

#### **PREFACE**

For this report, the Tricon v10 equipment qualification program and its test results are assessed against current regulatory criteria and discussed in a summary fashion. The purpose is to provide an independent assessment of the overall Tricon v10 equipment qualification program. This equipment qualification program for the Tricon v10 was initiated in 2006 and completed in 2007. The equipment qualification testing was performed at National Technical Systems (NTS) in Boxborough, MA. This new qualification of the Tricon v10 was performed in accordance with current NRC requirements and guidance and employs lessons learned from the previous successful qualification effort of the Tricon v9 which, in turn, improves the overall qualification process.

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# Independent Tricon v10 Equipment Qualification Assessment

#### 1.0 INTRODUCTION

Invensys-Triconex (I-T) introduced Version 10 (v10) of the Tricon, which supports new processors, software and manufacturing techniques. This is the successor to the Version 9 (v9) of the Tricon, which was nuclear qualified and approved for safety related use by the US Nuclear Regulatory Commission (NRC) in December 2001. The redeveloped Tricon v10 has new design documentation for the new Model 3008 Main Processor, the Next Generation Analog Input Differential (NGAID), the Next Generation Discrete Output (NGDO), and the Tricon Communication Module (TCM). The equipment qualification program\* for the Tricon v10 was initiated in 2006 and completed in 2007. The equipment qualification testing was performed at National Technical Systems (NTS) in Boxborough, MA. Representatives from both I-T and MPR Associates directed and were actively involved with the equipment qualification program. This qualification of the Tricon v10 was performed in accordance with current NRC requirements and guidance and employs lessons learned from the previous successful qualification effort, which in turn, improves the overall qualification process. For this report, the Tricon v10 qualification program and its results are assessed against current regulatory criteria and discussed in a summary fashion. Additional details regarding the Tricon v10 qualification effort can be found in the associated Triconex, NTS and MPR test reports, test procedures and other documents.

The Tricon v10 equipment qualification program must ensure that all digital instrumentation and control equipment can perform their design safety functions under all environmental conditions resulting from any normal mode of plant operation anticipated operational occurrences, design basis events and post-design basis events. The safety goal of equipment qualification is to avoid a common mode failure potential due to temperature, humidity, seismic, radiation, electromagnetic interference/radio frequency interference (EMI/RFI), surge, electrical fast transient (EFT), electrical surge discharge (ESD) and safety related to non-safety related isolation levels when it is required to perform a safety function. The unique characteristics of a digital system such as the Tricon v10 PLC presents the need for special qualification considerations to validate that the Tricon can perform its safety function under the required environmental and operational conditions. This need is expressed in varied regulations and guidance documents. Triconex has met this need with the application of their qualification program as discussed below.

<sup>\*</sup> Normally the term "equipment qualification program" refers to equipment qualification for a harsh environment, but for this report the term is used to encompass a qualification program for temperature, seismic, radiation, humidity, electromagnetic interference/radio frequency interference, surge withstand, electro-static discharge, electrical fast transient and isolation conditions for equipment located in a mild environment.

#### 2.0 ASSESSMENT

The Tricon v10 equipment Under Test (TUT) used to demonstrate acceptable equipment qualification was connected in a manner that simulates its expected installation when in actual use, including cables and connections. For example, in meeting this requirement, the need for integrated qualification testing of the Tricon v10 together with the cables, power supplies, pertinent input/output (I/O) modules, communication devices and necessary passive equipment was considered during the review of the Tricon v10 qualification program. The Triconex System Setup and Checkout Procedure (Triconex Document 9600164-502) documents the components to be tested prior to the start of each qualification test.

The Triconex System Description, Triconex Document 9600164-541, provides an overview and description of the TUT and test system. A detailed identification of the test equipment is provided in the Master Configuration List, Triconex Document 9600164-540.

The following Tricon v10 modules/equipment were part of this equipment qualification effort.

MODULE NUMBER	MODULE
8110	Main chassis
8111	Expansion Chassis
8112	Remote Expansion Chassis
8310	High Density Power Module 115 VAC
8311	High Density Power Module 24 VDC
8312	High Density Power Module 230 VAC
3008	Enhanced Main Processor
4352A	Communication Processors
3701	Analog Input-Differential, DC Coupled
3703E	Analog Input-Isolated, 16 Points
3721	NGAI, Analog Differential, 32 Points
3708E	Thermocouple Input, Differential, Isolated
3805E	Analog Output, Non-isolated, Common
	Return
3501T	Digital Input-Non-commoned, Isolated, 32
	pts
3502E	Digital Input-Commoned Groups of 8, 48 V
3503E	Digital Input-Commoned Groups of 8, 24 V
3511	Pulse Input-Non-commoned, Balanced

	Diff.
3601T	Digital Output-Non-commoned, Isolated,
	115 VAC
3603T	Digital Output-Commoned, Isolated, 120
	VDC
3623T	Digital Output-Supervised, Commoned,
	120 VDC
3607E	Digital Output-Non-commoned, Isolated,
	48 VDC
3636T	Digital Output-Relay Output, NO, Simplex
3625	NGDO, Digital Output, 32 pts, 24 VDC
1600083-600	RTD Signal Converter, 0 to 600 C
1600083-200	RTD Signal Converter, 0 to 200 C
1600024-040	RTD Signal Converter, 0 to -600 C
1600024-030	RTD Signal Converter, 0 to –200 C
1600024-020	RTD Signal Converter, 0 to -100 C
1600024-010	RTD Signal Converter, -100 to 100 C
1600082-001	RTD Signal Converter, 0 to 100 mV
1600081-001	RTD Signal Converter, 0 to 120 C
Varied	Passive components including cables,
	panels, slot blanks, chassis cable sets, and
	mounting brackets
4200	Primary RXM, Fiber Optic
4201	Remote RXM, Fiber Optic

A Test Specimen Application Program (TSAP) was developed to establish Tricon program logic and exercise selected input/output points and communication links in support of the required qualification-testing program. The overall purpose of the TSAP is to demonstrate functionality of the TUT during pre-qualification testing, qualification testing and post-qualification testing. It was generated using the specifications in EPRI TR-107330 as evidenced by the TSAP Software Requirements Specification. This is discussed in detail in varied Triconex Series 96000164 TSAP documents (9600164-517, 518, 513, and 537). A review of these documents led to the conclusion that the TSAP software is acceptable for its overall purpose. The TSAP is properly controlled, verified and validated for use for the qualification program testing acceptance process. A set of minimum documents listed in the EPRI TR has been developed for the TSAP. This includes the Software Quality Plan, Software Requirements Specification, Software Design Description, Software Verification and Validation Plan, User Documentation, and Software Configuration Management Plan. The TSAP provides a functioning TUT with software and diagnostics that are representative of those used in actual plant operation. The TSAP exercises all relevant portions of the TUT necessary to accomplish the safety function.

A System Setup and Checkout Procedure, Triconex Document 9600164-502, was developed using the guidance of EPRI TR-107330. The review of this procedure and

ensuing test results led to the conclusion that the qualification system was assembled, configured, integrated and functions in an acceptable manner.

Based on the review of the Triconex documents noted above, both the TUT and the TSAP were found to be acceptable as the established requirements and guidance were met by Triconex.

### 2.1 Pre-qualification Testing

The pre-qualification testing was designed to follow the requirements of Section 5.2 of EPRI TR-107330 by establishing baseline conditions for the TUT that followed the published specifications and by verifying system configuration/setup and proper operation. This testing exposes the TUT to various normal and abnormal conditions of input/output operation and power source variations. This testing includes operability testing and prudency testing as specified in EPRI-TR-107330, Sections 5.3, 5.4, 5.5 and 6.4.3. All testing prerequisites were met, although an engineering change order was required to address failures of two analog output points (3805 AO Module). These points were subsequently successfully retested. The system setup and checkout test documented the proper configuration and operation of the TUT.

The establishment of the baseline performance was acceptable and the results of the prudency testing showed the TUT was able to operate within specifications under dynamic conditions. The pre-qualification testing and the ensuing results meet the guidance presented in EPRI TR-107330, Section 5.

### 2.2 Qualification

The assessment of the Triconex equipment qualification program starts with a review of the general requirements for environmental design and qualification in the following areas: (1) the equipment shall be designed to have the capability of performing its design safety functions under all anticipated operational occurrences and normal, accident, and post-accident environments, and for the length of time for which its functions are required; (2) the equipment environmental, EMI/RFI, seismic, radiation, ESD, EFT, surge discharge and isolation qualification shall be demonstrated by appropriate testing and analyses; (3) documentation is available for test plans, specifications, qualification, procedures, results, and analysis; and (4) a quality assurance program meeting the requirements of 10 CFR Part 50, Appendix B, shall be established and implemented to provide assurance that all requirements have been satisfactorily accomplished. The qualification of the Tricon v10 is acceptable only when it can be ascertained these requirements have been met.

# 2.3 Radiation Testing

The objective of the Radiation Exposure Testing (RET) is to demonstrate that the TUT will not experience any failures due to expected radiation dosage as defined by Section 4.3.6 of EPRI-TR-107330.

The Tricon TUT met the radiation testing guidance as presented in the EPRI TR-107330 and also met the recently published guidance for radiation testing as presented in Regulatory Guide 1.209-2007.

## 2.4 Environmental Testing

The objective of Environmental Testing is to demonstrate the TUT will not experience failures due to abnormal service conditions of temperature and humidity. Environmental Testing of the TUT was performed in accordance with the requirements of Regulatory Guide 1.209, Sections 4.3.6 and 6.3.3 of EPRI TR-107330, IEEE 323-1983/2003 and IEEE 381-1977.

The environmental test results demonstrate that the Tricon v10 PLC will not experience failures due to abnormal service conditions of temperature and humidity. The test profile used during the Tricon v10 qualification testing bounds the test conditions required by Figure 4-4 of EPRI TR-107330.

The Tricon v10 environmental testing program demonstrated that the Tricon system meets the guidance set forth in IEEE 323-1983/2003, RG 1.209 and the guidance provided in the EPRI TR. Furthermore, the environmental testing demonstrated that the Tricon v10 will properly function under the EPRI TR prescribed temperature and humidity conditions.

# 2.5 Seismic Testing

The objective of Seismic Testing is to demonstrate the suitability of the Tricon v10 for qualification as a Category 1 seismic device based on seismic withstand type testing performed on the TUT. Seismic Testing of the TUT was performed to the specific requirements set forth in Sections 4.3.9 and 6.3.4 of EPRI TR-107330, which invokes IEEE Standard 344-1987, and to the general requirements of IEEE 381-1977, "Standard Criteria for Type Tests of Class 1E Modules Used in Nuclear Power Generating Stations."

The TUT met all applicable performance requirements during and after application of the seismic test vibration levels. Results of the Operability Test performed after Seismic Testing show that exposure to the Seismic Test conditions had no adverse effect on the TUT performance. Seismic testing demonstrates that the Tricon is qualified as a Category I seismic device within the test limits.

Due to limitations of the seismic test table, the five OBE tests and the SSE test of the Tricon v10 were performed using a Test Response Spectrum (TRS) that did not envelope the Required Response Spectrum (RRS). Therefore, a plant-specific evaluation will be

needed to determine whether the as-tested limits bound or mirror the plant seismic acceleration requirements. In addition, monitoring for chatter of the chassis alarm contacts during seismic testing was not done as a result of using an interposing relay in the contact monitoring circuit.

#### 2.6 EMI/RFI TESTING

The objective of electromagnetic interference/radio-frequency interference (EMI/RFI) testing is to demonstrate the suitability of the Tricon v10 PLC for qualification as a safety related, Class 1E device with respect to EMI/RFI emission levels and EMI/RFI susceptibility. Originally EPRI published TR-102323, "Guideline for Electromagnetic Interference Testing in Power Plants" to enable an alternative to site-specific EMI surveys to qualify digital systems such as the Tricon v10 in a plant's electromagnetic environment. This TR provided testing levels for both susceptibility and emission testing. Additionally, Sections 4.3.7 and 6.3.2 of EPRI TR-107330 provides high-level information for performing electromagnetic compatibility (EMC) tests on digital systems. Subsequently, the NRC published Regulatory Guide 1.180, which was revised (Revision 1) in October 2003. The purpose of this revision was to provide new guidance for complying with regulations for addressing the effects of EMI/RFI and power surges on safety related I&C systems. The technical basis for Regulatory Guide 1.180, Revision 1 was similar to those for the original Regulatory Guide (RG) with levels taken from varied NUREG/CRs. The revisions to the RG include endorsing MIL-STD-461E and the International Electrotechnical Commission (IEC) 61000 series of EMI/RFI test methods. It also extended the guidance to cover signal-line testing, incorporating frequency ranges where portable communications devices are increasingly used, and relaxing operating envelopes where experience and research warrants.

EMI/RFI Testing of the TUT was performed to the requirements of Sections 3 and 4 of NRC Regulatory Guide (RG) 1.180, Rev. 1. Each section endorses both Military Standard MIL-STD-461E series and IEC 61000 series EMI/RFI test methods.

EMI/RFI emissions testing of the TUT included both radiated and conducted emissions testing done to the MIL-STD-461E series test methods. EMI/RFI susceptibility testing of the TUT included both radiated and conducted susceptibility testing done to the IEC 61000 series test methods specified in Section 4 of NRC RG 1.180, Rev. 1.

EMI/RFI Testing of the TUT was performed in accordance with Test Procedure 9600164-510, "EMI/RFI Test Procedure," and NTS Test Procedure TP62987-07N-EMI, "Test Procedure for Electromagnetic Compatibility Qualification of the Tricon v10 Nuclear Qualification Project TRICON-Under-Test." All testing was performed with the TUT energized and operating under control of the executing TSAP software. The EMI/RFI Testing emissions acceptance levels or applied susceptibility test levels were taken from the applicable figures and tables of NRC RG 1.180, Rev. 1 and the referenced standards.

Evaluation of normal operating performance data (inputs, outputs and diagnostic indicators) demonstrated operation as intended, including the specific operational performance from Section 4.3.7 of EPRI TR-107330 with certain exceptions. The EMI/RFI susceptibility test results show that the certain Tricon v10 PLC input/output hardware does not fully comply with the minimum susceptibility thresholds. In addition, the EMI/RFI emissions test results demonstrate that the Tricon v10 PLC does fully comply with the allowable emissions levels of NRC RG 1.180, Rev. 1.

Prior to installing the Tricon v10 PLC in a nuclear safety related application, an evaluation of the input, output and communication module susceptibilities should be performed. Licensees should perform sufficient testing and analysis to ensure that the plant-specific EMI/RFI environment is bounded by the EMI/RFI capabilities of the Tricon v10 digital system. Furthermore, licensees should determine that the emissions will not affect surrounding equipment. The Tricon v10 EMI/RFI susceptibility and emission testing documented in the Triconex EMI/RFI test report provides the data required to perform this evaluation.

### 2.7 Electrical Fast Transient Testing

The objective of Electrical Fast Transient (EFT) Testing is to demonstrate the suitability of the Tricon v10 for qualification as a safety related device with respect to immunity to repetitive electrical fast transients on the power and signal input/output leads. The specific test method used for EFT Testing was the IEC 61000-4-4, Electrical Fast Transient/Burst Immunity Test. The EFT Test Procedure was developed in accordance with the guidance of NRC Regulatory Guide 1.180, Rev. 1, EPRI Report TR-107330, IEC 61000-4-4, the Triconex Master Test Plan (9600164-500), and the Triconex Nuclear Qualification Quality Plan, Document 9600164-002.

The TUT met all applicable operational and performance requirements during and after each application of the EFT Tests voltages. The applicable provisions of IEC 61000 and RG 1.180 were met by the Tricon v10 design.

## 2.8 Surge Withstand Testing

The objective of Surge Withstand Testing is to demonstrate the suitability of the Tricon v10 PLC for qualification as a safety related, Class 1E device for immunity to AC power and signal input/output line electrical surges. The specific test methods used for Surge Withstand Testing were IEC 61000-4-5, Surge Immunity (Combination Wave) Test and IEC 61000-4-12, Oscillatory (Ring) Wave Immunity Test. Sections 4.6.2 and 6.3.5 of EPRI TR-107330 provides additional guidance for digital systems undergoing surge testing.

The TUT met all applicable operational and performance requirements during and after each application of the Surge Withstand Test voltages. The guidance provided in RG 1.180, Revision 1 and both the EPRI TR and the IEC standard were followed and the results met the applicable guidance.

### 2.9 Electrostatic Discharge Testing

The objective of Electrostatic Discharge (ESD) Testing is to demonstrate the suitability of the Tricon v10 PLC for qualification as a safety related device with respect to immunity to electrostatic discharge exposure. EPRI TR-107330, Section 6.4.3 invokes EPRI TR-102323-R1 for ESD testing and acceptance guidance. RG 1.180 Revision 1 also provides a test method and guidance to be used for ESD Testing. This method is found in IEC 61000-4-2, Electrostatic Discharge Immunity Test.

The ESD guidance of RG 1.180 Rev 1, EPRI TR-102323-R1 and IEC 61000 were met by the Tricon v10 and the test procedure followed the appropriate guidance. The ESD Test results demonstrate that the Tricon v10 PLC will not experience operational failures or susceptibilities due to exposure to the test levels of electrostatic discharges.

# 2.10 Class 1E to Non-Class 1E Isolation Testing

The objective of Class 1E to Non-Class 1E Isolation Testing is to demonstrate the capability of selected Tricon v10 PLC modules to act as electrical isolation devices between the designated safety related hardware of the Tricon v10 and non-safety related field circuit connections. EPRI TR-107330, Section 4.6.4, specifies that Class 1E to Non-Class 1E isolation testing of the PLC under qualification should demonstrate that the isolation features conform to the guidance for Class 1E to Non-Class 1E connections given in IEEE 384-1981.

The Class 1E to Non-Class 1E isolation test results demonstrate that the PLC relay output module Model 3636T provides adequate electrical isolation per IEEE 384-1981. In addition, this testing demonstrates that the PLC Model 4352A TCM Communication Module MODBUS serial communication ports provide adequate electrical isolation per IEEE 384-1981. The Model 4211 Remote RXM fiber optic module is considered an acceptable Class 1E to Non-Class 1E isolation device by design, and was not tested due to this prior acceptance.

## 2.11 Performance Proof Testing

Performance proof testing was conducted at the completion of all qualification testing to demonstrate the continued acceptable performance of the TUT after being exposed to various qualification test conditions. The operability and prudency tests were performed as part of the performance proof tests. These procedures were developed in accordance with Sections 5.3 and 5.4 of EPRI TR-107330.

The test results of the Pre-Qualification Test, Prudency Test, and Performance Proof Test were evaluated with the purpose of determining any degradation in the performance of the TUT. This review established that the TUT performed in accordance with Invensys-

Triconex published specifications and EPRI TR-107330 guidance both before and after equipment qualification tests and no degradation in the performance of the TUT were identified.

## 2.12 Anomaly Reports

An important area of review is the anomaly reports resulting from the Tricon v10 equipment qualification testing process. These reports can be used to determine the validity of the test setup, integrity of the testing process, design completeness, qualification success of the design, failure cause and effect as well as other important qualification issues for the Tricon v10 system.

A review of the Qualification Project Anomaly Report (QPAR) log and supporting documentation proved that acceptable procedures were followed and all anomalies resolved properly. The anomaly disposition process was technically correct and followed an acceptable quality assurance program that met the relevant criteria of 10 CFR Appendix B.

The disposition of certain anomalies impacted the equipment qualification boundaries as discussed previously for EMI/RFI qualification.

#### 3.0 CONCLUSION

This independent assessment of the equipment qualification program covered the Tricon v10 equipment qualification program documentation and supporting descriptive information. This documentation and descriptive information included program planning documents, quality assurance manuals and plans, system and accuracy specifications, system drawings, software and hardware configurations, functional diagrams, test procedures, test reports, and anomaly reports. The basis for acceptance of this qualification program for the Tricon v10 as related to the primary areas of the equipment qualification review was conformance, within the test boundaries, with the NRC's regulatory criteria.

The Tricon V10 equipment qualification program and its results met the applicable requirements set forth in General Design Criteria (GDC) 1, 2, 4, and 23 of Appendix A to 10 CFR Part 50; and Criteria III, XI, and XVII of Appendix B to 10 CFR Part 50. All activities, including the TSAP, of the Tricon v10 equipment qualification program were performed under an acceptable Appendix B program that met the quality assurance criteria.

Acceptability was based on the equipment qualification program satisfying the applicable guidance set forth in the following primary guidance; EPRI TR-107330, EPRI TR-102323-R1 (ESD Testing), IEEE 323, IEEE 344, IEEE 381, IEEE 384, IEEE 7-4.3.2-2003, Regulatory Guide 1.100, Regulatory Guide 1.209, and Regulatory Guide 1.180, Rev 1 (which endorses portions of IEC 61000 and Military Standard 461E). The Tricon

v10 equipment qualification program met the regulations noted above and was performed in accordance with applicable regulatory standards and guides.

Acceptability was also based on the technical aspects of the equipment qualification program presented in the test procedures and test reports. An acceptable level of information including specifications and calculations to support acceptance was well documented. The TUT accurately portrayed the technical details regarding this acceptance. The particular boundaries achieved when compared to the standards are accurately presented in the assorted test procedures and reports.

This qualification acceptance includes postulated radiation, temperature, humidity, seismic (specific envelope as defined in Section 2.5), EMI/RFI (as clarified in Section 2.6), surge discharge, electrical fast transient, and electrostatic discharge conditions when the Tricon v10 is required to perform its safety function while located in a mild environment. Appropriate testing and analyses demonstrated this qualification. Furthermore, the three isolation features of the Tricon v10 have been successfully tested or analyzed and meet the applicable regulations and guidance for this area.

In applying the Tricon v10 system to a specific safety related application, the user must confirm that the tested qualification envelope bounds the actual plant-specific equipment qualification requirements. For EMI/RFI susceptibility and emission qualification, this confirmation process is described in Sections B and C of RG 1.180, Revision 1. For temperature/humidity and seismic qualification, the required boundaries are discussed in EPRI TR-107330, IEEE 344 and plant-specific data.

Procedure:	QAM 0.0	Title:	Introd	luctio	n		
Revision:	029	Page:	1	of	1	Approval Date:	09/15/06

#### COMPLETE REVISION - CHANGE BARS NOT INCLUDED

#### INTRODUCTION

This Quality Assurance Manual (QAM) delineates the essential practices and procedures required to ensure that the products designed, manufactured and serviced by the Triconex Product Line of Invensys meet the highest standards of quality, reliability and maintainability. These practices and procedures also apply to North American Project Operations (NAPO) application projects conducted at Triconex.

The QAM meets the nuclear quality assurance requirements of Title 10 of the Code of Federal Regulations, Part 50 (10CFR50), Appendix B, Criterion I through XVIII, as applicable. Additionally, the guidance of NQA-1-1994 has been utilized in preparing QAM procedures that are responsive to 10CFR50, Appendix B. The QAM also meets the requirements ISO 9001:2000, Quality Management Systems Requirements. The QAM applies to all nuclear and commercial quality-related activities.

The QAM is defined and authorized by its Table of Contents (QAM 0.1).

All procedures contained in the QAM are revision controlled documents. Any implementation of a new or revised procedure(s) or deletion of a procedure(s) will result in:

- 1. Increasing the revision level of the Table of Contents by one (1);
- 2. Updating the Table of Contents to indicate the new, revised or deleted procedure(s); and
- 3. Increasing the revision level of each specific QAM procedure by one (1). New QAM procedures are issued at Revision 0.

Quality Assurance Manual (QAM) procedures are available on the Invensys Process Systems (IPS) QA SharePoint website located at <a href="http://ips-sharepoint1.invs.com/quality/TriconexIrvQA/default.aspx">http://ips-sharepoint1.invs.com/quality/TriconexIrvQA/default.aspx</a>. Copies can be printed from this website; however, they will be annotated as "uncontrolled".

#### **VERBATIM COMPLIANCE**

All Triconex Quality System procedures (QAM 2.2) shall be followed verbatim in accordance with the requirements of QAM 2.1, Paragraph 4.3.4.

Note: Where routine changes are made to organization names, titles, etc., these changes are normally incorporated into procedures on an "as-revised" basis. Therefore, some inconsistency may exist during transition periods.

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0.2	Deleted	09/15/06	Quality Assurance Manual History
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1.2	018	06/15/06	Triconex Organization
1.3	012	09/15/06	Management Review
1.4	003	08/15/03	Customer Satisfaction Survey
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18.0	018	09/15/06	Training
19.0	008	08/05/05	Servicing
20.0	800	06/30/06	Statistical Techniques

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Section:	QAM 0.3	Subject:	Qualit	y Sys	tem Con	pliance	Cross-Reference
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(complete revision) TITLE ISO 9001 10CFR50, TRICONEX APPENDIX B QA MANUAL Management Responsibility 5, 6, 8 I. II 1.1, 1.2, 1.3, 1.4 2.1, 2.2, 2.3 **Quality System** 4, 5, 7 II, V Contract Review 5, 7 III 3.0 Design Control 7 III 4.0 Document and Data Control 4 VI 5.1, 5.2, 5.3 7 IV, VII 6.0 Purchasing Control of Customer Supplied Product 7 VIII 7.0 Product Identification and Traceability 7 VIII 8.0 ΙX 9.0 **Process Control** 6, 7 **Inspection and Testing** 7, 8 VII, X, XI 10.0 Control of Inspection, Measuring, and 7 XII 11.0 Test Equipment Inspection and Test Status 7 XIV 12.0 Control of Nonconforming Product 8 XV 13.1, 13.2 Corrective and Preventive Action 8 XVI 14.0

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Section:	QAM 0.3	Subject:	Qualit	y Sys	stem Con	pliance	Cross-Reference
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TITLE	ISO 9001	10CFR50, APPENDIX B	TRICONEX QA MANUAL
Handling, Storage, Packaging, Preservation, and Delivery	7	XIII	15.0
Control of Quality Records	4	XVII	16.0
Quality Audits	8	XVIII	17.0
Training	6	II	18.0
Servicing	7	None	19.0
Statistical Techniques	8	None	20.0
Reporting of Defects and Noncompliance	None	10CFR, Part 21	13.3

Section:	QAM 1.1	Subject:	Qualit	y Pol	icy		
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### 1. PURPOSE

The Triconex Site Manager has authorized issuance of this Quality Assurance Manual (QAM), and has committed Triconex to full compliance with the requirements therein. This QAM defines the essential practices and procedures required to assure that our products and services provide the highest level of quality attainable in all phases of our operation.

### 2. <u>DEPARTMENTS AFFECTED</u>

All departments

#### 3. SCOPE

The Quality System adopted by Triconex shall meet the requirements of ISO 9001:2000 and the Code of Federal Regulations, 10CFR50, Appendix B. These standards are implemented without any exclusions. It is the policy of Triconex to ensure that the requirements of these standards are understood, implemented, and maintained at all levels of the organization. In order to achieve this, the following Quality Policy and Company Values statements are adopted by the organization.

### 4. PROCEDURE

#### 4.1. QUALITY POLICY

INVENSYS TRICONEX IS COMMITTED TO SATISFYING CUSTOMER REQUIREMENTS BY IMPLEMENTING BEST PRACTICES AND BY CONTINUALLY IMPROVING THE EFFECTIVENESS OF THE QUALITY SYSTEM.

### 4.2. ENVIRONMENTAL, HEALTH AND SAFETY POLICY

Triconex shall comply with the environmental, health and safety policy of Invensys.

#### 4.3. COMPANY VALUES

- BE RESPONSIBLE TO CUSTOMERS NEEDS IN ALL PHASES OF OUR OPERATIONS
- PROVIDE THE HIGHEST LEVEL OF QUALITY ATTAINABLE IN ALL PHASES OF OUR OPERATIONS
- OPERATE PROFESSIONALLY WITH THE HIGHEST LEVEL OF HONESTY AND INTEGRITY
- DEVELOP AND GROW OUR EMPLOYEES
- BE MODEL CITIZENS IN ALL COMMUNITIES WHERE WE WORK

	Name	Signature	Title
Approvals:	Mike Phillips		Triconex Site Manager
	Paul Mesmer		Quality Director

Section:	QAM 1.1	Subject:	Qualit	y Pol			
Revision:	011	Page:	2	of	2	Date:	11/17/04

### 4.4. QUALITY OBJECTIVES

Quality objectives are determined periodically by Triconex management. These objectives shall be measurable, consistent with the quality policy, and communicated to all relevant functions and levels. The quality objectives shall be reviewed at appropriate intervals and, as a minimum, at the management review meeting (QAM 1.3).

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 1.3 Management Review

Section:	QAM 1.2	Subject:	Triconex Organization					
Revision:	018	Page:	1	of	10	Date:	06/15/06	

#### 1.0 PURPOSE

This procedure describes the functional organization of Triconex and defines the responsibilities and authorities within the organization. Triconex is a part of the Invensys Process Systems (IPS) Division of the parent company, Invensys, LLC. The Triconex Quality Program governs activities at the Triconex Irvine Facility. However, the Quality Program may also be applied to Triconex activities at the Webster Facility, or other locations, when specifically provided for in Triconex Procedures or Project Quality Plans.

#### 2.0 DEPARTMENTS AFFECTED

All departments

#### 3.0 SCOPE

This section of the Quality Assurance Manual (QAM), i.e., procedure, shall apply to the following groups within the Triconex Organization and, as applicable, other IPS Division groups supporting Triconex. Reporting relationships among groups are shown in Section 4.0 of this procedure and in upper level IPS Division management organization charts.

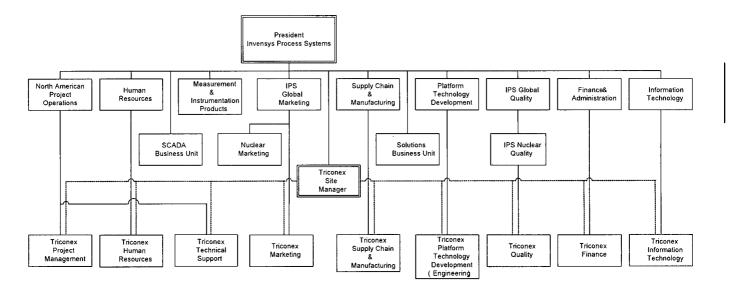
- Platform Technology Development (Engineering)
- Marketing
- Quality
- Information Technology
- Project Management
- Manufacturing
- Technical Support
- Human Resources
- Finance

	Name	Signature	Title
Author:	Ted Porfilio		Quality Assurance Engineer
Approvals:	Bob Rasmussen		Triconex Site Manager
	Paul Mesmer		Quality Director

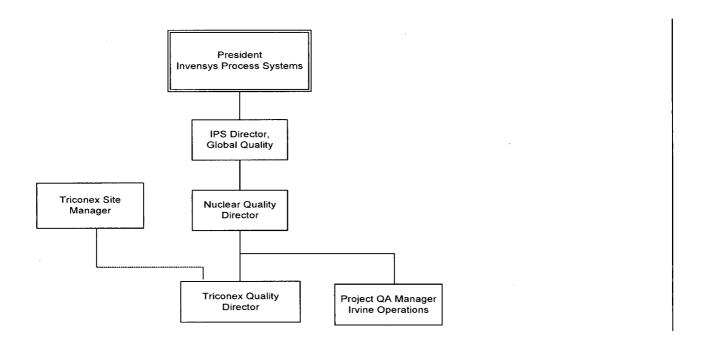
Section:	QAM 1.2	Subject:	Tricon	ex O	rganizati	on	
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## 4.0 PROCEDURE

### 4.1. ORGANIZATION CHART, IPS AND TRICONEX

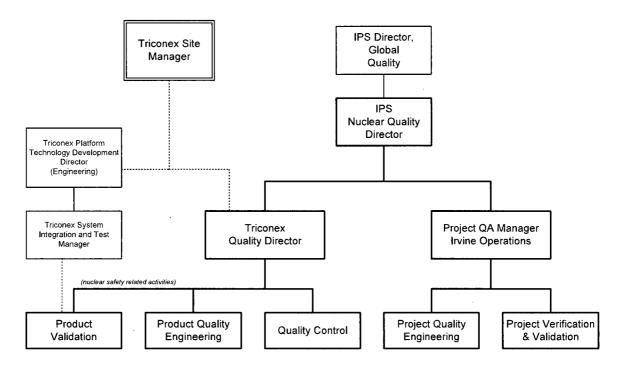


### 4.2. ORGANIZATION CHART, QA PROGRAM AUTHORITY



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#### 4.3. ORGANIZATION CHART, QUALITY ASSURANCE GROUPS



#### 4.4. RESPONSIBILITY FOR ORGANIZATIONAL CHARTS

Each group within the Triconex Organization shall prepare and maintain an organization chart showing personnel assignment within the organization. Personnel who have other employees reporting to them will be mentioned in the chart by function. Other personnel can be described by function group.

The organization chart shall clearly show who each person is reporting to. The chart shall be signed and dated. Vice Presidents or Directors in charge of departments are responsible for preparing and maintaining an up-dated chart for the department. Responsibilities should be defined in the department procedures.

#### 4.5. RESOURCES

#### 4.5.1. INTERNAL RESOURCES

Management shall identify, plan and provide adequate resources to effectively implement the quality management system and achieve the quality objectives. Resources shall be sufficient to maintain the quality system and to continually improve its effectiveness. Each group within the Triconex Organization shall identify resource requirements, provide adequate resources and assign trained personnel for management, performance of work and verification activities including internal audits. If personnel within any organization are not

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trained to do a specific task, the immediate supervisor is responsible to identify and request appropriate training. Meanwhile, the task may be performed by experienced temporary or contract personnel.

#### 4.5.2. OUTSOURCED RESOURCES

Controls for outsourced resources shall be determined and identified through the purchasing system.

### 4.6. RESPONSIBILITY AND AUTHORITY

Responsibility	Authority	QAM Reference
Management Review	Senior Management	QAM 1.3
Quality System	Quality Assurance	QAM 2.1
Contract Review	Quality Assurance	QAM 3.0
	Manufacturing	
	Nuclear Project Group	
Design Control	Engineering	QAM 4.0
	Nuclear Project Group	
Change Control	Engineering (CCB)	QAM 4.0
	Nuclear Project Group	
Document and Data Control	Engineering	QAM 5.1
	Manufacturing	
	Quality Assurance	
	Nuclear Project Group	
Purchasing	Manufacturing	QAM 6.0
	Nuclear Project Group	
Purchaser Supplied Product	Manufacturing	QAM 7.0
	Nuclear Project Group	
Identification and Traceability	Manufacturing	QAM 8.0
	Engineering	
	Nuclear Project Group	
Process Control	Manufacturing	QAM 9.0
Inspection and Testing	Manufacturing	QAM 10.0
	Quality Assurance	
	Product Assurance	
	Engineering	
	Nuclear Project Group	

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### 4.6. RESPONSIBILITY AND AUTHORITY (continued)

Responsibility	Authority	QAM Reference
Non-Conforming Product	Manufacturing (MRB)	QAM 13.2
	Nuclear Project Group	
Corrective/Preventive Action	Quality Assurance	QAM 14.0
	Product Assurance	
	Nuclear Project Group	
Material Handling	Manufacturing	QAM 15.0
	Nuclear Project Group	
Quality Records	Quality Assurance	QAM 16.0
	Manufacturing	
,	Engineering	
	Nuclear Project Group	
Internal Audits	Quality Assurance	QAM 17.0
Training	Human Resources	QAM 18.0
_	Each Department	
Servicing	Technical Support and	QAM 19.0
	Manufacturing	
Statistical Techniques	Quality Assurance	QAM 20.0

#### 4.7. TRICONEX INTERNAL/EXTERNAL INTERFACES

#### 4.7.1. INTERNAL INTERFACES

Triconex groups and Invensys Triconex Support groups interface on a routine basis at the Triconex facility in carrying out activities under the Triconex QA Program. In addition to personal interfacing and meetings, there are a number of standing boards or committees as defined in QA Program procedures, such as the QA Review Board (QARB), Change Control Board (CCB), Material Review Board (MRB), and Nuclear Oversight Board (TGM C-11). As a minimum, an annual Management Review Meeting is established to review QA issues (QAM 1.3).

Invensys Process Systems organizations provide corporate support to selected Triconex functions. Some of the more significant program areas are listed below along with their Invensys group interface.

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Invensys Group/Area	Triconex Program Area	QAM Reference
Customer Satisfaction	Technical Support Management Review Input	QAM 19.0 QAM 1.3, 1.4
Invensys Process Systems Field Offices Corporate Purchasing	Order Entry (new orders) RMA input Purchasing Data Maintenance	QAM 3.0 QAM 19.0 QAM 6.0
Human Resources	Training/Training Records	QAM 18.0
Corporate Quality Assurance	Corporate QA Policy Guidance and other QA issue support	QAM 1.1

#### 4.7.2. EXTERNAL INTERFACES

Triconex groups and Invensys Triconex Support groups have a number of external interfaces with:

- \* Other Invensys (Affiliate) groups (such as Sales Offices or other IPS product line groups engaged in joint projects with Triconex)
- \* Customers (such as visiting potential customer groups or audit teams)
- \* Regulatory or Certifying agencies

Activities associated with external interfaces are described, as necessary, in implementing procedures.

#### 4.8. TECHNICAL SUPPORT

Technical Support is responsible for the following functional responsibilities and authorities (see QPM 14.1 for additional detail):

- \* Primary Interface for Technical Issues
- \* Document Field Problems by Initiating Customer Contact Reports
- \* Troubleshoot Unexpected Events
- \* Initiate, monitor and implement corrective actions
- \* Customer interface for System Upgrades/RMA actions
- \* Provide Responses to Technical Inquiries
- \* Respond to Customer Complaints
- \* Maintain System Configuration Files
- \* Maintain Customer Net (web based site)
- \* Maintain E-mail Customer Mailing List
- \* Engineering Change Control Board (CCB) Interface
- \* Sales Order Interface

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- \* Generate Product Release Notices (PRNs)
- \* Generate Product Alert Notices (PANs) and other technical notices
- \* Provide Technical Publication Resources
- \* Provide Certified Product Training
- \* Enhance customer satisfaction by ensuring customer requirements are met.

### 4.9. TRICONEX QUALITY ASSURANCE (PRODUCT LINE)

The Triconex Quality Assurance Organization is an independent group within the Triconex product line organization with the authority and organizational freedom to identify quality problems, assure resolution, and verify implementation. The Triconex Quality Director reports directly to the IPS Nuclear Quality Director and is responsible for implementation of quality assurance strategies within the Triconex product line Organization. Among others, the following tasks, responsibilities and authorities are assigned to the Quality Assurance organization:

- \* Ensure that the requirements of ISO 9001 and, when applicable, the guidance of NOA-1 are met at all times.
- \* Monitor, maintain and, wherever possible, improve the quality system. This shall be achieved by conducting ongoing internal audits, preparing material for and participating in Management Review Meetings, analyzing quality related data such as receiving inspection reports, customer complaints, and third party audit reports with the objective to use the results to identify possible problem areas and initiate corrective or preventive action. See QAM 14.0. The need for improvement actions shall be communicated to top management.
- \* Perform quality control inspections for Triconex products.
- \* Perform, if necessary, vendor audits and source inspections in accordance with the requirements described in QAM 6.0.
- \* Identify the need for planning documents, procedures and Quality Plans to ensure that these documents are created in concert with existing procedures. Assist responsible personnel, where necessary, in creation of these documents. See QAM 2.2.
- \* Review and, where necessary, comment on all proposed procedure changes affecting Quality Assurance requirements. See QAM 2.2. Procedures related to Quality Assurance shall not be approved until all requirements defined in ISO 9001, this manual and, when applicable, the guidance of NQA-1 are met. See QAM 2.2.
- \* Plan, carry out and document a comprehensive system of internal audits, which will monitor and improve the effectiveness of the Quality System. See QAM 17.0.
- \* Monitor and participate in the non-conforming product control system. Assure disposition of non-conforming products and possible resulting corrective actions are completed in an orderly manner. See QAM 13.1.
- \* Determine if nonconforming conditions are reportable to the Nuclear Regulatory Commission (NRC) as required by 10CFR Part 21. See QAM 13.3.

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- \* Provide independent design validation and oversight of nuclear safety related (1E) Triconex products (see section 4.9.2 below).
- \* Ensure that archival quality records are maintained for the specified retention period and that they are retrievable. See QAM 16.0.
- \* Initiate Stop Work Memos. See QAM 2.1.
- \* Promote awareness of customer requirements.

The Triconex Quality Director may delegate authority and assign specific activities to other personnel to ensure that these tasks, responsibilities and authorities are implemented.

#### 4.9.1. QUALITY CONTROL

The Quality Control group is responsible for inspection of Triconex product activities associated with product line procurement, manufacturing, and shipping. Quality Control inspectors are fully independent from cost and schedule considerations.

#### 4.9.2. PRODUCT VALIDATION

The QA Product Validation Team (also referred to in some procedures as Product Assurance) is responsible for the independent validation of Triconex engineered products and product changes to confirm that stated requirements have been met. Product validation is carried out through independent testing of hardware and software in the Product Assurance Laboratory. Validation includes review and audit of engineering development documents. The Product Validation Team is responsible for various other quality interface functions with the Engineering department, including review and approval of engineering documents.

For all nuclear safety related (1E) Triconex products, the Product Validation Team Leader reports directly to the Quality Director for organizational independence in validation activities. For standard commercial products, the Validation Team reports to the System Integration and Test Manager. The Product Validation Team Leader utilizes matrixed personnel from the System Integration and Test group to perform validation under his/her direction. The System Integration and Test group is not responsible for performing design, but participates in providing verification and validation services to the responsible Engineering design groups. It is a strict requirement that Product Validation Team personnel shall not participate in the validation of any software or hardware systems for which they had design participation.

### 4.10. PROJECT QUALITY ASSURANCE

The Project QA group is responsible for oversight of all application project integration activities of the North American Project Operations organization conducted at the Triconex Irvine facility. This group, which reports to the Project QA Manager, is separate from the Triconex Quality Assurance Organization, but under the Triconex QA program and interfaces closely with the Triconex Quality Director. Among others, the following tasks, responsibilities and authorities are assigned to the Project Quality Assurance group:

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- \* Provide QA support, surveillance and audit of Project Management activities
- \* Identify the need for planning documents, procedures and Quality Plans to ensure that these project activities are conducted in accordance with generic QA requirements (primarily for nuclear projects) and meet the unique requirements of each customer application project. Prepare Quality Planning documents as defined in Project Procedures Manual (PPM).
- \* Conduct reviews of project documents to ensure that the requirements of ISO 9001 and, when applicable, the guidance of NQA-1 and other industry standards required by project-specific documents are met.
- \* Monitor and participate in actions to improve the quality system. Identify possible problem areas and initiate corrective or preventive action. Assist in resolving ARRs and other corrective action documents. See QAM 14.0.
- \* Perform quality control inspections for Project Integration activities in accordance with PPM procedures.
- \* Perform, if necessary, vendor audits and source inspections in accordance with the requirements described in QAM 6.0.
- \* Review and, where necessary, comment on all proposed procedure changes affecting Project Quality Assurance requirements.
- \* Monitor and participate in the non-conforming project material control system. Assure disposition of non-conforming products and possible resulting corrective actions are completed in an orderly manner.
- \* Determine if nonconforming conditions are reportable to the Nuclear Regulatory Commission (NRC) as required by 10CFR Part 21. See QAM 13.3.
- \* Ensure that archival quality records are maintained for the specified retention period and that they are retrievable. See QAM 16.0.
- \* Provide independent design validation and oversight in accordance with PPM procedures and customer specific project documents.
- \* Monitor and/or conduct testing activities system as defined in the applicable Project Quality Plan.

The Project QA Manager may delegate authority and assign specific activities to other personnel to ensure that these tasks, responsibilities and authorities are implemented.

# 4.11. IPS GLOBAL QUALITY ASSURANCE

Invensys Process Systems (IPS) QA provides oversight and guidance on quality policies and activities to various Invensys groups, including Triconex. This includes oversight and guidance on policies and activities related to nuclear customers, projects and orders. IPS Global QA may provide specialized expertise or direct support to Triconex, under the Triconex QA Program, for designated tasks, such as audits, reviews or problem resolution.

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#### 4.12. MANAGEMENT REPRESENTATIVE

The Triconex Quality Director shall act as the Senior Management representative for all quality related items within the Triconex Organization. The Quality Director has the responsibility:

- a) To ensure that Quality System requirements are established, implemented and maintained in accordance with the ISO 9001 standard, NQA-1 (10CFR50, Appendix B), and the policies and procedures of this manual.
- b) To report the performance of the Quality System to management for review as a basis for improvement of the Quality System.
- c) To ensure top management communicates the importance of meeting customer, regulatory and legal requirements.
- d) To ensure that quality objectives are established for the organization.
- e) To ensure the integrity of the Quality System is maintained when changes are planned and implemented.

A representative of the Quality Assurance organization shall act as the Quality Assurance interface for all internal and external customers as well as all departments within the Triconex Organization.

#### 4.13. TRICONEX SITE MANAGER

The Triconex Site Manager, as reflected in Sections 4.1, 4.2 and 4.3, is designated the senior manager at the Triconex Irvine facility, responsible for overall resource coordination, and with authority to approve the Triconex QA Manual.

### 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 1.1	Quality Policy
QAM 1.3	Management Review
QAM 2.1	Quality System
QAM 2.2	Quality System Procedures
QAM 6.0	Purchasing
QAM 13.1	Control of Nonconforming Product
QAM 13.3	10CFR Part21 Reporting of Defects and Noncompliance
QAM 14.0	Corrective and Preventive Action
QAM 16.0	Quality Records
QAM 17.0	Internal Quality Audits
QPM 13.4	Stop Work Memo
TGM C-11	Nuclear Oversight Board

# QAM 1.3 MANAGEMENT REVIEW

Revision: 012

Effective Date: September 25, 2006

	Name	Signature	Title	Date
Author:	Ted Porfilio		Quality Assurance Engineer	09/13/06
Approvals:	Bob Rasmussen		Triconex Site Manager	09/15/06
	George Hughes		Project Quality Manager	09/13/06
	Paul Mesmer		Product Quality Director	09/15/06

Procedure:	QAM 1.3	Title:	Management Review						
Revision:	012	Page:	2	of	5	<b>Approval Date:</b>	09/15/06		

## **CHANGE SUMMARY**

Reason for Change	Summary of Changes*
1) To implement the requirements of QAM 2.2, Revision 15.	1) Format changes consistent with QAM 2.2, Revision 015; change bars are not included for these changes.
2) Consistency with the actual operating practices associated with management self-assessment activities.	2) Modified/deleted requirements that were overly restrictive in practical application.
	3) Editorial changes for overall procedure consistency.

<sup>\*</sup>Specific changes to the procedure are indicated by vertical lines in the right margin.

### **CHANGE IMPLEMENTATION**

All requirements of this procedure shall be implemented as of its Effective Date. Management Review activities that are in process as of the Effective Date shall comply with all new and/or changed requirements at that time.

Procedure:	QAM 1.3	Title:	Mana	gemen	t Revie	W	
Revision:	012	Page:	3	of	5	Approval Date:	09/15/06

#### 1.0 PURPOSE

This procedure establishes requirements for evaluating the effectiveness of the Triconex Quality System.

#### 2.0 AFFECTED ORGANIZATIONS

All Triconex Departments
North American Project Operations (NAPO)

#### 3.0 SCOPE

Senior management plans and implements monitoring, measuring, analysis and improvement processes to continually improve the effectiveness of the quality management system. Management Review Meetings form an integral part of the Triconex Quality System.

#### 4.0 **PROCEDURE**

#### 4.1 CONTINUAL IMPROVEMENT

Senior management shall initiate objectives to continually improve process effectiveness. This is accomplished by measuring and analyzing processes, implementing changes and monitoring improvement progress. Opportunities for continual improvement may be accomplished using data sources such as:

- Results of audits
- Analysis of data
- Corrective and preventive actions
- Quality policy
- Quality objectives
- Management review meetings

In addition, metrics can be used as data sources for continual improvement. Metrics may include:

- Cost of quality
- Test yield
- Supplier performance
- Corrective actions (ARRs, SIDRs, etc.)

#### 4.2 MANAGEMENT REVIEW MEETING

The Quality System will be reviewed by senior management whenever it is deemed necessary, but with a minimum frequency of once per calendar year. If possible, the Triconex Site Manager and all upper management will attend the meeting. The objective of the meeting is to improve the effectiveness of the Quality System (QAM 2.1).

Procedure:	QAM 1.3	Title:	Mana	gemen	nt Revie	W	
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#### 4.2.1 AGENDA

Prior to each review meeting, an agenda will be developed and distributed to attendees. The agenda will include items to be reviewed and discussed with focus on needed changes:

- Quality policy changes
- Quality objectives review
- Audit results (QAM 17.0)
- Customer Satisfaction Survey (QAM 1.4) and customer support issues
- Development trends and improvement actions
- Process performance
- Product conformity
- Preventive and corrective actions status
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality system
- Continuous Improvement Activities
- Quality Improvement Plan follow-up and additions

The review/discussion may also include evaluating the various departments within the organization to ensure the quality of items, services, or processes as well as how they contribute to the improvement and effectiveness of the system.

#### 4.2.2 MEETING OUTPUT

Minutes of the Management Review Meeting shall be recorded. The minutes shall include the meeting date, a list of attendees, identification of items reviewed, decisions made and actions taken, as applicable.

Minutes of Management Review Meetings shall be considered Quality Records (QAM 16.0).

#### 4.3 MANAGEMENT SELF-ASSESSMENT

Each Triconex Department, including NAPO for application projects conducted at Triconex, regularly assesses the processes for which it is responsible. The intent of these self-assessment reviews is to identify management process weaknesses and barriers that hinder achievement of quality objectives and to ensure continuous improvement in terms of processes, products and services. These are in addition to the normal audits and surveillances performed by the Quality Department.

Department self-assessment reviews should address the following:

- Review Department policies and procedures to ensure that they are concise, adequate and serve their intended purpose
- Review training needs of current and new employees
- Review training programs for new employees and make improvements based on the past year's experience
- Review the Department's understanding of quality policies and procedures

Procedure:	QAM 1.3	Title:	Mana	gemen	t Revie	W	
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 Review the Department's performance in terms of following quality policies and procedures

A summary report of Department self-assessment activities should be generated and provided to the Triconex Site Manager in support of the annual Management Review Meeting. Internal monitoring of policy and procedure compliance may be planned and documented on a "Quality System Self-Assessment Report", Form Q0030, available from Quality Assurance.

Self-assessment activities should be reviewed as part of the annual Management Review Meeting.

#### 5.0 REFERENCES AND RELATED PROCEDURES

QAM 1.4	Customer Satisfaction Survey
QAM 2.1	Quality System
QAM 2.3	Quality Planning
QAM 14.0	Corrective and Preventive Action
QAM 16.0	Quality Records
QAM 17.0	Internal Quality Audit
Form Q0030	Quality System Self Assessment Report

Section:	QAM 1.4	Subject:	Customer Satisfaction Survey					
Revision:	003	Page:	1	of	2	Date:	8/15/03	

#### <u>1.</u> <u>PURPOSE</u>

To define a procedure for implementing a Triconex Customer Satisfaction Survey.

### 2. <u>DEPARTMENTS AFFECTED</u>

All

### 3. SCOPE

One of the primary elements of the Triconex Product Line Quality Policy (QAM 1.1) is to meet the current and future needs of our customers. Company Values include the intent to "be responsive to customers' needs in all phases of our operations." The Customer Satisfaction Survey provides a method for Triconex management to monitor the success achieved in these areas.

### 4. PROCEDURE

#### 4.1. GENERAL

A Customer Satisfaction Survey will be performed on a periodic basis in support of

- 1) The company policies of QAM 1.1
- 2) ISO 9001 objectives for
  - Achieving customer satisfaction
  - Management review for continuing suitability and effectiveness of the quality system.

This survey is normally conducted using outside contractors to assure independence and validity of results. Invensys Customer Satisfaction Center (CSC) has responsibility for Customer Satisfaction Survey activities, including general direction of the survey contractor. Triconex management participates in data collection and analysis related to Triconex products and services, and takes action on survey results as appropriate to improve the Triconex quality program.

#### 4.2. DATA COLLECTION

On a quarterly basis, the designated survey agency shall solicit information on routine customer contacts related to technical support and product performance.

The Invensys Customer Satisfaction Center (CSC) will extract, on a regular basis, data pertaining to customers that have been contacted in the previous period. That information will be specific to Triconex product line support activities.

	Name	Signature	Title
Approvals:	Tracey Sledge		VP & General Manager, Triconex
	Paul Mesmer		Quality Director

Section:	QAM 1.4	Subject:	Customer Satisfaction Survey						
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The contracted survey agency shall use this data to perform telephone surveys with a sampling of recent Triconex customer contacts. These surveys shall establish the level of satisfaction of the customers in their dealings with the Triconex product line technical support.

#### 4.3. DATA ANALYSIS AND RESULTS

The survey agency shall collate, evaluate, and provide the results in a formal Customer Satisfaction Report for the survey period. Survey results shall be categorized in the primary areas of customer contact such as technical support and product quality. Current period results shall be reported as well as longer-term trending information. Graphical and tabular information suitable for management review shall be provided in the report.

#### 4.4. MANAGEMENT REVIEW & ACTION

In order to enhance customer satisfaction, management shall ensure customer requirements are met. Upon issuance, the Customer Satisfaction Survey Report shall be distributed to Triconex product line management. Additional distribution to selected management will be made at the discretion of the Technical Support Manager.

It is the responsibility of each area primary recipient to review the report and initiate corrective actions where warranted by the survey results. Customer Satisfaction Survey results will be included in the agenda of the Triconex Management Review Meetings (reference QAM 1.3).

### 4.5. QA RECORDS

Customer Satisfaction Survey Reports shall be maintained as Quality Records in accordance with QAM 16.0. Minimum retention time shall be two years.

### 5. REFERENCES AND RELATED PROCEDURES

QAM 1.1 Quality Policy

QAM 1.3 Management Review

QAM 16.0 Quality Records

Section:	QAM 2.1	Subject:	Qualit	y Sys	tem		
Revision:	012	Page:	1	of	7	Date:	08/05/05

### 1.0 PURPOSE

This Procedure describes the Triconex Quality System.

## 2.0 DEPARTMENTS AFFECTED

All Departments

### **3.0 SCOPE**

This procedure together with QAM 2.2 and QAM 2.3 describes the Quality Assurance System in use by Triconex. This system is structured around the ISO 9001 standard and 10CFR50, Appendix B, and applies to all levels of the operation.

## 4.0 PROCEDURE

### 4.1. GENERAL

The Quality Assurance System shall meet all the requirements of ISO 9001-2000 and 10CFR50, Appendix B, utilizing guidance from NQA-1-1994, and shall be inclusive of the requirements of IPS Quality Manual IPS-Q1 and IPS Nuclear Quality Manual IPS-Q2. Reference to specific standards and requirements, including their level of applicability, shall be included in Department manuals/procedures, where appropriate, and quality plans, as necessary.

The requirements for control, maintenance and documentation of the quality system are described in detail in the procedures of the Quality Assurance Manual (QAM). Specific requirements related to certain Departments are described in lower level documents.

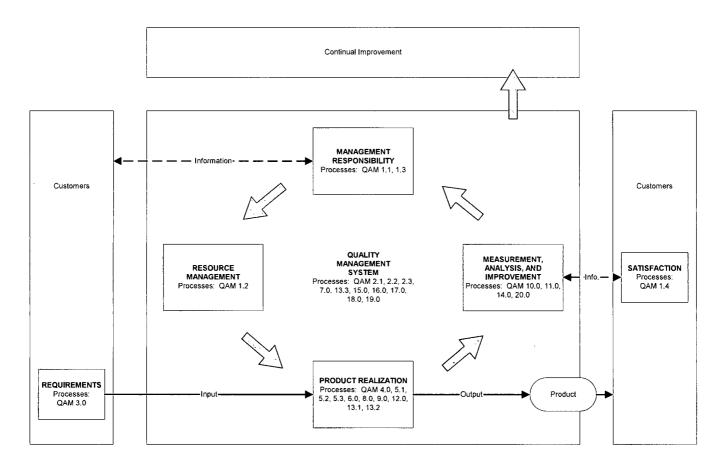
### 4.2. PROCESS APPROACH

The management of the organization and its processes can best be described by the process approach. The quality management system relies on the interaction between processes through a series of inputs and outputs. Customer requirement input and customer satisfaction feedback are critical components. Continual improvement is an important byproduct of the process. The procedures that address each element of the quality management system are indicated on the following flow diagram.

	Name	Signature	Title
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Approvals:	Mike Phillips		Triconex Site Manager
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## **Quality Management System Processes**



### 4.3. HIERARCHY OF DOCUMENTS

There are three levels of documents within the Quality System. The QAM is considered to be the highest level document. The Quality Director is responsible for implementation, maintenance, and control of the QAM. The Triconex Site Manager and the Quality Director shall approve all procedures within the QAM. The second level of documents is organized in departmental Manuals. These manuals contain all departmental Policies, Standards and Procedures. All documents in each manual shall be approved by the Quality Director or designee prior to issue. All other controlled documents are considered third-level documents. The development, approval, issuance, and control of third level documents are described in their governing first or second level procedures.

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#### 4.3.1. POLICIES

A Policy is used to describe a definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions. A policy may be an Invensys Corporate Policy, a Triconex Company Policy, or a Triconex Department Policy.

#### 4.3.2. STANDARDS

A standard is defined as a document describing a model or an example. Triconex shall adopt national and international standards where possible and/or required. Triconex may develop its own standards where national or international standards are not available or are inadequate. These standards shall be unambiguous. If a standard is referenced in or included in a procedure, the standard shall be adhered to in its entirety or the procedure shall identify the applicable parts/sections of the standard.

#### 4.3.3. PROCEDURES

A procedure is used to describe mandatory rules, actions or processes. Procedures can refer to Standards and Policies. When it is necessary to explain a Policy or set a Standard, and it is not feasible to create a separate Standard or Policy, it is acceptable to include the Policy and/or Standard in the Procedure.

**Note**: Within this manual the term 'Procedure' shall be used to refer to Policies, Standards and Procedures.

#### 4.3.4. VERBATIM COMPLIANCE

All procedures shall be followed verbatim. If a procedure cannot be followed as written, the user of that procedure shall immediately inform their supervisor of the procedure problem. The supervisor shall determine if the problem meets the requirements of an Emergency Procedure as described in Section 4.6 or an Interim Change Notice (ICN) as described in Paragraph 4.6.1. If the procedure problem does not meet any of these requirements, a revision to the affected procedure shall be processed and approved before the procedure can be used for any further activities.

#### 4.3.5. ANALYSIS OF DATA

Management shall determine the appropriate data to be collected and analyzed to demonstrate the suitability and effectiveness of the quality system. This data shall come from monitoring and measuring relevant processes including production results and customer field experience. One outcome of the analysis shall be specific areas where continual improvement is warranted. Preventive action opportunities shall also be investigated based on the process and product data.

A measurement of customer satisfaction shall be analyzed. Product requirements shall be checked for conformance. The performance of suppliers shall be monitored as well.

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#### 4.3.6. QUALITY ASSURANCE MECHANISMS

There are two basically independent mechanisms to ensure the effectiveness of the quality management system.

- a) A closed loop system of internal auditing, corrective and preventive action to ensure that the day to day activities conform to the requirements. The results of the internal audits and corrective actions are reported to the Quality Director (also see QAM 17.0) and used as inputs to the management review process.
- b) A periodical review of the Quality System by Senior Management (also see QAM 1.3). This review can result in adjustment of the Quality System to improve effectiveness, the development of a Quality Improvement Plan, or the adjustment of targets within a Quality Improvement Plan (see QAM 2.3). Conditions or potential process changes which could decrease the effectiveness of the Quality Program shall be brought to the attention of Senior Management.

### 4.4. COMMUNICATION TO EMPLOYEES

Senior management has established communication processes regarding the effectiveness of the quality management system. The m ethods i nclude, but a re not 1 imited t o, t he following:

- Procedures
- Company meetings
- Bulletin boards placed throughout the facility
- Team meetings
- Electronic media, including email and web sites

Communication regarding effectiveness takes place through a combination of the methods noted. Responsibilities and authorities are communicated in a similar manner.

### 4.5. CHANGES TO QUALITY MANAGEMENT SYSTEM

Any changes are planned and implemented to maintain the integrity of the quality system. Planning may involve flow charts, procedures, etc., to predict the impact of the change.

### 4.6. EMERGENCY PROCEDURES

The Quality Director may issue an Emergency Procedure if any of the following conditions exist:

- a) A major discrepancy is found between the requirements of ISO 9001 and existing procedures.
- b) A major discrepancy is found between actual working practice and an existing procedure.
- c) A criticality 1 or 2 Product Discrepancy Report is initiated. (QPM 13.2).

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If an existing procedure cannot be followed and is urgently needed to permit continued use, the procedure shall be marked-up (in red). The mark-ups shall be approved (initialed) and dated by the responsible department management and by QA. Each page of the procedure shall be clearly marked in red as "EMERGENCY PROCEDURE".

If there is no existing procedure, a working copy of a procedure shall be developed that adequately describes the steps necessary to complete the required actions and shall be approved by the responsible department management and by QA. Each page of the working copy shall be clearly marked in red as "EMERGENCY PROCEDURE".

The Emergency Procedure should only be used for special situations, where rapid responses are required, and existing procedures do not adequately handle the situation. When an Emergency Procedure is necessary, existing procedures should be reviewed after the emergency has been handled, to see if the existing procedures need improvement.

The emergency procedure is a way to ensure that the requirements of ISO 9001 are met at all times, to improve the effectiveness of the system and to ensure that changes in the Quality System are documented at the time of implementation. Completed emergency procedures are regarded as quality records and handled in accordance with QAM 16.0.

#### 4.6.1. INTERIM CHANGE NOTICE

An Interim Change Notice (ICN) is intended to implement changes to a drawing or procedure that are required to immediately correct the document's requirements in order to maintain verbatim compliance and allow continuation of the work activity with a minimum of interruption. An ICN is considered a permanent change to the affected drawing or procedure and, as such, ICNs are subject to the same document controls as the affected document.

For production (manufacturing) activities, an ICN requires additional processing to incorporate the change into the AGILE document system or else expire automatically after 30 days. For nuclear project integration activities, ICNs shall be incorporated into the next revision of the affected document. All ICNs shall be cancelled upon incorporation into the affected document or expiration.

Completed ICNs are Quality Records and shall be processed in accordance with QAM 16.0.

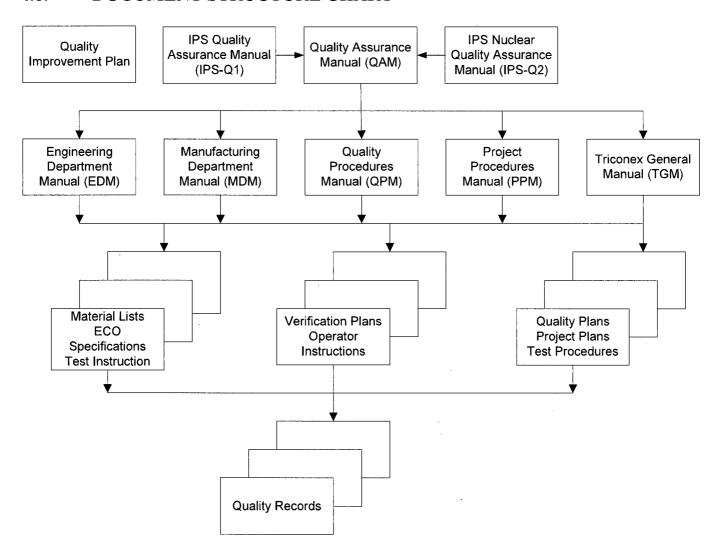
## 4.7. STOP WORK PROCEDURE

The Triconex Site Manager and the Quality Director each have the authority and responsibility to issue a Stop Work Memo in cases where applied workmanship, performed operations or tests, used material, violation of existing procedures or any other cause could result in compromising the quality of the final product or the safety of personnel or equipment. A Stop Work Memo can also be issued to halt the processing and shipment of product affected by a Product Discrepancy Report (PDR).

All affected Departments shall comply with a Stop Work Memo until such time as it is formally rescinded by the issuing authority.

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### 4.8. DOCUMENT STRUCTURE CHART



**NOTE:** The documents shown in the above chart are not inclusive. Each Quality System procedure identifies the documents related to that procedure or process.

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## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 1.3	Management Review
QAM 2.2	Quality System Procedures
QAM 2.3	Quality Planning
QAM 4.0	Design Control
QAM 17.0	Internal Quality Audit
QPM 13.2	Product Discrepancies
PPM 3.0	Drawing Preparation and Control
PPM 6.0	Test Controls
MDM 5.1	Manufacturing Document and Data Control
IPS-Q1	IPS Quality Manual
IPS-Q2	IPS Nuclear Quality Manual
NQA-1-1994	Quality Assurance Requirements for Nuclear Facility Applications
ISO 9001:2000	Quality Management Systems-Requirements

## QAM 2.2 QUALITY SYSTEM PROCEDURES

Revision: 015

Effective Date: October 16, 2006

	Name	Signature	Title	Date
Author:	Ted Porfilio		Quality Assurance Engineer	09/13/06
Approvals:	Bob Rasmussen		Triconex Site Manager	09/15/06
	George Hughes		Project Quality Manager	09/13/06
	Paul Mesmer		Product Quality Director	09/15/06

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## **CHANGE SUMMARY**

#### COMPLETE REVISION - CHANGE BARS NOT INCLUDED

Reason for Change	Summary of Changes*
1) Allow Quality System procedures to act as stand-alone documents within their respective manuals and allow for an implementation period.	1) Revised manual and procedure format requirements and the method of their issuance consistent with the Reason for Change.
2) Clarify the procedure with regard to current distribution and control practices.	2) Implemented requirements for an "Effective Date" and Change Implementation statement.
3) NMC/Dominion Audit 2005-0106, Finding 2005-106-08.	3) Enhanced the requirements regarding electronic versions of manuals and procedures.
4) Ensure a clear understanding of responsibilities and authorities for the implementation of procedure requirements and to eliminate the use of the phrase	4) Added a requirement for Department manuals and procedures to flow down the requirements of the QAM.
"or designee" throughout Quality System procedures.	5) Added a statement related to the responsibility and authority for implementing the requirements of
5) Transfer of responsibility for the Project Procedures Manual (PPM) to North American Project Operations (NAPO).	Quality System procedures.  6) Adjusted approval authorities for QAMs, QPMs and PPMs.
6) Assignment of a Project Quality Manager consistent with QAM 1.2, Triconex Organization.	7) Adjusted the responsibilities for the training of Project Quality Assurance personnel.

<sup>\*</sup>Specific changes to the procedure are indicated by vertical lines in the right margin.

## **CHANGE IMPLEMENTATION**

The back fit of changed format requirements is not required; manuals and procedures shall be updated to the new format requirements as they are revised after the Effective Date of this procedure. Procedures that are in the signature cycle as of the Effective Date of this procedure may continue to be processed without change. The signature authorities for Project Procedure Manual (PPM) procedures and the responsibilities for training Project Quality Assurance personnel shall be effective immediately upon approval of this procedure.

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### 1.0 PURPOSE

This procedure establishes the requirements for the preparation, review, approval, issuance and control of Triconex Quality System manuals and procedures.

### 2.0 AFFECTED ORGANIZATIONS

All Triconex Departments
North American Project Operations (NAPO)

## 3.0 <u>SCOPE</u>

This procedure is applicable to all Triconex Quality System manuals and procedures (Section 4.1).

## 4.0 PROCEDURE

### 4.1. GENERAL

Quality standard ISO 9001 requires that a supplier document and maintain a Quality System in order to ensure that their products and services conform to specified requirements. Additionally, 10CFR50, Appendix B requires that activities affecting quality be prescribed by and performed in accordance with documented instructions, procedures or drawings of a type appropriate to the circumstances. The Triconex Quality System implements these requirements.

The Quality Assurance Manual (QAM) is the highest level document within the Triconex Quality System. The Quality Procedures Manual (QPM), Manufacturing Department Manual (MDM) and Engineering Department Manual (EDM) are Department manuals and the Triconex General Manual (TGM) is a general manual that may cover several Departments within Triconex. These manuals, and their inclusive procedures, form the basis of the Triconex Quality System. In addition, for NAPO application projects conducted at Triconex, the NAPO Project Procedures Manual (PPM) is subject to the requirements of the Triconex QAM and, for the purposes of this procedure, the PPM shall be considered a Department manual within the Triconex Quality System. Note that quality plans are an extension of the Triconex Quality System; however, the requirements for these documents are addressed by other Triconex Quality System procedures.

All Department manuals and procedures shall flow down the requirements of the QAM without exception. Conflicts between the requirements of the QAM and Department manuals and procedures shall immediately be brought to the attention of the Product Quality Director for resolution, except for PPM conflicts with the QAM, which shall be brought to the attention of the Project Quality Manager for resolution.

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The Product Quality Director and Project Quality Manager, as applicable, have overall responsibility for the integrity of the Triconex Quality System and Department management is responsible for implementation of the system. In addition, the Product Quality Director and Project Quality Manager, as applicable, are responsible for the format, consistency and professionalism of all Quality System procedures.

Throughout all Quality System procedures, it is understood that the authority to execute an assigned responsibility may be delegated to a qualified individual by the responsible individual; however, responsibility for the assigned activity cannot be delegated without a revision to the governing procedure.

## 4.2. QUALITY ASSURANCE MANUAL

#### 4.2.1. **RESPONSIBILITIES**

The Product Quality Director is responsible for the maintenance and control of the QAM. The Triconex Site Manager, the Product Quality Director and the Project Quality Manager shall approve all QAM procedures prior to their release for use, i.e., Approval Date (Paragraph 4.2.3).

#### 4.2.2. MANUAL LAYOUT AND PROCEDURE FORMAT

#### 4.2.2.1. MANUAL LAYOUT

The procedures in this manual are arranged consistent with the numbering scheme of relevant paragraphs in the ISO-9001:1994 standard. Refer to ISO 9001:2000, Annex B for a cross-reference numbering scheme between the ISO 9001:2000 and ISO 9001:1994.

Procedures 0.X of the QAM define its scope and philosophy and identify its current contents:

QAM 0.0, Introduction

QAM 0.1, Table of Contents

OAM 0.2, Quality System Compliance Cross-Reference

Procedures 1.1 through 20.X of the QAM are its contents as identified by the Table of Contents.

#### 4.2.2.2. PROCEDURE FORMAT

All QAM procedures, except 0.0, 0.1 and 0.2, shall have the same format, including these major Sections:

- 1.0 PURPOSE
- 2.0 AFFECTED ORGANIZATIONS
- 3.0 SCOPE
- 4.0 PROCEDURE
- 5.0 REFERENCES AND RELATED DOCUMENTS

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All QAM procedures, except 0.0, 0.1 and 0.2, shall include the following:

- A title page identifying the QAM procedure number, title, revision, Approval Date and Effective Date. Additionally, the title page shall include a signature block for the author, Triconex Site Manager, Product Quality Director and Project Quality Manager.
- Subsequent pages of a QAM procedure shall include a header identifying the QAM procedure number, title, revision, page number, total number of pages and Approval Date.
- The second page of a QAM procedure shall be a Change Summary and Change Implementation statement. The reason(s) for change shall be included in the Change Summary and requirements regarding the implementation of the changes, including new or revised forms, shall be included under Change Implementation.

Quality Records pertinent to or generated by a procedure's activities shall be specifically addressed within the body of the procedure; see Section 4.4 for an example of a method to satisfy this requirement.

The changes to the QAM implemented via this revision of QAM 2.2, i.e., Revision 015, shall act as a format template for all subsequent changes to QAM procedures.

#### 4.2.3. ISSUE AND REVISION CONTROL

All procedures shall include an Approval Date and an Effective Date:

- The Approval Date represents the date that a procedure is available for activities such as training and implementation planning. This date is the date that the procedure is signed by the Product Quality Director. The new or changed requirements of the procedure may be implemented any time after the Approval Date, but implementation is not mandatory.
- The Effective Date represents the date that the procedure's new or changed requirements must be implemented. That is, from the Effective Date forward, all activities shall be in compliance with the new or changed requirements. Activities that are in process as of the Effective Date shall be governed by the Change Implementation statement.

Procedures 0.0, Introduction, and 0.2, Quality System Compliance Cross-Reference, of the QAM are generally static documents and are only reissued when they are revised. These procedures do not require a Title Page and a Change Summary/Implementation page; however, all pertinent information from the Title Page shall be incorporated into the document. The Effective Date for these procedures shall equal their Approval Dated.

Procedure 0.1, Table of Contents, authorizes the contents of the QAM and it shall be reissued with each change to the contents of the QAM. The Table of Contents shall be

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identified with a header that includes its Approval Date and identification of its revision level. The Effective Date for the Table of Contents shall equal its Approval Dated. All procedures contained in the QAM shall be listed on the Table of Contents, including their current revision level and Approval Date. The Table of Contents shall also include a signature block for the Triconex Site Manager and Product Quality Director and its revision level shall be incremented by one (1) each time a new Table of Contents is approved. Additionally, a Title Page and a Change Summary/Implementation page are not applicable to the Table of Contents.

Changed text within each QAM procedure shall be indicated by a vertical bar in the right margin of the procedure to positively identify requirement changes. Vertical bars, i.e., change bars, are not required for editorial changes such as grammar corrections, title changes, format changes and changes for procedure wording consistency; however, a summary of such changes shall be included in the Change Summary. For complete revisions of a procedure, change bars are not required, but a statement indicating that they have been omitted shall be included on the procedure's Change Summary page.

#### 4.2.4. PROCEDURE CHANGE COORDINATION

Changes to the QAM shall be reviewed to ensure that they are not in conflict with Quality Program requirements or reduce the overall effectiveness of the Quality Program.

If it becomes necessary to issue a new or revise a QAM procedure, the Product Quality Director, in conjunction with the Project Quality Manager, shall determine if Department review is required based upon the need for Department feedback regarding the potential impact of the new or revised requirement(s). If Departmental review is required, a draft of the new or revised procedure shall be made available to all affected Departments for review and comment, which may be conducted electronically. Each affected Department shall review the proposed new or revised QAM procedure to determine if the change affects any of the Department's procedures. The results of the review shall be forwarded to the Product Quality Director, which may be performed electronically. At the discretion of the Product Quality Director, documentation of the review and comment process may be maintained in Quality Assurance Organization (QAO) files.

It is the responsibility of the Product Quality Director to ensure that all Triconex personnel are notified when there is a change to the QAM; such notification may be performed electronically. It is also the responsibility of the Product Quality Director to ensure that Triconex Product Line Quality Assurance personnel are trained, as appropriate, upon issuance of these changes. It is the responsibility of the Project Quality Manager to ensure that Project Quality Assurance personnel are trained, as appropriate, on changes to the QAM. It is the responsibility of Department management to ensure that their personnel are trained, as appropriate, on changes to the QAM. Where necessary, for significant QAM changes, training assistance may be provided to the Departments by the Product Quality Director. Training shall be in accordance with the requirements of QAM 18.0, Training.

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#### 4.2.5. MANUAL DISTRIBUTION AND CONTROL

There are two types of distribution made of the QAM, "Controlled" and "Uncontrolled". The "Uncontrolled" copies are only supplied as a source of information about the Triconex Quality System. "Controlled" copies are considered the only official working copies of the QAM and individuals implementing the QAM shall only perform their activities in accordance with the requirements of "Controlled" copies.

The Product Quality Director is responsible for the distribution and control of the QAM and its inclusive procedures.

### 4.2.5.1. CONTROLLED COPIES

The QAM shall be available in electronic form on the IPS SharePoint website located at <a href="http://ips-sharepoint1.invs.com/quality/TriconexIrvQA/default.aspx">http://ips-sharepoint1.invs.com/quality/TriconexIrvQA/default.aspx</a>. This on-line version of the QAM is the only "Controlled" copy of the QAM within Invensys Process Systems (IPS) and it is considered current for use when viewed on the SharePoint website. Printed copies from this website are "Uncontrolled" and these copies are automatically annotated as to their "Uncontrolled" status. All copies of the QAM, whether annotated or not, are considered "Uncontrolled" and it is the responsibility of the user to ensure that a printed copy represents the latest approved issue prior to its use.

For customers of Triconex that require a "Controlled" copy of the QAM, the Product Quality Director shall address such requests on a case-by-case basis. The method of control for these copies of the QAM shall be at the discretion of the Product Quality Director.

#### 4.2.5.2. UNCONTROLLED COPIES

When there is a request for an "Uncontrolled" hardcopy of the QAM, this request shall be coordinated by the Product Quality Director. Depending on the nature of the request, the Product Quality Director shall determine if the recipient should receive an "Uncontrolled" hardcopy. Such copies of the QAM will not be updated and the provided copy of the QAM shall be clearly marked with the following:

#### "UNCONTROLLED COPY"

The Product Quality Director may recall any "Uncontrolled" copy of the QAM at any time.

### 4.3. DEPARTMENT MANUALS AND PROCEDURES

#### 4.3.1. RESPONSIBILITY

Each Department within Triconex is responsible for developing, issuing and maintaining its own Department manuals and procedures. The Quality Assurance Organization (QAO) can assist in this process, but should not be considered the driving force. Department manuals within the Triconex Quality System include the Quality Procedures Manual (QPM), Manufacturing Department Manual (MDM), Project Procedures Manual (PPM), Triconex

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General Manual (TGM) and Engineering Department Manual (EDM). Department manuals and procedures shall be approved by the responsible Department's management and the Product Quality Director, except for PPMs, which shall be approved by the IPS Project Operations Director, Nuclear and the Project Quality Manager. Additional approvals may be included as directed by Department management.

The procedures contained in Department manuals are the most important tools for documenting and controlling the Quality System in use by Triconex. Therefore, it is essential that each responsible Department evaluate its activities against new or revised requirements of the QAM to determine whether the absence of a corresponding new or revised Department procedure would adversely affect the quality of the service or product provided.

#### 4.3.2. GENERAL FORMAT

In general, procedures should be as simple and concise as practical. Procedure detail should be commensurate with the level of control necessary to ensure compliance with the requirements of the QAM.

The format of Department manuals and procedures should be consistent with the QAM, where practical: QPM, MDM, PPM and TGM procedures shall be formatted similar to QAM procedures, as indicated in Paragraph 4.2.2.2, and EDM procedure format may vary to suit the needs of the Engineering Department. All Department manuals shall contain procedures equivalent to QAM 0.0 and QAM 0.1, as described in Paragraph 4.2.2.1. The identification of procedures in the MDM, PPM and QPM shall correspond to the ISO numbering scheme consistent with the QAM.

Regardless of the general procedure format implemented by each Department, the identification and dating requirements of Paragraphs 4.2.2.2 and 4.2.3 shall apply and Quality Records shall always be addressed.

#### 4.3.3. ISSUE AND REVISION CONTROL

The originating Department shall control the issuance and revision of all documents described in this procedure, unless stated otherwise in the QAM.

It is the responsibility of each Department head to ensure that procedures and any new procedure requirements are in place and being implemented as of the Effective Date of the procedure unless delayed or staged implementation is specifically allowed for in the procedure.

The revision control requirements of Paragraph 4.2.3 shall be applied to the QPM, MDM, PPM, EDM and TGM and their inclusive procedures.

#### 4.3.4. PROCEDURE CHANGE COORDINATION

Changes to Department procedures shall be reviewed to ensure that they are not in conflict with QAM requirements or reduce the overall effectiveness of the Quality Program.

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The results of this review shall be documented in Department files and forwarded to the Product Quality Director, which may be performed electronically.

When any other Department or any other Department procedure, i.e., QPM, EDM, MDM, PPM or TGM, is affected by a changed Department procedure, the proposed change shall be reviewed by the affected Department to determine if the proposed change impacts that Department's activities or procedures. The results of this review shall be forwarded to the Product Quality Director, which may be performed electronically.

It is the responsibility of Department managers to ensure that their personnel are notified of procedure changes, which may be performed electronically, and trained, as appropriate, upon issuance of these changes. It is also the responsibility of Department managers to ensure that their personnel are trained, as appropriate, with regard to QAM changes. With regard to Triconex Product Line Quality Assurance personnel, it is the responsibility of the Product Quality Director to ensure their training on Department procedures and Triconex Product Line quality plans, as appropriate. With regard to Project Quality Assurance personnel, it is the responsibility of the Project Quality Manager to ensure their training on Department procedures and NAPO application project quality plans. Training shall be in accordance with the requirements of QAM 18.0, Training.

#### 4.3.5. MANUAL DISTRIBUTION AND CONTROL

Provisions for distribution, control and use of Department manuals and procedures shall be in accordance with the requirements Paragraph 4.2.5. The Product Quality Director is responsible for the distribution and control of the QPM, MDM, EDM, PPM and TGM and their inclusive procedures.

#### 4.3.6. EXCEPTIONS

The Emergency Procedure outlined in QAM 2.1, Quality System, Section 4.6, is the only exception to Paragraphs 4.3.1 through 4.3.5.

## 4.4. QUALITY RECORDS

The master copy, which may be electronic, of all signed and issued Triconex Quality System manuals and procedures are Quality Records and shall be processed in accordance with QAM 16.0.

## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 1.2	Triconex Organization
QAM 2.1	Quality System
QAM 16.0	Quality Records
QAM 18.0	Training
EDM	Engineering Department Manual
MDM	Manufacturing Department Manual

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PPM	Project Procedures Manual
QPM	Quality Procedures Manual
TGM	Triconex General Manual

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### 1.0 PURPOSE

This procedure describes the requirements and tools used for Quality Planning. Effective Quality Planning will result in more effective Quality Control System and improved Product Quality.

## **<u>2.0</u> <u>DEPARTMENTS AFFECTED</u>**

Engineering
Manufacturing
Quality Assurance
Nuclear Project Group

## 3.0 SCOPE

This procedure provides a general outline for effective Quality Planning. It can be used as a guideline to identify parts of the Quality System (QAM 2.1) that can be used as tools for effective Quality Planning.

## 4.0 PROCEDURE

### 4.1. GENERAL

Triconex Quality Planning shall be consistent with all other requirements of the Quality System described in this manual. The following tools are used for effective Quality Planning:

- Quality Objectives
- Quality Plans
- Quality Improvement Plan

During development of these plans consideration shall be given to following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- a) The identification and acquisition of any controls, processes, equipment, fixtures, resources and skills that may be needed to achieve the required quality.
- b) Ensuring the compatibility of the design, the production process, installation, servicing and documentation.
- c) Updating Quality Control and inspection and testing techniques.

	Name	Signature	Title
Author:	Ted Porfilio		Quality Assurance Engineer
Approvals:	Mike Phillips		Triconex Site Manager
	Paul Mesmer		Quality Director

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- d) The identification of any measurement requirement involving capability that exceeds the known state of the art in sufficient time for the needed capability to be developed.
- e) The identification of suitable verification at appropriate stages in the product realization.
- f) The clarification of standards of acceptability for all features and requirements.
- g) The identification and preparation of quality records.

## 4.2. QUALITY OBJECTIVES

Management shall ensure that quality objectives are established at various organizational levels. The objectives should be measurable and consistent with quality management system procedures and the quality policy. The objectives shall include those needed to meet product requirements. Quality objectives are intended to drive continual improvement and examples include (but are not limited to):

- Inventory turns
- Cost of quality
- Customer returns rate

## 4.3. QUALITY PLANS

For projects related to the development of new products, services or manufacturing processes, the Quality Director may require the development of a Quality Plan. The Quality Plan shall be developed by the Quality Assurance Department in close cooperation with the Development Team.

For application projects, the Quality Director shall require the development of a Quality Plan. See Project Procedures Manual (PPM) 1.0.

A Quality Plan is considered a Quality Record as per QAM 16.0. The plan should define the following, if it is not covered by existing procedures:

- a) The quality objectives to be obtained and possible methods to meet these objectives.
- b) The specific allocation of responsibilities and authority during the project.
- c) Specific procedures and work instructions.
- d) A method of plan verification and change control.

## 4.4. QUALITY IMPROVEMENT PLANS

Findings, conclusions and recommendations, reached as a result of review and evaluation of the Quality System (Also see QAM 1.3) can be submitted in a formal Quality Improvement Plan. This plan can be a guideline for adjusting the Quality System and improvement of its effectiveness (QAM 2.2). A Quality Improvement Plan is considered a Quality Record as per QAM 16.0. The plan should contain the following:

a) Target areas for improvement within operations.

## **■ TRICONEX CORPORATION QUALITY ASSURANCE MANUAL**

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- b) Definitions of specific targets to be reached.
- c) Methods of measurement to be used
- d) Means of evaluations.

The Quality Improvement Plan can be used as a tool to measure quality, and its related costs.

## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 1.3	Management Review
QAM 2.1	Quality System
QAM 2.2	Quality System Procedures
QAM 16.0	Quality Records
PPM 1.0	<b>Application Project Controls</b>

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## <u>1.</u> <u>PURPOSE</u>

This procedure describes the process to be followed when Triconex Product Line receives a customer contract/purchase order (PO) or receives customer contract/PO information from other Invensys groups. The process for developing and reviewing Sales Orders (SO) assigned to purchase orders is also described in this procedure.

## 2. <u>DEPARTMENTS AFFECTED</u>

Finance

Order Administration

Manufacturing

**Quality Assurance** 

**Project Group** 

## 3. SCOPE

The Order Administration Department is responsible for ensuring that all Sales Orders are reviewed and all sales order issues are coordinated with appropriate groups for resolution.

## 4. PROCEDURE

### 4.1. GENERAL

Generally, customer purchase orders are divided into two categories: 1) standard Triconex products (hardware), and 2) application projects (integrated systems).

For application projects, the Project Manager (PM) will review the purchase order per Project Procedures Manual (PPM) 1.0.

The purchase order requirements for standard Triconex products and application projects are entered into the business system as a Sales Order for production by Triconex Irvine. Sales orders are generally entered by Invensys regional personnel and occasionally by the Order Administration department based on an external or internal purchase order. Sales orders specify the Triconex products required to satisfy the customer requirements. Order Administration shall coordinate the review of these Sales Orders in house to assure that the order can be satisfied. There are several types of Sales Orders depending on the source of the order:

- a) Direct customer order
- b) International Invensys Associate order
- c) Domestic Stock Transport Order (STO)
- d) Internal purchase order
- e) Vendor order (piece parts interchange to vendor)

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	Paul Mesmer		Quality Director

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Categories a) through d) result in Triconex finished product and/or integrated systems being shipped to a customer, associate, or within Triconex, and are subject to this procedure.

## 4.2. PROPOSAL / QUOTATION

This is not a Triconex function. Proposals and quotations are generated by other Invensys entities. As requested, Triconex may provide input to support a proposal for Triconex products.

### 4.3. PURCHASE ORDER REVIEW

When a Purchase Order (PO) is received by an Invensys Sales Office, local order entry personnel enter the pertinent PO information, including PO technical and quality requirements into the business system as a Sales Order. The order review path depends on the whether the order is a standard product order (hardware) or an application project (integrated system).

#### 4.3.1. HARDWARE ORDERS

For standard hardware orders, the sales order information is reviewed by factory personnel for adequate definition and ability to meet customer requirements (see section 4.4). Factory Sales Order reviews are conducted and documented per MDM 3.1.

### 4.3.2. PROJECT ORDERS

For application project orders, an Invensys Project Manager is initially assigned to the Sales Order to coordinate all project actions. If assigned to the Triconex Project Integration group, the purchase order/contract review is performed by the project manager per PPM 1.0. The Project Manager (PM) shall review the PO to assess the customer technical requirements and determine the resources needed to meet these requirements. Additionally, the QA representative shall also review any nuclear customer POs to assess the quality requirements imposed by the customer and assure that they are translated into appropriate project documents as required by project procedures (PPMs).

After all reviews are completed and all problems resolved, Order Administration will enter (or update) the purchase order information into the business system (e.g., SAP) and establish a Sales Order for the purchase order. Product hardware requirements for the factory are detailed in the Sales Order.

### 4.4. SALES ORDER REVIEW

Once the Sales Order has been entered into the system, Order Administration generates a Sales Order Folder. The folder, which includes all available information related to the order, is circulated to the following departments to highlight any discrepancies or special requirements:

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Department

Areas of Concern

Order Administration

Overall review

Quality Assurance

(Nuclear plant orders only) Quality & certification issues

Manufacturing

Availability, delivery, compatibility, configuration

Finance

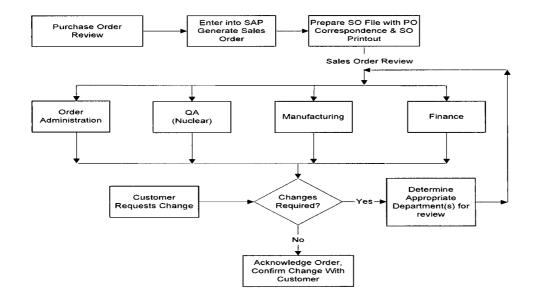
Pricing/commercial issues

The Sales Order shall be reviewed for completeness and accuracy by the appropriate departments. Any review comments shall be documented and all comments shall be resolved by Order Administration. The review, comment resolution, and approval shall be documented on the Order Review Form and Sales Order Folder documentation. The Order Administration department shall maintain records of the review and approval. These records shall be regarded as quality records per QAM 16.0.

All sales orders, except vendor orders, are subject to the below review and acknowledgment process. The Order Administration Department (coordinating with Invensys associates, as necessary) has the responsibility to coordinate resolution of sales order issues, such as availability, delivery date, and pricing. The customer related issues shall be resolved either prior to or as part of the Sales Order Acknowledgment process (See MDM 3.2).

For nuclear orders, copies of applicable external customer purchase orders received by Invensys associates should be provided to Triconex Order Administration (mandatory for class 1E nuclear safety related purchase orders) and included in the sales order folder.

#### SALES ORDER REVIEW PROCESS



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### 4.5. SALES ORDER REVIEW MEETING

In order to resolve any issues which may effect scheduled ship dates, the Finance Department shall prepare a list of open Sales Orders for discussion in a weekly meeting. The meeting is chaired by the Finance Department with the participation of representatives of Order Administration, Manufacturing, and Finance, and may include other affected departments.

#### 4.6. AMENDMENTS

Amendments to Sales Orders may be processed as required. All records of Amendment to Sales Orders are regarded as Quality Records as per QAM 16.0.

### 4.7. CERTIFICATE OF CONFORMANCE

A Certificate of Conformance is optional on routine commercial orders and will be issued only if requested by a customer. For nuclear safety related (class 1E) orders, a Nuclear Certificate of Conformance per QPM 10.9 is required.

The certificate lists the customer purchase order and documents that fact that the product or system meets referenced requirements (or identifies exceptions or waivers, as applicable). For nuclear 1E orders or when required by other customers, the C of C will be listed as a specific documentation requirement in the Sales Order. The Quality Director or designee shall sign each certificate.

### 4.8. SALES ORDER ADMINISTRATION RECORDS

All records relating to Sales Order Review are considered as quality records as described in QAM 16.0. These records are:

- a) Customer order configuration, as applicable.
- b) Customer Purchase Order, as applicable.
- c) Purchase Order review records.
- d) Preliminary and revised Sales Order.
- e) Sales Order acknowledgment and cover letter.
- f) Order Review Form, as applicable.
- g) Other order-related technical documents.
- h) Customer communication, including hard copy of electronically transmitted documents.
- i) Shipment documents.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
QPM 10.9	Nuclear Product Certification
MDM 3.1	Sales Order Administration
MDM 3.2	Sales Order Acknowledgment
PPM 1.0	Application Project Administrative Controls

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### 1.0 PURPOSE

This procedure describes the requirements to control design development, design review, design verification and validation (V&V), approval and release of the design documents, and final as-built design of the product. Implementation of these controls will ensure that the design control requirements of ISO 9001 and, when applicable, the guidance of NQA-1 are met.

### **2.0 DEPARTMENTS AFFECTED**

Engineering
Nuclear Project Group
Manufacturing
Quality Assurance
Marketing

### 3.0 SCOPE

Design control includes design and development planning, design input, design review, design output, design verification, design validation and design changes. This procedure defines the responsibilities for design control and describes the process that provides the necessary control. The Director, Platform Technology Development shall have design authority. Design control responsibility is shared by Marketing, Engineering, Quality Assurance and the Nuclear Project Group (for application projects). Design activities are documented to ensure that specified design requirements are met.

For application projects, the primary design requirements are defined in the customer purchase order and/or specifications. The design process for application project design is slightly different than the design process for Triconex product. Therefore, application project design terminology, documents produced, and organizations/personnel involved may be different than those described in this procedure.

The design control methodology described in PPM 2.0 is consistent with the methodology described in this procedure.

## 4.0 PROCEDURE

### 4.1. ORGANIZATIONAL AND TECHNICAL INTERFACES

Prior to the start of project design for a "new" product, the Marketing organization will develop a Market Requirements Document (MRD) per TGM C-1. See Paragraph 4.4.1.

This document will contain the basic market requirements for the new product or the upgrade requirements for an existing product.

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	Paul Mesmer		Quality Director

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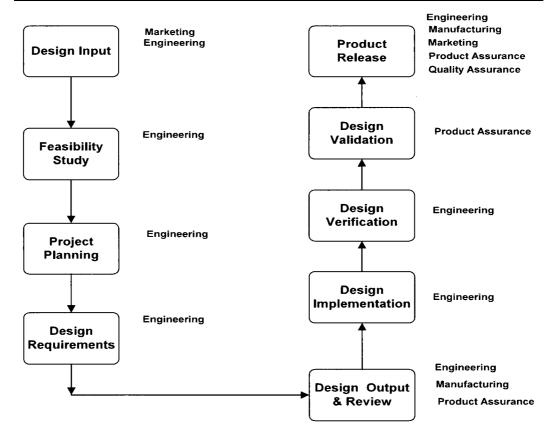
When the product is approved for the design phase, the project will be planned in accordance with the requirements of Paragraph 4.2. An Engineering Project Plan (EPP) will be developed. The EPP defines statement of work, a list of tasks, project deliverables, and schedule milestones. The project costs are part of the EPP and may provide input for Return On Investment calculations.

For application project activities, the Project Quality Plan and/or the Project Plan defines the statement of work, the project organization and responsibilities, the list of tasks, project deliverables, and schedule milestones. Refer to PPM 1.0 for details of the project planning activities.

#### 4.1.1. ORGANIZATIONAL RESPONSIBILITIES

The Engineering Department will conduct regular documented meetings to update the progress of the design and development of the new product. The representatives of Finance, Marketing, Manufacturing, and Product Assurance attend on an as needed basis. For application project-related design responsibilities, see PPM 2.0.

### PRODUCT DESIGN PROCESS/ORGANIZATIONAL RESPONSIBILITIES



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### 4.2. DESIGN AND DEVELOPMENT PLANNING

All design and development activities shall be planned with the objective to control, document, and monitor these activities. The plan shall contain at least the following:

- a) Activity assigned to qualified personnel with adequate resources
- b) Defined schedules for each activity and sub-activity within the plan
- c) A definition of a plan/review/update process

The plans should be updated as the design evolves. More detailed requirements for the planning of design and development activities are described in EDM 12.00 (product) and PPM 1.0 (application projects).

For application projects, refer to PPM 2.0 for design and development processes.

#### 4.3. **DESIGN INPUT**

Design input is defined as all technical requirements, which establish the characteristics of a finished product.

For application projects, design input is primarily defined by the customer purchase order and/or specification.

#### 4.3.1. REQUIREMENTS DEFINITION

The initial requirements for generic product design are established in the Marketing Requirements Definition per TGM C-1. This document defines the product market need, application, operational environment and, as applicable, performance requirements specified by the customer, including the requirements for delivery and post-delivery activities. This document also includes requirements not stated by the customer, but they are necessary to meet the customer's specified or intended use, and any additional requirements determined by Marketing and/or Engineering. Design requirements shall be unambiguous and mutually consistent, i.e., not in conflict with each other.

Additionally, pricing/cost profile and all other related marketing specifications shall be included.

For application projects, design requirements are defined by the customer purchase order and/or specification. These requirements are translated into design documents in accordance with the requirements of PPM 2.0, Design Control.

#### 4.3.2. PREVIOUS OR SIMILAR DESIGN

Where applicable, design information from previous or similar approved design shall be evaluated. Prior to initiating the design development process, Product Discrepancy Reports (PDR's) of earlier versions of the same or similar product shall be reviewed. This is to ensure that any documented problems with earlier versions are considered in the design of the new release.

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### 4.3.3. STATUTORY AND REGULATORY SAFETY REQUIREMENTS

For standard products, the Safety Engineer shall assure that all newly designed hardware and subsequent design changes shall comply with all applicable statutory and regulatory safety requirements. Per EDM 70.00, all new hardware product design specifications and design activities shall include participation by the product line Safety Engineer to assure compliance with the statutory and regulatory safety requirements.

For application projects, the applicable quality, statutory, and regulatory safety requirements are defined in the customer purchase order and/or specifications. Compliance with these requirements is achieved by the design control processes defined in PPM 2.0.

### 4.4. DESIGN OUTPUT AND DESIGN REVIEW

#### 4.4.1. DESIGN OUTPUT

Design outputs are those documents developed to translate hardware and/or software design requirements into:

- 1. Functional requirements specifications.
- 2. Technical design specifications.
- 3. Functional diagrams/drawings.
- 4. Test specifications and test procedures.

Design analysis developed to support product or project design shall be controlled by procedures that include provisions for the following, as applicable:

- a) Identifying documents to permit ready reference and retrieval
- b) Defining the objective of the analyses
- c) Definition of design inputs and their sources
- d) Documenting the results of literature searches or other applicable background data
- e) Documenting assumptions and identifying those that are required to be verified
- f) Identification of computer calculations, including computer type, code or programming, inputs and outputs
- g) Review and approval

Design output shall be documented in a manner such that design input requirements can be verified. The design outputs shall:

- 1) Meet the input requirements.
- 2) Contain or reference product acceptance criteria.
- 3) Provide the information needed for purchasing, production and provisions for servicing.
- 4) Specify those characteristics of the design that are important to the safe and proper operation of the product.

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### 4.4.2. DESIGN REVIEW (IN-PROCESS/MULTI-DISCIPLINE)

A design review is a formal, documented, comprehensive and systematic examination of a design to evaluate the design requirements and the capability of the design to meet these requirements and identify problems and propose solutions. Design Reviews are used for formal phase end design reviews and for other general design reviews as required during product or project development. All final design documents will be reviewed by an independent review engineer for the independent design verification per Section 4.6.

Product design reviews are scheduled by Engineering per the EPP and the project schedule. The number of reviews conducted depends on the complexity of the design. Engineering will typically publish a design review agenda in advance. The agenda will identify the time that each segment of the design review is planned to begin and outline the subjects to be reviewed in each segment. The subjects to be reviewed should include the following, as applicable:

- a) Adequacy of the resources to perform the design and development tasks.
- b) Progress of the planned design and development process.
- c) Meeting design verification and validation goals.
- d) Identification and evaluation of potential hazards or fault modes.
- e) Life-cycle data on performance of product.
- f) Control of changes and their affect during the design and development process.
- g) Identification and correction of problems encountered.
- h) Opportunities for design and development improvement.
- i) The statutory and regulatory safety requirements are adequately addressed.

All affected department managers shall participate in the design review. The design review is the formal method of communication to inform all affected parties of the design results at any particular stage. (Ref. EDM 12.30)

The appropriate information discussed during the design review meeting shall be recorded in Meeting Minutes. The Meeting Minutes shall be maintained as Quality Records per QAM 16.0.

Design output documents shall be approved prior to release.

For application project in-process design reviews, refer to PPM 2.0. In process design reviews are performed to verify that the system design documents will result in the construction and operation of the system to meet all customer requirements. Design documents shall be reviewed and approved prior to their release for procurement, manufacturing or assembly unless otherwise controlled under conditional release. For nuclear safety-related projects, all final design documents shall be reviewed by an Independent Review Engineer (IRE) or the independent Verification and Validation Group, as appropriate, in accordance with Section 4.6.

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#### 4.5. DESIGN IMPLEMENTATION

Based on design output documents (design specifications), Engineering shall translate the design output into hardware modules and software code and develop the appropriate design documentation.

For application projects, the Project Engineer/Project Designer performs this task.

### 4.6. DESIGN VERIFICATION

Design verification is performed to verify the adequacy of the design. Design verification can be accomplished by one or more of the following:

- a. The performance of design reviews,
- b. The use of alternate calculations, or
- c. The performance of qualification tests.
- d. Verification of computer programs shall include appropriate testing.

If design review is to be used as the method for design verification, the following items shall be addressed, as applicable:

- a) Were the design inputs correctly selected?
- b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverification when the detailed design activities are completed?
- c) Was an appropriate design method used?
- d) Were the design inputs correctly incorporated into the design?
- e) Is the design output reasonable compared to design inputs?
- f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- g) Was an evaluation performed to include analysis of failure modes to assure the part's failure would not prevent the component from performing its safety related function?

A design review checklist that addresses the above review questions shall be used when performing design verification by design review.

When alternate calculations are used as the method for design verification, a review is performed to address the appropriateness of the assumptions, input data, and the computer program or other calculation method used.

If qualification testing is the method to be used to verify the adequacy of the design, the qualification test plan shall define the test conditions, including testing under the most adverse design conditions. Refer to EDM 75.00, Maintenance of Nuclear 1E Qualification.

Design verification shall be performed by qualified personnel who are not directly involved in the design. Individuals performing design verification shall not have immediate supervisory responsibility for the individual performing the design, have not specified a

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singular design approach, have not ruled out certain design considerations, or have not established the design inputs for the particular design aspect being verified.

Design verification will be performed in accordance with the applicable PPMs or EDMs. Triconex Products:

Nonconformance to the requirements that are found shall be documented with a Quality Discrepancy Report (QDR). The QARB will review each QDR and determine the disposition. Engineering will schedule the correction of the discrepancy.

Product specifications, hardware drawings, test procedures, etc., will be reviewed, approved, and released via an Engineering Change Order (ECO) to Manufacturing to fabricate pilot-production models. The output at this stage will determine if the design can be manufactured.

Any changes to the hardware requirements during this stage of the design phase will require an Engineering Change Request (ECR) be submitted to Change Control Board (CCB) for approval. Any changes to the design that affect hardware, software/firmware configuration, test procedures, or other design documentation will also be controlled utilizing ECR or ECO procedure and requires approval by the CCB. See Section 4.8 for details related to design changes.

At this point, the product can also be released as an alpha/beta release for regulatory testing or limited on-site testing by third parties.

**Application Projects:** 

Deficiencies/discrepancies identified in documents during the design verification process will be documented on a Design Review Comment Sheet. All comments shall be resolved prior to approval of the affected document(s). Refer to PPM 2.0. Software deficiencies/discrepancies identified during the verification phase are controlled in accordance with PPM 7.0.

### 4.7. **DESIGN VALIDATION**

**Triconex Products:** 

After the design verification is complete, the product will be released for the QA Product Validation Test (PVT). The design validation is performed to ensure that the product is capable of meeting the requirements for the specified application or intended use (design specifications). Product Validation will perform the PVT. A PVT test plan will be prepared by Product Validation.

Any discrepancies found during the Product Validation Testing phase shall be documented using the QDR process as described in QPM 4.2. Following disposition of the QDR, an Engineering Change Request (ECR) or electronic equivalent may be required to incorporate the design changes as a result from the QDR disposition

The design will not be released to manufacturing for production until the PVT plan is successfully completed.

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#### **Application Projects:**

Application project design validation is performed in accordance with PPM 2.0. Nonconforming conditions related to hardware, software or testing that are identified during design validation shall be documented on a System Integration Deficiency Report (SIDR) and controlled in accordance with PPM 10.0.

#### 4.7.1. PRODUCT RELEASE

Product Assurance shall approve release of the final product after the PVT is complete and satisfactory. The design shall then be formally approved/released by Engineering as described in EDM 12.00.

Following release of the Software Release Definition (SRD) through the CCB, Triconex Technical Publications shall prepare a Product Release Notice (PRN), based on the SRD, describing the new release to the customers.

The PRN shall be approved by the CCB and released via an Engineering Change Order (ECO). The released PRN shall be published and available to the customers through the Triconex CustomerNet web site.

Shipment of the newly released product will commence following the production release by CCB.

### 4.8. DESIGN CHANGES

**Triconex Products:** 

In general the design changes on a product are approved by the CCB. The CCB is responsible for the approval of the Engineering documentation for hardware at the time that the documentation is released to Manufacturing for the pilot production units to be fabricated. The CCB will review and approve the Engineering documentation for the product firmware when the system has passed the system level PVT.

**Application Projects:** 

The details for application project design change process are described in PPM 2.0.

Changes to approved designs shall be reviewed and approved in the same manner as the original design.

All design changes shall be reviewed and evaluated to assure that the impact of the change or cumulative effect of multiple changes is carefully considered, i.e., material substitutions, performance, interchangeability, environmental/seismic, test and equipment qualification. This evaluation shall be documented.

#### 4.8.1. DESIGN CHANGES PRIOR TO PRODUCT RELEASE

Changes in the design of a product before the product is released to Manufacturing shall be controlled by the Engineering Department. During the design phase of the project, the main source of input for design change will be a result of design analysis and design review.

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At this stage of the project, it is the responsibility of the Project Engineer to maintain a logbook, keep minutes or use whatever technique is necessary to record the design changes including the use of ECR/ECO.

### 4.8.2. DESIGN CHANGES AFTER PRODUCT RELEASE

A new design is released to manufacturing in essentially two (2) stages. Initially the hardware is released to manufacturing to allow pilot production units to be fabricated. Some of these units will be used to perform the PVT by Product Assurance.

Following the completion of the PVT, the system firmware will be released to manufacturing.

All initial designs shall be formally released to manufacturing through the CCB. Any changes to the design following product release will also require the approval of the CCB.

Design changes will be initiated on an Engineering Change Request (ECR) or electronic equivalent. Following approval of the ECR by the CCB, the design change will be documented on an ECO as described EDM 21.00.

### 4.8.3. DESIGN CHANGES AFTER PRODUCT DELIVERY

When the need for design changes are identified after a product has been delivered, the design changes shall be evaluated for the effect of the change on all affected parts and products in the field. Affected customers shall be notified of any necessary actions, if required, per QPM 14.3.

## 4.9. CHANGE CONTROL BOARD DUTIES (PRODUCT LINE)

The CCB is responsible for the approval and implementation of all initial ECO's and any subsequent design changes. The CCB is responsible to evaluate all changes for impact analysis, implementation of the changes, establish effectivities, assure all ECO's and new drawings are adequate and complete and assure that all inter-related changes are released simultaneously or per a planned schedule, as described in EDM 21.00.

## 4.10. QUALITY RECORDS

All design documents are quality records and shall be controlled per QAM 16.0.

## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
EDM 12.00	Product Development Process
EDM 12.30	Design Reviews
EDM 21.00	Engineering Change Order Control
EDM 70.00	Safety Regulatory
QPM 4.2	Quality Discrepancy Report
QPM 14.3	Technical Support Documentation
PPM 1.0	Application Project Administrative Controls

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PPM 2.0	Design Control
PPM 7.0	Application Program Development
PPM 10.0	Nonconformance & Corrective Action
TGM C-1	Marketing Requirements Document

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### 1.0 PURPOSE

This procedure describes the general document and data control system, which is used by Triconex. For application projects, Project Procedures Manual (PPM) 4.0 describes the document and data controls, including those described in QAM 5.2 and QAM 5.3.

Implementation of these systems will ensure that all quality-related documents and data are controlled in a manner consistent with the requirements of ISO 9001 and, when applicable, the guidance of NQA-1.

### 2.0 DEPARTMENTS AFFECTED

All Departments

### 3.0 SCOPE

This procedure applies to the control of all quality related documentation and data, including software, used by Triconex in the development, manufacturing and service of the product, and in the implementation of application projects.

## 4.0 PROCEDURE

### 4.1. GENERAL

In general, the document control system is based on a system that requires the initial issue of documents to be reviewed and approved by specified parties prior to release. All changes to these documents after initial release will require review and approval by the same functions that approved the original document issue. The documents shall be uniquely identified using a document number and a revision number to ascertain the most current document revision. A Master List system is utilized to maintain control and to allow update of these documents in a timely manner and to assist in the removal of obsolete documentation when required.

### 4.2. **DOCUMENT TYPES**

The following is a list of quality related documents by organization which will be controlled after initial release. This list is not inclusive of all documents that may be generated by each department. All documents shall be developed and controlled in accordance with the governing department procedures.

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Approvals:	Mike Phillips		Triconex Site Manager
	Paul M esmer		Quality Director

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### 4.2.1. ENGINEERING

Engineering Departmental Manual (EDM)

**Drawings** 

**Product Specifications** 

Test Specifications/Procedures

**Engineering Orders** 

Approved Manufacturers List

User's Manuals

National and International Standards used to specify the Product

#### 4.2.2. MANUFACTURING

Manufacturing Department Manual (MDM)

Manufacturing Test Procedures

Approved Vendors List

Workmanship Standards

### 4.2.3. QUALITY/PRODUCT ASSURANCE

Quality Assurance Manual (QAM)

Quality Procedure Manual (QPM)

Project Procedures Manual (PPM)

Triconex General Manual (TGM)

Validation Test Procedures

ISO Quality Standards

Internal/External Audit Checklists

## 4.2.4. TRICONEX TECHNICAL PUBLICATIONS (ENGINEERING)

Product Release Notices (PRN)

Product Alert Notices (PAN)

Technical Advisory Bulletins (TAB)

Technical Application Notes (TAN)

### 4.2.5. MARKETING

**Marketing Procedures** 

Price List

Contracts

**Product Withdrawal Notices** 

### 4.2.6 NUCLEAR PROJECT GROUP

Customer Purchase Orders/Requirements/Specifications

Design Specifications/Requirements

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Design Drawings/Logic Diagrams

Test Specifications/Procedures/Reports

Test Software Development Documents

Verification and Validation (V&V) Test Plans/Procedures/Reports

Project Plans/Quality Plans

**Procurement Documents** 

Vendor Documents

Integration Parts/Material/Dedication Documents

Assembly/Inspection Records

Quality Verification Records

### **4.3. FORMS**

Forms that support Quality Program activities shall be controlled as necessary to establish uniformity in program implementation and facilitate maintenance of quality records. Each department shall maintain a list of authorized forms and a file of current forms. Electronic lists and files are acceptable. Department managers and supervisors are responsible for ensuring that current forms are in use and for approving revisions to forms under their control.

#### 4.4. WORK AIDS

Work Aids, such as reference lists compiled from different controlled documents can be used to increase efficiency. The Work Aid shall be readable, dated, and signed or initialed by the issuer (generally the area supervisor). It is the responsibility of the issuer to insure that the information provided by the Work Aid is correct and that the Work Aid is updated in case the underlying controlled document is modified.

# 4.5. QUALITY RECORDS

Records associated with document control activities are considered to be Quality Records in accordance with QAM 16.0.

# 5.0 REFERENCES AND RELATED DOCUMENTS

EDM	Engineering Departmental Manual
MDM	Manufacturing Department Manual
QPM	Quality Procedure Manual
PPM	Project Procedures Manual
TGM	Triconex General Manual

Section:	QAM 5.2	Subject:	Document Approval and Issue				
Revision:	007	Page:	1	of	2	Date:	11/17/04

## 1. PURPOSE

This procedure describes the system used by Triconex Products for approval and issuance of controlled documentation.

# 2. <u>DEPARTMENTS AFFECTED</u>

All Departments

# 3. SCOPE

This procedure applies to all documentation identified in QAM 5.1 as being controlled. All organizations will be responsible for controlling and issuing their individual operating procedures. All documentation released through the Change Control Board (CCB) will be issued from and controlled by Engineering Services document control.

## 4. PROCEDURE

# 4.1. GENERAL

The documentation being controlled at Triconex Products actually falls into two categories and each category is controlled and issued in a slightly different manner. These categories are engineering documentation controlled through the Change Control Board (CCB) per EDM 21.00 and organizational documents, which are controlled and issued by each individual organization.

### 4.2. ENGINEERING DOCUMENTS

Engineering documents are typically the Engineering drawings, specifications and test procedures associated with the design and release of the hardware. Other types of documents which are controlled by Engineering Services document control are Approved Manufacturers List, User's Manuals, Product Release Notice, Application Notes, Product Alert Notice and Technical Advisory Bulletins. As is defined in the detailed Engineering operating procedures, the initial release of these documents is by Engineering Change Order (ECO) per EDM 21.20, which is reviewed and approved by the CCB (EDM 21.10).

These documents will be issued to designated personnel per an automatic distribution list that is controlled by Engineering Services per EDM 22.10. By document type, this list defines the organization and which documents shall be issued. Upon receiving the new documentation, it is the responsibility of the document holder to remove the obsolete documentation from the files.

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	Paul Mesmer		Quality Director

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#### 4.3. ORGANIZATIONAL DOCUMENTS

Each organization will be responsible for control and issuance of their individual operating procedures, and workmanship standards, if applicable, in accordance with QAM 2.2. These documents will require a minimum of two signatures for initial release or subsequent changes. Copies of the documents shall be controlled by a unique number and a master list will be maintained by the responsible organization. Any changes to these documents will be identified by changes to the revision letters of the individual procedures. It is the responsibility of the document holder to remove the obsolete procedures and replace them with the new procedures when they are received.

A Work Aid is defined as a document or a tool that contains information from different controlled documents. The issuance of Work Aids should be limited to cases where the aid can increase efficiency. The Work Aids can be issued by, or with approval of the responsible area supervisor. The aid shall be dated and signed or initialed by the issuer(s). The area supervisor is responsible for the accuracy of the information provided.

#### 4.3.1 PROJECT DOCUMENTS

Project documents shall be controlled in accordance with PPM 4.0.

# 5. REFERENCES AND RELATED DOCUMENTS

QAM 2.2	Quality System Procedure
QAM 5.1	Document and Data Control
EDM 21.00	Engineering Change Order Control
EDM 21.10	Engineering Change Request (ECR)
EDM 21.20	Engineering Change Order (ECO)
EDM 22.10	Automatic Distribution Engineering Documentation
PPM 4.0	Project Document & Data Control

Section:	QAM 5.3	Subject:	Document Changes				
Revision:	009	Page:	1	of	2	Date:	11/17/04

# 1. PURPOSE

This procedure describes the system used by Triconex to control document changes.

# 2. <u>DEPARTMENTS AFFECTED</u>

All Departments

# 3. SCOPE

This procedure describes how changes are made to the documents issued and controlled by the Engineering Document Control system, and organizationally controlled documents such as procedures and standards.

### 4. PROCEDURE

# 4.1. DOCUMENT REVISIONS

Revisions to documents shall be reviewed and approved by an authority at the same or higher level than the original approver. In general, changes to documents will be reviewed and approved by the same functions that performed the original approval of the documents. A document revision history on engineering documents changes will be maintained. A master list will be available to identify the current revision of the documents. It is the responsibility of the person receiving the updated version of the document to remove the obsolete version.

#### 4.1.1. ENGINEERING DOCUMENTS

After initial release, the only method of making revisions to these documents is by initiating an Engineering Change Request (ECR) or electronic equivalent per EDM 21.10 which again must be approved by the Change Control Board (CCB). The changes are then released on an Engineering Change Order (ECO). It is the responsibility of the document holder to remove the obsolete procedures and replace them with the new procedures when they are received.

#### 4.1.2. ORGANIZATION DOCUMENTS

Any changes to these documents will be identified by changes to the revision letters of the individual procedures. It is the organization's responsibility to ensure that the document master list is updated. It is the responsibility of the document holder to remove the obsolete procedures and replace them with the new procedures when they are received.

	Name	Signature	Title
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Section:	QAM 5.3	Subject:	Document Changes				
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#### 4.1.3. URGENT CHANGES

Compliance with approved, controlled documents is required. Working to marked-up documents is forbidden. Therefore, when document errors or conflicts are noted that make compliance impractical, the condition should be brought to the attention of management and prompt corrections made. In urgent situations, paragraphs 4.1.1 and 4.1.2 above may permit accelerated availability of revised documents in the work area, as follows:

- 1. For engineering documents, a temporary advance release may be made based on a "preliminary release" stamp and an ECR/ECO approved by the Research & Development Director and the Quality Director, or designees.
- 2. For other organizational documents, a revised document may likewise get a preliminary release pending formal issuance, provided that it is stamped/marked and has been approved by the affected department manager and the Quality Director, or designees.

Preliminary releases will be valid until superseded by the normally released document (not to exceed 60 days). Affected department managers are responsible for retrieving superseded or obsolete documents from the work areas.

#### 4.1.4 PROJECT DOCUMENTS

Project documents shall be controlled in accordance with PPM 4.0.

# 5. REFERENCES AND RELATED DOCUMENTS

EDM 21.10	Engineering Change Request (ECR)
QAM 5.2	Document Approval and Issue
PPM 4.0	Project Document & Data Control

Section:	QAM 6.0	Subject:	Purchasing					
Revision:	020	Page:	1	of	9	Date:	06/30/06	

## 1.0 PURPOSE

This procedure describes the Purchasing functions and it ensures that purchased products conform to specified requirements.

# 2.0 DEPARTMENTS AFFECTED

Manufacturing

Quality Assurance

Engineering

Finance

Purchasing

Nuclear Project Group

### 3.0 SCOPE

This procedure describes the purchasing activities within Triconex. Purchasing activities consist of Supplier ranking, Supplier selection, purchasing data requirements and documentation, and the verification of purchased products. This procedure shall also be followed for nuclear safety-related (1E) purchasing activities. For non-safety related nuclear and commercial application projects, this procedure should be followed. On an exception basis, the purchasing activities may be performed by other Invensys groups, i.e., Foxboro, Webster, etc., as directed in the applicable Project Plan/Quality Plan (PQP). When the activities are conducted by other Invensys groups, a copy of the purchasing records shall be forwarded to and maintained by the Triconex Irvine facility.

# 4.0 PROCEDURE

### 4.1. GENERAL

Once approved Purchase Requisitions are generated (MDM 6.1), the Purchasing Department orders material via Purchase Order. Where necessary the parts drawing and other engineering released specification will be submitted to the Supplier along with the purchase order. All materials and services incorporated into or directly related to Triconex products will be procured from Suppliers who have been approved in accordance with this procedure.

Safety-related materials for Projects will normally be purchased from Triconex approved Suppliers as described below. However, 1) interim approval may be granted for urgently needed items and 2) as directed or approved by the customer, project materials may be

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supplied by the customer (ref QAM 7.0) or purchased by Triconex from customer-approved Suppliers for that particular project. Evidence of customer approval of specific Suppliers shall be on file in Project files.

### 4.2. SUPPLIER RANKING

All suppliers will be "ranked" (categorized) by the types of products or services they provide and level of Quality Assurance approval. The rank classifications are as follows and are assigned by Purchasing/Quality Assurance within the supplier record contained in the Approved Supplier List (ASL) and/or Nuclear Approved Supplier List (NASL).

RANK	DEFINITION
#1	Any supplier who fabricates, manufactures, assembles, and/or provides services to
	Triconex engineering specifications.
#2	Any supplier who supplies Triconex or its subcontractors Triconex engineering
	specified purchased parts, purchased products, or purchased services.
#3	Any supplier who supplies Triconex with any product or service necessary to the
	operation of the business but not directly related to or consumed by Triconex products
	(This includes contract personnel working under the Triconex QA Program).
#4	Supplier no longer viable or disqualified.
(suffix N)	Any supplier with an approved <u>nuclear</u> -grade quality program who supplies equipment
	or services to Triconex for a nuclear power plant application.
	Nuclear suppliers will be either 1N or 2N.
(suffix D)	Any supplier with an approved commercial quality program that supplies commercial
	equipment or services to Triconex that will be dedicated for a nuclear power plant
	application. Commercial nuclear suppliers will be ranked either 1D or 2D.
(suffix C)	Any supplier with a "conditional qualification." Prior to procurement from these
	suppliers, the listed conditions on the SQ record should be reviewed for any restrictions,
	additional purchase order requirements, or other conditions.

### 4.3. SUPPLIER SELECTION

Triconex will select its suppliers based on their ability to meet contract requirements, the quality of their product or service, and the cost of the product or service. The process of selection can be initiated at any time by the Manufacturing, Quality Assurance, or Engineering Organization with a request to the Purchasing Department, for a short list of prospective suppliers for a product or service. The Purchasing Department will prepare a list of prospective new suppliers.

#### 4.3.1. SUPPLIER EVALUATION

For new suppliers with a ranking of 1 or 2, the required sections of Form #642-00008-001, Supplier Self-Assessment Form, will be completed and maintained by Purchasing. Prior

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to issuance of the Supplier Self-Assessment Form to the supplier, Quality Assurance may edit the Form to delete, or N/A, the questions that do not apply to the supplier. Upon receipt of the completed Supplier Self-Assessment Form from the Supplier, Quality Assurance shall attach the Invensys Triconex Supplier Approval, Form P001-07 in front of the Supplier Self-Assessment Form. This combined document constitutes the Invensys Triconex Supplier Questionnaire and shall be used to document supplier approval by the Supplier Assessment Team (SAT). The SAT, consisting of one or more representative of the departments affected, will recommend a prospective supplier based on the results of returned Supplier Self-Assessment Forms and/or additional in-depth audits.

#### 4.3.2. SUPPLIER SURVEY

The need for a Supplier site survey to evaluate their manufacturing and quality capabilities will be determined by the SAT. A site survey may be waived if the Supplier is currently registered to the ISO 9000 series.

#### 4.3.3. SUPPLIER APPROVAL

Selection of new Suppliers ranked 1 or 2 will be a joint decision of the organizations involved. Purchasing can approve Suppliers ranked 3. Per definition, Suppliers ranked 4 in the ASL are no longer viable or disqualified. The process of Supplier selection will be documented. A more detailed description of the system requirements and selection criteria is given in QPM 6.1 and MDM 6.2.

To expedite urgent procurement situations, provisions for interim approval of Suppliers are established in MDM 6.2 or PPM 5.0, as applicable.

#### 4.3.4. APPROVED SUPPLIER LIST (ASL)

Manufacturing in conjunction with Purchasing will maintain an Approved Supplier List (ASL). This list will contain all Suppliers approved and used by Triconex per MDM 6.2.

All Suppliers are ranked and the approved list maintained by Purchasing as the ASL. The ASL listings are reviewed by the QARB on an annual basis, along with the proposed Supplier Audit Schedule, and/or reviewed as required on individual Suppliers. This review is to confirm appropriateness of the ASL listing and identify actions such as additional Supplier audits or ASL status changes. Recommendations for rank change of a Supplier will be approved by the Quality Director prior to ASL change.

The ASL documentation is considered quality assurance records per QAM 16.0 requirements.

#### 4.3.5. SUPPLIER AUDITS

Quality Assurance will perform Supplier quality assurance audits on an as-required basis as reflected in the Supplier Audit Schedule. The audit frequency will be determined based on the type of product, performance history, current procurement intent, and criticality of the item in the Triconex system. Supplier audits are performed in accordance with QPM 17.1.

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#### 4.3.6. NUCLEAR SUPPLIERS

For Suppliers who provide nuclear safety-related equipment or services (rank 1N/2N), evaluations will address the Supplier's ability to meet the quality assurance requirements of 10 CFR50, Appendix B. An audit/survey of the Supplier's facility is required as part of the evaluation process.

Nuclear product line procurements are controlled in accordance with MDM 6.3 and 6.4. Project procurements are controlled in accordance with PPM 5.0.

NOTE: Nuclear safety-related items are those items procured for a nuclear power plant application, but which are not being specifically dedicated by Triconex, i.e., the responsibility for meeting the nuclear quality assurance regulations shall be delegated to the supplier in the purchase order.

Items which are procured commercially (from Suppliers other than nuclear Suppliers as described above) for nuclear power plant safety related applications shall be dedicated for nuclear use by Triconex in accordance with guidance from EPRI NP-5652, GL 89-02, and GL 91-05 as described in QPM 6.2 for Triconex products or PPM 5.0 for application project materials. Triconex is responsible for determining suitability of use for these items and for potential reportability of defects per 10CFR21 (QAM 13.3).

#### 4.3.7 COMMERCIAL NUCLEAR SUPPLIERS

For suppliers who provide commercial equipment or services (rank 1D/2D), surveys will address the supplier's ability to control the critical characteristics of the associated Dedicated Parts Evaluation (DPE). A survey of the supplier's facility is required as part of the process.

### 4.3.8 NUCLEAR APPROVED SUPPLIER LIST (NASL)

In addition to the ASL, an NASL will be maintained to document those Suppliers, which are rank 1N/2N, that have been evaluated and found to meet the requirements of Paragraph 4.3.6 to provide nuclear safety-related equipment or services. The NASL listings are reviewed along with the ASL listings by the QARB on an annual basis in accordance with Paragraph 4.3.4.

#### 4.4. APPROVED PARTS AND COMPONENTS

Only Triconex-approved parts and components, as specified below, will be procured and incorporated into Triconex products and systems (applies to rank 1 and 2 purchases).

#### 4.4.1. APPROVED MANUFACTURER LIST (AML)

Engineering will maintain an Approved Manufacturer List (AML). This list will contain all basic components, each listing the manufacturers that are acceptable to Triconex. New components and their manufacturers will be selected and approved in accordance with EDM 62.00 and EDM 63.00.

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#### 4.4.2. PARTS/SERVICES TRACEABILITY

For nuclear application projects, an Integration Parts List (IPL) or equivalent shall be maintained for all purchased parts and materials/items and services used in safety-related applications (PPM 5.0). Only approved integration items/services are acceptable for procurement and use in nuclear safety-related application projects. Integration commercial items/services to be used in nuclear safety-related applications shall be evaluated and dedicated per PPM 5.0. Triconex is responsible for 10CFR21 reportability requirements for purchased integration items/services in accordance with QAM 13.3.

For selected consumable integration parts and materials, i.e., bulk items that do not require accountability or traceability, Triconex may delegate the procurement and material control functions to an integration Supplier who is approved and listed on the ASL and controlled under their approved quality program. In these instances, the quality requirements for these functions shall be clearly described in the purchase order. The Supplier shall provide a copy of their purchase order, purchasing data, and material control and inspection documents to Triconex prior to close out of the purchase order.

#### 4.4.3. PURCHASE ORDER CLASSIFICATION

Triconex Purchase Orders are issued under three categories:

### 1) Nuclear Safety-Related

Procurement from a Supplier with an approved nuclear-grade quality program for items/services supplied to a nuclear power plant for safety-related application.

#### 2) Commercial Nuclear Dedicated

Procurement from a Supplier with an approved commercial quality program with purchase order requirements that allow commercial grade dedication for use in nuclear safety-related applications.

#### 3) Commercial

Procurement from a Supplier with an approved commercial quality program.

The procurement of Nuclear Safety-Related and Commercial Nuclear Dedicated items and services require the approval of Quality Assurance.

### 4.5. PURCHASING DATA

Items/services are ordered according to three purchasing categories: Nuclear Safety-Related, Commercial Nuclear Dedicated and Commercial.

Purchasing data will describe the item/service ordered, including the type, class, grade, Triconex part number or other identification, where applicable. Specifications, drawings, process requirements, inspection instructions, requirements for approval or qualification of the item/service and the quality assurance system standard to be applied or required conformity to the Triconex AML will also be included where applicable.

The purchasing data for nuclear safety-related items and services shall include:

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- a) Statement of the scope of work.
- b) Technical requirements by reference to specific drawings, codes, specifications.
- c) Requirement for an accepted, documented quality assurance program, implemented, and meeting applicable code/regulatory requirements.
- d) Requirement for right of access to plant facilities and records for source inspection/audit.
- e) Identification of document submittals for approval.
- f) Identification of deliverable records.
- g) Requirement for reporting and approving disposition of nonconformances.
- h) Requirements for records availability, retention and disposition.
- i) Requirements for extending applicable technical and QA requirements to lower tier suppliers.
- j) Requirements for review and approval of software and services, including engineering services, studies, and evaluations.
- k) Applicability of 10CFR21.
- 1) Identification of the Purchase Order as "Nuclear Safety-Related".

Quality Assurance shall approve all requisitions for nuclear-related procurements (as indicated by an "N" ranked Supplier or item/service being "dedicated" for nuclear) or as indicated in specific "conditional" notes for the Supplier requiring QA review prior to issuance of the PO. Supplier qualification records shall be consulted during this review to assure any approval conditions or restrictions are incorporated. Upon review of procurement documents, QA assures that the approved Supplier program invoked in the PO does meet any specific customer quality requirements; this will vary from project to project.

#### 4.5.1. DOCUMENTATION PACKAGE

Manufacturing will provide the Supplier with a complete package of Engineering Data prior to production and control the changes and updates during production. The initial package will contain at least the following:

- a) All relevant Engineering and Manufacturing instructions.
- b) A Material List
- c) An Approved Manufacturer List
- d) All applicable Engineering Change Orders.

The package can also include any special manufacturing or quality assurance related instruction, forecast and schedules.

The updated packages for a certain part will be sent to the Suppliers on the ASL for that part. Manufacturing will be able to ensure that the packages were received in full, and in good condition. The packages will include a required implementation schedule/data and any special instructions to ensure correct implementation of the change/update.

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### 4.5.2. PURCHASING RECORDS

The following records are regarded as quality assurance records and will be maintained in accordance with QAM 16.0 requirements.

<u>Document</u>	Responsible Department
a) Supplier Approval Documentation	Manufacturing
b) Supplier Audit Reports	Quality Assurance
c) Approved Supplier List (ASL)	Manufacturing/Purchasing
d) Approved Manufacturer List (AML)	Engineering
e) Approved Integration Parts List (IPL)	Nuclear Project Group
f) First Article Inspection Reports	Quality Assurance
g) Source Inspection Reports	Quality Assurance
h) Purchase Orders	Purchasing
i) Nuclear Approved Supplier List (NASL)	Manufacturing/Purchasing
e) Approved Integration Parts List (IPL) f) First Article Inspection Reports g) Source Inspection Reports h) Purchase Orders	Nuclear Project Group Quality Assurance Quality Assurance Purchasing

## 4.6. VERIFICATION OF PURCHASED PRODUCTS

#### 4.6.1. PURCHASED MATERIALS

Purchased material will be verified to meet procurement requirements in accordance with QPM 10.2, Receiving Inspection.

### 4.6.2. FIRST ARTICLE

Whenever a Supplier is ordered to manufacture a part for the first time or when the Supplier did not manufacture the part for more than a year, a Quality Assurance Inspector or a quality assurance assignee will perform a First Article Inspection, prior to acceptance of the batch per QAM 10.0.

The process of the First Article Inspection will be mutually agreed with the Supplier. The Quality Assurance Inspector may perform a source inspection per QAM 10.0 if it is not possible or reasonable to fully inspect items upon receipt.

#### 4.6.3. SERVICES-COMMERCIAL

Confirmation of acceptability of services is the responsibility of the ordering supervisor, who is responsible for monitoring or reviewing the results of the service prior to authorizing payment.

#### 4.6.4. SERVICES-NUCLEAR

Nuclear Safety-Related services will be accepted by review of documentation or by surveillance/audit of the service. Nuclear safety-related purchase orders will contain provisions (Section 4.5) for document review & approval or audit access, as necessary.

Commercial services which affect the quality of a nuclear qualified product shall be controlled and dedicated in accordance with a Dedicated Parts Evaluation (DPE) for the services in accordance with QPM 6.2.

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# 4.7. SUPPLIER DISQUALIFICATION

After a review and disqualification order by QA, any Supplier disqualified for the following quality assurance reasons, shall have their rank changed to 4 in the ASL:

- a) The Supplier failed to implement requested corrective action in a timely manner.
- b) Unacceptable defects in received product or unacceptable workmanship standards.
- c) The results of the quality assurance audit indicate that the quality or safety of Triconex final product might be in jeopardy by using this Supplier parts.
- d) Missing the delivery schedule frequently.
- e) Other requirements deemed necessary for quality assurance of the final product as per QA review.

Audited Suppliers that are not selected or existing Suppliers, disqualified and changed to Rank 4, will be notified by Purchasing and a purchase order block placed in the business system.

### 4.8. CUSTOMER VERIFICATION OF SUBCONTRACTED PRODUCT

Where specified in the contract, Triconex customers will be afforded the right to verify, at the subcontractor's premises and/or at the Triconex facility in Irvine, that subcontracted product conforms to specified requirements. Triconex will not use such verification as evidence of effective control of quality assurance by the subcontractor.

### 4.9. SUPPLIER ANALYSIS SYSTEM

Quality Assurance will maintain a Supplier analysis system. The system will be used to evaluate and reevaluate the performance of Suppliers listed on the ASL, depending on the type of product, the impact of Supplier product on the quality of final product and/or quality assurance records of the previously demonstrated capability and performance of Suppliers.

# 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 5.1	Document and Data Control
QAM 7.0	Control of Customer Supplied Product
QAM 10.0	Inspection and Testing
QAM 13.3	10CFR21 Reporting of Defects and Noncompliance
QAM 16.0	Quality Records
MDM 6.2	Supplier Selection
MDM 6.3	Nuclear Part Numbers
MDM 6.4	Control of Standard Purchase Requisitions
EDM 62.00	Component Specifications, New Parts
EDM 63.00	Component and Manufacturers Selection
QPM 6.1	Source Evaluation and Supplier Selection
QPM 6.2	Dedication of Commercial Grade Items

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QPM 10.2 Receiving Inspection PPM 5.0 Materials & Services

Form #642-0008-001, Supplier Self-Assessment

Form #P001-07, Invensys Triconex Supplier Questionnaire

Section:	QAM 7.0	Subject:	Control of Customer Supplied Product					
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# 1. PURPOSE

This procedure describes the requirements for receiving, handling, storage and maintenance of customer supplied product as well as the methods of reporting non-conformities, loss, or damages to the customer.

## 2. **DEPARTMENTS AFFECTED**

Manufacturing Quality Assurance Technical Support Nuclear Project Group

# 3. SCOPE

Customer supplied product is defined as product/parts supplied by the customer for incorporation into the final product. Customer supplied product/parts may also include Triconex products previously purchased by the customer. This procedure ensures that these products/parts are appropriately identified as customer supplied and are handled and used in such way that damage or deterioration is prevented.

# 4. PROCEDURE

# 4.1. GENERAL

In general, customer supplied product shall be handled identical to the way Triconex purchased product is handled. For application projects, customer supplied material is addressed in PPM 5.0.

### 4.2. RECEIVING

Customer supplied product/parts shall be uniquely identified to the specific Sales Order by means of a tag or sticker and shall be inspected/tested as described in QAM 10.0. The customer supplied documentation, if available, shall be used as the inspection/test criteria. Any discrepancy with the documentation shall be relayed to the customer, and the product shall not be accepted until a waiver of specification is received from the customer. If the customer did not supply any documentation with the product the inspection criteria shall be "fitness for use".

#### 4.3. HANDLING AND STORAGE

Customer supplied product shall be handled and stored as described in QAM 15.0 and related Material Handling procedures in order to prevent damage and deterioration.

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	Paul Mesmer		Quality Director

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## 4.4. DAMAGE REPORTING

If damage or deterioration of the customer supplied product occurs, the product shall be regarded as non conforming product in accordance with QAM 13.1 and QAM 13.2. The material review board shall report the damage to the customer and negotiate the disposition and financial consequences. Non-conforming customer supplied product shall not be used by Triconex without a written waiver from the customer.

# 5. REFERENCES AND RELATED DOCUMENTS

QAM 10.0	Inspection and Testing
QAM 15.0	Handling, Storage and Shipping
QAM 13.1	Control of Non-Conforming Product
QAM 13.2	Non-Conforming Product Review and Disposition
PPM 5.0	Control of Materials and Services

Section:	QAM 8.0	Subject:	Produ	ct, Pa	rts, and N	Material	Identification and Traceability
Revision:	016	Page:	1	of	4	Date:	08/05/05

### 1.0 PURPOSE

This procedure describes the methods of product, parts and material identification and traceability used by Triconex.

## 2.0 DEPARTMENTS AFFECTED

Manufacturing
Engineering
Quality Assurance
Technical Support
Nuclear Project Group

## 3.0 SCOPE

The nature of the Triconex product line requires a high degree of traceability. This procedure covers the methods of product, parts, and material identification and traceability during all stages of production, delivery and installation as well as the system used by Triconex to identify and trace product, parts, and materials in use by customers. Section 4.1 applies to Product Line items and section 4.2 addresses identification and traceability for Project Integration materials.

# 4.0 PROCEDURE

## 4.1. GENERAL

The material identification system used during production is based on four separate systems:

- a) A part numbering system for basic product components, sub-assemblies, assemblies and final product (EDM 23.00) together with a revision control system (EDM 20.00).
- b) Hardware serialization control system for all Printed Circuit Board Assembly (PCBA) designated by the part number 74xxxxx-xxx (MDM 8.0).
- c) Software version and revision control for all software and firmware (EDM 20.00).
- d) A part numbering system for documents associated with products.

These requirements form the basis of the model number configuration control system which is used to control the final products compatibility and interchangeability (EDM 20.00).

#### 4.1.1. PRODUCT PART NUMBERS

The Triconex product part numbering system shall be used as defined in EDM 23.00. The number consists of a seven digit base number and a three or four digit dash number. Part numbers shall be assigned by the Engineering Services Group and controlled by the Change

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	Paul Mesmer		Quality Director

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Control Board. The Engineering Services Group shall maintain a part number assignment log. Where appropriate and possible the part number shall be legibly and indelibly applied to the item so as not to affect the function or life span of the item.

#### 4.1.2. HARDWARE SERIALIZATION

Manufacturing shall, upon receiving, serialize all parts designated by part number 74xxxxx-xxx. Serialization of parts and material shall be performed in accordance with MDM 8.0.

#### 4.1.3. SOFTWARE/PRODUCTION FIRMWARE IDENTIFICATION

The production firmware will be identified by an attached label. The label shall show firmware Title, Revision (META) number and the part number. The META number will be assigned in accordance with EDM 20.00 and is controlled by the Change Control Board and the Software Release Definition (SRD).

#### 4.1.4. TEST FIRMWARE IDENTIFICATION

The test firmware will be identified by an attached label. The label shall show firmware title, revision (META) number and the part number. The META number will be assigned in accordance with EDM 20.00 and is controlled by the Change Control Board. The test firmware number will be identified in the applicable Test Procedures. If the test firmware needs to be changed then the applicable Test Procedure will need to be revised and controlled through the Change Control Board (Agile).

#### 4.1.5. NON-TAGGED OR LABELED ITEMS

Where individual items cannot be tagged or labeled with their part number and/or serial number because of size, quantity and/or other constraints, one label may be used for the entire quantity. The label shall be attached or located on the container or bundle near the item to which it applies in such way that the parts can be unambiguously identified. To maintain traceability, when a partial issue of the item is necessary, the partial issue shall be tagged or otherwise marked to identify the part number and/or serial number. Where labeling is considered impractical, impossible or insufficient, material shall be physically segregated, controlled and identified in accordance with written procedures.

#### 4.1.6. PRODUCTION ORDER TAG

For serialized parts, the part number together with the serial number and the revision level shall be copied on to the Production Order Tag (POT). The Production Order Tag may be attached to the product or available in electronic form. Among other usage, the Production Order Tag is used for process flow control and to identify the in-process inspection and test status of the product (QAM 12.0). Production Order Tags shall be filed by part number or by sales order number. The Quality Assurance Department shall maintain these records in accordance with QAM 16.0 and QPM 8.0. Paper RMA tags (QPM 19.1) are maintained by Manufacturing. The database files are maintained by Information Technology.

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#### 4.1.7. ELECTRONIC DATABASE

A Manufacturing database may alternately be used to provide the equivalent Production Order Tag information on processing, inspection, and testing status (MDM 9.1).

#### 4.1.8. NON CONFORMING MATERIAL

Items or material located in the storage, inspection, manufacturing, system testing or shipping area that cannot be identified by their part number, drawings, or other means shall be regarded as non-conforming material and shall be immediately segregated from conforming material. Serialized items that cannot be identified by their production order tag, and that are not in the process of being shipped or integrated in an assembly shall be regarded as non conforming material. In case non-conforming material is found by any Triconex employee it is his or her duty to inform the responsible supervisor. The supervisor shall segregate the non-conforming material as per QAM 13.1.

#### 4.1.9. PRODUCT AND SYSTEM TRACEABILITY IN THE FIELD

The system configuration ordered by the customer is a customer specific combination of final Triconex products, parts, and materials. Triconex Technical Support shall maintain available records of product and systems shipped to customers including sales order number, part number, quantity, serial number, version and revision level listings, and inspection/test results.

It will be the responsibility of Manufacturing to supply all required documents that constitute this file record. These records shall be regarded as Quality Records as per QAM 16.0.

#### 4.1.10. PRODUCT AND SYSTEM TRACEABILITY DOCUMENTATION

Upon shipping, Manufacturing will complete a system folder for each system, by sales order. The system folder shall contain a detailed description of the followings:

- a) The System Configuration Sheets which include applicable part numbers and/or serial numbers.
- b) Short Ship Authorization (if applicable)
- c) Pre Ship Checklist
- d) Product Shipment Checklist
- e) System Hardware Layout Discrepancy Tracking Sheet
- f) Pre Test Checklist
- g) System Test Compliance Sheet
- h) Loose Item Packing List

**Note**: Older files compiled before 1993, may not contain all above mentioned documents.

The Technical Support Department shall verify that all documentation is available in the folder and shall otherwise take appropriate action to complete the folder. The files shall be

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kept by the Technical Support Department. They shall be regarded as quality records as per QAM 16.0.

## 4.2. SYSTEM INTEGRATION ITEMS AND SERVICES TRACEABILITY

For application projects, controls for the identification and traceability of integration items and services are described in Project Procedures Manual (PPM) procedures PPM 5.0 and PPM 8.0.

Items shall be identified by Triconex Part Number, including IPL number or equivalent for nuclear safety-related materials, manufacturer's part numbers or by commercial commodity description corresponding to the drawing Bill of Material (BOM). Tagging and labeling of materials shall be in accordance with Section 4.1.5. Traceability of purchased items/services to the Purchase Order shall be maintained.

Subassemblies in process shall be traceable to the applicable Sales Order and shall be identified/marked appropriately as to system or cabinet number so as to clearly correspond to the inspection checklists and other associated quality records. As noted in 4.1.6, a POT is used to provide traceability for Triconex products. Project Integration assemblies do not use POTs, but are traceable to integration checklists as described in PPM 8.0.

Project Integration records are maintained by the Project Group and are retrievable by Sales Order number.

# 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 13.1	Control of Non-Conforming Product
QAM 16.0	Quality Records
QPM 8.0	Production Order Tags Filing System
MDM 8.0	Product, Parts, and Material Serialization
MDM 9.1	Manufacturing Process
EDM 20.00	Configuration Management
EDM 23.00	Document Numbering System
PPM 5.0	Control of Material & Services
PPM 8.0	System Integration Implementation

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## 1.0 PURPOSE

This procedure describes the general requirements for all Manufacturing processes that affect the quality of product produced and serviced by Triconex Products.

## **2.0 DEPARTMENTS AFFECTED**

Manufacturing Technical Support Quality Assurance

### 3.0 SCOPE

This procedure is applicable to all processes used by Triconex Products that affect the quality of products or services offered. Triconex Products is required to:

- a) Plan, identify and document the process steps required to produce the product.
- b) Ensure that the processes are carried out under controlled conditions.
- c) Demonstrate compliance with reference standards, quality plans and controlled procedures.
- d) Approve necessary processes and process parameters.
- e) Measure appropriate process parameters to assure customer requirements are satisfied.
- f) Establish and communicate criteria for workmanship.
- g) Maintain equipment, software, and services to ensure continuing process capability.
- h) Periodically revalidate the process, where applicable.

# 4.0 PROCEDURE

### 4.1. PRODUCTION PLANNING

Manufacturing shall plan and document the production activities on a regular basis.

#### 4.2. PRODUCTION CONTROL

Manufacturing shall identify and document the steps in the production process describing the typical process and identifying the process stages. Appropriate inspection points shall be determined in accordance with QAM 10.0. Quality Assurance will ensure that the processes are carried out under controlled conditions.

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### 4.3. WORKMANSHIP STANDARDS

The Triconex Products has adopted the following workmanship standards:

IPC-A-610 Acceptability of Electronic Assemblies
 IPC-7711 Rework of Electronic Assemblies

• IPC-7721 Repair and Modification of Printed Boards and Electronic

Assemblies

• IPC-A-600 Acceptability of Printed Boards

Copies of IPC standards that are applicable to the work being carried out are maintained in Receiving Inspection, Manufacturing Engineering and on the production floor. These workmanship standards shall also apply to all Manufacturing rework stations and all RMA activities. These standards shall also be used as benchmark during Receiving Inspection and In Process Inspection.

### 4.4. WORK ENVIRONMENT

Procedures, personnel and equipment used in processes shall meet the requirements of applicable nationally recognized codes, standards or specifications (e.g. Regulatory Safety Compliance Standards). The work environment needed to achieve conformity of product requirements shall be established and managed. Good housekeeping practices shall be maintained in all staging areas, including orderly material and equipment arrangement, freedom from clutter on floors, orderly arrangement of test setup and wiring runs, and general cleanliness of all work areas.

#### 4.5. USE OF PROCEDURES

All stations with activities that affect the quality of the product and all test and inspection stations shall operate in accordance with documented and controlled procedures as per QAM 2.2, Quality System Procedures.

## 4.6. EQUIPMENT

Equipment used in processes shall be calibrated or adjusted with calibrated equipment, if necessary. All equipment referenced in any test procedure requires that the pre-set limits on each equipment must be maintained during the process. These limits and the means to measure/control them shall be described in documented and controlled procedures. The measuring equipment shall be controlled as per QAM 11.0. Equipment that does not meet the requirements of QAM 11.0 shall be immediately segregated and identified as non-conforming material as per QAM 13.1.

### 4.7. CERTIFICATION OF PERSONNEL

Personnel performing tasks that require a high level of manual dexterity or interpretive ability of the operator shall be certified as per QAM 18.0.

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### 4.8. SPECIAL PROCESSES

Where the result of a process cannot be fully verified by subsequent inspection or testing, the process shall be recorded and monitored continuously to ensure compliance with documented requirements. This will be accomplished by:

- Develop procedures or instructions to validate the process. These procedures or
  instructions shall be reviewed and approved prior to use. The procedure or instruction
  shall specify the equipment to be used and how it will be controlled, specify
  acceptance criteria, and provide a method for reviewing and approving the results to
  indicate acceptability of the process.
- 2. The equipment used to perform the verification shall be appropriate for its intended use, approved for use, and controlled. Personnel training and certification requirements shall also be specified.
- 3. Any records to be developed and maintained to document the results of the process shall be specified.
- 4. The process shall be periodically revalidated per steps 1, 2, and 3, above, to ensure the process continues to produce acceptable results.

#### 4.9. PROCESS MEASUREMENT

Processes shall be measured by the inspection and test acceptance rates (QAM 10.0). Reports will be generated from the Manufacturing Database System (MDS) and made available to upper management. Management shall assure that customer's requirements are satisfied.

## 4.10. QUALITY RECORDS

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All documents generated by use of this procedure are quality records and should be handled in accordance with QAM 16.0.

# 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 2.2	Quality System Procedures
QAM 10.0	Inspection and Testing
QAM 11.0	Control of Inspection, Measuring and Test Equipment
QAM 13.1	Control of Non-Conforming Product
QAM 16.0	Quality Records
QAM 18.0	Training and Certification of Personnel

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# QAM 10.0 INSPECTION AND TESTING

Revision: 017

Effective Date: September 25, 2006

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Approvals:	Bob Rasmussen		Triconex Site Manager	09/15/06
	George Hughes		Project Quality Manager	09/15/06
	Paul Mesmer		Product Quality Director	09/15/06

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# **CHANGE SUMMARY**

Reason for Change	Summary of Changes*
<ol> <li>To implement the requirements of QAM 2.2, Revision 15.</li> <li>Implementation of "N" part numbers.</li> <li>Revise procedure to agree with process changes driven by system test process improvements.</li> </ol>	<ol> <li>Format changes consistent with QAM 2.2, Revision 015; change bars are not included for these changes.</li> <li>Revised Paragraph 4.2.1 to include "N" PCBA part numbers.</li> <li>Process updates, which include the handling of system deficiencies and performance of Pre-Test, Final QA and Ship activities.</li> </ol>

<sup>\*</sup>Specific changes to the procedure are indicated by vertical lines in the right margin.

# **CHANGE IMPLEMENTATION**

All requirements of this procedure shall be implemented as of its Effective Date. Manufacturing activities that are that in process as of the Effective Date of this procedure may continue without change.

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## 1.0 PURPOSE

This procedure describes the requirements for independent inspection and testing activities in order to verify the specified requirements for products and integrated systems are met. Inspection and testing are necessary to verify the adequate performance of personnel, processes and equipment to provide assurance that the final product meets its specification.

# 2.0 <u>AFFECTED ORGANIZATIONS</u>

Manufacturing Department
Quality Assurance Department
Engineering Department
North American Project Operations (NAPO)

# 3.0 SCOPE

This procedure shall apply to all inspections and testing performed by Triconex. This includes the inspection and testing of customer returns per QAM 19.0 and customer supplied products/materials per QAM 7.0. For NAPO application projects conducted at Triconex, test and inspection activities are described in this procedure and in Project Procedures Manual procedures PPM 6.0 and PPM 8.0. Unless clarified to apply to product or application project activities, the generic requirements of this procedure are applicable to all inspection and test activities.

This procedure does not apply to design verification activities or Quality Assurance Product Validation activities. These activities are described in QAM 4.0.

# 4.0 PROCEDURE

## 4.1. GENERAL

The nature of the product manufactured by Triconex makes it necessary to implement a 100% functional test of all critical assemblies. As a result of this strategy, Triconex has implemented these tests as part of the manufacturing and application project system integration processes. All inspections, tests and verification activities shall comply with the following requirements:

- a) They shall be performed by personnel independent of those having direct responsibility for the work that is being verified.
- b) They shall be performed in accordance with documented and controlled inspection, test or verification procedures.
- c) Inspection, verification and test results shall be documented and evaluated for acceptability.

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## 4.2. TEST CONTROL

### **4.2.1. FUNCTIONAL TESTING (PRODUCT)**

Functional testing shall be performed by the Manufacturing Department as part of the manufacturing process. All Printed Circuit Board Assemblies designated by part number 74xxxxx-xxx and 74xxxxx-xxxN shall be 100% functionally tested, either in-house (MDM 9.1) or by the vendor. Manufacturing Engineering is responsible for the development, issuance and control of the functional test procedures and test fixtures.

## **4.2.2.** SYSTEM PRE-TEST (PRODUCT)

The System Pre-Test will be performed by the Manufacturing Department. The System Pre-Test shall be carried out to ensure that all system modules are correctly configured in the system and that the documentation matches the system. Form 216, Pre-Test Checklist, shall be followed as a procedure. (NOTE: Trident does not require Pre-Test Inspection, since it is not assembled as a configured system.)

## 4.2.3. SYSTEM ACCEPTANCE TEST (PRODUCT)

The System Acceptance Test shall be performed in accordance with the relevant System Test procedure as issued and controlled by Manufacturing Engineering. The test will be performed by the Manufacturing Organization. Test results shall be recorded on the System Test Compliance Sheet. System alterations are reflected on the Configuration Sheet, i.e., configuration changes. System component failures and discrepancies may be reworked to bring them into conformance without issuance of an MRR; however, a nonconforming condition is documented on the associated POTR, if applicable. A system shall not be made available for the next stage of the manufacturing process unless it has passed all applicable tests. The test results shall be documented in the System Folder.

#### 4.2.4. TEST OF CUSTOMER RETURNED ITEMS

Customer returned items shall be tested as described in QPM 19.2.

#### 4.2.5. TEST OF CUSTOMER SUPPLIED PRODUCTS/MATERIALS

Customer supplied products/materials shall be tested in accordance with customer supplied documentation per QAM 7.0.

### 4.2.6. INTEGRATED APPLICATION PROJECT TESTING

Testing of integrated application projects includes hardware, software and customerwitnessed testing, e.g., Factory Acceptance Testing (FAT). These testing activities are addressed in PPMs 6.0 and 8.0.

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#### 4.2.7. TEST PROCEDURES

Testing shall be performed in accordance with approved test procedures. Departments responsible for developing test procedures shall ensure that testing activities are adequately defined and documented.

Specific content and format of test procedures may vary as appropriate to the activity. However, test procedures shall include the following attributes, where applicable:

- a) Title and revision number.
- b) Objective (what the test is intended to accomplish).
- c) References (governing source documents or other documents relevant to the test).
- d) Prerequisites (conditions that need to be satisfied before the test).
- e) Precautions (conditions which may cause injury to personnel or damage to equipment).
- f) Provisions for recording measuring and test equipment used, including calibration status.
- g) Step-by-step instruction in sufficient detail to allow a qualified individual to perform the test with minimum supervision.
- h) Provision for recording data in the body of the procedure, attached data sheets or electronic files.
- i) Identification of test personnel and date test was performed. Provision for initialing and dating key steps in the procedure should be provided, as necessary.
- j) Acceptance criteria.
- k) Witness or hold points, where required.
- 1) Required test software, if used.
- m)Provision for handling deficiencies or deviations.
- n) Provision for review/approval of test results.

Unless otherwise defined in Department procedures, test procedures and associated software will be approved and issued through the Change Control Board (CCB) in accordance with EDM 21.00 and EDM 21.10. Application project test procedures and associated software are controlled per PPMs 6.0 and 7.0. Changes to test procedures/test software will be handled in the same manner as the original issue.

#### 4.2.8. TEST SOFTWARE

Software developed to support test procedures or perform automatic testing functions shall be controlled, validated and approved for use. Configuration control, i.e., logging of revision/version, maintenance of change records, etc., shall be maintained for test software. The identity and version of software to be utilized during tests shall be clearly specified in test procedures or in associated work documents. Test software developed for application projects shall be controlled in accordance with PPM 7.0.

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Test software shall be validated to the degree necessary to ensure that the associated test is being conducted in accordance with its test procedures and specifications.

Software validation shall be documented in a validation memo/report that includes, as a minimum, the purpose of the software, input requirements/references, a description of the validation method, results and signature of person performing the validation. Test software and associated validation documentation are considered to be Quality Records to be handled in accordance with QAM 16.0.

Software developed as a testing aid, e.g., debugging and troubleshooting, which is not relied upon for quality verification, is not subject to the requirements of this Section.

### 4.3. INSPECTION

#### 4.3.1. SOURCE INSPECTION

Source inspection will be performed by Quality Assurance Inspectors (QPM 10.1). Source inspection at the vendor's site will be coordinated in advance and the Quality Assurance Inspector is authorized to carry necessary documents with himself or herself for Source Inspection at the site. Triconex Products Quality Assurance Inspectors shall perform Source Inspection:

- a) If it is not possible or reasonable to fully inspect items upon receipt.
- b) If the Product Quality Director or Project Quality Manager elect to perform Source Inspection for any reason at any given time.

#### 4.3.2. RECEIVING INSPECTION

The Quality Assurance Inspector shall perform a receiving inspection in order to ensure that incoming product is not used or processed until it has been verified as conforming to specified requirements. The following inspection methods are in use:

- a) 100% inspection
- b) Sample inspection

Receiving inspection shall be performed as outlined in QPM 10.2 and PPM 5.0. Material that is accepted shall be either moved to stock, directly to the manufacturing or to the application project area, as applicable.

Discrepancies found during Receiving Inspection shall be recorded on a Material Review Report (MRR) and shall be submitted for material review. For application projects, discrepancies found during Receiving Inspection shall be recorded on a System Integration Deficiency Report (SIDR) and processed in accordance with PPM 10.0.

## 4.3.3. IN-PROCESS INSPECTION

In-Process inspections will be performed by Quality Assurance Inspectors. An in-process inspection for production items shall be carried out in order to verify that rework, upgrade and repair activities were conducted in accordance with specified requirements. An

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in-process inspection shall be performed on all Printed Circuit Board Assemblies (74xxxxx-xxx & 74xxxxx-xxxN part numbers) that have passed functional testing. Rejected Printed Circuit Board Assemblies shall be recorded on the applicable POTR and moved to the rework station.

Accepted Printed Circuit Board Assemblies shall be moved to the mechanical assembly station. The in-process inspection for production items shall be carried out as outlined in QPM 10.3. (NOTE: Trident receives in-process inspection only if rework is performed.)

In-process inspections of application projects, i.e., integrated systems, are performed in accordance with PPM 8.0. In-process inspections include verification that an assembled, integrated system meets customer requirements as delineated by project specific drawings and documents.

### 4.3.4. SYSTEM PRE-SHIP/FINAL INSPECTION (PRODUCTION ITEMS)

The Pre-Ship Inspection shall be performed by a Quality Assurance Inspector. Pre-Ship Inspection functions are the final check that:

- a) The System matches the Sales Order.
- b) The documentation is complete and correct.
- c) The correct modules are installed.
- d) Any configuration changes are documented and are acceptable.
- e) The system has successfully passed the System Acceptance Test.
- f) Applicable system component POTRs are complete.
- g) System shortages are addressed.

During a Pre-Ship Inspection, final inspection is recorded for the individual boards by the Quality Assurance Inspector. A Pre-Ship Inspection for product shall be carried out after the system has passed the System Acceptance Test in accordance with QPM 10.5. Pre-ship inspection of application projects is conducted in accordance with PPM 8.0.

#### 4.3.5. QUALIFICATION TESTING

Where design adequacy is to be verified by qualification testing (ref. QAM 4.0), this shall be identified in the appropriate project plans or associated verification plans. Qualification testing shall be consistent with guidance in section 4.2.3 of NQA-1-1994, including:

- a) Clear definition of test configuration and setup;
- b) Demonstration of performance adequacy under conditions that simulate the most adverse design conditions; and
- c) Evaluation of test results by the responsible design organization to assure that the test requirements have been met.

Qualification of Triconex products for use in nuclear safety-related (1E) applications is described in EDM 75.00.

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#### 4.3.6. INSPECTION OF CUSTOMER RETURNED PRODUCT

Customer returned product is inspected upon receiving per QPM 10.2. The Customer Service group shall arrange for the repair or upgrade of the product as per customer requirement following QAM 19.0. The product shall be inspected as per QPM 10.3, In-Process Inspection and QPM 10.5, Pre-Ship Inspection.

#### 4.3.7. INSPECTION OF CUSTOMER SUPPLIED PRODUCTS/MATERIALS

Customer supplied products/materials are inspected by Receiving Inspection per QPM 10.2. The inspector shall note on the inspection reports that inspection was for customer supplied products/materials. For application projects, customer supplied material is addressed in PPM 5.0.

#### 4.4 WAIVED INSPECTIONS OR TESTS

Waivers of required inspections and tests are not allowed. Materials and equipment proceeding past process checkpoints without required inspections or tests are considered nonconforming and are dispositioned by the MRB (reference QAM 13.2).

### 4.5 INSPECTION REPORTS AND TEST RECORDS

All completed inspection and test records are considered to be Quality Records in accordance with QAM 16.0. Inspection and test records shall identify, as a minimum, the inspector or data recorder, the date, the type of observation, the results, the acceptability and the action taken in accordance with any deficiencies noted.

# 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 4.0	Design Control
QAM 6.0	Purchasing
QAM 7.0	Control of Customer Supplied Product
QAM 10.1	Test Procedure Development
QAM 13.1	Control of Non-Conforming Product
QAM 13.2	Non-Conforming Product Review and Disposition
QAM 16.0	Quality Records
QAM 19.0	Servicing
QPM 10.1	Source Inspection
QPM 10.2	Receiving Inspection
QPM 10.3	In Process Inspection
QPM 10.5	Pre Ship Inspection
QPM 19.2	Customer Service Diagnosis and Test
MDM 9.1	Manufacturing Process
MDM 9.1.1	Product Sampling Plan
EDM 21.00	Engineering Change Order Control
EDM 21.10	Engineering Change Request (ECR)

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EDM 75.00	Maintenance of Nuclear 1E Qualification
PPM 5.0	Control of Materials and Services
PPM 6.0	Test Controls
PPM 7.0	Application Program Development
PPM 8.0	System Integration Implementation
PPM 10.0	Nonconformance & Corrective Action

Section:	QAM 11.0	Subject:	Control of Inspection, Measuring and Test Equipment				
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### 1.0 PURPOSE

This procedure describes the requirements and methods used to purchase and control inspection, measuring and test equipment.

## 2.0 DEPARTMENTS AFFECTED

Manufacturing

Engineering

**Product Assurance** 

Quality Assurance

Nuclear Project Group

### 3.0 SCOPE

This procedure applies to all inspection, measuring and test equipment in use by all organizations within the Triconex Irvine facility.

## 4.0 PROCEDURE

# 4.1 SELECTION OF EQUIPMENT

All purchase requisitions for standards and for measuring and test equipment shall be processed according to the instructions described in QAM 6.0. Purchasing with the following additions:

- a) Selection of make and type shall be made with approval of all parties involved.
- b) Required accuracy and repeatability of measurement shall be specified, if applicable.
- c) Acceptance requirements shall include a means for determining that the equipment can be successfully calibrated.
- d) Appropriate operating and maintenance manuals are ordered with the equipment.

# 4.2 EQUIPMENT CALIBRATION STATUS

All inspection, measuring, and test equipment shall be evaluated as to "Calibration Required" or "Calibration Not Required" status. The status of the equipment shall be determined using the following criteria:

a) The status shall be "Calibration Required" in the event equipment is used to measure, record or verify a product variable in case the value of this variable will affect the quality of the final product.

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- b) The status shall be "Calibration Required" if the equipment is going to be used to control a process variable that will affect the quality of the final product.
- c) The status shall be "Calibration Not Required" if the equipment is going to be used to monitor a variable or to generate a variable input that can be measured with calibrated equipment.
- d) The status shall be "Calibration Not Required" if the equipment is going to be used as indicator of a variable that can and shall be measured, verified or adjusted at a later stage in the process of design or manufacturing.
- e) The status shall be "Calibration Not Required" if the use of the equipment does not affect the quality of the final product.

## 4.2.1 CALIBRATION REQUIRED

Equipment for which the status is determined to be "Calibration Required" shall be labeled with a calibration sticker indicating the calibration date and the calibration due date. The equipment make, model and/or serial number shall be used to identify the equipment and link it to its calibration records. A master list of "Calibration Required" equipment shall be maintained by Quality Assurance.

### 4.2.2 CALIBRATION NOT REQUIRED

Equipment for which the status is determined to be "Calibration Not Required" can be labeled with a sticker, which states "CALIBRATION NOT REQUIRED" or similar text. Note: The use of the "Calibration Not Required" sticker is optional. If the equipment has the status calibration required as per 4.2, then a valid calibration sticker shall be affixed to the instrument. All other equipment shall be regarded as having either the status "Calibration Not Required" or as out of calibration. In both cases the instrument cannot be used for the operations described in paragraph 4.2 a) and b).

# 4.3 CONTROL OF EQUIPMENT

The Quality Assurance Department shall maintain a master file of all equipment that requires calibration.

Upon receipt of new equipment, a receiving inspection shall be performed by the QA department to verify that specifications and purchasing requirements have been satisfied. As a minimum, the make, model and serial number shall be recorded by Quality Assurance. The new equipment shall be added to the calibration equipment list. A new Triconex (TCNX) control number (ID #) shall be assigned and attached to the equipment and a new folder created for the equipment with TCNX number on the folder. The instrument identification will then be entered into the calibration database for tracking purposes; the Department and individual responsible for the instrument shall be referenced in the database. Upon receipt, new equipment shall be sent to an approved calibration service for calibration prior to use in a quality affecting application.

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Any deviation to this policy for initial calibration documentation must be approved by the Quality Director via a memo to file concluding that use of the equipment prior to the next calibration cycle would have no significant effect on a Triconex product.

New equipment requiring calibration shall not be used until the calibration label is affixed and the equipment is added to the Triconex calibration control system.

# 4.4 EQUIPMENT MAINTENANCE

Where equipment requires maintenance on a regular basis in order to function properly and/or for safety reasons the maintenance interval or due date shall be affixed to the equipment and/or the equipment shall be included in a documented and controlled maintenance system. The organization within Triconex responsible for the equipment shall ensure that their equipment is properly maintained.

#### 4.4.1 ANTI-TAMPER STICKERS

To preclude unauthorized equipment adjustments, which could invalidate calibration status, anti-tamper stickers should be applied to measuring and test equipment where appropriate. Stickers may be applied by either a calibration supplier or Triconex quality assurance personnel.

#### 4.4.2 BATTERY REPLACEMENT

Battery replacement in a calibrated item may necessitate the removal of anti-tamper stickers on test equipment. If this is required, new anti-tamper stickers shall be affixed by the Quality Assurance Department.

## 4.5 EQUIPMENT USE

It is the responsibility of personnel using measuring and test equipment to:

- a) Know when calibrated equipment is required for their activity,
- b) Know the required accuracy for planned measurements and select equipment for use accordingly, and
- c) Verify that, when necessary, the equipment bears a valid calibration sticker and is within its calibration interval (calibration due date not exceeded).

When procedures specify measuring equipment to be used, it is the responsibility of the procedure writer to assure that the specified equipment is capable of the required accuracy.

Inspection, test and measuring equipment shall be used as intended and in accordance with the operating instruction only. Any incident, event or measurement that reflects doubt on the accuracy or safe operation of the equipment shall be reported by the user to his/her supervisor. The supervisor shall take appropriate action to ensure that the equipment is not further used until re-calibrated and/or repaired, by using the system for non conforming material as described in QAM 13.1. The disposition of equipment that passed the calibration due date shall be in accordance with the same procedure.

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### 4.6 TRACEABILITY OF CALIBRATION STANDARDS

The calibration of equipment shall be performed using standards or references traceable to national or international accepted standards. Where possible, traceability to the National Institute of Standards and Technology (NIST) shall be obtained. In case traceability to national or international standards is not feasible, the methods, equipment, and references used to calibrate the equipment shall be documented in detail.

### 4.7 CALIBRATION

Calibration of equipment can be carried out by the equipment manufacturer, a third party specialized in calibration, or by certified Triconex personnel. Unless otherwise stated the electronic equipment shall be calibrated twice per year and mechanical equipment shall be calibrated once every 2 years. Where applicable, calibration results and calibration techniques shall be documented in a calibration certificate.

The Triconex purchase order issued to a calibration supplier shall specify the quality requirements (e.g., meet the requirements of ANSI Z540, including immediate notification to Triconex of any out of calibration findings, including any primary calibration standards that were found out of calibration and/or out of tolerance).

### 4.8 OUT OF CALIBRATION

Where equipment is found to be "out of calibration", it shall be documented on an Out of Calibration Notice and Assessment Form Q0036. The Quality Director or designee shall distribute the form to functional areas (i.e. Production Test, Systems Integration, QC Inspection, Labs) to notify them of the condition, and to confirm if the equipment had been used. The Quality Director or designee shall assess the significance and impact of usage of the out of calibration equipment. The Quality Director shall determine if a recall of affected product and/or customer notification is required. Any products, in house or shipped, whose quality is affected by the out of calibration evaluation shall be documented on a Material Review Report (MRR) per QAM 13.1 or a System Integration Deficiency Report (SIDR) per PPM 10.0, as appropriate. Out of Calibration Assessments resulting in affect on product quality shall be reviewed by the QARB, as applicable.

For hardware used in nuclear safety-related projects whose quality is affected by equipment found out of calibration, the Quality Director shall also assess previous test and/or inspection results for 10CFR Part 21 applicability per QAM 13.3.

Records of assessments shall be maintained and regarded as quality records as per QAM 16.0.

### 4.9 DETERMINATION OF CALIBRATION INTERVAL

The calibration interval shall be determined using the following criteria:

a) In the event the manufacturer specifies a required calibration interval. This interval shall be the maximum allowable interval unless calibration records can support the use of a longer interval.

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b) A nominal six (6) month interval shall be used for electronic equipment, and a two (2) year interval shall be used for mechanical equipment unless criteria requires shorter intervals as noted in Paragraph (a) above. These intervals may be lengthened or shortened provided that the calibration history supports the use of a different interval. Documentation supporting the change in calibration interval shall be included in the calibration records.

NOTE: Established calibration intervals may be extended for 30 days maximum to allow for minor cycle schedule variations, e.g., 7 months maximum for a nominal 6 month interval.

### 4.10 CALIBRATION RECORDS

The calibration records shall be maintained by the Quality Assurance Department. The calibration certificates shall be reviewed and accepted. Evidence of who reviewed each certificate shall be maintained. The records shall contain at least the following:

- a) Make, model, serial number of the equipment and location (or other way of identification)
- b) Calibration certificates or detailed calibration results and, a maintenance schedule (if applicable),
- c) Maintenance or repair history (if any).

The calibration records are regarded as quality records and handled in accordance with QAM 16.0.

### 4.11 CONTROL OF TEST FIXTURES

Manufacturing test fixtures shall be controlled in accordance with MDM 11.3. Periodic inspection shall verify that test fixtures (1) continue to function satisfactorily and (2) are using the test software currently specified in the test procedures (reference QAM 10.0.). The verifications shall be documented. These verification documents are regarded as quality records and handled in accordance with QAM 16.0.

### 4.12 CALIBRATION SUPPLIER AUDIT SCHEDULE

Triconex shall conduct an audit of calibration suppliers every 3 years, as a minimum, in accordance with QAM 17.0. The audit may be performed at the supplier facility or on-site at the Triconex Irvine facility, or a combination of both.

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## 5.0 REFERENCES AND RELATED DOCUMENTS

(	)AM 6.0	Purchasing
	QAM 10.0	Inspection and Testing
(	QAM 13.1	Control of Non-Conforming Product
(	QAM 13.3	10CFR Part 21 Reporting of Defects and Noncompliance
(	QAM 17.0	Audit Program
(	QAM 16.0	Quality Records
N	MDM 11.3	Manufacturing Board Test Fixture Verification/Testing
P	PPM 10.0	Nonconformance & Corrective Action
F	Form Q0036	Out of Calibration Notice and Assessment Form

Section	: QAM 12.0	Subject:	Inspection and Test Status							
Revision	: 012	Page:	1	of	4	Date:	4/30/04			

### 1. PURPOSE

The purpose of this procedure is to define the system used to identify the inspection and test status for Triconex Products and systems.

### 2. <u>DEPARTMENTS AFFECTED</u>

Manufacturing Quality Assurance Nuclear Project Group

### 3. SCOPE

This procedure defines the method of identifying the inspection and test status of all Triconex product, and systems throughout the manufacturing cycle. This applies to product which is procured for new manufactured assemblies as well as product which has been shipped to Triconex for repair or upgrade. This also applies to application project inspection and test activities. It is essential that during all stages of the manufacturing process, the test and inspection status of material, sub-assemblies, assemblies, final product, and systems can be identified in order to ensure that the product or system conforms to the requirements.

### 4. PROCEDURE

### 4.1. GENERAL

When serialized product is processed through receiving, a Production Order Tag is created in accordance with QAM 8.0 which defines the routing, and is also used to identify the inspection status through the manufacturing process. The inspection and test status of system configurations can be determined by their accompanying System Configuration Sheet, System Hardware Layout Discrepancy Tracking Sheet and System Test Compliance Sheet. These forms are started at different stages in the process and travel with the system until it is shipped. Non-serialized parts which are not identified by Production Order Tags are considered to be conforming unless they are identified as non-conforming in accordance with QAM 13.1.

### 4.2. SYSTEM INTEGRATION INSPECTION AND TEST STATUS

System inspection and test status for system integration projects is maintained through the use of the System Integration Completion Checklist which constitutes the assembly traveler (PPM Form 8-1) in accordance with PPM 8.0. Test control is maintained in accordance with PPM 6.0. Inspection status of received materials in controlled in accordance with PPM 5.0, which requires materials to identified by part number (if assigned), P.O. number, and indication of inspection status.

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	Paul Mesmer		Quality Director

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### 4.3. USE OF AUTHORIZED STAMPS

In order to be able to identify the inspection and test status of the product or system, the Production Order Tag and other forms of inspection status forms shall be stamped, initialed, or completed electronically at pre-defined process stages. Each person authorized to "stamp off" a process shall be assigned a unique personal stamp or login identifier. The issuing and use of the stamp shall be in accordance with the Quality Procedure QPM 12.1. The stamp, initials, or login name shall identify the person.

### 4.4. INSPECTION STATUS RECORDS (PRODUCT)

### 4.4.1. RECEIVING INSPECTION

All material received by Triconex are processed through Triconex Receiving Department. Following confirmation of part identification, the parts that require serialization will be serialized. A Production Order Tag will be created electronically or by using paper tags as noted:

Beige Tags (new product)

Green Tags (Material returned from customer for credit or replacement)

Pink Tags (Material returned and owned by the customer.)
Blue Tags (Material used with demo and training equipment)

For nuclear material, an orange sticker will be affixed to the Production Order Tag or an electronic flag will be set in the database.

Personnel in Receiving will "stamp off" the appropriate step, open a Batch Report and process parts to Receiving Inspection. Following acceptance of the item by Receiving Inspection, the results are entered in the computer database and the inspector will "stamp off" or record the results.

The parts that do not require serialization shall be processed through Receiving and Receiving Inspection using the Batch Report. Once accepted by Receiving Inspection the parts can be moved to stockroom or issued to production control. Non serialized parts do not require any other inspection / testing until assembled into its final assembly.

Material that is rejected at Receiving Inspection shall be regarded as non-conforming material as per QAM 13.1.

### 4.4.2. MANUFACTURING PROCESS

All serialized assemblies will be issued to the manufacturing floor with the Production Order Tag which at all times identifies the inspection and test status of the module or assembly. If during the manufacturing process, the item is found to be non-conforming per QAM 13.1, it will be identified with a "RED TAG", and the discrepancy will be documented on a Material Review Report (MRR), and the assembly will be segregated and processed by the Material Review Board (MRB) per QAM 13.2.

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### 4.4.3. CUSTOMER RETURNS (RMA)

All return items will be issued to the RMA area with the Production Order Tag which at all times identifies the inspection and test status of the module or assembly during the repair process. Refer to QPM 19.1 for purpose of the Production Order Tags. If during the servicing process, the assembly cannot be reworked, it will be identified with a "RED TAG" and the assembly will be segregated and processed by the MRB (QAM 13.2).

### 4.5. LOGS/CHECKLISTS (PRODUCT)

Logs, checklists, or computer system entries at various operations during the manufacturing process will be utilized to define the inspection and test status of work in process. The data referenced in this paragraph will be regarded as quality records as per QAM 16.0.

### 4.5.1. RECEIVING INSPECTION RECORD

All material processed through receiving inspection will be entered into the appropriate computer systems. This will be used to document the receiving inspection results on a daily basis.

### 4.5.2. REWORK LOG SHEET

All work that is processed through the manufacturing rework station is logged in to the computer database system. This will identify by board part number, serial number, vendor, and the daily rework activity.

### 4.5.3. BURN-IN TEST RECORD

All modules or assemblies which are processed through Burn-In Test are recorded in a computer database system. This record documents the burn-in activity by module serial number and identifies whether the item passed or failed the Burn-In Test. Items that do not pass burn-in are so documented on the Production Order Tag and processed in the appropriate manner.

### 4.5.4. PRE TEST SYSTEM CHECKLIST

A system level inspection is performed on every system prior to System Acceptance Test. The Pre Test Checklist is used to document the inspection status of the system prior to System Acceptance Test.

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### 4.5.5. SYSTEM CONFIGURATION SHEET

The System Configuration Sheets are used to document the complete system configuration. These sheets shall describe the current configuration of the system by part number and serial number at all times. Manufacturing will stamp off the System Configuration Sheet after acceptance of the System Pre Test and System Acceptance Test by the Quality Inspector. Any changes made on the System Configuration Sheet are recorded on the System Hardware Layout Discrepancy Tracking Sheet.

### 4.5.6. SYSTEM HARDWARE LAYOUT DISCREPANCY TRACKING SHEET

Any change to the System Configuration Sheet shall be recorded on the System Hardware Layout Discrepancy Tracking Sheet. After the change is completed, the operator shall record the entry. The Quality Inspector shall verify that all changes are conforming to the requirements and if so, stamp or record the inspection.

### 4.5.7. SYSTEM TEST COMPLIANCE SHEET

The System Test Compliance Sheet forms an integral part of the System Acceptance Test. Each step in this test procedure is "stamped off" after the system has passed the test.

### 4.5.8. PRE SHIP CHECKLIST

A Pre Ship Inspection is performed on each system prior to delivery of the completed system. The Pre Ship Checklist identifies the inspection status of the system prior to packaging for delivery.

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 8.0	Product, Parts, and Material Identification and Traceability
QAM 13.1	Control of Non-Conforming Product
QAM 13.2	Non-Conforming Product Review and Disposition
QAM 16.0	Quality Records
QPM 12.1	Control and Use of Stamps
QPM 19.1	Return Material Authorization System
PPM 5.0	Materials & Services
PPM 6.0	Test Control
PPM 8.0	System Integration Implementation

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### 1. PURPOSE

This procedure describes the system used by Triconex to ensure that product and integrated system items which do not conform to specified requirements are prevented from inadvertent use or installation.

### 2. **DEPARTMENTS AFFECTED**

Manufacturing
Quality Assurance
Engineering
Finance
Nuclear Project Group

### 3. SCOPE

This procedure applies to all manufacturing and production areas of the Triconex Irvine facility. This includes application project activities. This procedure covers the identification, documentation, evaluation, segregation, and disposition of non-conforming material and product. This procedure is also applicable for application projects. These provisions are provided to assure that all Triconex products and systems meet internal and external requirements prior to shipment unless otherwise documented and approved by appropriate parties.

### 4. PROCEDURE

### 4.1. GENERAL

### 4.1.1. NONCONFORMING MATERIAL OR PRODUCT

Material or product is considered nonconforming if it does not meet Triconex specified requirements. Nonconforming items are handled in accordance with paragraph 4.2.

### 4.1.2. APPLICATION PROJECT NONCONFORMANCES

Application project parts and materials (items) are considered to be nonconforming if they do not meet specified project requirements. All nonconforming items shall be documented on a Material Review Report (MRR) per section 4.2.1 and 4.2.2. MRRs and other mechanisms for in-process rework of hardware and documentation are processed in accordance with Project Procedures Manual (PPM) 10.0.

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Application project assemblies (i.e., cabinets/cabinet wiring, etc.) and integrated systems which are found to not fully meet project requirements (purchase order, specifications, drawings, etc.) may be reworked to bring them into conformance without issuance of a MRR. The discrepancy, rework instructions, rework inspections, and retest instructions (if applicable) shall be documented and controlled to ensure that identified deficiencies are corrected prior to moving to the next phase. These deficiencies shall be tracked and trended in accordance with QAM 14.0 to determine the need for additional corrective action

### 4.1.3. UNRELEASED/UNAPPROVED PRODUCT

Triconex products shall be fully released or approved for production prior to shipment to customers. Exceptions must be authorized in writing by Triconex and the customer by means of a Beta Agreement (see TGM C-7).

### 4.1.4. PRODUCT NOT MEETING CUSTOMER REQUIREMENTS

Product or systems which are found to not fully meet customer requirements (purchase order, specifications, drawings, etc.) are routinely reworked to bring them into conformance. The Sales Order and/or customer drawings may require revision to resolve the conflict. Items shall meet customer requirements prior to final acceptance by QA Inspection or authorization for shipment unless deviations are approved by the customer. Short Ship Authorization (MDM 9.3) or other equivalent documentation shall be used for this purpose and included in the system folder.

### 4.2. NONCONFORMING MATERIAL AND PRODUCT

In general non-conforming material and product is controlled by the Material Review Board (MRB). The responsibilities of the MRB are detailed in MDM 13.2. The MRB shall consist of representatives of :

- a) Manufacturing
- b) Quality
- c) Engineering
- d) Finance

For application project nonconformances, the Project Material Review Board (PMRB) performs the MRB functions described in MDM 13.2. The responsibilities of the PMRB are detailed in PPM 10.0.

### 4.2.1. IDENTIFICATION

Non-conforming material can and shall be identified by all Triconex personnel. The Following material should be regarded as non-conforming:

- a) Material that is rejected at Receiving Inspection
- b) Material obviously not fit for use (damaged)
- c) Parts that can be identified with 74xxxxx-xxx part numbers that do not have a Production Order Tag and are not in the process of being shipped, or that do not have a serial number.

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- d) Material that cannot be positively identified by part number or Engineering Drawing or Documentation
- e) Equipment that is out of order or out of calibration. The equipment shall be evaluated in accordance with QAM 11.0, Paragraph 4.8.
- f) All material that during the manufacturing or service process is identified as not in compliance with its specification, and that cannot be reworked or repaired as part of the normal manufacturing or service process.
- g) Other items of indeterminate quality as determined by the Quality Director.

### 4.2.2. **DOCUMENTATION**

Nonconforming items, with exception for those that can be reworked in-house shall be documented on a Material Review Report (MRR) form. Out of calibration items shall be evaluated as noted in e) above. Discrepant hardware items identified in-process for rework (reference section 4.2.1 and 4.2.2) are documented on Discrepancy Sheets per product and project procedures. Discrepant documentation or in process software are documented and controlled on other established correction mechanisms such as Document Review forms or application program Anomaly Reports (PPM 7.0)

### 4.2.3. SEGREGATION

Once non-conforming material has been identified, the identifier shall inform the supervisor responsible for the area. The supervisor shall mark the material with the appropriate form (red tag) and organize segregation of the material.

Where feasible the material shall be moved to the designated Material Review Board (MRB) location. If this is not practical, the supervisor shall clearly mark the material or area to prevent inadvertent use. The disposition shall be determined by the MRB (QAM 13.2).

### 4.2.4. MATERIAL REJECTED AT RECEIVING INSPECTION

Material that is rejected at Receiving Inspection shall be positively identified as **REJECT**. The reason for rejection shall be noted on a Material Review Report (MRR) and the MRR number shall be noted on the Production Order Tag. The material shall be moved by the inspector to the designated MRB location for further disposition by the MRB (QAM 13.2).

### 4.2.5. CUSTOMER SERVICE NON-CONFORMING MATERIAL

Non-conforming material identified within the Customer Return (RMA) Area shall be marked with the appropriate form(s) and moved to the Non-Conforming Material Area for further disposition by the MRB.

### 4.2.6. CONTROL OF CUSTOMER SUPPLIED PRODUCT

Customer supplied product that is found to be defective shall be regarded as non-conforming product in accordance with QAM 13.2. For application projects, customer supplied material is addressed in PPM 5.0. The Material Review Board shall report the

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damage to the customer and negotiate the disposition and financial consequences. Nonconforming customer supplied product shall not be used by Triconex without a written waiver from the customer.

### 4.3. EVALUATION

Where indications exist that the cause of the condition is a breakdown of the Triconex or supplier's quality program, the Quality Director shall consider the issuance of an Action Request Report (ARR) or a Corrective Action Report (CAR) per QPM 14.2. For significant conditions adverse to quality, the condition shall be documented on an ARR and the Quality Director shall report the condition(s) to the appropriate levels of Triconex Management for immediate action, as necessary, to correct the condition.

### 4.4. RECORDS

Material Review Reports and related documentation are considered Quality Records in accordance with QAM 16.0.

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 7.0	Control of Customer Supplied Product
QAM 13.2	Non-Conforming Product Review and Disposition
QPM 14.2	Corrective Action Document Processing
MDM 9.6	Board Level Test and Rework
MDM 13.2	Review and Disposition of Non-Conforming Product
TGM C-7	Beta Program
PPM 5.0	Control of Materials and Services
PPM 10.0	Nonconformance & Corrective Action

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### **PURPOSE** <u>1.</u>

This procedure describes the responsibility to review and authority for disposition of nonconforming product within Triconex Products.

### <u>2.</u> DEPARTMENTS AFFECTED

Manufacturing

**Product Assurance** 

Quality Assurance

**Technical Support** 

Engineering

Finance

Nuclear Project Group

### **3**. **SCOPE**

The non-conforming product documented on Material Review Reports (MRRs) shall be reviewed in accordance with this procedure. This procedure also defines the responsibility for review and authority for disposition of non-conforming product. This procedure includes the mechanisms used to purge non-conforming material, and to recall non-conforming product from the field.

This procedure is also applicable for application projects.

### <u>4.</u> 4.1. **PROCEDURE**

### **GENERAL**

Non-Conforming Product Review and disposition is attained by the Material Review Board (MRB) as described below. For application projects, the Project Material Review Board (PMRB) performs the same functions described below. The responsibilities of the PMRB are detailed in Project Procedures Manual (PPM) 10.0.

#### 4.2. DISPOSITION

The MRB shall review all non-conforming material on a regular basis. The requester shall inform the MRB in case immediate review is required. The MRB shall decide upon the disposition of all non-conforming material. The following dispositions are possible:

- a) Return to Vendor
- b) Use As Is
- c) Rework
- d) Repair
- e) Scrap

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For Repair, Use As Is and Scrap dispositions the MRB shall complete the Material Review Report (MRR) form, organize and monitor the disposition of the material. For Repair or Use As Is dispositions, the justification for the acceptability of the disposition shall be documented on the MRR.

### 4.3. EVALUATION

All material identified as non-conforming per QAM 13.1 shall be evaluated by the Material Review Board as per MDM 13.2 or PPM 10.0. Where indications exist that the cause of the condition is a breakdown in a supplier's quality program, the Quality Director shall consider issuance of a Corrective Action Report, per QPM 14.2.

The MRB shall evaluate the repair and rework disposition of the item(s) to determine the impact on the design or the impact on testing. The repair/rework shall be accomplished in accordance with approved procedures or instructions. The reworked/repaired item shall be re-inspected and re-tested to the original requirements, unless special re-testing is specified in the disposition. If the disposition results in a change to any documents, the documents shall be listed in the disposition. The affected documents will be changed in accordance with the governing department procedure.

### 4.4. WAIVERS AND CONCESSIONS

In the event the disposition of non-conforming material is decided as "Use As Is" the MRR form shall be regarded as the concession. (Note: The MRR is used to disposition deviations from Triconex requirements, not customer requirements. Waivers or exceptions to customer requirements are handled as part of Sales Order Administration.)

### 4.5. MATERIAL PURGE

Where the non-conformity found is possibly not isolated to the single item or controlled batch a material purge might be necessary to segregate all non-conforming product. The material purge shall be organized by the MRB. The MRB shall give clear and unambiguous instructions to the supervisors of the relevant areas. The supervisors will perform the purge or assign personnel to perform the purge, segregate purged material, and report back to the MRB as per instructions. The MRB shall prepare a Purge Report stating the results of the purge per area, the disposition of the material and references to the resulting MRR forms

### 4.6. IMMEDIATE PRODUCT RECALL

In the event that there is suspicion that non-conforming product has been shipped to our customers in the field, the Quality Director can decide to recall these products from the field. A Product Discrepancy Report (PDR) shall be issued if non-conforming product is in the field. The Manager, Technical Support shall identify the location and end users of possible non-conforming material in the field using the product identification and traceability system as described in QAM 8.0. The Technical Support department shall notify the customer and

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supply him with instructions which guarantee safe operation and instructions to return the material using the RMA system as described in QAM 19.0. The Quality Director shall maintain separate records of recalled product as part of the PDR. The records shall contain the problem identification, recall reason, product affected, customers affected, quantity recalled, corrective action taken, and other relevant documentation.

For nuclear products, the Quality Director shall also determine if the nonconforming product is reportable for 10CFR Part 21 requirements. See QAM 13.3.

### 4.7. MATERIAL REVIEW REPORT VERIFICATION AND CLOSEOUT

The MRR is stamped with an "MRB Action Closed" stamp when all actions have been completed and placed in MRR files.

### 4.8. RECORDS

The Material Review Board (MRB) shall maintain records of all Material Review Report (MRR) forms. These records shall be regarded as Quality Records as per QAM 16.0

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 13.1	Control of Non-Conforming Product
QAM 13.3	10CFR Part 21 Reporting of Defects and Noncompliance
QAM 8.0	Product Identification and Traceability
QAM 14.0	Corrective and Preventive Action
QAM 16.0	Quality Records
QAM 19.0	Servicing
MDM 13.2	Review and Disposition of Non-conforming Product
QPM 14.2	Corrective Action Document Processing
PPM 10.0	Nonconformance & Corrective Action

Section:	QAM 13.3	Subject:	10CFF	R Par	t 21 Rep	orting of	Defects and Noncompliance
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### 1. PURPOSE

The Code of Federal Regulations 10CFR Part 21 requires that defects and/or deviations which could affect nuclear safety be reported to the Nuclear Regulatory Commission (NRC). This procedure describes the process for identifying and evaluating defects and/or deviations, and reporting to the NRC when required.

### 2. <u>DEPARTMENTS AFFECTED</u>

All Triconex Departments IPS Quality Assurance

### <u>3.</u> <u>SCOPE</u>

This procedure applies to TRICONEX products developed for and/or supplied to nuclear customers. This includes commercial grade items dedicated for nuclear per QPM 6.2.

For application projects, the commercial grade dedication process for nuclear application items is described in Project Procedures Manual (PPM) 5.0.

### 4. PROCEDURE

### 4.1. **RESPONSIBILITY**

All employees of Triconex are responsible for identifying potential product deficiencies that could affect nuclear safety to the attention of their supervision. Such deficiencies are normally reported on a PDR, but may be identified on other documents. Supervisors shall assure that safety related deficiencies are reported to the Quality Assurance Review Board (QARB).

The QARB is responsible for reviewing nonconformance data and evaluating for 10CFR Part 21 reportability any identified defect and/or deviation which could affect the safety function of TRICONEX equipment used in a nuclear facility (reference QPMs 13.2 and 14.0). The Triconex Quality Director is responsible for notifying the Invensys Process System (IPS) Nuclear Quality Director of potential 10CFR Part 21 issues. The IPS Nuclear Quality Director participates in the QARB evaluation of potentially reportable defects and is responsible for forwarding items determined to be reportable to the IPS Global Quality Director (GQD). The IPS GQD is designated as the responsible Invensys nuclear officer for reporting to the NRC under 10CFR Part 21.

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### 4.2. **DEFINITIONS (As used in 10CFR Part 21)**

### Defect means:

- (1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or
- (2) The installation, use, or operation of a basic component containing a defect as defined in this section; or
- (3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or
- (4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to part 50 of this chapter.

### **Deviation** means

a departure from the technical requirements included in a procurement document.

### Basic component.

- (1) (i) When applied to nuclear power plants licensed pursuant to 10 CFR part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:
  - (A) The integrity of the reactor coolant pressure boundary;
  - (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
  - (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1), §50.67(b)(2), or §100.11 of this chapter, as applicable.
  - (ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR part 50, appendix B, or commercial grade items which have successfully completed the dedication process.
- (2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.
- (3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

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### Commercial grade item.

- (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).
- (2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:
  - (i) Not subject to design or specification requirements that are unique to those facilities or activities;
  - (ii) Used in applications other than those facilities or activities; and
  - (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

### Dedication.

- (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.
- (2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

### 4.3. DATA SCREENING AND EVALUATION

The Quality Assurance Review B oard (QARB) reviews de ficiencies and/or de viations reported on A ction R equest R eports (ARR), Q uality D iscrepancy Reports (QDR), and Product Discrepancy Reports (PDR). The QARB will review any other potential deficiencies brought to its attention for reportability review. D uring this review, the reported problem will be screened to determine if the problem could affect the safety function of the product. Any problem which could result in a failure of the safety function of the equipment will be examined in detail to determine if it is reportable using the following screening criteria:

- 1) Is the deviation or noncompliance safety related? (could affect the safety mission of the product) If answer is yes, continue to next question.
- 2) Was the item supplied to a nuclear facility in the USA? If yes, continue to next question.

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- 3) Was it supplied as a "basic component?" (supplied for safety-related application)
- 4) Could this condition cause unexpected operation of the product, such as failure to perform its expected function, unpredicted operation, unexpected failure mode, behavior outside the bounds of the FMEA analysis, higher than normal failure rates, etc. If yes, go to next question.
- 5) Could this condition result in the system not operating as designed (i.e., could this have an adverse effect on the safety function of the Triconex equipment used in a nuclear facility)? Assume the product is relied upon for a safety function. If yes, the condition is considered a "defect," which requires notification to the Invensys GQD and initiation of a 10CFR Part 21 reporting pursuant to the following sections.

Evaluate deviations and nonconformances potentially associated with nuclear safety as soon as practicable and in all cases, within 60 days of discovery, in order to identify a reportable defect or noncompliance that affects nuclear safety. If the evaluation cannot be completed within 60 days from discovery, an interim report will be submitted to the NRC. The interim report should describe the deviation or noncompliance and when the evaluation will be completed. This interim report must be submitted in writing within 60 days of the discovery.

The worksheet in Figure 1 may be used as an aid in the evaluation and follow-up of deficiencies. However, the QARB minutes shall be the record of the potential reportability evaluation and, if reportable, the PDR will track all follow-up actions and will record date and time of subsequent notification and reporting steps.

If the QARB determines that the item is reportable under 10CFR Part 21, i.e., that the item

- 1) Fails to comply with the rules and regulations relating to nuclear safety, or
- 2) Contains a defect,

the Invensys GQD shall be informed as soon as practical, and in all cases, within 5 working days after completion of the evaluation. This notification will normally be made by the IPS Nuclear Quality Director, or in his absence, the Triconex Quality Director. Proceed with notification per section 4.4. (Note: The notification and evaluation is not required if it is known that the NRC has been previously notified in writing of the defect or noncompliance.)

### 4.4. NOTIFICATION TO THE NRC

When it has been determined that the condition is reportable, the NRC will be notified by the IPS GQD or his designee as follows:

1) Initial notification by facsimile to the NRC at FAX (301) 816-5151 or by telephone at (301) 816-5100 within 2 days following the receipt of this information by the GQD.

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Verification that the NRC received the FAX should be made by calling the NRC. This reporting requirement does not apply to interim reports.

2) Written notification shall be provided to the NRC within 30 days following the identification of the defect or noncompliance to the GQD.

### 4.5. WRITTEN REPORTS TO THE NRC

All written communications and reports concerning these requirements will be addressed to:

Document Control Desk U. S. Nuclear Regulatory Commission Washington, DC, 20555

The IPS Nuclear Quality Director shall coordinate preparation and submittal of the 10CFR Part 21 report to the NRC, with input from cognizant Triconex departments. The written report shall include, as a minimum, the following information to the extent known:

- 1) The name and address of the individual(s) submitting the report. (GQD or designee)
- 2) A description of the condition, activity, or component which fails to comply or contains a defect.
- 3) The name and address of the company which supplied the defective component or noncompliance.
- 4) The nature of the defect or noncompliance.
- 5) The date on which the defect or noncompliance was discovered.
- 6) If the condition is a defective component, identify the number and location of all such components used by or being supplied to a nuclear facility.
- 7) The corrective action that has been, is being, or will be taken, the name of the individual or organization responsible for the action, and the length of time that has been or will be taken to complete the action.
- 8) Any advice related to the defect or noncompliance that has been, is being, or will be given to affected customers.

Triconex may be required to provide additional information to the NRC relating to defects or noncompliance. The NRC may obtain additional information from other reporting entities.

### 4.6. INSPECTIONS

The NRC shall be permitted to inspect records, premises, activities, and components as necessary to verify compliance to these requirements.

### 4.7. NOTIFICATION TO AFFECTED NUCLEAR CUSTOMERS

A copy of the 10CFR Part 21 report will be sent to affected nuclear customers for their information by the Triconex Quality Director or his designee. See QPM 13.2.

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### 4.8. RECORDS

Records shall be prepared and maintained as objective evidence of these requirements, specifically:

- 1) Retain evaluations of all potential 10CFR Part 21 deviations and noncompliance referred to the QARB for a minimum of 5 years after the date of the evaluation;
- 2) Retain 10CFR Part 21 reports to the NRC and any notifications sent to affected nuclear customers for a minimum of 5 years after the date of notification;
- 3) Retain a record of affected nuclear customers for 10 years after delivery of the component or service associated with the component.

The NRC shall be afforded a reasonable opportunity to inspect all records associated with these requirements. These records are controlled in accordance with QAM 16.0.

### 4.9. POSTING REQUIREMENTS

Current copies of the following documents are required to be posted in a conspicuous position within the Triconex facility:

- 1) 10CFR Part 21 regulations;
- 2) Section 206 of the Energy Reorganization Act of 1974; and
- 3) The procedure(s) developed to implement these requirements.

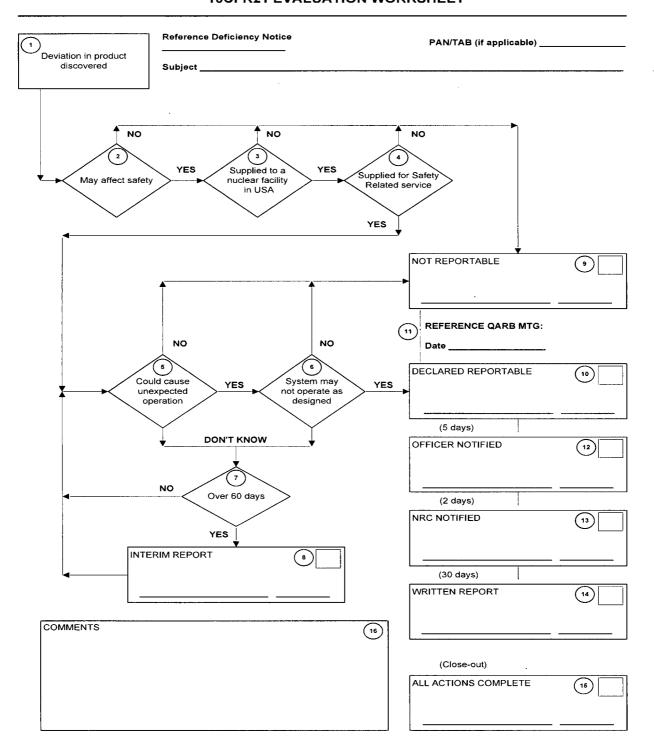
If posting of the above is not practicable, a notice will be posted which describes the regulations/procedures, including the name of the individual to whom reports may be made, and identifies where they are located.

### 5. REFERENCES AND RELATED DOCUMENTS

10CFR Part 21	Code of Federal Regulations (CFR), Title 10, Part 21 - Reporting
	of Defects and Noncompliance
QAM 1.2	Triconex Organization
QAM 13.2	Nonconforming Product Review and Disposition
QAM 16.0	Quality Records
QPM 6.2	Dedication of Commercial Grade Items
QPM 13.2	Product Discrepancies
QPM 14.0	Quality Assurance Review Board
PPM 5.0	Materials & Services

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## Figure 1 10CFR21 EVALUATION WORKSHEET



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### Figure 1: 10CFR21 Evaluation Worksheet - General Guidelines

- 1. Potential product deviation or deficiency discovered and submitted to QARB for evaluation.
- 2. Deficiency could affect safety aspects of product.
- 3. Product was supplied to a nuclear facility in the USA.
- 4. Product was supplied for nuclear safety related application (as indicated on the P.O.).
- 5. Deficiency could cause unexpected operation of the product.
- 6. Potential exists (conservative view) for Tricon system to not operate as designed.
- 7. Assess whether reportability decision has been (or will be) made within 60 days of discovery.
- 8. If evaluation will not completed within 60 days, provide interim report to NRC.
- 9. QARB makes decision that item is not reportable under 10CFR Part 21.
- 10. QARB makes decision that item is reportable under 10CFR Part 21.
- 11. Note the date of QARB meeting referencing this evaluation.
- 12. If reportable, notify IPS GQD within 5 days.
- 13. Provide telephone or fax notification to the NRC within 2 days of notifying GQD.
- 14. Provide followup written report within 30 days of notification.
- 15. Monitor actions required for notification and reporting and confirm completion. Confirm that auditable records are available.
- 16. Provide comments or clarification, where appropriate, attaching additional sheets, if necessary.

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### 1.0 PURPOSE

This procedure describes the processes for identifying and determining the cause of problems, and assigning and monitoring corrective or preventive actions to correct those identified conditions. This procedure will include Triconex vendor supplied materials and processes as well as Triconex manufactured materials and processes.

### 2.0 DEPARTMENTS AFFECTED

All Departments

### 3.0 SCOPE

This procedure applies to all corrective or preventive action taken with the objective to eliminate actual or potential nonconformities. Any such action shall be to a degree appropriate to the magnitude of the problems and encountered risk. The focus of this effort shall be to assure customer requirements are met.

For application projects, additional corrective action processes are described Paragraph 4.5.6 and in Project Procedures Manual (PPM) 10.0.

### 4.0 PROCEDURE

### 4.1. GENERAL

All corrective and preventive actions shall be controlled using one of the methods described in Section 4.5. A corrective or preventive action shall not be closed until the effectiveness of the action has been reviewed. The Quality Assurance Review Board (QARB) shall review the effectiveness of corrective and preventive actions per QPM 14.0 and provide management oversight of corrective action programs.

For significant conditions adverse to quality, the cause of the condition shall be determined and corrective or preventive action shall be taken to preclude repetition.

The QARB shall monitor trends, e.g., by review, categorization or key word, to identify previously implemented corrective and preventive actions that did not preclude repetition, i.e., were not effective. When an ineffective corrective or preventive action is identified, the QARB shall generate an ARR to document and correct the condition.

### 4.2. CORRECTIVE ACTION

Corrective action is the process by which the Quality System can minimize or eliminate the recurrence of a problem. This means that the problem has happened and there might be

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records of it occurring. Typically corrective actions would be generated as a result of customer complaints or the identification or analysis of nonconforming material.

### 4.3. PREVENTIVE ACTION

Preventive action is the process by which the Quality System can prevent any future occurrence of a potential problem; that means the problem is a potential problem which may happen in the future. Typically preventive actions would be generated as a result of analysis of available source of information such as Receiving Inspection data, In-Process Inspection or test data, audit results or nonconforming material disposition. Metrics and Management Reviews are established for monitoring trends warranting preventive action (reference QAM 1.3 and PPM 10.0).

### 4.4. IDENTIFICATION

The need for corrective or preventive action can be revealed by analysis of the following:

- Inspection records
- Test results
- Material Review Reports
- Customer complaints
- Field failure data

Furthermore, the need for corrective or preventive action can be revealed by internal or external audit observations, Management Review results, or observations and reports by personnel.

### 4.5. REPORTS

### 4.5.1. ACTION REQUEST REPORT

The Action Request Report (ARR) is used to document the need for corrective or preventive action (QPM 14.2). The ARR targets corrective action for internal deficiencies that are not related to specific products or vendors. Generally, the ARR is used to report discrepancies observed during internal audits, surveillances and third party audits conducted at Triconex; however, an ARR may be initiated at any time to document internal deficiencies that are not related to specific products or vendors. ARRs may also be used by other Triconex organizations to provide tracking of internal action items for improvements of procedures or processes in the absence of other administrative tracking systems.

ARRs will be logged in by the Quality Assurance Department and effectiveness of the action taken will be reviewed by the QARB. When assigned an ARR, Triconex personnel shall support the ARR process and carry out their responsibilities in accordance with this procedure and guidance defined in QPM 14.2.

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### 4.5.2. CORRECTIVE ACTION REPORTS

Corrective Action Reports (CARs) are used to describe and request corrective actions from Triconex vendors only. CARs are normally generated and controlled by the Triconex Quality Engineer (QE). The QE shall maintain records of all Corrective Actions Reports. Status and trends of CARs will be reviewed by the QARB.

### 4.5.3. PRODUCT DISCREPANCY REPORTS

The Product Discrepancy Reports (PDRs) are used to report nonconformities that cause released product to deviate from functional performance or reliability requirements of the current release. PDRs are generally issued by the Product Validation test engineers, Engineering, or Technical Support. However anyone may initiate a PDR.

PDRs will be logged in by Product Validation and reviewed by the QARB. PDRs can result in an Engineering Change Request (ECR). However, PDRs will not be used to report designer initiated product change.

### 4.5.4. QUALITY DISCREPANCY REPORT

The Quality Discrepancy Report (QDRs) is used to report functional or reliability nonconformances on product in the development or product validation phase. QDRs are issued by Product Validation test engineers or Engineering.

QDRs will be logged in by Product Validation and reviewed by the QARB on a regular basis. Any QDR that does not get resolved prior to the release of product shall be converted into a PDR.

### 4.5.5. MINUTES OF MEETING

Corrective or preventive action can also be initiated and recorded in the minutes of meetings. This method of initiating corrective actions shall be used for Quality System improvements, corrective actions resulting from management reviews or other long-term quality improvement initiatives. Where corrective actions are initiated in regularly scheduled meetings, the minutes of the meeting will state the corrective action required, the date the action was opened, the individual responsible for completing the action, and the date at which the corrective action is required to be completed. During each meeting the open actions will be reviewed and where possible closed.

### 4.5.6. CORRECTION OF ISOLATED DEFICIENCIES

The reports described above are utilized for correction of generic or potentially generic deficiencies in products or implementation of quality affecting activities. Other mechanisms exist for correction of isolated or individual deficiencies in the processing of documentation or product hardware. For example:

• In-process hardware discrepancies, which can be reworked in the manufacturing process, are documented on discrepancy sheets as described in QPM 10.4. These are used only for reworking deficient items and can receive no other disposition unless processed on an MRR per QAM 13.1.

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- Document deficiencies noted in the review or verification cycle for design documents are documented on comment resolution documents as described in EDM 90.00 and PPM 2.0.
- Project application software deficiencies identified during verification and validation are documented on a System Integration Deficiency Reports (SIDR) in accordance with PPM 7.0.
- Administrative Databases may be used by Triconex groups to track internal preventive action items (such as for continuous improvement initiatives) to completion.

Any trends noted in correction of deficiencies which indicates a generic quality program deficiency shall be brought to the attention of the Quality Director for issuance of an ARR or other quality improvement action. Review of activities for adverse quality trends are described in QAM 1.3 and PPM 10.0.

### 4.5.7. REPORTING OF DEFICIENCIES TO THE NRC (NUCLEAR QUALIFIED ITEMS)

In accordance with Federal Regulation 10CFR21, any deficiencies in material and services provided to nuclear power plants for safety related application must be reported to the NRC. The QARB reviews generic corrective action documents for potential reportable items as described in QAM 13.3 and QPM 13.2.

### 4.6 **QUALITY RECORDS**

EDM 00 00

All documents generated in response to this procedure are quality records and shall be controlled in accordance with the requirements of QAM 16.0.

### **5.0 REFERENCES AND RELATED DOCUMENTS**

Product Varification

EDM 90.00	Product Verification
PPM 2.0	Design Control
PPM 6.0	Test Control
PPM 7.0	Application Program Development
PPM 8.0	System Integration Implementation
PPM 10.0	Nonconformance & Corrective Action
QAM 1.3	Management Review
QAM 13.1	Control of Nonconforming Product
QAM 13.3	10CFR21 Reporting of Defects and Noncompliance
QAM 16.0	Quality Records
QPM 4.2	Quality Discrepancy Report
QPM 10.4	Pre Test Inspection
QPM 13.2	Product Discrepancies
QPM 14.0	Quality Assurance Review Board
QPM 14.2	Corrective Action Document Processing

## **TRICONEX CORPORATION QUALITY ASSURANCE MANUAL**

Section:	QAM 15.0	Subject:	Handl	ing, S	Storage,	Packagin	g, Preservation and Delivery
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### 1.0 PURPOSE

This procedure describes the requirement for the proper handling, storage, packaging, preservation (if any), and delivery of all material, assemblies, sub-assemblies in order to prevent damage and deterioration, and to ensure that product received by the customer meets the highest quality standards.

### **<u>2.0</u> <u>DEPARTMENTS AFFECTED</u>**

Manufacturing
Project Operations (System Integration)
Quality Assurance

### <u>3.0</u> <u>SCOPE</u>

This procedure applies to the handling, storage, and packaging of all items and material throughout the manufacturing, system integration, servicing, and delivery process. All materials and products are handled, stored, packaged, preserved, and delivered in a manner to assure its acceptability for use.

### 4.0 PROCEDURE

### 4.1. GENERAL

During all stages of the process, Invensys Triconex personnel shall follow all existing procedures on handling, storage and packaging in order to prevent deterioration or damage of material used, and to ensure the intended quality level for the final product.

### 4.2. CUSTOMER SUPPLIED ITEMS AND MATERIALS

Customer supplied items and materials shall be inspected in accordance with QPM 10.2, handled, and stored in accordance with MDM 15.2 and MDM 15.2.3. For system integration projects, customer supplied items and materials will be handled and stored in accordance with PPM 5.03.

### 4.3. VENDOR SUPPLIED MATERIAL

Purchasing will ensure that the proper packaging requirements will be specified for all purchase orders. Receiving will verify that no material is received by Triconex with obvious shipping damage, as per QAM 10.0 or PPM 5.02 for system integration project receiving. Such material will be returned to the vendor without further inspection.

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## **TRICONEX CORPORATION QUALITY ASSURANCE MANUAL**

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### 4.4. HANDLING

All Electro Static Discharge (ESD) sensitive devices such as Integrated Circuits (IC's), Programmable Devices (PAL's) and Erasable Program Devices (EPROM's) shall be handled in the approved method as described in MDM 15.2.2. Wrist straps are required to be used when handling ESD devices. ESD sensitive circuit boards and assemblies shall be stored in ESD protective packaging and the assemblies shall be removed from that packaging only at static safe work stations by a properly grounded operator. All other materials shall be handled in accordance with the requirements as defined in Manufacturing Procedure MDM 15.2. For system integration projects, items and materials will be handled in accordance with PPM 5.03.

### **4.4.1. STORAGE**

Designated storage areas are provided for materials received and in process. All items in the stockroom are to be stored in individual locations by part number in accordance with the requirements of MDM 15.2. For system integration projects, items and materials will be stored in accordance with PPM 5.03.

### 4.5. PACKAGING

The method of packaging used to ship all Triconex products is specified and controlled in accordance with MDM 15.4. All packaged systems will have "Unpacking Instructions" included with an "**OPEN ME FIRST**" label attached to the package. For system integration projects, items and materials will be packaged in accordance with PPM 5.04.

### 4.6. PRESERVATION

Triconex products and systems are appropriately packaged to prevent damage and deterioration. There is no special preservation methods required. Products and systems awaiting shipment are packaged and stored in a controlled environment.

### 4.7. **DELIVERY**

Products shall be shipped to the customer in accordance with Manufacturing Procedure MDM 15.6. For system integration projects, items and materials will be shipped to the customer in accordance with PPM 5.04

### **5.0** REFERENCES AND RELATED DOCUMENTS

QAM 10.0:	Inspection and Testing
QPM 10.2	Receiving Inspection
MDM 15.2	Material Handling
MDM 15.2.3	Receiving
PPM 5.02	Receiving & Receipt Inspection
PPM 5.03	Material Handling & Storage
PPM 5.04	Material Packaging & Shipping

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### 1.0 PURPOSE

This procedure establishes the requirements for the identification, control, collection, maintenance and retention of all quality records.

### 2.0 DEPARTMENTS AFFECTED

All Departments

### 3.0 SCOPE

In order to be able to demonstrate the achievement of an effective quality system, all quality-related documentation shall be retained for a period of time, as specified by this procedure. If required by contract, specific customer required quality related documentation can be retained for the time periods as specified by the contract requirements. For application projects, Project Procedures Manual (PPM) 4.0 and PPM 8.0 provide instructions for project document and data identification, collection, storage, and control.

### 4.0 PROCEDURE

### 4.1. RECORDS

### **4.1.1. GENERAL**

Quality records are defined as those documents necessary to maintain the product quality history throughout the life of the product, i.e., to provide objective evidence of quality and compliance with program requirements. Quality records are also maintained to help assure continued viability of the company in case of disaster. Quality records may be either electronic records or hard copy (paper) documents. Quality records shall include, but are not limited to the following records:

- Management Review Minutes
- Contract Reviews
- Design Reviews
- Quality Plans
- Quality Improvement Plans
- Product Specifications
- Audit Reports
- Vendor Ouestionnaires
- Rework Records

- Burn-In Data
- Calibration Records
- Material Review Reports
- Production Order Tags
- System Configuration Records Files
- QA Review Board Minutes
- QA Stamp Control Log
- Corrective/Preventive Action Reports
- Inspection Records

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- Training Records and Procedures
- 10CFR21 Reports to the NRC and Nuclear Customers
- Sources of Design Inputs

- Customer Contact Data
- All records generated for application projects
- Drawings and Specifications

### 4.1.2. RECORD CREATION

All records shall be generated using ink, marker, or other permanent recording method. The use of pencil or erasable ink is not allowed. An exception to this is the System Configuration Sheets where pencil is necessary to allow for module changes during the manufacturing cycle. Other exceptions are allowed if only specifically authorized in the governing procedure, i.e., electronic record maintenance. A document is considered a quality record when it is completed and authenticated (if required) by stamps/signatures.

Where electronic records are allowed by procedure, reasonable measures shall be employed to prevent unauthorized personnel from creating or changing quality records. Measures for authentication of electronic records shall be established which provide assurance that (1) only authorized individuals may approve or alter quality records and (2) the identity of the person approving or altering the record is known.

### 4.1.3. CHANGE METHOD

Changes to records should be documented for traceability by following these steps:

- Draw a single line through the item to be changed;
- Write the correct information nearby;
- Record the initials of the person making the change; and
- Register the date the change was made.

Correction fluid ("White Out") or correction tape shall not be used for any quality record. One exception is that White Out may be used on sales order review documents for cost and schedule changes only. Authorized changes to electronic records shall reflect, as a minimum, the date, person making the change, and indication of area changed. Change history will be maintained.

### 4.2. RETENTION TIME

All quality records as described in ISO 9001, will be retained for a period of 10 (ten) years, unless otherwise specified in QPM 16.0. Customer specific quality related documentation such as special test requirements and their test results, customer specifications, or other proprietary documentation shall be retained for a period of 10 (ten) years unless otherwise specified by the contract.

Critical records such as system configuration records and product design documentation shall not be destroyed.

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Nuclear records (such as nuclear equipment qualification and all nuclear safety-related records) shall be designated "permanent" and shall be retained for the life of the affected products and integrated systems.

### 4.3. **RESPONSIBILITY**

All current records shall be maintained by the responsible departments as defined in the departmental operating procedures and listed in the master list. Access to completed records should be restricted where practical. Records that are not accessed on a regular basis can be moved to the archive area under the responsibility of the Quality Assurance Department.

### 4.4. ARCHIVE

Records that are moved to the archive area shall be identified. The box, container or other storage device shall be marked with the time period covered by the records and the record type. Records will not be removed from the area without the permission of the Quality Director or designee.

### 4.5. RECORD QUALITY

All records in the archive area shall be legible, identifiable, and maintained in such a way that deterioration is minimized.

Dual-location storage should be maintained for "permanent" records, nuclear safety-related quality records, and other critical records where inadvertent loss could have significant adverse consequences to the company. Copies may be in either hard copy or electronic format. Periodic backups of important network data, for example, shall be maintained in a separate designated storage location.

Storage provisions for records stored on media subject to deterioration (such as magnetic media or photographic film) should be given special consideration. Where expected media life could be exceeded, data should be periodically transferred to fresh or more durable media to assure retrievability over the required retention period. Where special tools or programs are necessary for subsequent retrieval of stored information, those tools should be treated equivalent to the records with which they are associated.

### 4.6. **RETRIEVEABILITY**

All records retained by the departments shall be readily retrievable. Archive records shall be retrievable within 48 hours.

### 4.7. AVAILABILITY

Where required by contract, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

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### 5.0 REFERENCES AND RELATED DOCUMENTS

EDM 22.00 Engineering Document Control
PPM 4.0 Project Document & Data Control
PPM 8.0 System Integration Implementation
QPM 16.0 Quality Records Retention

## QAM 17.0 AUDIT PROGRAM

Revision: 013

Effective Date: September 25, 2006

	Name	Signature	Title	Date
Author:	George Vaslos		Senior Quality Engineer	09/13/06
Approvals:	Bob Rasmussen		Triconex Site Manager	09/15/06
	George Hughes		Project Quality Manager	09/15/06
	Paul Mesmer		Product Quality Director	09/15/06

Procedure:	QAM 17.0	Title:	Audit	Progra	am		
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### **CHANGE SUMMARY**

Reason for Change	Summary of Changes*
1) To implement the requirements of QAM 2.2, Revision 15.	1) Format changes consistent with QAM 2.2, Revision 015; change bars are not included for
2) The responsibilities of the QARB were modified in the latest revision of QPM 14.0.	these changes.  2) The QARB no longer is required to approve the
3) The term "vendor" is being generically changed to "supplier" in QMS documentation.	Internal Audit schedule and the Supplier Audit schedule.
4) The term "Triconex Corporation" is no longer valid.	<ul><li>3) The term "vendor" was changed to "supplier".</li><li>4) The term "Triconex Corporation" was changed to "Triconex".</li></ul>

<sup>\*</sup>Specific changes to the procedure are indicated by vertical lines in the right margin.

## **CHANGE IMPLEMENTATION**

All requirements of this procedure shall be implemented as of its Effective Date. Quality Assurance Review Board (QARB) activities that are in process as of the Effective Date shall comply with all new and/or changed requirements at that time.

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### 1.0 PURPOSE

The purpose of this procedure is to describe the Triconex Audit Program, which includes internal audits and supplier audits. These audits are used to determine the effectiveness of the Quality System.

### 2.0 DEPARTMENTS ORGANIZATIONS

All Triconex Departments

### 3.0 SCOPE

It is the policy of Triconex to improve the quality of the existing Quality System on an ongoing basis. Internal quality audits are carried out periodically to improve the existing system, to ensure that current work practices are reflected in company procedures, and to ensure that current work practices are in accordance with the requirements of ISO 9001 and 10CFR50, Appendix B.

Supplier audits are performed as deemed necessary to assure that the quality systems of Triconex suppliers are being effectively implemented, consistent with quality standards imposed or approved by Triconex.

### 4.0 PROCEDURE

### 4.1. GENERAL

All areas of activity that impact the Triconex quality process shall be audited under the direction of the Product Quality Director. These audits will be conducted on a scheduled basis and will be documented in formal reports.

Trained auditors will be assigned to conduct the audits. Auditors will be certified in accordance with QAM 18.0 and have no direct responsibility for functions being audited.

Audits will be conducted in accordance with QPM 17.1.

### 4.2. INTERNAL AUDITS

The Internal Quality Audit process is a tool which allows Triconex to continuously improve its Quality System. Internal audits will be planned and performed in accordance with written procedures, plans, or checklists. Quality related activities are audited against the requirements of ISO 9001, 10CFR50, Appendix B (nuclear), and the existing Triconex procedures. The Internal Audit Schedule is approved by the Product Quality Director.

### 4.3. SUPPLIER AUDITS

Quality Assurance will perform supplier quality assurance audits on an as-required basis. The audit frequency will be determined based on the type of product, performance history, current procurement intent, and criticality of the item in the Triconex system.

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The audits will be performed against the requirements in the applicable ISO 9000 Series, supplier quality program, and Triconex quality assurance procedures, where imposed. Nuclear suppliers will be audited to the requirements of 10CFR50, Appendix B.

An annual Supplier Audit Schedule will be developed and approved by the Product Quality Director.

### 4.4. AUDIT REPORTS AND CORRECTIVE ACTIONS

Audit planning and results are documented in audit reports. The audit report will identify the deficiencies found during the audit. Copies of audit reports will be distributed, as a minimum, to the Product Quality Director and responsible management in the area audited.

The discrepancies found during the audits will be reported using the Corrective and Preventive Action Reporting tools described in QAM 14.0. In general, an Action Request Report (ARR) will be generated by the Auditor or the Product Quality Director on deficiencies noted in internal audits. Corrective Action Reports (CARs) will be written to document problems noted in supplier audits.

The auditor may suggest or recommend changes if areas for improvement are noted. These observations should be recorded in the audit report, but an ARR is not required. The auditee will consider the suggestion and may or may not act upon it.

### 4.5. QUALITY PROGRAM SURVEILLANCE

The Triconex audit program may be augmented by other documented quality surveillance activities. Surveillance Reports and Self-Assessment Reports may be used as a means to plan, conduct, and document independent verifications or the monitoring of selected activities for compliance with quality program requirements. Quality Surveillances are conducted in accordance with QPM 17.2. Surveillance Reports may be used to document QA verification of actions taken in response to a corrective action document. Surveillance Reports and Self-Assessment Reports may support, but not take the place of, scheduled quality program audits.

Surveillances may be assigned at the discretion of the Product Quality Director or Project Quality Manager for any purpose. Assigned personnel will normally, but not necessarily, be part of the quality organization. Surveillances may be preplanned and coordinated with area management or conducted without prior notice. Deviations from Quality Program requirements will be documented on an Action Request Report (ARR), consistent with QAM 14.0, and referenced in the Surveillance Report.

### 4.6. AUDIT PROGRAM REVIEW

The Triconex Audit Program is subject to upper management review by means of the Annual Management Review Meeting (QAM 1.3), the Quality Assurance Review Board (QARB), which is responsible for corrective action document processing and audit schedule review, and internal audits by personnel independent of the Quality Assurance Department.

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In addition to these reviews, external audits by ISO audit agencies, customers, and other outside agencies provide for continuing assessment and improvement of the audit program.

### 4.7. QUALITY RECORDS

Audit Reports and Surveillance Reports will be regarded as quality records per QAM 16.0. The Quality Assurance Department is responsible for the maintenance of these records.

### 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 1.3	Management Review
QAM 5.1	Document and Data Control
QAM 6.0	Purchasing
QAM 14.0	Corrective and Preventive Action
QAM 16.0	Quality Records
QAM 18.0	Training
QPM 17.2	Quality Surveillances

## QAM 18.0 TRAINING

Revision: 018

Effective Date: September 25, 2006

	Name	Signature	Title	Date
Author:	Ted Porfilio		Quality Assurance Engineer	09/13/06
Approvals:	Bob Rasmussen		Triconex Site Manager	09/15/06
	George Hughes		Project Quality Manager	09/15/06
	Paul Mesmer		Product Quality Director	09/15/06

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## **CHANGE SUMMARY**

Reason for Change	Summary of Changes*
<ol> <li>To implement the requirements of QAM 2.2, Revision 15.</li> <li>To ensure that employee and contractor competency, skills, training and certification records are maintained as Quality Records.</li> </ol>	<ol> <li>Format changes consistent with QAM 2.2, Revision 015; change bars are not included for these changes.</li> <li>Delete Human Resources (HR) and replace with Quality Assurance (QA), as appropriate, throughout the procedure.</li> </ol>

<sup>\*</sup>Specific changes to the procedure are indicated by vertical lines in the right margin.

## **CHANGE IMPLEMENTATION**

All requirements of this procedure shall be implemented as of its Effective Date. All records of employee and contractor competency, skills, training and certification located in Human Resources as of the Effective Date of this procedure shall be relocated to Quality Assurance and maintained as Quality Records.

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### 1.0 **PURPOSE**

This procedure describes the requirements for the training and certification of Triconex Products employees and contractors. Personnel training requirements for North American Project Operations (NAPO) application projects conducted at Triconex are described in Project Procedures Manual (PPM) 9.0, Personnel Training & Qualification.

## 2.0 <u>AFFECTED ORGANIZATIONS</u>

All Triconex Departments

### 3.0 SCOPE

This procedure applies to all personnel performing work affecting product quality. Personnel shall be competent on the basis of appropriate education, training, skills, and experience. The term "supervisor" means "hiring supervisor" with regard to contractors.

## 4.0 **PROCEDURE**

#### 4.1. COMPANY POLICY

It is the policy of Triconex Products to assign tasks or projects to competent employees or contractors. The objective of this policy is to improve the quality of the product, services offered, and the quality of the overall work performed. The importance of continuous training and education of all levels of employees and contractors, and the positive impact on the overall quality of the system which training and education provides, is recognized by and endorsed by Triconex Products Management. As such, Triconex and contractor employers will provide all reasonable resources to achieve this goal.

#### 4.2. GENERAL

### 4.2.1. COMPETENCY, AWARENESS AND TRAINING

The responsible Department Supervisor shall:

- 1. Determine the necessary competence for personnel performing work affecting product quality. Training requirements for each job function shall be established.
- 2. Provide training or take other actions necessary to satisfy these needs.
- 3. Evaluate the effectiveness of the actions taken (by testing the individual on the training material provided, or by evaluation of the individual's performance related to the training). The evaluation shall be documented.
- 4. Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- 5. Ensure that appropriate records of personnel education, training, skills, and experience are provided to Quality Assurance.

#### 4.2.2. COMPETENCY REQUIREMENTS

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#### **4.2.2.1. EMPLOYEES**

Each department supervisor is responsible for ensuring that employees are appropriately trained and are competent to perform the functions described in the specific job descriptions. The Human Resources (HR) Department documents each employee's job description and the competency requirements for that position (see TGM A-1). A competency record referencing the job description is signed by the responsible supervisor to certify that the employee is competent to perform the duties described. This record includes an assessment of any training requirements that need to be satisfied prior to starting the job.

The basis for the competency by the supervisor shall be:

- a) Evidence of education, experience, skills, and training in the employee's file; and
- b) Knowledge of the person's capability through interview or other knowledge of work performance.

#### 4.2.2.2. CONTRACTORS

When a contractor position is needed, the responsible supervisor shall complete a Contractor Requisition. The Contractor Requisition shall specify the competency and skill requirements for the specific position to be filled. The contractor's employer documents each contractor's job description and competency requirements for that position. The responsible Supervisor will ensure that the contractor is trained and competent to perform the functions described in the Contractor Requisition.

The final agreement between the contractor's employer and the Triconex hiring supervisor certifies the contractor is competent to perform the duties described in the Contractor Requisition.

## 4.3. TRAINING REQUIREMENTS

#### 4.3.1. TRAINING PLANNING

Determining the training requirements for each employee or contractor shall be the responsibility of their supervisor. This is a continuous process to identify the training needs of the employees and contractors in order to improve productivity and the quality of the product. Training planning may take the form of a formal Training Plan for the group or as individual training assessments as part of the hiring and annual evaluation process. In addition to routine training, special training requirements may develop for special circumstances, new processes, or for remedial purposes as a result of identified QA program deficiencies.

Training planning should be systematic and based on the job function being performed. The minimum training and skill requirements are established in the Job Description and/or in the Contractor Requisition. The supervisor shall also review contractor performance and skill requirements defined in the Contractor Requisition annually to identify further training

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requirements to ensure that all appropriate training requirements have been identified and documented.

#### 4.3.2. IMPLEMENTATION

Depending on the type, training may be implemented internally by supervision, other internal Invensys organizations, or external (Third Party training courses). For available Invensys corporate training courses, the identified training needs shall be given to the Invensys Learning Organization who will organize and schedule the training. QA training modules are also available from Corporate Quality Assurance.

The supervisor is responsible for coordinating with HR or the responsible training organization to ensure the completion of any training identified as "required training."

Training methods may include classroom sessions, computer based, staff meeting, team tailboard meetings, OJT, or reading lists. Supervisors should ensure that training method is appropriate to the circumstances and promote diversity in training methods (versus inordinate reliance on passive reading lists).

#### 4.3.3. DOCUMENTATION OF TRAINING

As a minimum, a training attendance sheet shall be used to document all training sessions (reading assignments may be documented on appropriate reading lists).

At the completion of any training, the training instructor or responsible supervisor shall forward all training records, such as attendance sheets, certificates, etc. to Quality Assurance, who will control all completed training records.

When appropriate, upon the successful completion of internal training, Triconex will issue a certificate. A certificate or other appropriate document will be used to record the successful completion of externally conducted training. A copy of the completed certificate will be forwarded to Quality Assurance.

#### 4.3.4. ORIENTATION

Triconex orientation training (TGM A-3) will be provided to all employees and to contractors when necessary. This training will include, but is not limited to, a review of the Triconex quality assurance program, management expectations for program implementation, and a discussion on the awareness of the relevance and importance of their activities and how they contribute to the success of the quality objectives. The orientation training record will be forwarded to Quality Assurance.

#### 4.3.5. QUALITY PROGRAM/PROCEDURE REVISIONS

Periodically, changes are made to the Quality Assurance Manual (QAM) and/or department procedures. The Product Quality Director shall issue an email to all affected personnel whenever there is a change to Quality System procedures to provide visibility to the changes and to request review for applicability to individual job functions. Each

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department supervisor shall review the changes, as applicable, to determine the impact of the changes on the department's activity. The supervisor shall ensure that the changes are understood and implemented and is responsible for providing more formal training on process changes, when necessary.

On an annual basis, the Product Quality Director shall provide refresher training to Triconex personnel on the requirements of the Triconex Quality Program.

### 4.4. CERTIFICATION

When appropriate, a certificate will be issued indicating that the recipient has reached a sufficient level of expertise and or training that qualifies him/her to perform a described task. A copy of the certificate will be forwarded to Quality Assurance.

#### 4.4.1. AUDITOR CERTIFICATION

Employees or contractors performing quality system audits, or those performing process or product audits shall be qualified and trained, and shall have no direct responsibility for those activities which they are auditing. Triconex auditors shall be certified based on evidence of formal training, previous auditor certification or experience, and/or other demonstrated skills. Certification of auditors shall be done in accordance with QPM 18.1, Certification of QA Personnel.

### 4.4.2. INSPECTOR CERTIFICATION

Triconex quality control inspection personnel shall be certified based on evidence of formal training, experience, and/or other demonstrated skills. An eye exam shall be required for certification and renewed every 3 years. Certification of inspectors shall be done in accordance with QPM 18.1, Certification of QA Personnel.

#### 4.4.3. PROCESSES REQUIRING CERTIFICATION

Employees and contractors assigned tasks or involved in projects related the following processes require training and certification prior to performing any work:

- a) Handling of electrostatic discharge (ESD) sensitive product.
- b) Soldering.

## 4.5. QUALITY RECORDS

All records of employee and contractor competency, skills, training, and certification are quality records per QAM 16.0 and shall be controlled by Quality Assurance. This includes all records described in this procedure, and those records described in QPM 18.0, TGM A-1, and TGM A-3. Each department supervisor is responsible for ensuring that all training records are forwarded to Quality Assurance.

An electronic database may serve as an alternative method to store employee training data. If an electronic database is used, the database shall contain all relevant information relative to employee and contractor competency, training, skills, and certification. The

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database shall be maintained to reflect current training information. The database should be validated periodically to ensure that no data has been lost or damaged.

Quality Assurance shall control employee and contractor training records during the length of employment and for a minimum of two years after date of termination.

## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
QPM 18.1	Certification of QA Personnel
PPM 9.0	Personnel Training & Qualification
TGM A-1	Job Description
TGM A-3	Employee Orientation

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### 1.0 PURPOSE

This procedure describes the activities relating to customer service for the Triconex Product Line.

### **<u>2.0</u> <u>DEPARTMENTS AFFECTED</u>**

Technical Support Manufacturing Engineering

## 3.0 SCOPE

This scope of this procedure includes the Triconex Technical Support group and Manufacturing/RMA group as they relate to customer service. This procedure describes the Technical Support Department's responsibilities and tasks needed to provide technical information in direct support of the Triconex Product Line and its customers, both external and internal. This procedure also addresses the responsibility for customer notification of potential product safety issues.

Product repair and upgrades are the responsibility of the Manufacturing department. This procedure does not address the details of the various service and warranty programs that Triconex Products offers to its customers. These programs are described in the System Log Book and other literature provided to the Customers.

## 4.0 PROCEDURE

## 4.1. TECHNICAL SUPPORT

#### 4.1.1. STRUCTURE

All Technical Support Engineers report directly to the Manager, Technical Support, and operate within the Triconex manufacturing facility in Irvine, CA. Technical Support Engineers provide technical product support to the worldwide Invensys Service Centers supporting Triconex products and to individual customers.

#### 4.1.2. CUSTOMER TECHNICAL SUPPORT AVAILABILITY

Triconex Technical Support and the Invensys Customer Satisfaction Center (CSC) shall provide a 24 hours per day, 7 days per week telephone support for all its customers.

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Approvals:	Mike Phillips		Triconex Site Manager
	Paul Mesmer		Quality Director

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#### 4.1.3. TECHNICAL SUPPORT RESPONSIBILITY

The Triconex Product Line Technical Support engineers have the following responsibilities:

- a. The Triconex Technical Support Group must provide prompt, positive notification to all affected customers when a significant discrepancy <u>affecting safety</u> is identified affecting Triconex products in the field.
- b. To maintain good relation with customer under all circumstances.
- c. To initiate, monitor and implement corrective action within the organization in case of reported process or product discrepancies, contract discrepancies or customer complaints.
- d. To respond to all customer queries and complaints in a timely manner with the objective to satisfy the customer's requirements (QPM 14.1).
- e. To insure customer complaints are given top priority over all other customer response issues.
- f. To act as the facilitator of technical information flow to and from the field by the means of technical documentation.
- g. Assist the quality organization in monitoring field performance and customer satisfaction.
- h. To act as an information conduit to Quality and Engineering in the case of product design discrepancies noted in field performance.
- i. To act as an information conduit to Marketing on field conditions that could impact sales efforts.

### 4.1.4. TECHNICAL SUPPORT TASKS

#### 4.1.4.1. DIRECT CUSTOMER SUPPORT

- a. Be available during normal business hours to respond to technical inquiries from customers via phone, fax and / or email.
- b. Provide customer access to technical support during non-business hours 365 days per year.
- c. Be the primary Customer Interface for trouble shooting unexpected events, gathering relevant information from the customer and relaying this information to the appropriate personnel within the corporation.

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- d. Notify customers in a timely fashion as to product deviations from published specifications.
- e. CustomerNet Internet based system shall be maintained to facilitate access to technical information by Triconex/Invensys customers. This shall be the primary means of technical notification to the users of Triconex equipment. Monitor web activity over end user network (CustomerNet) and insure timely and accurate information content of that site.
- f. Technical Support Engineers are to achieve the rank of Certified Instructor in order to support Training needs. Periodically it may be necessary to require Technical Support Engineer to monitor or conduct a training class. It is the responsibility of each Technical Support Engineer to remain current and proficient to meet this effort.
- g. Inquiries relating to Product training, service, upgrades, warranty, etc. will be referred to other appropriate Invensys groups.
- h. Periodic field service activity when necessary to resolve emergency need in a cost effective manner. Each Technical Support Engineer is required be trained, qualified for task, and to maintain proficiency in his or her ability to function effectively in this environment. Authorized Triconex materials and manufacturer's guidance shall be followed for these services. Repair activities, if any, performed by the Technical Support groups will meet the same workmanship standards that applied to the manufacturing process of the original product. Where these standards are not defined in the Product Specifications or Engineering Standards the IPC-R-700 requirements shall apply.

#### 4.1.4.2. PERFORMANCE ACTIVITY TRACKING

- a. Document customer queries and complaints in the computer database system.
- b. Technical Support manager to provide a summary of all customer contacts to Quality Assurance Review Board.
- c. Insure timely registration of information into contact reporting system. This must be done in a timely fashion in order to insure a minimum of error and omission.
- d. Track Engineers training achievements with respect predetermined training schedule and goals.

#### 4.1.4.3. DOCUMENT PREPARATION AND DISTRIBUTION

Triconex Technical Publications responsibility will generate, based on Engineering release documentation, technical notifications such as:

- Product Alert Notice (PAN)
- Technical Advisory Bulletins (TAB)

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- Product Release Notices (PRN)
- Technical Application Notes (TAN).

See Quality Procedures Manual QPM 14.3 for details on documentation processing)

#### 4.1.4.4. PRODUCT TRACEABILITY

Invensys/Triconex shall maintain customer information records (system configuration records) and data systems, which will facilitate the ability of Technical Support to locate all Serialized Hardware and software to end users of Triconex products. These records shall facilitate traceability of product modules to specific customers or locations in case of product alerts, upgrade recommendations, or recalls.

The Technical Support group shall maintain a product traceability system based on accurate and timely Manufacturing and Order Entry End User data. This tracking system will be reliant on accurate serialization information pertaining to units shipped to customers as described in the Quality Assurance Manual. Manufacturing maintains customer order information on the data system and provides hard copy customer records (System Folders) to Technical Support per QAM 8.0 and MDM 9.8.

#### 4.2. CUSTOMER TRAINING

Invensys/Triconex Products understands that for the Customers to be able to use its Products in the proper manner, a certain level of proficiency is required to operate and maintain the system. To achieve this, Invensys/Triconex offers their Customers extensive courses on the Operation and Maintenance of the Triconex Products. Training services may be purchased from the Invensys/Triconex Training Department. Training classes are conducted by qualified instructors in Triconex facilities or customer sites.

#### 4.3. SERVICING/REPAIRS

Repairs to Triconex products are controlled by the Return Material Authorization (RMA) system which assures that repairs and modifications are performed using authorized, qualified personnel and parts.

#### 4.3.1. **AUTHORIZATION**

The Manufacturing group in Irvine is the only authorized location to perform repair work on any Triconex triple modular redundant (TMR) products. The Triconex Irvine facility and the Invensys/Triconex Texas facility are authorized to repair turbomachinery products.

#### 4.3.2. RMA PROCESS

The RMA process used by the customer to obtain repairs, upgrades, or other services, consists of obtaining an RMA control number from the Invensys CSC, requesting services, and sending products back to the authorized repair facility, as necessary. Work is performed, as requested, and repaired/new hardware returned to the customer. All RMA actions are documented in the business data systems to provide a full historical record of repairs,

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including inspections and tests, for all product modules. The RMA process is described more fully in QPM 19.1 and MDM 19.1.

#### 4.3.3. WORKMANSHIP STANDARDS

All repair activities performed by the customer service groups will meet the same workmanship standards that applied to the manufacturing process of the original product. Where these standards are not defined in the Product Specifications or Engineering Standards the IPC-R-700 requirements shall apply.

#### 4.3.4. SOFTWARE / FIRMWARE UPGRADES

Depending on the customer selected service program, the RMA group will perform upgrades of hardware, software and firmware. These upgrades will be made strictly in compliance with the applicable Product Release Notice. The Triconex RMA group is not allowed to alter or modify the product in any other way than described in Engineering Orders. Customer specific modification shall be documented and controlled by the Change Control Board (QAM 4.0).

#### 4.3.5. PRODUCT TRACEABILITY - MANUFACTURING GROUP

The Manufacturing group in Irvine shall maintain a product traceability system applicable to RMA processes which meets the following minimum requirements:

- a. Complete documented Return Material Authorization (RMA) system with the ability to authorize, track and document customer returns.
- b. Documented procedures for the RMA and product traceability system including processes for the transfer of data between Irvine and other Invensys organizations.

### 4.4. QUALITY RECORDS

Technical Support, RMA, and other service-related records as defined in implementing procedures are maintained in accordance with QAM 16.0.

## 5.0 REFERENCES AND RELATED DOCUMENTS

QAM 4.0	Design Control
QAM 8.0	Product Identification and Traceability
QAM 14.0	Corrective and Preventive Action
QPM 14.1	Customer Contacts
MDM 19.1	RMA Processing

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### <u>1. PURPOSE</u>

This procedure describes the guideline for the use of statistical techniques required for verifying the acceptability of process capabilities and product characteristics.

## 2. <u>DEPARTMENTS AFFECTED</u>

Quality Assurance Engineering Manufacturing

## 3. SCOPE

Unless otherwise stated in this procedure, the usage of statistical techniques is optional. It is the responsibility of each area using a certain technique to verify that it is applicable and to use the technique in the proper manner.

## 4. PROCEDURE

The following process/function requires the usage of statistical techniques:

Sample Inspection Reliability Calculations Product Test Sampling

### 4.1. SAMPLE INSPECTIONS

Where procedures require sample inspections, the MIL-STD-105 sampling tables shall be used unless clearly otherwise stated. Allowable deviations from the standard shall be documented in these procedures. The procedures shall provide the method of determining the required AQL and inspection method.

### 4.2. RELIABILITY CALCULATIONS

Unless otherwise stated, reliability predictions used by Triconex shall be based upon parts count methods described in MIL-HDBK-217 or Bellcore Issue 6, or upon actual field return data.

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#### 4.3. DATA ANALYSIS

Data is analyzed to determine direct or indirect correlations between variables. Where data analysis utilizes statistical techniques, it is the responsibility of the author of the analysis report to ensure that statistical techniques used are documented in the report or properly referenced. Graphical representations of data and the linear interpretation of data (i.e.; best fit straight line calculations) are not considered statistical techniques.

### 4.4. PRODUCT TEST SAMPLING

Production products that meet certain test performance criteria may be eligible for test on a sample basis. The detailed requirements are specified in MDM 9.1.1, Product Sampling Plan.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 10.0 Inspection and Testing MDM 9.1.1 Product Sampling Plan