without degrading performance of that equipment. A voltage stabilizing transformer of sufficient size shall supply power to each PLC CPU and remote I/O power supply. Digital inputs shall also be powered by this transformer.

3. Programming Terminal

- a. The programming terminal shall be an Owner supplied IBM compatible personal computer equipped with programming software and a hardware interface to permit program downloading to, and program uploading from the PLC CPU. The terminal shall provide a means of monitoring program execution and overall system status. Terminal interactions such as I/O forcing, data manipulation, and system initiation shall be supported by the programming terminal. The terminal shall be furnished with the necessary software for on-line and off-line program development and off-line program documentation.

4. I/O Modules

- a. Digital Inputs
 - i. The discrete input modules shall be able to accept inputs from devices such as limit switches, pushbuttons, pressure switches, level switches, temperature switches and flow switches. Each input voltage shall be optically isolated from the input card electronics and the energized state of an input shall be indicated with light emitting diodes. Internal protection shall be provided to protect against external voltage transients. Required mounting racks, cabling, power supplies and any interfacing equipment shall be supplied with the modules.
 - ii. High density digital inputs, 16 points per card, shall be used whenever a large number of devices of a given signal level are required. Higher density cards, 32 points, shall not be used without Owner's approval.

b. Digital Outputs

- i The discrete output modules shall be able to activate solenoids, starters, and coils. Each output voltage shall be optically isolated from the output card electronics. The individual outputs shall have light emitting diodes to indicate when the output is energized.
- ii Internal suppression shall be provided to prevent false triggering. Required mounting racks, cabling, power supplies and any interfacing equipment shall be supplied with the modules. External loading characteristics including minimum loads for Triacs and maximum inductive loads shall be stated. These loading characteristics shall be observed in the selection and interfacing to Supplier supplied instrumentation.
- iii High density digital outputs, 16 points per card, shall be used whenever a large number of devices of a given signal level are required. Higher density cards, 32 points, shall not be used without Owner's approval.

c. Analog Inputs

- i The analog input modules shall be able to convert analog signals (typically supplied by an instrumentation transducer) to a digital signal which then may be used by the processor. Proper isolation shall be supplied to protect against voltage transients. Required mounting racks, cabling, power supplies and any interfacing equipment shall be supplied with the modules.
- ii Multi channel analog input modules shall be configured for use in the differential and not single ended mode. Whenever appropriate for the given application the analog signal level shall be standardized on 4-20 ma
- iii All analog input modules shall have an analog to digital conversion resolution of at least 12 bits.

d. Analog Outputs

- i The analog output modules shall be able to convert digital values from the processor to analog signals for use by a user device. Proper isolation shall be supplied to protect against voltage transients. Required mounting racks, cabling, and power supplies and any interfacing equipment shall be supplied with the modules.
- ii Whenever appropriate for the given application the analog signal level shall be standardized on 4-20 ma.
- iii All analog output modules shall have a digital to analog conversion resolution of at least 12 bits.

e. Serial Data Ports

- i The preferred interface for Serial Data Ports shall be RS-422 (or RS-485). However, whenever interconnecting devices support only EIA-232,

Supplier shall take into account the cabling distances between the Serial Port at the PLC and the connection to any intelligent field device. For any applications requiring installed cable lengths in excess of 50 feet, Supplier shall supply appropriate line driver modems.

- ii Supplier shall supply all protocol software to reliably and efficiently communicate to specified instrumentation in accordance with the Functional Specification.

5. Operator Interface Station

- a. The Operator Interface Station (OIS) shall be programmed to display graphic screens depicting the equipment in appropriate operational and alarm modes relating to the Piping and Instrumentation Diagrams (P&ID's). All graphic screens shall be approved by the Owner prior to release for fabrication.

C. Fabrication and Manufacture

1. Control Panel and Enclosures

- a. Supplier shall furnish all control panels and enclosures in accordance with the NEMA 12 service rating if the control panels or enclosures are located within non-GMP, non-hazardous areas. Control panels and enclosures located within GMP process areas will be stainless steel NEMA 4X, watertight, corrosion resistant construction, as a minimum, and as required by the electrical classification of that area. Enclosures shall be sloped for cleanability.
- b. In GMP process areas, exterior panel surfaces shall be crevice free and shall be finished to a surface RA of 35 micro-inches. Exterior screw type clamps are not permitted. Conduit and tubing penetrations shall be through the sides or bottom. Provisions shall be made to "pipe-away" instrument air exhaust from solenoid valves and condensate from coalescing filters to a location outside the clean area unless otherwise noted. Enclosures shall be constructed to permit easy cleaning with bleach and caustic solutions.

2. Assembly

- a. The panel arrangement and assembly practices shall be in accordance with the referenced standards and comply with the PLC manufacturer's published assembly and installation instructions.
- b. The assembly shall be complete and include mounting and wiring of all components. Additionally, all components shall be properly configured for the intended application; all jumpers or DIP switches shall be set by Supplier.

3. Wiring

- a. Wiring practices shall be in accordance with the referenced electrical specifications.
- b. Conductors and cables shall be run without splices from terminal to terminal.
- c. Terminals on terminal blocks shall be plainly identified to correspond with markings on the diagrams.
- d. All conductors shall be so terminated to prevent fraying of strands and to permit easy disconnection.
- e. Identification tags shall be Sleeve-type tags and made of oil-resistant material. Sleeve-type tags shall be applied so they will not slip off the wire.
- f. Terminal blocks shall be wired and mounted so the internal and external wiring does not cross over the terminals. Not more than 2 conductors shall be terminated at each terminal connection.
- g. Panel conductors shall be supported where necessary to keep them in place. Wiring channels shall be permitted where made of a flame-retardant insulating material.
- h. Where back-connected control panels are used, access doors or swingout panels that swing about a vertical axis shall be provided.

2.03 COMPONENTS

A. PLC Components

- 1. Allen-Bradley SLC 5/05 processor, **or approved equal**
- 2. SLC 5/05 compatible Power Supply and Chassis
- 3. SLC 5/05 compatible Digital and Analog I/O Modules
- 4. Special Interconnecting Cabling
- 5. SLC 5/05 compatible Network Interface Card, which will support communication links via an Ethernet network. These links include PLC to Operator Interface Station and a plant data highway.

B. Operator Interface

- 1. For system(s) or equipment requiring operator interface capabilities involving text and/or screen graphics, the Supplier shall supply a 21 CFR Part 11 compliant operator interface.

2. For system(s) or equipment requiring limited operator interface without text or graphics, the Supplier shall supply a control panel with all the necessary handswitches and status lights for interfacing with the PLC.
3. PLC and operator interface configuration software shall be Supplier's standard, contingent upon approval of the Owner.

2.04 DOCUMENTATION

- A. The Seller shall supply documentation including the following in accordance with GAMP Guide for Validation of Automated Systems in Pharmaceutical Manufacture :
 1. Software QA program
 2. Functional Design Specification
 3. Software Design Description including as a minimum the following items:
 - a. List of all input and output signals associated with the process control system and the PLC address associated with each signal.
 - b. Summary of all alarm and interlock trip setting.
 - c. Summary of all recipe parameters, including high limit, low limit, and default values.
 4. The Seller shall provide all application source code to the Buyer. To meet these requirements, the Seller shall supply a printout of the final Software Configuration, including the following items.
 - a. A table of registers for each PLC.
 - b. A complete MMI/SCADA configuration printout.
 - c. A complete, fully annotated ladder logic printout.
 - d. Printouts of any other application software programs employed for the process and mechanical package.
- B. The Seller shall provide all loadable code to the Buyer on magnetic media /CD ROM. The loadable code must be the final program revision after the FAT is completed and any changes have been made. Furthermore, if the vendor performs any on-site startup and any changes are made, the latest revision must be submitted.
- C. The Seller shall supply samples of the above documentation to be included with the Seller's bid.
- D. The Seller shall provide a copy of any configuration software package not currently owned by the Buyer.
- E. Test Procedures
 1. In addition to written test plans and procedures for the entire process or mechanical package, written test plans and procedures including but not limited to a Factory Acceptance Test and a Site Acceptance Test for the process control system software shall be submitted for review & approval.

F. Testing Records

1. Seller shall provide full documentation of all testing results. An example of this documentation package shall be included with the Seller's bid.

PART 3 EXECUTION

3.01 PERFORMANCE REQUIREMENTS

- A. The PLC system performance requirements as defined within the Suppliers Functional Specification shall be met.
- B. Supplier shall design the system for industrial duty involving 24 hours a day, 7 days a week service.

3.02 SITE CONDITIONS

- A. The equipment shall be suitable for use in an industrial environment containing microscopic metallic and liquid particles and dusty materials. Equipment shall operate reliably under the following ambient conditions:
 1. Temperature: 0 to 50 degrees C unless otherwise specified.
 2. Humidity: 5 percent to 95 percent relative humidity, noncondensing.
 3. Elevation: up to 3300 feet above mean sea level.
 4. Power Required: 220 VAC, 1 phase, 60 Hz, Uninterruptible Power Supply (UPS).
 5. Voltage: 90-110 percent of rated voltage.
 6. Frequency: +/- 2 percent of rated frequency.
 7. Impulse Voltage: 200 percent peak voltage up to 1 ms duration with a rise time of 500 nanosecond to 500 microseconds.
 8. Voltage Drop: Reduction of 50 percent of peak voltage for 1/2 cycle or 20 percent for 1 cycle. More than 1 second between successive reductions.
 9. Micro-interruption: Supply disconnected or at zero voltage for 3 ms at any random time in the cycle. More than 1 second between successive reductions.
 10. Electrical Noise: The PLC System shall be designed and tested to operate in a high electrical noise environment.

3.03 DOCUMENTATION

- A. Instrument Calibration Sheets and calibration stickers shall be provided by the equipment Supplier showing the calibration data, results, calibration date, test equipment serial number and technician's initials. All calibrations shall be traceable to the National Institute of Standards Technology (NIST). Calibration stickers shall be applied to each device.

- B. Operator/User Manual - This manual shall describe the system and how to operate it in everyday language. The manual shall contain as a minimum the calibration procedures, control diagrams, wiring diagrams, loop sheets, instrumentation data sheets, operator interface control procedures (system access, security features, etc.) and alarms.
- C. Maintenance Manual - This manual shall be written for the engineer who has responsibility for supporting and maintaining the system once it is installed. This manual shall contain as a minimum the hardware configuration, I/O list, logic flow diagrams, preventive maintenance procedures, common troubleshooting problems/solutions and software (development, testing, support and maintenance) information. Detailed function descriptions, program software, application source code as well as other design documentation necessary to permit a qualified software engineer to maintain the software shall also be included in this manual.
- D. Test Documentation - Test documentation shall be supplied for any computer based system to demonstrate that the system which was delivered operates the way it was designed to operate. This documentation shall also include software test protocols and software development QC records.
- E. Functional Description - The functional description will provide a detailed sequence of operation providing all required actions and expected results. It shall be provided within 3 weeks of order placement. 4 copies shall be provided.
- F. Validation Documentation - Validation documentation shall be provided to include Installation Qualification and Operational Qualification Protocols, description of validation experiments, list of summary data and documented evidence that the design intentions are met.

End of Specification