



# TRICONEX

## INVENSYS PROCESS AUTOMATION

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February 27, 2001

Document Control Desk  
United States Nuclear Regulatory Commission  
Washington, DC 20555

Subject: Nuclear 1E Qualification of the TRICON TMR Programmable Logic Controller (PLC) –  
Additional Reference Documents

- References:
1. Letter, T. Martel (Triconex) to NRC, October 2, 2000, subject; Nuclear 1E Qualification of the TRICON TMR PLC – Final Qualification Summary Report Submittal
  2. Project Number 709

Gentlemen:

In Reference 1, we provided the results of our qualification testing and analyses in our final summary (topical) report, Triconex Document No. 7286-545. The letter summarized the documents transmitted in support of the NRC review of the TRICON Qualification. As a result of our recent discussions, it was noted that two other documents would be helpful in your review, i.e., the Triconex Quality Assurance Program Description and a TRICON Response Time Calculation which was referenced in other documents submitted. Accordingly, the following two documents are enclosed:

- Triconex Quality Assurance Manual, Rev 15 (Uncontrolled Copy)
- Calculation 426-001/SCS-01, Rev. 2, "Test Tricon Maximum Response Time Calculation"

If you have any questions, please contact me at (281) 360-6401 or Mr. Michael Phillips at (949) 885-0711.

Sincerely,

J. Troy Martel, P. E.  
Triconex Nuclear Qualification Project Director

Enclosure

cc: L. Raynard Wharton, NRC (w/o enclosure)  
P. Loeser, NRC

*Dob2*

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MPR Associates, Inc.  
 320 King Street  
 Alexandria, VA 22314

**CALCULATION TITLE PAGE**

Client	Triconex Corporation	Page 1 of 14
Project	Tricon PLC Qualification	Task No. 426-9901-001-0
Title	Test Tricon Maximum Response Time Calculation	Calculation No. 426-001/SCS-01

Preparer-Date	Checker-Date	Reviewer/Approver-Date	Rev. No.
 S.L. STEIMAN 9/30/99	 J. Gratz 9/30/99	 MITCHELL ALBERS 9/30/99	0
 S.L. STEIMAN 10/14/99	 J. Gratz 10/14/99	 MITCHELL ALBERS 10/14/99	1
 S.L. STEIMAN 12/23/99	 J. Gratz 12/23/99 1/3/99 JAS	 MITCHELL ALBERS 12/23/99	2

**QUALITY ASSURANCE DOCUMENT**

This document has been prepared, checked, and reviewed in accordance with the Quality Assurance requirements of 10CFR50 Appendix B, as specified in the MPR Quality Assurance Manual.



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### RECORD OF REVISIONS

Calculation No.  
426-001/SCS-01

Prepared By  
*Sam A. Ho*

Checked By  
*[Signature]*

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Revision	Description
0	Initial Issue
1	Revised to incorporate actual MP Scan time setting of 67 milliseconds. Also corrected error in revision numbers of drawing references.
2	Revised to include Operability Test Procedure revision number in List of References (Section 5).



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426-001/SCS-01

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### 1.0 Purpose

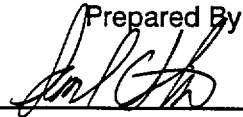
The purpose of this calculation is to determine the maximum response time of the test Tricon PLC. Two test Tricon response times are calculated, the response time from receiving a discrete input to setting a discrete output, and from changing an analog input to setting a discrete output. The results of this calculation will be used as the acceptance criteria for the Triconex Nuclear Qualification Test Program Operability Test (Reference 5.1).

### 2.0 Results

The maximum calculated response times for the Analog Input to Digital Output and Digital Input to Digital Output sequences are shown in Table 2.0 below.

Table 2.0

PLC Configuration	Maximum Response Time
Analog Input (Model 3704E) to Digital Output (Model 3623)	264 milliseconds
Digital Input (Model 3501E) to Digital Output (Model 3601E)	177 milliseconds

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### 3.0 Discussion

#### 3.1 PLC Modules for the Specified I/O Points

Section 3 of the Operability Test Plan (Reference 5.1) defines the I/O points for the inputs and outputs that will be tested for response time. These points are PY431 to PY431D for the analog input to digital output sequence and PY432 to PY432R for the digital input to digital output sequence. Per Reference 5.2, PY431 is an analog input located in Chassis 2, Slot 4, Point 4, and PY431D is a digital output located in Chassis 4, Slot 5, Point 1. Per Reference 5.3, PY432 is a digital input located in Chassis 4, Slot 1, Point 1, and PY432R is a digital output located in Chassis 4, Slot 2, Point 1. Reference 5.4 identifies the PLC modules for each location in a given PLC chassis. The module types are as follows:

PY431	Type 3704E, 4-20 ma Analog Input Module
PY431D	Type 3623, 120 VDC Digital Output Module
PY432	Type 3501E, 115 VAC Digital Input Module
PY432R	Type 3601E, 115 VAC Digital Output Module

#### 3.2 Response Time Determination

The method for determining the response time of a given PLC configuration was provided by Triconex in References 5.5 and 5.6 (see Attachment A). The equation for response time is as follows:

$$\text{Max. Response time} = \text{Input Filter} + \text{IO Poll} + \text{IOC Poll} + \text{MP Scan} + \text{MP Scan} - \text{TSX Comm} \\ - \text{Diag} - \text{Read Dbase} + \text{Outputs}$$

The individual terms of this equation are defined in the following paragraphs.

##### Input Filter

Reference 5.5 defines this term as one input filter time constant. Reference 5.6 specifies the equation for the analog input filter time constant based on the -3dB normal mode rejection frequency. The Tricon Technical Product Guide (Reference 5.7) specifies the -3dB normal mode rejection frequency for the model 3704E input module as 8 Hz. Therefore, the time constant of the 3704E input module is:

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$$\tau = \frac{1}{2\pi f} = \frac{1}{2\pi(8\text{Hz})} = 20 \text{ ms}$$

Reference 5.6 also specifies that the digital input filter time constant is equal to the input delay time specified by the Tricon Technical Product Guide. Per Reference 5.7, the input delay time for the model 3501E 115 VAC digital input module is 8 ms.

#### IO Poll

Per Reference 5.5, IO Poll is the maximum input module update rate. Reference 5.7 specifies the input update rate for the 3704E analog input module as 75 ms. Per Reference 5.6, the IO Poll time for digital input modules is zero.

#### IOC Poll

References 5.5 and 5.6 define IOC Poll as the poll time of all input modules of the PLC chassis. Attachment B contains a completed worksheet from the Tricon Technical Product Guide (Reference 5.7) used to determine the poll time based on the I/O configuration of the PLC given by the General Equipment Arrangement Drawing, Reference 5.4. From Attachment B, the poll time for the PLC input module configuration is equal to 35 ms. Per Reference 5.6, the overhead time can be included in either the IOC Poll time or the Outputs time. For this calculation, it will be included in the IOC Poll time and has a value of 5 ms for the four chassis PLC configuration. Therefore, the IOC Poll time for both the analog and digital input module calculations is equal to 40 ms.

#### MP Scan

Reference 5.5 defines the MP Scan time as the scan time of main processor control program. Per Section 3, Response Time Test, of the Operability Test Procedure (Reference 5.1), the preset TSAP scan time is 67 milliseconds, therefore this number will be used in this calculation.

#### TSX Comm

Reference 5.5 defines TSX Comm as 8 ms for the worst case TSX synchronization window.

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DIAG

Reference 5.5 defines Diag as 5 ms for the worst case TSX diagnostic buffer.

Read DBase

Reference 5.5 defines Read DBase as 1 ms for the worst case TSX communication buffer.

Outputs

References 5.5 and 5.6 define Outputs as the poll time for all output modules undergoing a change of state. The operability time response test procedure is performed while the TSAP is running in the test Tricon. The TSAP continuously operates points on each PLC output module, therefore all output modules must be accounted for in the calculation. From the worksheet in Attachment B, the output poll time is 9 ms.

**4.0 Calculation**

Summing all of the terms from Section 3.2, the response time of the PLC is as follows:

	Analog Input PY431 3704E	Digital Output PY431D 3623	Digital Input PY432 3501E	Digital Output PY432R 3601E
Input Filter		20 ms		8 ms
IO Poll		75 ms		0
IOC Poll		40 ms		40 ms
MP Scan		67 ms		67 ms
MP Scan		67 ms		67 ms
TSX Comm		8 ms		8 ms
Diag		5 ms		5 ms
Read DBase		1 ms		1 ms
Outputs		9 ms		9 ms
<b>Total</b>		<b>264 ms</b>		<b>177 ms</b>





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**5.0 References**

- 5.1 Triconex Procedure Number 7286-503, "Nuclear Qualification of Tricon PLC System, Operability Test Procedure," Rev. 2
- 5.2 Triconex Drawing 7286-531, "So. Texas Project Nuclear Operating Co. Generic Qualification System Pressure Bistable Simulation Loop Diagram," Sheet 1 Rev. 3, Sheet 2 Rev. 2
- 5.3 Triconex Drawing 7286-532, "So. Texas Project Nuclear Operating Co. Generic Qualification System Prudency Testing Simulation Loop Diagram," Sheet 1 Rev. 1, Sheet 9 Rev. 1
- 5.4 Triconex Drawing 7286-102, "So. Texas Project Nuclear Operating Co. Generic Qualification System General Equipment Arrangement," Sheet 1 Rev. 1
- 5.5 Email, Gary Hufton (Triconex) to Paul Villeneuve (MPR Associates), Subject "RE: Response Time Calculation," 9/24/99
- 5.6 Telecon Memorandum, Gary Hufton (Triconex) to Sam Steiman (MPR Associates), Subject "Clarification of 9/24/99 E-mail Subject 'RE: Response Time Calculation'," 9/29/99
- 5.7 Triconex Part No. 9791007-004, "Tricon Technical Product Guide Version 9.2 Systems," June 1997



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**Attachment A**

**Triconex Response Time Calculation Information**

Reference 5.5, Email, Gary Hufton (Triconex) to Paul Villeneuve (MPR Associates), Subject "RE: Response Time Calculation," 9/24/99

Reference 5.6, Telecon Memorandum, Gary Hufton (Triconex) to Sam Steiman (MPR Associates), Subject "Clarification of 9/24/99 E-mail Subject 'RE: Response Time Calculation'," 9/29/99

**3 pages**



SUBJECT: Fw: RE: Response Time Calculation  
DATE: Sat, 25 Sep 1999 15:07:17 -0500  
FROM: pvilleneuve@mpra.com

Mitch,

Prepared By: *[Signature]*

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A response from Gary H about time response.

Paul

-----  
From: "Hufton, Gary (TcnIrv)" <GaryH@Triconex.com>  
Subject: RE: Response Time Calculation  
Date: Fri, 24 Sep 1999 14:53:37 -0700  
To: pvilleneuve@mpra.com  
Cc: "Miller, Scott (TcnIrv)" <ScottM@Triconex.com>

Received: from chi6-1.relay.mail.uu.net (chi6-1.relay.mail.uu.net [199.171.54.98])  
by gateway.mpra.com (8.9.1/8.9.1) with ESMTTP id RAA29107  
for <pvilleneuve@mpra.com>; Fri, 24 Sep 1999 17:54:10 -0400 (EDT)

Received: from tazz.triconex.com by chi6sorsrvll.alter.net with ESMTTP  
(peer crosschecked as: mail.triconex.com [208.203.116.2])  
id QQhic126307

for <pvilleneuve@mpra.com>; Fri, 24 Sep 1999 21:54:09 GMT  
Received: (from uucp@localhost) by tazz.triconex.com (8.7.3/8.7.3) id OAA03663 for  
<pvilleneuve@mpra.com>; Fri, 24 Sep 1999  
14:54:07 -0700 (PDT)

Received: from tcnirvex1.irvine.triconex.com(192.146.114.10) by tazz.triconex.com  
via smap (V3.1.1)

id xma003657; Fri, 24 Sep 99 14:54:06 -0700

Received: by TCNIRVEX1 with Internet Mail Service (5.5.2448.0)  
id <TPL2JTKW>; Fri, 24 Sep 1999 14:54:04 -0700

Message-Id: <199909242154.OAA03663@tazz.triconex.com>

From: "Hufton, Gary (TcnIrv)" <GaryH@Triconex.com>

To: pvilleneuve@mpra.com

Cc: "Miller, Scott (TcnIrv)" <ScottM@Triconex.com>

Subject: RE: Response Time Calculation

Date: Fri, 24 Sep 1999 14:53:37 -0700

MIME-Version: 1.0

X-Mailer: Internet Mail Service (5.5.2448.0)

Content-Type: text/plain;

charset="iso-8859-1"

Estimating Maximum Tricon Response Time:

Max. Response Time = Input\_Filter + IO\_Poll + IOC\_Poll + MP\_Scan + MP\_Scan -  
TSX\_Comm - Diag - Read\_DBase + Outputs

As measured from step change at any input point to programmed step change at  
any output point.

Where:

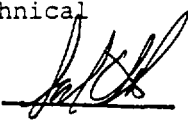
Input\_Filter = 1 input filter time constant, see I/O module data sheet for  
specification

IO\_Poll = max. input module update rate, see I/O module data sheet for  
specification

IOC\_Poll = max. I/O Controller (located on the MP) poll of all I/O modules,  
see Tricon Technical Product Guide for calculation method.

MP\_Scan = Main Processor Control Program scan time, , see Tricon Technical Product Guide, Appendix A for estimation method.

TSX\_Comm = 8 ms, worst case TSX synchronization window

Prepared By: 

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Diag = 5 msec, worst case TSX Diagnostic Buffer

Read\_DBase = 1 msec, worst case TSX Communication Buffer

Outputs = I/O Controller communication to Output Modules, , see Tricon Technical Product Guide, Appendix A for estimation method.

Sorry for the delay,  
Gary

P.S. - The vast majority of our applications are not time critical, therefore giving our customers this complicated formula has proven to be for trouble than it's worth. When asked we simply calculate it for them!

-----Original Message-----

From: pvilleneuve@mpira.com [mailto:pvilleneuve@mpira.com]  
Sent: Wednesday, September 22, 1999 1:46 PM  
To: garyh@triconex.com  
Subject:

Gary,

I need a document detailing how the maximum response time for a configured PLC is calculated. I am aware that the response time is a function of the scan time and the I/O poll time. I am also aware that the poll time is dependent on the number and type of I/O modules. However, I am not clear as to how each module's input update rate is included (i.e. 75ms for the 3704E module).

Thank you for your assistance.

-----  
Name: Paul Villeneuve, P.E. |  
E-mail: pvilleneuve@mpira.com |  
Phone: (703) 519-0431

-----End of Original Message-----

-----  
Name: Paul Villeneuve, P.E. |  
E-mail: pvilleneuve@mpira.com |  
Phone: (703) 519-0431





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426-001/SCS-01

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**Attachment B**

**Tricon Poll Time Determination, Page 67 of the Tricon Technical Product Guide (Reference 5.7)**

**1 page**

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# Appendix A

## TRICON Scan Time & Memory Usage



The TRICON controller uses a scan-based mode of operation, performing required control functions on a cyclical basis. The period of this cycle is the scan time, which is composed of three elements:

- the time required to collect the input data (input poll time)
- the time required to execute the control program
- the time required to implement the outputs (output poll time)

Input polling is asynchronous and overlaps control program execution. Therefore the control program execution (CPE) time must be larger than the input poll time to ensure stable operation of the system. If the scan time is set to a value less than the total poll time, the TRICON will try to execute the control program without the benefit of updated field inputs. This condition is to be avoided, and care should be taken to set the scan time to a value equal to or greater than the required time.

In earlier systems, the CPE time was always considerably larger than the total poll time, so the scan time was essen-

tially equal to the CPE time. In Version 9 systems, the processing power of the model #3006 Main Processors significantly reduces the CPE time, and consequently consideration must be given to both the input and output poll times when computing the scan time. In general, if the size of the control program is proportional to the amount of physical I/O in the system, the CPE time will be larger than the input poll time required. However, if the system configuration has an unusually large amount of physical I/O and/or a small control program, the scan time should be set considering both the total poll time and the CPE time. This is necessary because under these conditions, the total poll time required could exceed the CPE time. In such a case, the scan time should be set to whichever of the two is greater.

The following worksheets for estimating TRICON scan time and memory usage provide a mechanism to calculate the required scan time based on both the system's I/O configuration and the approximate composition and size of the control program.

**Note:**

Due to the extensive testing that is required, Triconex has not yet fully determined the effect of TriStation 1131 function calls on the minimum system scan time and memory usage in V9.2 systems.

### Estimating TRICON V9 Scan Time

Poll Time	Number Used	Poll Time	Subtotal
<i>(Independent of Dictionary Editor entries.)</i>			
64-point DI modules	<u>1</u> x	1.2 msec	= <u>1.2</u>
32-point DI modules	<u>1111</u> x	1.1 msec	= <u>4.4</u>
64-point AI modules	<u>1</u> x	7.2 msec	= <u>7.2</u>
32-point AI/TC modules	<u>111</u> x	4.1 msec	= <u>12.3</u>
16-point AI/TC modules	<u>11</u> x	2.5 msec	= <u>5.0</u>
8-point PI modules	<u>1</u> x	4.7 msec	= <u>4.7</u>
32-point DO modules	<u>1</u> x	1.0 msec	= <u>1.0</u>
16-point DO modules	<u>1111</u> x	0.9 msec	= <u>5.4</u>
8-point SDO modules	<u>1</u> x	0.9 msec	= <u>0.9</u>
8-point AO modules	<u>1</u> x	1.8 msec	= <u>1.8</u>
			<b>Poll Time</b> <u>44</u> msec
Overhead = 1 msec per chassis (minimum of 5 msec) =			<u>5</u> msec
<b>TOTAL POLL TIME =</b>			<u>49</u> msec

*(continued on next page)*

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

<b>Section:</b>	QAM 0.0	<b>Subject:</b>	Introduction		
<b>Revision:</b>	015	<b>Page:</b>	1	of	1
		<b>Date:</b>	01/05/01		

## Introduction

This manual describes the essential practices and procedures required to ensure that the products designed, manufactured, and serviced by the Triconex Corporation meet the highest standards of quality, reliability, and maintainability.

The Triconex Corporation has elected to expand the traditional Quality Assurance Program to include all quality-related activities both before and after sale of the product. Therefore, in preparing this manual, major consideration was given to the requirements of ISO 9001, revised 1994 issue. The content of this **Quality Assurance Manual** have been prepared based on the 20 chapters format of ISO 9001.

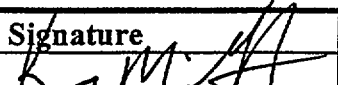
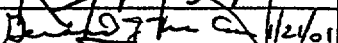

This **Quality Assurance Manual** also meets the quality assurance requirements of Title 10 of the Code of Federal Regulations 10CFR50, Appendix B, Criterion I through XVIII, as applicable. Note: Throughout this manual, wherever ISO 9001 is referenced, the applicable requirements of 10CFR50, Appendix B also apply.

This **Quality Assurance Manual** is a controlled document and revision numbers are indicated throughout. It is important to apply current quality assurance procedures to each work activity. Changes to this **Quality Assurance Manual** will be distributed to Control Copy Holders only. The superseded pages or sections must be removed.

(Note on consistency of terminology: Where routine changes are made to organization names, titles, etc., these changes are normally incorporated into procedures as an "as-revised" basis. Therefore, some inconsistency in terminology may exist during transition periods. For example, "Triconex Products Division" is being transitioned to "Triconex Corporation.")

<b>Quality Assurance Manual</b> <b>Control Number</b>	
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	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann	 1/24/01	VP Research & Development
	Aad Faber		Director, Product Assurance



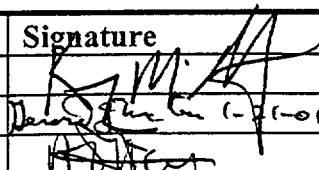
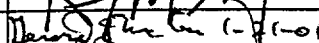
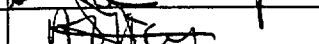
# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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1.4	000	04/23/99	Customer Satisfaction Survey
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14.0	007	01/05/01	Corrective and Preventive Action
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17.0	009	04/23/99	Audit Program
18.0	012	01/05/01	Training
19.0	006	04/14/00	Servicing
20.0	006	04/14/00	Statistical Techniques

	<u>Name</u>	<u>Signature</u>	<u>Title</u>
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance

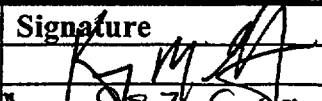
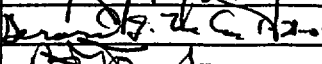

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## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 0.2	<b>Subject:</b>	Quality Assurance Manual History		
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### Quality Assurance Manual History

Revision	Release Date	Changes
000	May 1986	Original Release
001	Jan 01, 1991	Quality Improvements
002	Sep 30, 1994	Total revision in order to comply with ISO 9001 requirements.
003	Feb 05, 1995	Revised for Quality Improvement and to eliminate discrepancies found by DNV during the Pre-Assessment Audit, on Dec. 14-16th, 1994.
004	Aug 21, 1995	General update of all Manual Sections to resolve discrepancies found by DNV during the Assessment Audit, on April. 8-10, 1995 as well as to include changes in the Triconex Organization as per July 24, 1995 and correct some minor editorial errors.
005	Apr 10, 1996	Revised for Quality Improvement and to resolve discrepancies found by DNV during the Assessment Audit, on September 25-26, 1995 and corrected some minor editorial errors.
006	Jan 01, 1997	Updated Org. chart in QAM 1.2 and added paragraph 4.3.4 in QAM 2.1
007	May 06, 1997	Updated procedures to comply with Title 10 of the Code of Federal Regulations 10CFR50, Appendix B, Criterion I through XVIII, as applicable.
008	Jun 20, 1997	Updated numerous procedures as a result of internal and nuclear industry audits.
009	Aug 29, 1997	QAM 0.3, 1.2, 4.0, 5.1, 5.3, 6.0, 7.0, 10.0, 13.1, 13.2, 13.3, 16.0, 18.0: Updated procedures as a result of HL&P nuclear audit findings and internal procedure enhancements. Added QAM 0.3 and QAM 13.3.
010	Dec 8, 1997	QAM 6.0, 7.0, 8.0, 10.0, 12.0, 15, 17.0, 18.0: Updates for Quality Improvement, preparation for nuclear work, and internal audit findings.
011	Mar 20, 1998	QAM 1.3, 6.0, 10.0, 16.0, 17.0, 18.0: Quality improvement and internal audit findings.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance

# ■ TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 0.2	<b>Subject:</b>	Quality Assurance Manual History				
<b>Revision:</b>	015	<b>Page:</b>	2	<b>of</b>	2	<b>Date:</b>	01/05/01

Revision	Release Date	Changes
012	Sep 30, 1998	QAM 1.2, 2.2, 5.1, 10.0, 11.0, 13.1, 13.2, 18.0. Quality improvement and audit findings.
013	Apr 23, 1999	QAM 1.3, 1.4, 6.0, 11.0, 19.0. Quality Improvements and audit findings. Organizational realignments. Added new QAM 1.4.
014	Apr 14, 2000	QAM 2.2, 8.0, 10.0, 12.0, 16.0, 19.0, 20.0. Quality Improvements and audit findings.
015	Jan 5, 2001	QAM 3.0, 8.0, 14.0, 18.0. Audit findings.

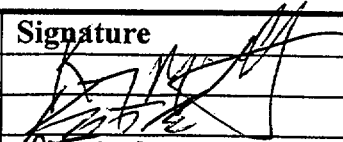
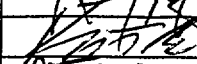

## SUMMARY OF CURRENT CHANGES (QAM Rev 015)

<u>QAM</u>	<u>REV</u>	<u>TITLE</u>	<u>CHANGES</u>
3.0	007	Contract Review	Add paragraph on Certificate of Conformance. (Relocated per ARR 256)
8.0	009	Product, Parts, and Material Identification and Traceability	Remove reference to Certificate of Conformance and move to QAM 3.0. (ARR 256)
14.0	007	Corrective and Preventive Action	Clarified responsibility for CAR processing. (ARR 218)
18.0	012	Training	Added inspector certification and eye exam requirements per ARR 258.

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

<b>Section:</b>	QAM 0.3	<b>Subject:</b>	Quality System Compliance Cross-Reference			
<b>Revision:</b>	001	<b>Page:</b>	1	of	2	<b>Date:</b> 04/23/99

TITLE	ISO 9001	10CFR50, APPENDIX B	TRICONEX QA MANUAL
Management Responsibility	4.1	I, II	1.1, 1.2, 1.3, 1.4
Quality System	4.2	II, V	2.1, 2.2, 2.3
Contract Review	4.3	III	3.0
Design Control	4.4	III	4.0
Document and Data Control	4.5	VI	5.1, 5.2, 5.3
Purchasing	4.6	IV, VII	6.0
Control of Customer Supplied Product	4.7	VIII	7.0
Product Identification and Traceability	4.8	VIII	8.0
Process Control	4.9	IX	9.0
Inspection and Testing	4.10	VII, X, XI	10.0
Control of Inspection, Measuring, and Test Equipment	4.11	XII	11.0
Inspection and Test Status	4.12	XIV	12.0
Control of Nonconforming Product	4.13	XV	13.1, 13.2
Corrective and Preventive Action	4.14	XVI	14.0

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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

<b>Section:</b>	QAM 0.3	<b>Subject:</b>	Quality System Compliance Cross-Reference			
<b>Revision:</b>	001	<b>Page:</b>	2	of	2	<b>Date:</b> 04/23/99

TITLE	ISO 9001	10CFR50, APPENDIX B	TRICONEX QA MANUAL
Handling, Storage, Packaging, Preservation, and Delivery	4.15	XIII	15.0
Control of Quality Records	4.16	XVII	16.0
Quality Audits	4.17	XVIII	17.0
Training	4.18	II	18.0
Servicing	4.19	None	19.0
Statistical Techniques	4.20	None	20.0
Reporting of Defects and Noncompliance	None	10CFR, Part 21	13.3

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

<b>Section:</b>	QAM 1.1	<b>Subject:</b>	Quality Policy		
<b>Revision:</b>	007	<b>Page:</b>	1	of	1
		<b>Date:</b>	04/23/99		

**1. PURPOSE**

Triconex Corporation has authorized the creation of this Quality Assurance Manual (QAM) which defines 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. DEPARTMENTS AFFECTED**

All departments

**3. SCOPE**

The Quality System adopted by Triconex Corporation shall meet the requirements of the ISO 9001 (1994) and the Code of Federal Regulations, 10CFR50, Appendix B. It is the policy of the Triconex Corporation 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 Company Mission and Quality Policy, and Company Values statement are adopted by the Corporation.

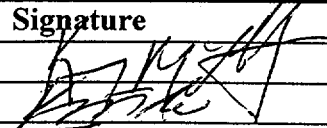
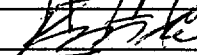
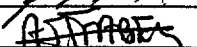
**4. PROCEDURE**

**4.1 COMPANY MISSION AND QUALITY POLICY**

THE MISSION OF TRICONEX CORPORATION IS TO BE THE WORLDWIDE LEADER IN SAFETY AND CRITICAL PROCESS CONTROL SOLUTIONS BY MEETING THE CURRENT AND FUTURE NEEDS OF OUR CUSTOMERS WITH PRODUCTS AND SERVICES THAT PROVIDE INDUSTRY LEADERSHIP IN QUALITY AND VALUE.

**4.2 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
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>

**TRICONEX CORPORATION**  
**QUALITY ASSURANCE MANUAL**

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

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization		
<b>Revision:</b>	009	<b>Page:</b>	1	of	6
		<b>Date:</b>	04/23/99		

**1. PURPOSE**

This procedure describes the functional organization of TRICONEX CORPORATION, and defines the responsibilities and authorities within the organization.

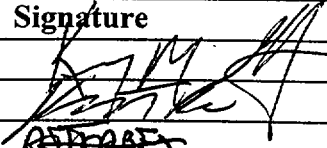


**2. DEPARTMENTS AFFECTED**

All departments

**3. SCOPE**

This section of the manual shall apply to the following organizations within TRICONEX CORPORATION.

- Product Assurance
- Customer Satisfaction
- Engineering
- Manufacturing
- Marketing and Sales
- Finance and Administration
- Training and Customer Service
- Systems Integration (Project Operations Irvine)

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

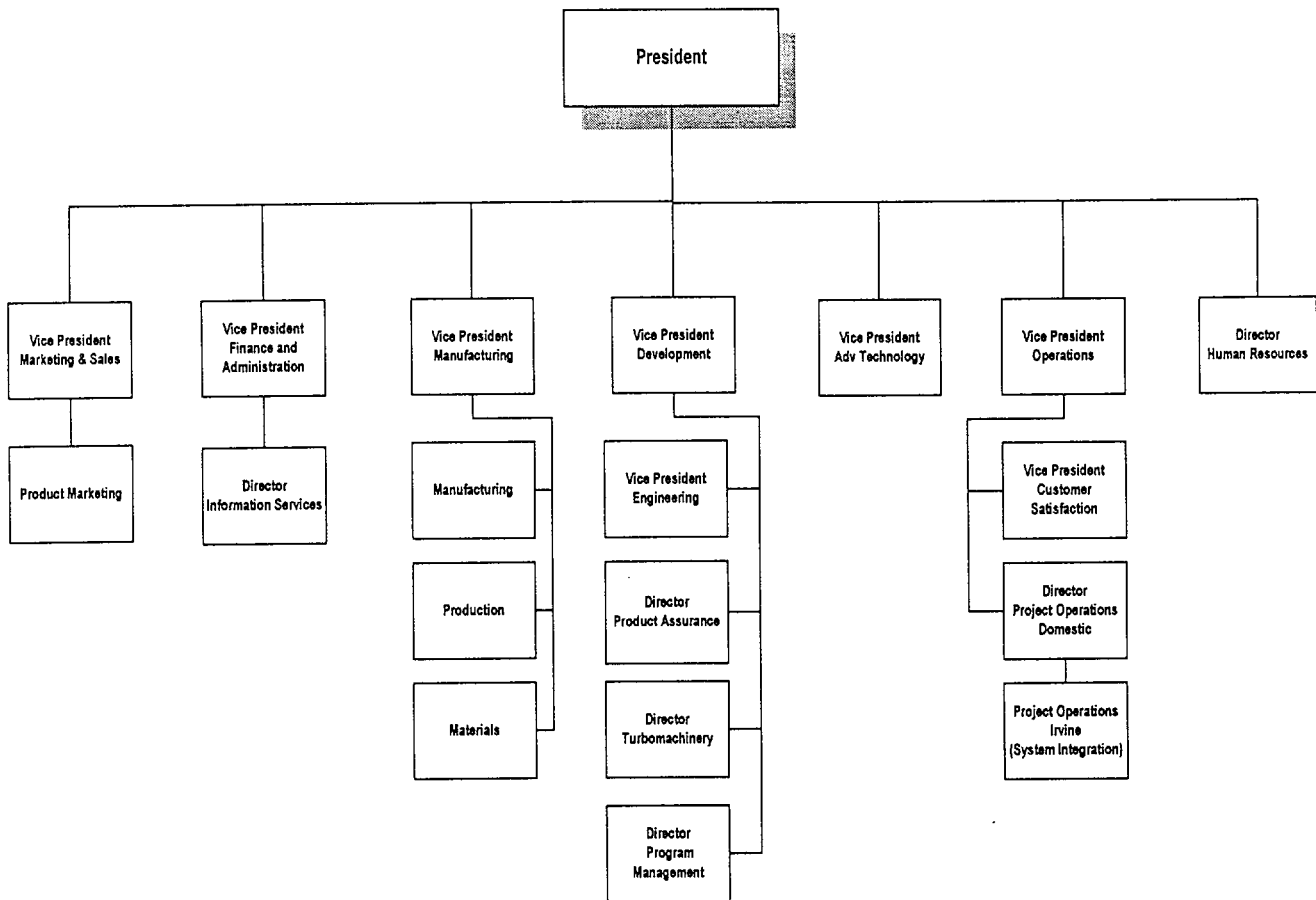


# **TRICONEX CORPORATION** **QUALITY ASSURANCE MANUAL**

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization			
<b>Revision:</b>	009	<b>Page:</b>	2	of	6	<b>Date:</b> 04/23/99

## 4. PROCEDURE

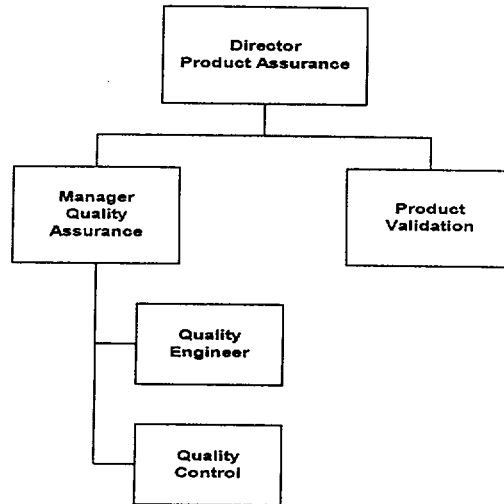
### 4.1. ORGANIZATIONAL CHART, TRICONEX CORPORATION



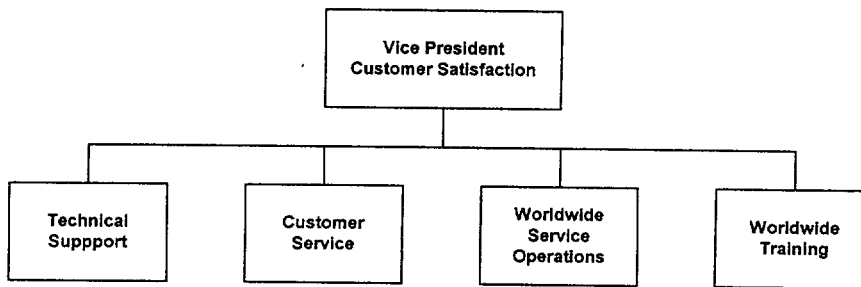
# **TRICONEX CORPORATION** **QUALITY ASSURANCE MANUAL**

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization		
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		<b>Date:</b>	04/23/99		

## 4.2 ORGANIZATIONAL CHART, PRODUCT ASSURANCE



## 4.3 ORGANIZATIONAL CHART, CUSTOMER SATISFACTION



## 4.4 RESPONSIBILITY FOR ORGANIZATIONAL CHARTS

Each organization within the Triconex Corporation shall prepare and maintain an organizational 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 organizational chart shall show clearly 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. The charts should be maintained in the form of a procedure.

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization		
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		<b>Date:</b>	04/23/99		

### 4.5. RESPONSIBILITY AND AUTHORITY

Responsibility and Authority	Department /Organization/ Functions	QAM reference
Management Review	Senior Management	QAM 1.3
Quality System	Product Assurance	QAM 2.1
Contract Review	Product Assurance and Sales & Marketing	QAM 3.0
Design Control	Engineering	QAM 4.0
Change Control	Engineering (CCB)	QAM 4.0
Document and Data Control	Engineering and Product Assurance	QAM 5.1
Purchasing	Manufacturing	QAM 6.0
Purchaser Supplied Product	Manufacturing	QAM 7.0
Identification and Traceability	Manufacturing and Engineering	QAM 8.0
Process Control	Manufacturing	QAM 9.0
Inspection and Testing	Manufacturing Product Assurance Engineering	QAM 10.0
Test Equipment	Manufacturing Product Assurance Engineering	QAM 11.0
Test Status	Manufacturing	QAM 12.0
Non Conforming Product	Manufacturing (MRB)	QAM 13.2
Corrective / Preventive Action	Product Assurance	QAM 14.0
Material Handling	Manufacturing	QAM 15.0
Control of Quality Records	Product Assurance	QAM 16.0
Internal Audits	Product Assurance	QAM 17.0
Training	Human Resources Customer Satisfaction and Each Department	QAM 18.0
Servicing	Customer Satisfaction	QAM 19.0
Statistical Techniques	Product Assurance	QAM 20.0

# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization				
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### 4.6. PRODUCT ASSURANCE

The Product Assurance Department is an independent organization within the Triconex Corporation. The Director, Product Assurance reports directly to the Vice President of Development. The Director, Product Assurance is responsible for global implementation of Quality Assurance strategies within the Triconex Corporation. Among others, the following tasks, responsibilities and authorities are assigned to Product Assurance organization:

- To ensure that the requirements of the ISO 9001 standards are met at all times.
- To monitor, maintain and where ever 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
- To perform, if necessary, vendor audits and source inspections in accordance with the requirements laid down in QAM 6.0.
- To identify the need for planning documents, procedures and Quality Plans to ensure that these documents are created in coherence with existing procedures. Assist responsible personnel, where necessary, in creation of the document. See QAM 2.2
- To review, and where necessary, comment on all proposed procedures affecting Quality Assurance. See QAM 2.2
- Procedures related to Quality Assurance will not be approved until all requirements laid down in ISO 9001 Standard and in this manual are met. See QAM 2.2
- To plan, carry out and document a comprehensive system of internal audits which will determine and monitor and improve the effectiveness of the Quality System. See QAM 17.0
- To 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.
- To determine if nonconformances are reportable to the Nuclear Regulatory Commission (NRC) as required by 10CFR Part 21. See QAM 13.3.
- To maintain and secure the records of all quality related documents for the specified retention period, ensuring that they are identifiable, legible and retrievable. To ensure that the documents are disposed of in an orderly manner after the retention period. See QAM 16.0
- To initiate a Stop Working Memo. See QAM 2.1

The Director, Product Assurance can delegate responsibilities and authorities, and assign specific tasks to other personnel to ensure that the previous listed requirements are met.

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.2	<b>Subject:</b>	Triconex Organization				
<b>Revision:</b>	009	<b>Page:</b>	6	of	6	<b>Date:</b>	04/23/99

## 4.7. CUSTOMER SATISFACTION

Closely allied with the Product Assurance Department is the Customer Satisfaction Department. Customer Satisfaction is responsible for the customer interface on quality issues after sales and product shipment. The Vice President of Customer Satisfaction is responsible for technical support, customer service (return material repair/upgrade), field service, and customer training on Triconex products.

## 4.8. RESOURCES

Each organization within the Triconex Corporation 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 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 contracted personnel.

## 4.9. MANAGEMENT REPRESENTATIVE

The Vice President of Development shall act as the Senior Management representative for all Quality related items within Triconex Corporation. The Director, Product Assurance, as his designee, has the responsibility:

- a) To ensure that Quality System requirements are established, implemented and maintained in accordance with the ISO 9001 standard, the policies and procedures of this manual.
- b) To report the performance of the Quality System to the Management for review as a basis for improvement of the Quality System.

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

## 5. REFERENCES AND RELATED DOCUMENTS

ISO 9001	1994
QAM 1.1	Company Policy
QAM 2.1	Quality System
QAM 2.2	Quality System Procedures
QAM 6.0	Purchasing
QAM 13.1	Control of Non-Conforming Product
QAM 13.3	10CFR Part 21 Reporting of Defects and Noncompliance
QAM 14.0	Corrective and Preventive Action
QAM 16.0	Quality Records
QAM 17.0	Internal Quality Audits

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.3	<b>Subject:</b>	Management Review			
<b>Revision:</b>	006	<b>Page:</b>	1	of	3	<b>Date:</b> 04/23/99

### 1. PURPOSE

To define a procedure for reviewing the effectiveness of the Quality Assurance System.

### 2. DEPARTMENTS AFFECTED

All

### 3. SCOPE

The management review meetings form an integral part of the Triconex Corporation Quality System. All areas of the operation shall be reviewed at all levels. Implementation of Quality Improvement programs, corrective action or other revisions of the Quality System shall be carried out with the highest priority by the affected departments.

### 4. PROCEDURE

#### **4.1. MANAGEMENT REVIEW MEETING**

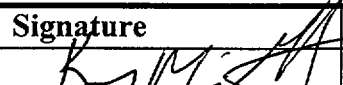
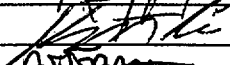

The Quality System will be reviewed by Senior Management whenever it is deemed necessary, but with a minimum frequency of once a year. If possible the President of the company and all Vice Presidents will attend the meeting. The objective of the meeting is to improve the effectiveness of the Quality System (QAM 2.1).

#### **4.2. REVIEW**

##### **4.2.1 AGENDA**

Prior to each review meeting, a meeting agenda will be developed and distributed to the attendees. The agenda will include the items to be reviewed/discussed and identify for which of these items preventive and/or corrective actions should be evaluated during the meeting.

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. The results of internal or external Quality System Audits (QAM 17.0) as well as the Customer Satisfaction Survey (QAM 1.4), Customer Complaint reports, and Quality Improvement Plans can form the basis for this evaluation.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

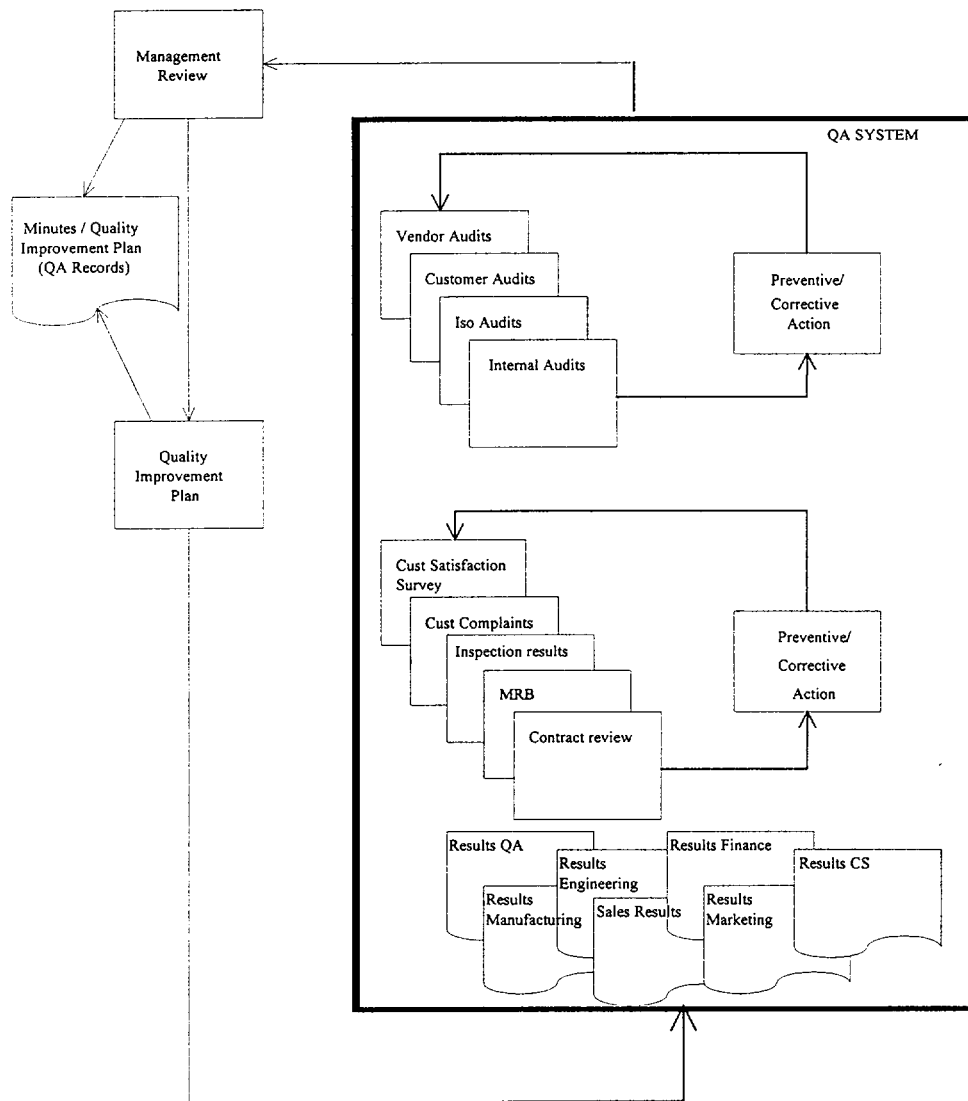
# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.3	<b>Subject:</b>	Management Review		
<b>Revision:</b>	006	<b>Page:</b>	2	of	3
		<b>Date:</b>	04/23/99		

## 4.3. RESULT

Minutes of the meeting will be taken. The minutes will be considered as Quality Records (QAM 16.0). The minutes will include identification of those present, any relevant corrective/preventive actions implemented/identified (QAM 14.0), any change of targets within an existing Quality Improvement Plan (QAM 2.3), or the initiation of a new Quality Improvement Plan if required.

## 4.4. FLOW CHART



# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.3	<b>Subject:</b>	Management Review				
<b>Revision:</b>	006	<b>Page:</b>	3	of	3	<b>Date:</b>	04/23/99

## 5. 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



 **TRICONEX CORPORATION**  
**QUALITY ASSURANCE MANUAL**

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# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.4	<b>Subject:</b>	Customer Satisfaction Survey		
<b>Revision:</b>	000	<b>Page:</b>	1	of	2
		<b>Date:</b>	04/23/99		

**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

All

**3. SCOPE**

One of the primary elements of the Triconex Company Mission and Quality Policy (QAM 1.1) is to meet the current and future needs of our customers. Triconex 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

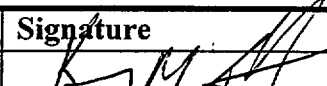
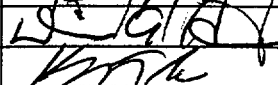


- 1) the company policies of QAM 1.1
- 2) ISO 9001 objectives for
  - achieving customer satisfaction (ISO Section 1.0)
  - management review for continuing suitability and effectiveness of the quality system (ISO Section 4.1.3).

This survey is normally conducted using outside contractors to assure independence and validity of results.

**4.2. DATA COLLECTION**

On a quarterly basis (or as directed by Triconex management), the designated survey agency shall solicit information on routine customer contacts related to selected company activities (training, sales, technical support, etc.).

Triconex organizations shall maintain customer contact information, as appropriate, and provide the requested data to the VP Customer Satisfaction, who shall transmit the data to the agency on a scheduled basis.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Dennis Harris		VP Customer Satisfaction
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 1.4	<b>Subject:</b>	Customer Satisfaction Survey				
<b>Revision:</b>	000	<b>Page:</b>	2	of	2	<b>Date:</b>	04/23/99

The 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 Corporation.

## 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, as directed by Triconex management, in the primary areas of customer contact such as training, sales, technical support, etc. Categorization of data by Triconex facility location or generic functional area may also be included, as appropriate. 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

Upon issuance, the Customer Satisfaction Survey Report shall be distributed to Triconex top management, including , as a minimum, the President and the responsible Vice Presidents of the functional areas involved in the survey. Additional distribution to selected management will be made at the discretion of the VP Customer Satisfaction.

It is the responsibility of each area Vice President 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

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 2.1	<b>Subject:</b>	Quality System		
<b>Revision:</b>	006	<b>Page:</b>	1	of	4
		<b>Date:</b>	04/23/99		

### 1. PURPOSE

This Procedure describes the Triconex Corporation Quality System.

### 2. DEPARTMENTS AFFECTED

All Departments

### 3. SCOPE

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

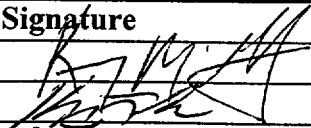
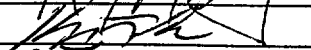

### 4. PROCEDURE

#### 4.1 GENERAL

The Quality Assurance System shall meet all the requirements of ISO 9001. The requirements for control, maintenance and documentation of the 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 HIERARCHY OF DOCUMENTS

There are three levels of documents within the Quality System. The QAM is considered to be the highest level document. The Director, Product Assurance is responsible for implementation, maintenance, and control of the QAM. All procedures within the QAM are subject to approval by the President of Triconex Corporation, the Vice President Development, and the Director, Product Assurance. The second level of documents are organized in departmental Manuals. These manuals contain all departmental Policies, Standards and Procedures. All documents in each manual are subjected to approval by the Director, Product Assurance prior to issue. All other controlled documents are considered third-level documents. The control, issue and sign off of third level documents are described in their governing first or second level procedures.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 4.3 SELECTION AND USE

#### 4.3.1 POLICIES

A Policy shall be 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.

#### 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 can develop its own Standards in case National or International Standards are not available or in case they are not adequate. These Standards shall be unambiguous. If a Standard is adopted 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 shall be used to describe mandatory rules, actions or processes. Procedures can refer to Standards and Policies. In cases where 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

In case a procedure can not be followed as intended it is up to the user of that procedure to inform his or her supervisor of the ambiguity in the procedure. The supervisor shall provide proper instructions and ensure that, if required, corrective action will be taken as per QAM 14.0

### 4.4 QUALITY ASSURANCE MECHANISMS

There are two basically independent mechanisms to ensure that the requirements laid down in this manual and in ISO 9001 are met.

- 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 Director, Product Assurance (also see QAM 17.0) and used as inputs to the management review process.

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- 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)

### 4.5 EMERGENCY PROCEDURES

The Director, Product Assurance can decide to issue an Emergency Procedure in the following cases:

- 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 priority 1 or 2 Product Discrepancy Report is initiated. (QAM 4.0)

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.

### 4.6 STOP WORK PROCEDURE

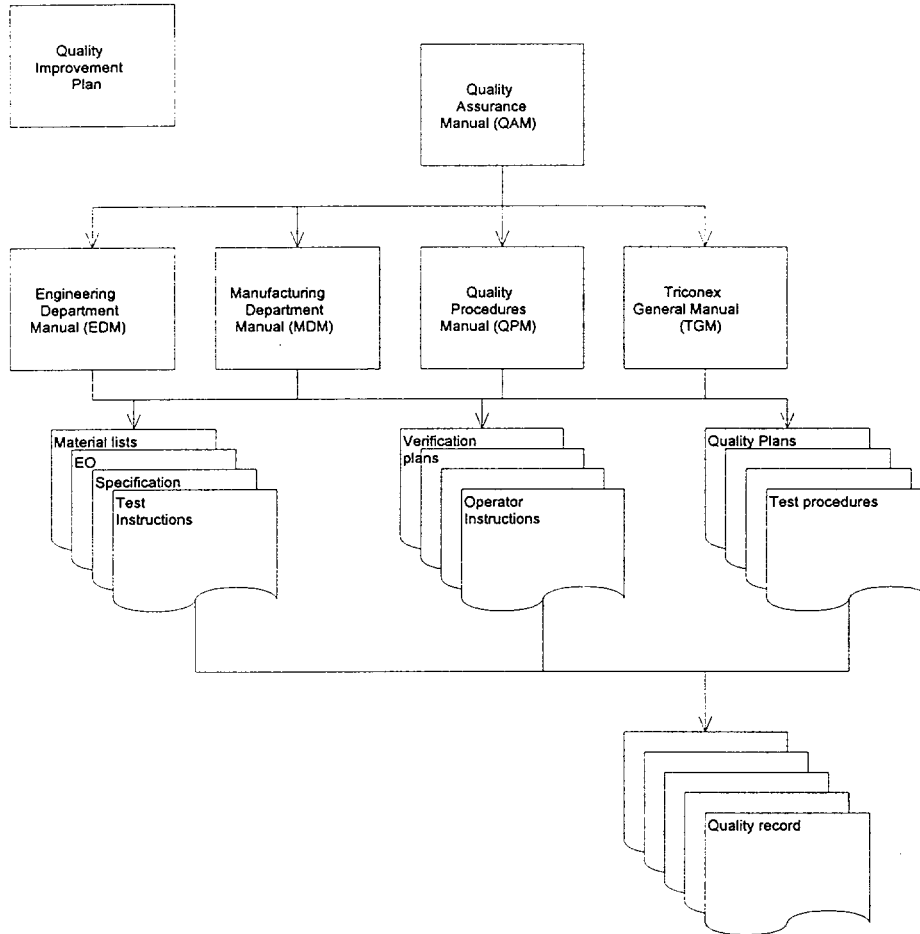
A Stop Work Memo is issued by:

- a) The Vice President of Development and the Director, Product Assurance 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 would result in compromising the Quality of the final product or the safety of personnel or equipment.
- b) The STOP WORK MEMO can also be used to halt the processing and shipment of product affected by a Product Discrepancy Report.

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## 4.7 DOCUMENT STRUCTURE CHART



## 5. 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

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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**1. PURPOSE**

This procedure defines a system to control drafting, approvals, issuing and revision of Manuals (as described in QAM 2.1 Para. 4.7), Policies, Standards and Procedures, in addition to establishing the relation between this manual and other manuals/procedures.

**2. DEPARTMENTS AFFECTED**

All departments within the Triconex Corporation.

**3. SCOPE**

ISO 9001 requires that the supplier shall document and maintain a Quality System in order to ensure that our products and services conform to specified requirements. Proper control of this manual is essential to meet this requirement. It is the responsibility of each Triconex Corporation employee to ensure that the requirements laid down in this procedure are followed.

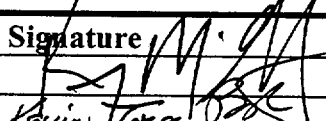
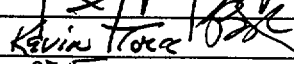
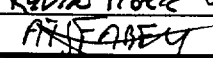
**4. PROCEDURE**

**4.1. QUALITY PROGRAM DOCUMENT HIERARCHY**

The Quality Assurance Manual (QAM) is considered to be the highest level document within the Triconex Corporation Quality System. This Manual will therefore describe the Quality Assurance and Control systems in a general manner. More detailed descriptions of the process can be found in the departmental manuals which are issued by the various Organizations or Departments within the Triconex Corporation.

The Quality Procedures Manual (QPM), Manufacturing Department Manual (MDM) and Engineering Departmental Manual (EDM) are the primary departmental manuals within the Triconex Corporation. The Triconex General Manual (TGM) is a general procedures manual covering several departments or organizations within Triconex, such as Administration, Finance, Sales and Marketing, and Systems Integration (Irvine). TGM procedures cover activities which are directly related to the quality of the products, but also may include certain non-quality related administrative procedures.

All new or re-issued procedures in the departmental manuals shall be approved by the Director, Product Assurance before they become effective.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>



# TRICONEX CORPORATION

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### 4.2. QA MANUAL

#### 4.2.1. RESPONSIBILITIES

The Director, Product Assurance has overall responsibility for the Triconex Quality Program. As his designee, the Manager, Quality Assurance is responsible for maintenance and control of the QAM. All QAM procedures shall be approved by the Corporation President, the VP Development, and the Director, Product Assurance prior to issuance.

#### 4.2.2. FORMAT OR LAYOUT

##### 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 standard, i.e., by subject area 1 through 20 (Management Responsibility, Quality System, Contract Review, etc.). Where this numbering scheme is adhered to, it is considered to be a convenient method of automatic referencing. In other cases, relevant procedures shall be referenced in paragraph 5 of each QAM procedure. The Director, Product Assurance or his designee shall also maintain a document reference list.

Section 0 of the Manual defines the current contents of the manual and consists of:

QAM 0.0: Introduction

QAM 0.1: Table of Contents

QAM 0.2: QAM History

##### 4.2.2.2 PROCEDURE FORMAT

All procedures in this manual shall have the same format or layout including these major sections:

1. Purpose
2. Departments Affected
3. Scope
4. Procedure
5. References

Each procedure will have a title block header identifying procedure number, title, revision number, effectivity date, and page numbering. Page one of each procedure will contain a signature block for the Corporation President, the VP Development, and the Director, Product Assurance. Quality Records pertinent to the prescribed procedure activities shall be specifically addressed within the body of the procedure.

#### 4.2.3. ISSUE AND REVISION CONTROL

Implementation of a new or revised procedure in the QAM will always result in a revision of QAM 0.0: Introduction, QAM 0.1: Table of Contents, and QAM 0.2: QAM History. A new procedure will have revision 000. The revision number of each revised procedure shall be increased by 1. The revision number of the QAM, as reflected in QAM 0.0, shall be increased by 1 each time a new or revised procedure is issued.

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Changed text within each procedure shall be indicated by a change bar in the right margin to provide visibility of program changes. For each manual revision, a summary of associated procedure changes will be included in QAM 0.2. QAM 0.2 will also provide a history of manual changes.

A procedure shall only be considered effective after it has been signed off by the Corporation President, and QAM 0.0, QAM 0.1 and QAM 0.2 have been updated. The procedure shall take effect on the date listed in QAM 0.2 .

#### 4.2.4. PROCEDURE CHANGE COORDINATION

If it becomes necessary to issue or revise a procedure within the QAM, a draft proposal will be written. The Director, Product Assurance will assure that this new procedure is not in conflict with any other procedure prior to release. If the procedure does not agree with other procedures he will take appropriate measures to revise affected procedures or he will order a redraft of the proposal.

It is the responsibility of the Director, Product Assurance to ensure that organizations or departments affected by a new or revised procedure are informed before the procedure becomes effective. It is the responsibility of each department Head to ensure that procedures and requirements are in place as of the effective date of the procedure.

It is the responsibility of the Manager, Quality Assurance to ensure notification of QAM changes to personnel subject to the QAM. Where appropriate for significant program changes, training assistance will be provided to other organizations.

#### 4.2.5. MANUAL DISTRIBUTION AND CONTROL

There are two types of distribution made of this QAM, Controlled and Uncontrolled. The uncontrolled copies are supplied as a source of information about Triconex Corporation Quality System. Controlled copies are considered official working copies that describe the current Quality System.

##### 4.2.5.1. CONTROLLED COPIES

The Director, Product Assurance will maintain a record of issued QAMs and will assign a unique copy number to each copy. Each recipient of a QAM will sign for receipt of the Manual. Each recipient is responsible for updating his copy of the manual with revised or new issued procedures and familiarizing himself with changes received.

##### 4.2.5.2. UNCONTROLLED COPIES

In case a third party requests a copy of the QAM this request shall be coordinated by the Director, Product Assurance. Depending on the nature of the request, the Director, Product Assurance can decide whether or not the recipient shall receive future revision levels. If so, this will be clearly noted on the distribution list together with recipients name and address. It

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## QUALITY ASSURANCE MANUAL

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is the recipients responsibility to keep his address current. In the event it is decided not to provide future revisions, the manual shall be clearly marked, with the following words:

### "UNCONTROLLED COPY"

Uncontrolled copies of the manual shall not be listed on the distribution list. The Director, Product Assurance can recall any copy of the QAM or stop distribution of revision levels to third party recipients.

The QAM may also be available in electronic form on the local network and accessible by company personnel. This on-line version of the QAM is considered to be uncontrolled and for information only.

## 4.3. DEPARTMENTAL PROCEDURES AND MANUALS

### 4.3.1. RESPONSIBILITY

Each Organization within the Triconex Corporation is responsible for identifying the need, drafting, issuing, and maintaining its own procedures. The Product Assurance department can assist in this process, but should not be considered the driving force. Department Manuals supporting the Quality Program include the Quality Procedures Manual (QPM), Manufacturing Department Manual (MDM), Triconex General Manual (TGM), and Engineering Departmental Manual (EDM). Department management personnel responsible for each procedure are indicated in the procedure signature block.

Even though procedures are the most important tool for documenting and controlling the Quality Assurance System in use by Triconex Corporation, it is essential to evaluate prior to issuing or revising a procedure, whether the absence of the new or revised procedure would adversely affect the quality of the service or product provided. Furthermore, when issuing or revising a procedure, it should be considered that a complicated procedure is more likely ineffective than a simple and concise outline of the process. Procedure detail should be commensurate with the level of control necessary to ensure product quality.

### 4.3.2. GENERAL FORMAT

The format of the department Manuals and procedures should be consistent with the QAM, where practical. The QPM, MDM, and TGM shall be formatted similar to the QAM, as indicated in section 4.2.2.2. EDM procedure format may vary to suit the needs of the Engineering Department. All Department Manuals shall contain procedures equivalent to QAM 0.0, 0.1, and 0.2 as described in section 4.2.2.1. MDM and QPM manual chapters will correspond to the ISO numbering scheme, consistent with the QAM format.

Regardless of general format, the following identification system is mandatory for all procedures.

- a) Document Name
- b) Procedure number and version (master list/ manual number)
- c) Effectivity Date (normally the date indicated on the procedure)
- d) Author

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## QUALITY ASSURANCE MANUAL

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In order to make it possible for the user to verify that the document is complete, it is necessary to number all pages in the following way:

**Page xx of xx Pages.**

Other numbering systems are allowed under the condition that it should always be possible for the user to verify that the document is complete.

All Policies, Standards and Procedures are considered controlled documents and all document control procedures apply unless otherwise stated. (See QAM 5.1)

### 4.3.3. ISSUE AND REVISION CONTROL

The issuing and the revision of all documents described in this procedure shall be controlled by the originating department, unless stated otherwise in this manual. Each document shall be signed by the author, and approved by the responsible Vice President and the Director, Product Assurance. Additional sign off requirements can be regulated per organization. A procedure shall be considered effective after it has been signed off by the required entities.

The internal audit system, customer contact reporting system, product discrepancy reporting system as well as change control system and corrective or preventive action system can be used to identify the need for, and initiate new issue or revision of a procedure.

Consistent with section 4.2.3, new and revised procedures shall always result in the revision of the corresponding 0.0, 0.1, and 0.2 documents. The revision number of QPM, MDM, and TGM procedures shall be increased by 1 with each revision (the EDM procedure numbering scheme may include decimal changes for minor revisions).

Changed text within each procedure shall be indicated by a change bar in the right margin to provide visibility of program changes. For each manual revision, a summary of associated procedure changes will be included in the corresponding "0.2" document, which will also provide a history of the department manual changes.

### 4.3.4. PROCEDURE CHANGE COORDINATION

Changes to department procedures shall be reviewed to assure that they are not in conflict with QAM requirements. Proposed changes should generally be reviewed by other groups which may be affected by the procedures.

It is the responsibility of department managers to ensure that personnel affected by procedure changes are notified (and trained as appropriate) upon issuance of the changes.

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### 4.3.5. MANUAL DISTRIBUTION AND CONTROL

Provisions for distribution and control of department procedure manuals shall be equivalent to section 4.2.5. The Manager, Quality Assurance is responsible for distribution and control functions for the QPM, MDM, and TGM manuals. Engineering shall control the EDM procedures manual.

All policies, Standards and Procedures will be listed in the Controlled Documents Master list. Procedures Manuals, such as this manual, can be listed as single document under the condition that the separate procedures contained in the manual are properly controlled, that a manual history is kept within the manual, and that the distribution is controlled.

### 4.3.6. EXCEPTIONS

The Emergency Procedure outlined in QAM 2.1, paragraph 4.5, is the only exception to paragraphs 4.3.1 through 4.3.5 of this procedure.

### 4.4. QUALITY RECORDS

The Master copy of all signed and issued Manuals and procedures will be kept as Quality Records in accordance with QAM 16.0. Records supporting Controlled Manual distribution and maintenance are also considered Quality Records.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 0.0	Introduction
QAM 0.1	Table of Contents
QAM 0.2	Quality Assurance History
QAM 2.1	Quality System
QAM 5.1	Document Control
QAM 16.0	Quality Records
EDM	Engineering Departmental Manual
MDM	Manufacturing Department Manual
QPM	Quality Procedures Manual
TGM	Triconex General Manual

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

<b>Section:</b>	QAM 2.3	<b>Subject:</b>	Quality planning		
<b>Revision:</b>	005	<b>Page:</b>	1	of	2
		<b>Date:</b>	04/23/99		

**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

Engineering  
 Manufacturing  
 Product Assurance

**3. 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. PROCEDURE**

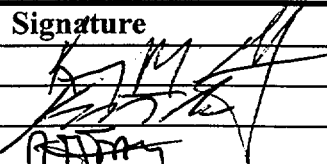
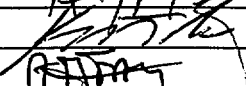
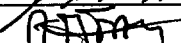
**4.1 GENERAL**

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

- Quality Plans
- Quality Improvement Plan

Quality Planning requirements shall be documented in either a Quality Plan and/or 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
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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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 PLANS

For projects related to the development of new products, services or manufacturing processes, the Director, Product Assurance can order the development of a Quality Plan. The Quality Plan shall be developed by the Product Assurance Department in close co-operation with the Development Team. 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.

### 4.3. 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.
- 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 make Quality (and its related costs) measurable.

## 5. 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

# ■ TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 3.0	<b>Subject:</b>	Contract Review		
<b>Revision:</b>	007	<b>Page:</b>	1	of	5
		<b>Date:</b>	01/05/01		

**1. PURPOSE**

To establish and maintain a documented procedure for Proposals / Quotations, Sales Order review and ongoing contracts implementation.

**2. DEPARTMENTS AFFECTED**

- Sales and Marketing
- Finance
- Contracts
- Manufacturing
- Customer Satisfaction
- Product Assurance

**3. SCOPE**

The Contracts Department shall have the responsibility to ensure that all contracts (Sales Orders and ongoing Contracts) are reviewed and all contract review activities are coordinated.

**4. PROCEDURE**

**4.1. GENERAL**

The Proposal/Quotation when requested by the Customer, and Sales Order / Contract review are distinctly divided in three different process.

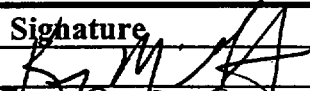
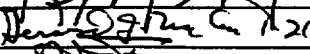
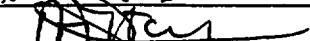
- a) Proposals/Quotations.
- b) The Sales Order Review.
- c) The Ongoing Contract Review.

**4.2. PROPOSAL / QUOTATION**

When Customers request a Quote or ask for a proposal (TGM C-2), the information is reviewed continuously, until the exact configuration is well recognized by both the Customer and Triconex Sales and Marketing (TGM C-3) .

When Customers request a Quote for spares or ask for a proposal, the information is reviewed by Customer Satisfaction to ensure that spares ordered/requested are compatible with their existing systems.

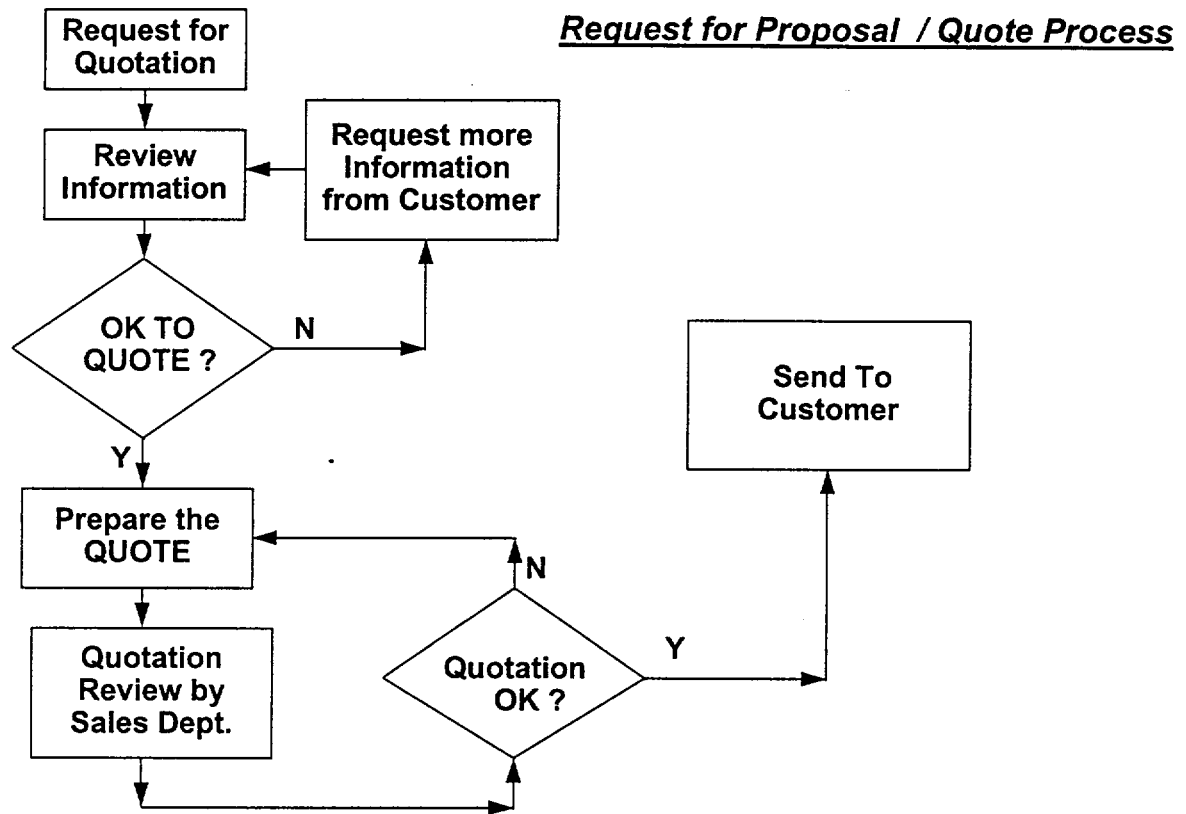
For Proposals which involve nuclear customers, information is reviewed by Quality Assurance to confirm the capabilities of Triconex to satisfy the requested quality and certification requirements.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance



# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 3.0	<b>Subject:</b>	Contract Review		
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### 4.3. SALES ORDER REVIEW

Sale orders are individual contracts for the purchase of Triconex Products based upon a customer submitted purchase order.

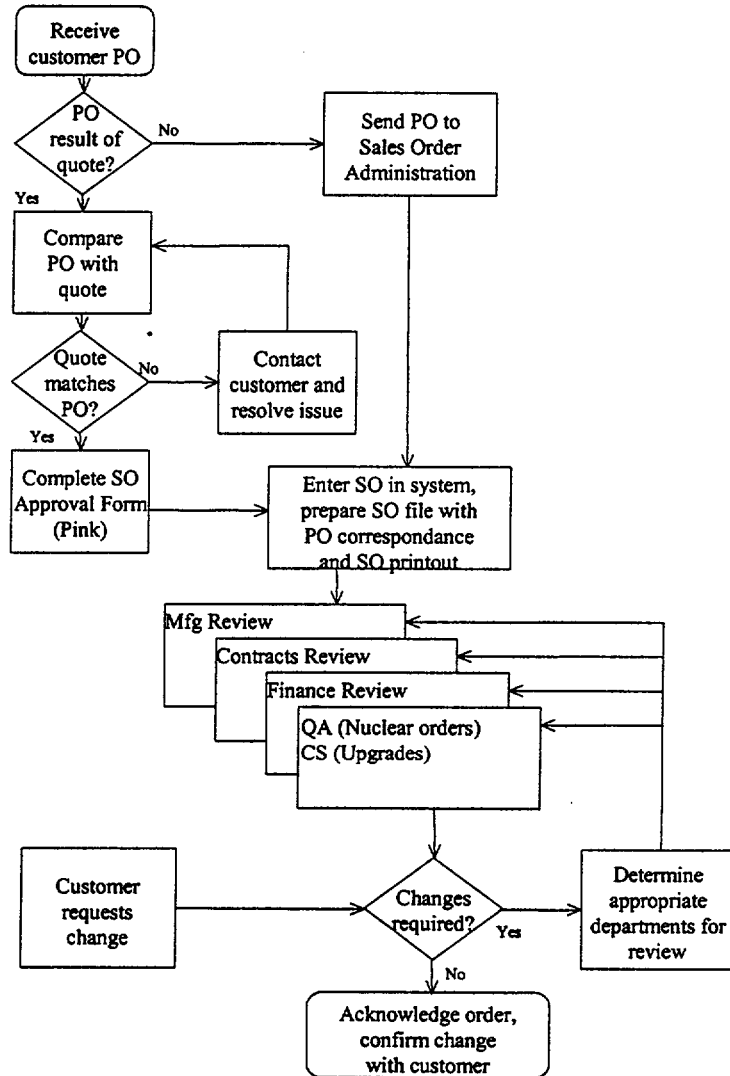
Once the Sales Order Administration Department enters the Sales Order, the package is circulated to the following departments (TGM B-1) to highlight any discrepancies or special needs in the order:

<u>Department</u>	<u>Areas of Concern</u>
Manufacturing	Availability, Delivery, Specification, Compatibility
Contracts	Commercial issues
Finance	Payment terms / Overall review
Customer Satisfaction	(Upgrades only) Upgrade issues
Product Assurance	(Nuclear plant orders only) Quality & certification issues

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 3.0	<b>Subject:</b>	Contract Review				
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The review and approval shall be documented. The Sales Order Administration department shall maintain records of the review and approval. These records shall be regarded as Quality records as per QAM 16.0.



# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 3.0	<b>Subject:</b>	Contract Review				
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The Sales Administration Department has the responsibility to resolve both internal and external (Customer) related 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 (TGM B-2).

All orders received ( in writing or verbal) are entered and are subject to the above review (Order Review Form) and acknowledgment process. The company does not normally accept verbal orders for standard products, however, exception can be made for previous Triconex known customers. The Order Form is used to document such verbal orders. The form shall contain all the required information to process the order as if it was received in writing.

#### 4.4. ONGOING CONTRACTS

An Ongoing Contract is a mutually-agreed upon written master agreement between the Company and a Customer. Such an agreement contains the product specifications and those standard terms and conditions of sale upon which all future orders are based. The company has entered into Ongoing Contracts with both intermediary and end user customers.

The Contract department is the focal point of Ongoing Contract review, implementation and management. Integral to the implementation stage of these contracts are discussions as necessary between the Contract Department and Marketing, Finance, Manufacturing, Customer Satisfaction, and Product Assurance.

Whenever product is being sold on the basis of an ongoing contract, this contract will be reviewed by the Contract Department first. If the product to be sold is not contained in price list, the Customer Satisfaction department will review the contract. When required, the review shall be performed in close coordination with the customer with the intention resolving any outstanding differences. The review shall be documented and records shall be retained by the Contracts department. These records shall be regarded as Quality Records as per QAM 16.0.

#### 4.5. SALES FORECAST MEETING

In order to solve any issues which may effect scheduled ship dates, the Contracts Department shall prepare a list of updated Sales Orders and coordinate the different activities in a weekly meeting. The meeting is chaired by the Contracts Department with the participation of the representative of Sales Order Administration, Inside Sales, Manufacturing and Cost Accounting.

#### 4.6. AMENDMENTS

All amendments to Sales Orders are processed as described in TGM B-1. All records of Amendment to Sales Orders are regarded as Quality Records as per QAM 16.0.

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Amendments to Ongoing Contracts shall be agreed upon by all parties involved and the documented evidence of the amendment shall be regarded as Quality Records as per QAM 16.0

## 4.7. CERTIFICATE OF CONFORMANCE

A Certificate of Conformance is optional and will be issued only if requested by a customer. The certificate lists the customer purchase order and documents that the product or system meets all requirements. When required by the customer, the C of C will be listed as a specific documentation requirement in the Sales Order. The Director, Product Assurance or the Manager, Quality Assurance shall sign each certificate.

## 4.8. CONTRACT RECORDS

All records relating to Contract Review (Sales Orders and Ongoing Contracts) are considered as Quality records as described in QAM 16.0. These records are:

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

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
TGM B-1	Order Administration Overview
TGM B-2	Sales Order Acknowledgment
TGM C-2	Proposal
TGM C-3	Purchase Order Review and Approval

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**QUALITY ASSURANCE MANUAL**

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## QUALITY ASSURANCE MANUAL

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### 1. PURPOSE

This procedure describes the requirements for the control, Verification and Validation of the engineering design of the product in order to ensure specified requirements are met. It also outlines the systems in place which are available to implement the necessary control required.

### 2. DEPARTMENTS AFFECTED

Engineering  
 Manufacturing  
 Product Assurance  
 Customer Satisfaction  
 Marketing

### 3. SCOPE

Design Control includes design and development planning, design input, design review, design output, design verification, design validation and design changes. This procedure provides the general outline for control, defines the main responsibilities for design control and available systems to provide the necessary control.

### 4. PROCEDURE

#### 4.1 GENERAL

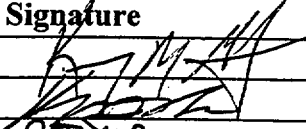
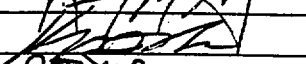

Design control responsibility is shared by three organizations, namely Marketing, Engineering, and Product Assurance. Specifics of the process are found in the following paragraphs, and are documented to ensure that specified requirements are met.

#### 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 Time Spans for each 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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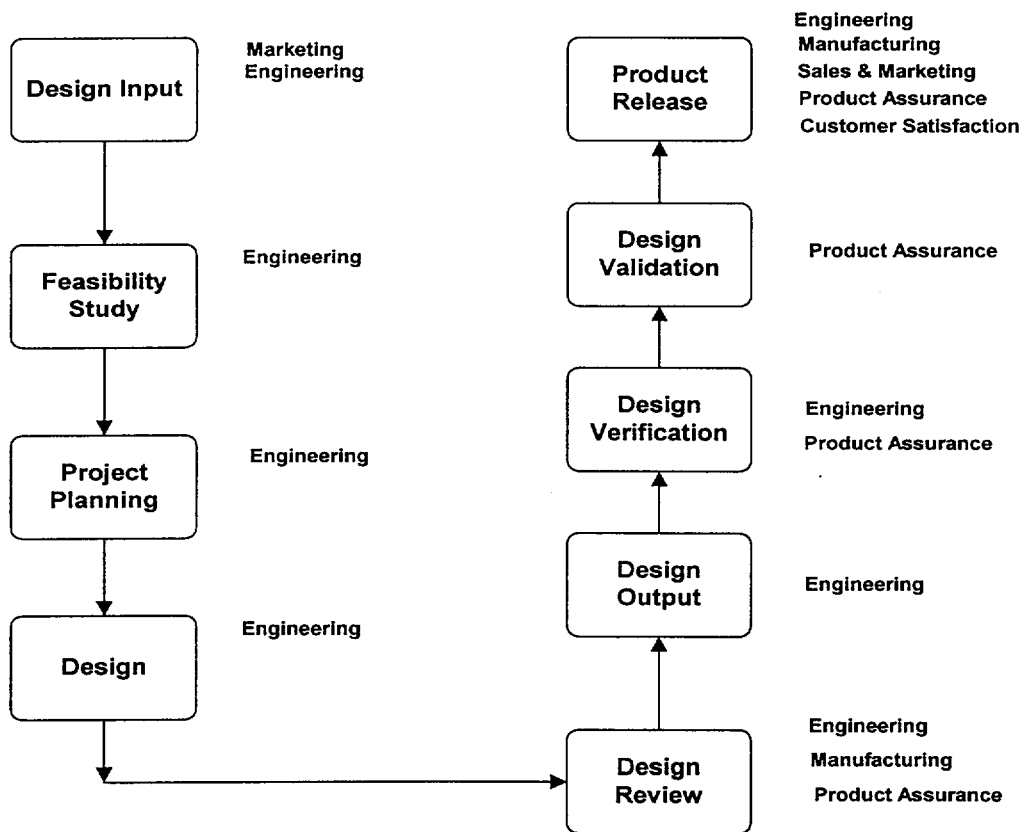
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### 4.3 ORGANIZATIONAL AND TECHNICAL INTERFACES

Prior to the start of project design for a "new" product, the Marketing organization will develop a Market Requirements Definition. This document will contain the basic market requirements for the new product or the upgrade requirements for an existing product. When senior management decides that the product will be approved for the design phase, the project will be planned in accordance with the requirements of paragraph 4.1 and 4.2. of this procedure. Upon approval 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 Engineering Project Plan and may provide input for Return On Investment calculations.

#### 4.3.1 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.



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### 4.4 DESIGN INPUT

The design input is defined as all requirements that are utilized in the design phase of the project which help establish the characteristics of the finished product. Design inputs to Engineering can be submitted in various methods. The following is a list of those methods:

#### 4.4.1 REQUIREMENTS DEFINITION

The initial requirements for product design are established in the Marketing Requirements Definition (TGM C-1). This document defines the product market need, application, operational environment, performance requirements, pricing/cost profile and all other related marketing specifications.

#### 4.4.2 PRODUCT DISCREPANCY REPORTS (PDR'S)

Prior to initiating the product development, 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.

#### 4.4.3 NATIONAL AND INTERNATIONAL REGULATORY SAFETY REQUIREMENTS

The Safety Engineer shall be responsible to assure that all newly designed hardware and subsequent design changes shall comply with all applicable Regulatory requirements. Per EDM 70.00, all new hardware product design specifications and design activities shall include participation by safety Engineer to assure compliance with the regulatory safety requirements.

#### 4.4.4 QUALITY DISCREPANCY REPORT (QDR)

Any discrepancies found during the Product Verification Testing phase shall be documented using the QDR process as described in Quality Procedure QPM 4.2. Following disposition of the QDR an Engineering Change Request (ECR) may be required to incorporate the design modification.

#### 4.4.5 ENGINEERING CHANGE REQUEST (ECR)

If a proposed fix or correction of a PDR is approved by the Quality Assurance Review Board, the proposed fix or correction will be documented on an ECR and will be approved by Change Control Board (CCB). The (CCB) will review the change request and assess the overall impact to implement the change.

### 4.5 DESIGN REVIEW

Design reviews are scheduled by Engineering. 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



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is planned to begin and outline the subjects to be reviewed in each segment. All the managers from different organizations who are affected shall be invited to the design review.

The design reviews are considered the main formal method of communication to inform all parties regarding the design results at any particular stage. The Meeting Minutes shall be recorded and maintained. They are considered Quality Records. (See QAM 16.0)

### 4.6 DESIGN OUTPUT

Engineering shall document the design output. Design output shall be documented in a manner so initial requirements can be verified. The design output criteria are:

- a) The design input requirements are met.
- b) The acceptance criteria is established.
- c) Those characteristics of the design that are important to the safe and proper operation of the product are highlighted, and,
- d) The design output documents are prepared before the release.

### 4.7 DESIGN VERIFICATION

Design verification is performed to ensure that design output meets the design input requirements. Therefore at the end of the design process, a design verification will be scheduled per Engineer Project plan. Product specifications, hardware drawings, test procedures, etc., will be reviewed and released via an Engineering Order (EO) to Manufacturing to fabricate pilot-production models. The output at this stage will determine the manufacturability of the design. Any changes to the hardware requirements during this stage of the design phase will require an ECR be submitted to CCB for approval.

The design verification will be performed by qualified personnel not directly responsible for the design of the product under test. This verification will be performed to the design specifications and/or the applicable test procedures. Non-conformance to the requirements that are found shall be documented with a Quality Discrepancy Report (QDR). The Quality Assurance Review Board will review each QDR and determine disposition. Engineering will schedule the correction of the discrepancy. After the design verification is complete, the product will be released for the QA Validation Procedure test. Any changes to the design that affect hardware, software/firmware configuration or test procedure documentation will also be controlled utilizing ECR or EO procedure and requires approval by the CCB. 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.

### 4.8 DESIGN VALIDATION

Following a successful Design Verification, Product Validation is performed. The Design Validation is performed to ensure that the product conforms to defined user needs

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and/or requirements. The Product Validation Test will be carried out under the responsibility of the Product Assurance Department. A test plan will be prepared by Product Assurance.

The product will not be released to manufacturing for production until the Product Validation test plan is successfully completed.

### 4.8.1 PRODUCT RELEASE

The Director, Product Assurance is responsible for approving release of the final product after Product Validation is complete and satisfactory. The product shall then be formally approved/released by Engineering as described in EDM 12.00. Following that, the Customer Satisfaction shall prepare a Product Release Notice (PRN) describing the new release to the customers. The PRN shall be approved by the Vice President of Customer Satisfaction and the President of the Company, and shall be released via an Engineering Order. The released PRN shall be published and available to the customers.

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

### 4.9 DESIGN CHANGES

In general the Design Changes on a product are approved by the Change Control Board (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 Product Validation Test.

#### 4.9.1 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. 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.

#### 4.9.2 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 Product Validation Testing by Product Assurance. Following the completion of the Product Validation Testing, the system firmware will be released to manufacturing. All initial designs shall be formally released to manufacturing through the Change Control Board (CCB). Any changes to the design following release, will

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also require the approval of the Change Control Board (CCB). Design changes will be initiated on an Engineering Change Request (ECR). Following approval of the ECR by the Change Control Board (CCB), the design change will be documented on an Engineering Order (EO) as described EDM 21.00.

### 4.9.3 CHANGE CONTROL BOARD DUTIES

The CCB is responsible for the approval and implementation of all initial Engineering Orders (EO'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 EO'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 SYSTEMS INTEGRATION

The Systems Integration (SI) Department develops drawings and supporting documentation to facilitate customer application of Triconex Products based on customer-specified design information. As such, no basic Product or system functional design is performed by SI. To the extent that design information is received and translated into system assembly documents, SI procedures shall include, as a minimum, appropriate controls for:

- a) Document control
- b) Verification of incorporation of design data
- c) Document review
- d) Validation testing
- e) Development of application software

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
EDM 12.00	Product Development Process
EDM 21.00	Engineering Order Control.
EDM 70.00	Safety Regulatory
QAM 16.00	Quality Records
QPM 4.2	Quality Discrepancy Report.
TGM C-1	Marketing Requirements Definition
TGM D-1	System Integration Process

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## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 5.1	<b>Subject:</b>	Document and Data Control		
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**1. PURPOSE**

This procedure describes the general document and data control system which is used by Triconex Corporation. This system ensures that all Quality related documents and data are controlled in a manner consistent with the requirements of ISO 9001.

**2. DEPARTMENTS AFFECTED**

All Departments

**3. SCOPE**

This procedure covers the control of all Quality related documentation and Data, including software used by Triconex Corporation in the development, manufacturing and service of the product.

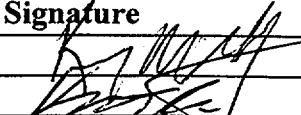
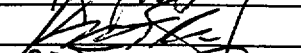

**4. PROCEDURE**

**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 releases will require review and approval by the same functions who 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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### 4.2.1. ENGINEERING

Engineering Departmental Manual (EDM)  
Drawings  
Product Specifications  
Test Specifications/Procedures  
Engineering Change Requests  
Engineering Orders  
Approved Manufactures 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. PRODUCT ASSURANCE

Quality Assurance Manual (QAM)  
Quality Procedure Manual (QPM)  
Triconex General Manual (TGM)  
Validation Test Procedures  
ISO Quality Standards  
Internal Audit Checklists

### 4.2.4. CUSTOMER SATISFACTION

Technical Advisory Bulletins  
Product Alert Notices  
Application Notes  
Product Release Notices

### 4.2.5. SALES AND MARKETING

Sales and Marketing Procedures  
Price List  
Contracts  
Proposals

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### 4.2.6 SYSTEMS INTEGRATION

- Drawings
- Application Software
- Test Procedures
- Integration Parts List

### 4.3. FORMS

Forms which 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 in provide 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. REFERENCES AND RELATED DOCUMENTS

- EDM : Engineering Departmental Manual
- MDM : Manufacturing Department Manual
- QPM : Quality Procedure Manual
- TGM : Triconex General Manual

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**QUALITY ASSURANCE MANUAL**

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## QUALITY ASSURANCE MANUAL

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		<b>Date:</b>	04/23/99		

### 1. PURPOSE

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

### 2. DEPARTMENTS AFFECTED

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

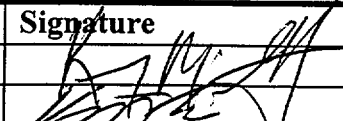
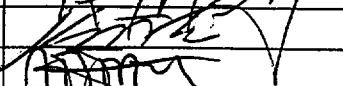

#### 4.1. GENERAL

The documentation being controlled at Triconex Corporation actually falls into two (2) 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 Order (EO) 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>



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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 Initialized by the issuer(s). The area supervisor is responsible for the accuracy of the information provided.

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 2.2	Quality System Procedure
QAM 5.1	Document and Data Control
EDM 21.00	Engineering Order Control
EDM 21.10	Engineering Change Request
EDM 21.20	Engineering Order
EDM 22.10	Automatic Distribution List

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 1. PURPOSE

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

### 2. DEPARTMENTS AFFECTED

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

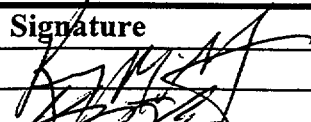
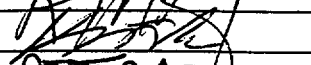

In general, the changes to documents will be reviewed and approved by the same functions that performed the original approval of the documents. A document Revision History on Engineering Documents changes will be maintained. A Master List will be available to identify the current revision of the documents. 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) per EDM 21.10 which again must be approved by the Change Control Board (CCB). The changes are then released on an Engineering Order (EO). 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
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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### 4.1.3. URGENT CHANGES

Compliance with approved, controlled documents is required. Working to marked up documents is generally forbidden (certain exceptions are defined in Systems Integration procedure TGM D-5). 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 approved by the VP Engineering and the Director, Product Assurance 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 Director, Product Assurance 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.

## 5. REFERENCES AND RELATED DOCUMENTS

- EDM 21.10: Engineering Change Control
- QAM 5.2 Document Approval and Issue

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<b>Section:</b>	QAM 6.0	<b>Subject:</b>	Purchasing		
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		<b>Date:</b>	04/23/99		

## 1. PURPOSE

This procedure describes the Purchasing functions, and it ensures that purchased product conforms to specified requirements.

## 2. DEPARTMENTS AFFECTED

- Manufacturing
- Product Assurance
- Engineering
- Finance
- Purchasing

## 3. SCOPE

This procedure describes the purchasing activities within the Triconex Corporation. Purchasing activities consist of vendor ranking, vendor selection, purchasing data requirements and documentation, and the verification of purchased products. The purchasing activities may be initiated by either:

- a) Signed Manual Purchase Requisition
- b) System Generated Purchase Requisition, or
- c) Buy Card

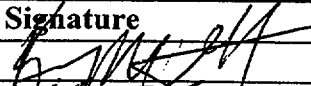


## 4. PROCEDURE

### 4.1 GENERAL

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

### 4.2 VENDOR RANKING

All vendors will be "ranked" (categorized) by the types of products or services they provide. The rank classifications are as follows and are assigned by Purchasing within the vendor record contained in the Approved Vendor List (AVL).

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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RANK	DEFINITION
#1	Any vendor who fabricates, manufactures, assembles, and/or services to Triconex engineering specifications.
#2	Any vendor who supplies Triconex or its subcontractors Triconex engineering specified purchased parts, purchased products, or purchased services.
#3	Any vendor 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.
#4	Disapproved vendor.
(suffix N)	Any vendor with an approved <u>nuclear</u> -grade quality program who supplies equipment or services to Triconex for a nuclear power plant application. <u>Nuclear</u> vendors will be either 1N or 2N.

### 4.3 VENDOR SELECTION

Triconex Corporation 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, Product Assurance, or Engineering Organization with a request to the Purchasing Department, for a short list of prospective vendors for a product or service. The Purchasing Department will prepare a list of new prospective vendors.

#### 4.3.1 VENDOR QUESTIONNAIRE

For vendors with a rankings of 1 or 2, a Vendor Questionnaire (VQ) will be completed by (or for) the prospective vendor and maintained by Purchasing. The Vendor Assessment Team (VAT), consisting of one or more representative of the departments affected, will recommend a prospective vendor based on the results of returned VQ and/or additional in-depth audits.

Vendor acceptability will be based on evaluation of the results generated during the site survey, interviews conducted during the vendor selection process, and the VAT evaluation of the vendor's ability to meet requirements of the Triconex Corporation, including the Triconex quality assurance system.

#### 4.3.2 VENDOR SURVEY

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

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### 4.3.3 VENDOR APPROVAL

Selection of new vendors ranked 1 or 2 will be a joint decision of organizations involved with final approval of the QARB. Purchasing can approve vendors ranked 3. Per definition, vendors ranked 4 in the AVL are disapproved vendors. The process of vendor 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 vendors are established in MDM 6.2.

### 4.3.4 APPROVED VENDOR LIST (AVL)

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

All vendors are ranked and the approved list maintained by Purchasing as the AVL. The AVL listings are reviewed by the QARB on annual basis (along with the proposed Vendor Audit Schedule) and/or reviewed as required on individual vendors. This review is to confirm appropriateness of the AVL listing and identify actions such as additional vendor audits or AVL status changes. Recommendations for rank change of a vendor will only be approved by the Quality Assurance Review Board (QARB) prior to AVL change.

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

### 4.3.5 VENDOR AUDITS

Product Assurance will perform vendor quality assurance audits on an as-required basis as reflected in the Vendor 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. Vendor audits are performed in accordance with QPM 17.1.

### 4.3.6 NUCLEAR VENDORS

For vendors who provide nuclear safety-related (S/R) equipment or services (rank 1N/2N), evaluations will address the vendor's ability to meet the quality assurance requirements of 10 CFR Part 50, Appendix B. An audit/survey of the vendor's facility is required as part of the evaluation process.

NOTE: Nuclear S/R items are those items procured for a nuclear power plant application but which are not being specifically dedicated by Triconex under TGM D-4, i.e., the responsibility for meeting the nuclear quality assurance regulations is delegated to the supplier in the purchase order.

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### 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 for the Triconex Corporation. New components and their manufacturers will be selected and approved as per EDM 62.00 and EDM 63.00.

#### 4.4.2 SYSTEM INTEGRATION PARTS

Materials for system integration projects are selected and controlled in accordance with TGM D-4. Integration parts are listed on the Integration Parts List. Approved materials, manufacturers, and any special acceptance requirements are listed on the Integration Parts Specifications (IPS) for the item. The IPS will contain requirements for "dedication" of system integration materials for use in nuclear power plant applications.

### 4.5 PURCHASING DATA

Purchasing data will describe the product ordered, including the type, class, grade, Triconex part number or other identification, where applicable. Specifications (including IPS), drawings, process requirements, inspection instructions, requirements for approval or qualification of product 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 S/R equipment and services will include (1) the requirement for a vendor quality program meeting the criteria of 10 CFR Part 50, Appendix B, (2) the requirement for vendor compliance with 10 CFR Part 21, and (3) the requirement for identifying the Purchase Order as "Nuclear Safety-Related." Requisitions for nuclear-related procurements shall be reviewed by Quality Assurance prior to issuance of PO.

#### 4.5.1 DOCUMENTATION PACKAGE

Manufacturing will provide the vendor 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 Orders.

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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 vendors on the AVL 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.

## 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>	<u>Responsible Department</u>
a) Vendor Approval Documentation	Manufacturing
b) Vendor Audit reports	Product Assurance
c) Approved Vendor List (AVL)	Manufacturing/Purchasing
d) Approved Manufacturer List (AML)	Engineering
e) First Article Inspection Reports	Product Assurance
f) Source Inspection Reports	Product Assurance
g) Purchase Orders	Purchasing
h) Integration Parts List/Specifications	Systems Integration

## 4.6 VERIFICATION OF PURCHASED PRODUCTS

Whenever a vendor is ordered to manufacture a part for the first time or when the vendor 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 vendor. The quality assurance inspector can decide to perform a source inspection per QAM 10.0 in case it is not possible or reasonable to fully inspect items upon receipt.

Integration parts for nuclear orders require verification of the acceptance method specified on the IPS. This will normally be done as part of receiving inspection, but may also involve source inspection or additional vendor qualification activities.

## 4.7 VENDOR DISQUALIFICATION

A vendor may be disqualified and their rank changed to 4 in the AVL following a review and disqualification order by the QARB for the following quality assurance reasons:

- a) The vendor failed to implement requested corrective action in a timely manner.
- b) Unacceptable defects in received product or unacceptable workmanship standards.



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- 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 vendor parts.
- d) Missing the delivery schedule frequently.
- e) Other requirements deemed necessary for quality assurance of the final product as per the QARB review.

Audited vendors that are not selected or existing vendors changed to rank 4, will be notified by Purchasing.

### 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 VENDOR ANALYSIS SYSTEM

Product Assurance will maintain a Vendor Analysis System. The system will be used to monitor the performance of AVL dependent upon the type of product, the impact of vendor product on the quality of final product and/or quality assurance records of the previously demonstrated capability and performance of vendors.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 5.1	Document and Data Control.
QAM 10.0	Inspection and Testing
QAM 16.0	Quality Records
MDM 6.2	Vendor Selection
EDM 62.00	Component Specifications, New Parts
EDM 63.00	Component and Manufacturers Selection
QPM 6.1	Source Evaluation and Vendor Selection
TGM D-4	System Integration Material Control

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 7.0	<b>Subject:</b>	Control of Customer Supplied Product			
<b>Revision:</b>	007	<b>Page:</b>	1	of	2	<b>Date:</b> 04/23/99

### 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  
Customer Satisfaction  
Product Assurance

### 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

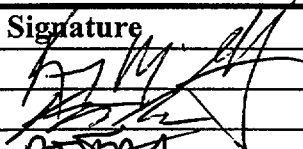


In general, customer supplied product shall be handled identical to the way Triconex purchased product is handled.

#### 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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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 Corporation 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

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

<b>Section:</b>	QAM 8.0	<b>Subject:</b>	Product, Parts, and Material Identification and Traceability		
<b>Revision:</b>	009	<b>Page:</b>	1	of	4
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**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

- Manufacturing
- Engineering
- Systems Integration
- Customer Satisfaction
- Product Assurance

**3. 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.

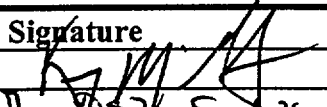
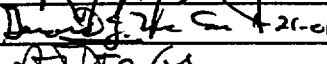

**4. PROCEDURE**

**4.1. GENERAL**

The material identification system used during production is based on five 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 parts and materials used for integrated systems.
- e) A serialization control system for parts and materials used for integrated systems where traceability is required.

These five subsystems together form the model number configuration control system which is used to control the final products compatibility and interchangeability (EDM 20.00) and identification and traceability of parts and material used in system integration.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 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 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 System Integration Part Numbers

The system integration part numbering system shall be used as defined in TGM D-4. The Systems Integration Department shall maintain an Integration Parts List (IPL) which identifies the parts and/or materials used during fabrication and assembly of integrated systems.

### 4.1.3 Hardware Serialization

Manufacturing shall, upon receiving, serialize all parts designated by part number 74xxxxx-xxx and the system integration parts which require traceability as determined by the Integration Parts List (IPL) per TGM D-4. Serialization of parts and material shall be performed in accordance with MDM 8.0.

### 4.1.4 Software / Firmware Identification

The firmware can be identified by the 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 Triconex Product Release Notice (PRN).

### 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.

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### 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. The production order tag shall be attached to the product and shall remain with the product until it passes the final inspection and shipped to the customer. 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). The production order tags shall be filed by part number and serial number. The Product Assurance department shall maintain these records in accordance with QAM 16.0. RMA tags (QPM 19.1) are maintained by the Customer Service group.

### 4.1.7 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.

### 4.1.8 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 Customer Satisfaction shall maintain full records of product and systems shipped to customers including part number, quantity, serial number, version and revision level listings, and inspection/test results. These records shall be regarded as Quality Records as per QAM 16.0.

### 4.1.9 Product and System Traceability Documentation

Upon shipping, Manufacturing will complete a system folder for each system. 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) System Check List Pre-Ship
- d) System Check List Product shipment
- e) System configuration discrepancy tracking sheet
- f) System check list pre-test
- g) System test compliance sheet
- h) Loose Item Packing List

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*Note: Older files compiled before 1993, may not contain all above mentioned documents.*  
The Customer Satisfaction 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 kept by the Customer Satisfaction department. They 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 16.0	Quality Records
MDM 8.0	Product, Parts, and Material Serialization
EDM 20.00	Configuration Management
EDM 23.00	Document Numbering System
TGM D-4	System Integration Material Control

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## QUALITY ASSURANCE MANUAL

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**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

- Manufacturing
- Customer Satisfaction
- Product Assurance

**3. SCOPE**

This procedure is applicable to all processes used by Triconex Corporation that affect the quality of products or services offered. Triconex Corporation 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) Monitor, control and approve necessary processes and process parameters.
- e) Establish and communicate criteria for workmanship.
- f) Maintain equipment to ensure continuing process capability.



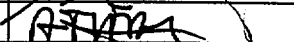
**4. PROCEDURE**

**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 and maintain a flow diagram 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>



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### 4.3. WORKMANSHIP STANDARDS

The Triconex Products has adopted the following Workmanship Standards:

- IPC-A-610 Acceptability of Printed Board Assembly
- IPC-R-700 Suggested Guidelines for Modification, Rework and repair of Printed Boards and Assemblies.
- IPC-A-600 Acceptability of Printed Boards

Martin Marietta and Honeywell Workmanship Guidelines are utilized as reference for clarity on an as needed basis. 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 Triconex Customer Service/Repair centers 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).

### 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 Procedure.

### 4.6. EQUIPMENT

Equipment used in processes shall be calibrated or adjusted with calibrated equipment, if necessary. The pre-set limits on each equipment must be maintained during the process. These limits and 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.

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

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## 4.8. SPECIAL PROCESSES

In the event that the result of a process cannot be fully verified by subsequent inspection or testing this process shall be recorded and monitored continuously to ensure compliance with documented requirements. Personnel involved in these processes shall be certified.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 2.2	Quality System Procedure
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 18.0	Training and Certification of Personnel

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

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**1. PURPOSE**

This procedure describes the requirements for independent inspection and testing activities in order to verify the specified requirements for products 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. DEPARTMENTS AFFECTED**

- Manufacturing
- Product Assurance
- Customer Satisfaction
- Engineering
- Systems Integration

**3. SCOPE**

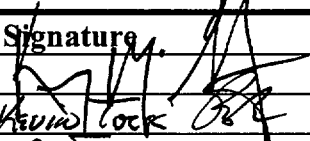
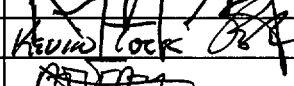
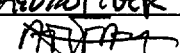
This procedure shall apply to all inspections and testing performed by Triconex. This includes the inspection and testing of customer returns per QAM 19.0 and customer supplied products/materials per QAM 7.0. This procedure does not apply to design verification activities or Quality Assurance Product Validation activities. These activities are described in QAM 4.0.

**4. 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 process. 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>

# TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 4.2 TEST CONTROL

#### 4.2.1 FUNCTIONAL TESTING

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

#### 4.2.2 SYSTEM PRE-TEST

The System Pre-Test will be performed by the Manufacturing organization. The System Pre-Test shall be carried out to ensure that all systems modules are correctly configured in the system and that the documentation matches the system. The System Check List Pre-Test shall be followed as a procedure. The system will not be submitted for System Pre-test Inspection until all items on the check list have been followed and have been stamped off by manufacturing technicians.

#### 4.2.3 SYSTEM ACCEPTANCE TEST

The System Acceptance Test shall be performed in accordance with the relevant System Test procedure as issued and controlled by the Manufacturing Engineering organization. The test will be performed by the Manufacturing Organization. The test results shall be recorded on the System Test Compliance sheet. System alteration, failures, and discrepancies shall be recorded on the System Hardware Layout Discrepancy Tracking Sheet. The system shall not be made available for the next stage of the process unless it passed all applicable tests. The System Acceptance Test can be repeated if the customer wishes to witness the 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 TEST PROCEDURES

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

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Specific content and format of test procedures may vary as appropriate to the activity. In general, test procedures should include the following recommended attributes:

- 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 or attached data sheets).
- 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) Required test software, if used
- l) Provision for handling deficiencies or deviations
- m) Provision for review/approval of test results.

Unless otherwise defined in organizational procedures (such as for Systems Integration projects), test procedures and associated software will be approved by cognizant personnel and issued through the Change Control Board (CCB) in accordance with EDM 21.00 and EDM 21.10. Changes to test procedures/test software will be handled in the same manner as the original issue.

### 4.2.7 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 records of changes) 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 shall be validated to the degree necessary to assure that the test is being conducted in accordance with the test procedures and specifications. Software validation shall be documented in a validation memo/report which includes, as a minimum, the purpose of the software, input requirements/references, description of validation method, results, and signature of person performing the validation. Test software and associated validation

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documentation are considered to be Quality Records to be handled in accordance with QAM 16.0.

Software developed as an testing aid (e.g., debugging, trouble-shooting), but which is not relied upon for quality verification is not subject to the above.

### 4.3 INSPECTION

#### 4.3.1 SOURCE INSPECTION

Source Inspection will be performed by Quality Assurance inspectors. 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 fully possible or reasonable to fully inspect items upon receipt.
- b) If a first article inspection is required as per QAM 6.0
- c) The Manager, Quality Assurance or Director, Product Assurance may 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) Inspection (all PCBA's)
- b) Sample Inspection
- c) Ship to stock (proven records of zero defects). This method is not allowed for parts described in paragraph (a) above.

The receiving inspection shall be performed as outlined in QPM 10.2. Material that is accepted shall be either moved to the raw stock area or directly to the manufacturing area. Discrepancies found during Receiving Inspection shall be recorded on the Production Order Tag and shall be submitted for material review.

#### 4.3.3 IN-PROCESS INSPECTION

In-Process inspections will be performed by Quality Assurance Inspectors. The In-Process inspection shall be carried out in order to verify that rework, upgrade and repair activities are carried out in accordance with specified requirements. The In-Process inspection shall be performed on all Printed Circuit Board Assemblies (74xxxxx-xxx part numbers) that have passed the function test. Rejected Printed Circuit Board Assemblies shall be recorded and returned to the rework station. Accepted Printed Circuit Board Assemblies shall be moved to the mechanical assembly station. The In-Process inspection shall be carried out as outlined in QPM 10.3.

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### 4.3.4 SYSTEM PRE-TEST INSPECTION

Pre test system inspections will be performed by Quality Assurance Inspectors. The System Pre-Test Inspection is an In-Process Inspection on System level. The inspection shall be carried out after the system configuration is completed. When the system passes the System Pre-Test Inspection, the system will be made available for System Acceptance Test. In case the systems fails the System Pre-Test Inspection, manufacturing personnel shall correct all discrepancies found prior to re-submitting the system for System Pre-Test Inspection. The System Pre Test Inspection shall be carried out in accordance with QPM 10.4.

### 4.3.5 SYSTEM PRE-SHIP INSPECTION

The System Pre-Ship inspection shall be performed by a Quality Assurance inspector. The 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

During the Pre-Ship inspection, the Production Order tags of the individual boards are collected and the Final Inspection box is stamped off or initialed by the Quality Assurance inspector. The Pre-Ship inspection shall be carried out after the system has passed the System Acceptance Test in accordance with QPM 10.5.

### 4.3.6 INSPECTION OF SYSTEM INTEGRATION PROJECTS

In-Process, Pre-Test, and Pre-Ship inspections are performed by QA on system integration projects, in a fashion similar to the applicable paragraphs described above. The System Integration process is defined in TGM D-1.

### 4.3.7 INSPECTION OF CUSTOMER RETURNED PRODUCT

Customer returned product is inspected upon receiving as per QPM 10.2. The Customer Service group shall arrange for the repair or upgrade 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. The Quality Assurance inspector shall note on the inspection reports that inspection was a customer return.

### 4.3.8 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.



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## 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 results, the acceptability, and the action taken in accordance with any deficiencies noted.

## 5. 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 10.2	Receiving Inspection
QPM 10.3	In Process Inspection
QPM 10.4	Pre Test 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
TGM D-1	System Integration Process
EDM 21.00	Engineering Order Control
EDM 21.10	Engineering Change Request (ECR)

# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 1. PURPOSE

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

### 2. DEPARTMENTS AFFECTED

Manufacturing  
Engineering  
Product Assurance

### 3. SCOPE

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

### 4. PROCEDURE

#### 4.1 SELECTION OF EQUIPMENT

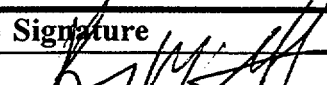
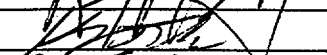

All purchase requisitions for standards and for measuring and test equipment shall be processed according to the instructions described in QAM 6.0. Purchasing with the following additions:

- 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.
- 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.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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- 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 Product 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 Product Assurance department shall maintain a master file of all equipment that requires calibration.

Upon receipt of new equipment, the receiver shall verify and inspect the equipment to determine that specifications and purchase requirements have been met and shall supply Product Assurance with make, model, and serial number. If the new equipment requires calibration, it shall be routed to the Product Assurance organization for addition to the calibration equipment list. A new TCNX number shall be assigned and attached to the equipment and a new folder created for the equipment with TCNX number on the folder. A Calibration Sticker shall be attached indicating that the equipment is new and the due date for the next calibration cycle. For new equipment, an initial calibration certificate from the manufacturer shall be considered valid until the next scheduled Triconex calibration cycle.

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.

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### 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 vendor or Triconex Product 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 Product 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.

### 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

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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.

### 4.8 OUT OF CALIBRATION

Where equipment is found to be "out of calibration" the Manager, Quality Assurance or designee shall assess the validity of previous inspections and / or test results. The Manager, Quality Assurance shall inform the Director, Product Assurance if it is determined that previous inspection or test results could have been affected by the use of the equipment that was possibly "out of calibration." The Director, Product Assurance shall decide if a recall of affected product and / or Customer notification is required. The assessments shall be documented. Records of these 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.
- b) A 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.

### 4.10 CALIBRATION RECORDS

The calibration records shall be maintained by the Product 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)

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- b) Calibration Certificates or detailed calibration results and, a maintenance schedule (if applicable),
  - c) Maintenance or repair history (if any).
- The calibration records shall be regarded as Quality Records as per 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.)

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 6.0	Purchasing
QAM 10.0	Inspection and Testing
QAM 13.1	Control of Non-Conforming Product
QAM 16.0	Quality Records
MDM 11.3	Manufacturing Board Test Fixture Verification/Testing

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### 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. DEPARTMENTS AFFECTED

Manufacturing  
Systems Integration  
Customer Satisfaction  
Product Assurance

### 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, product which has been shipped to Triconex for repair or upgrade, and integrated systems. 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.

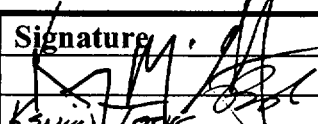
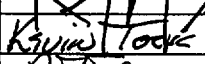
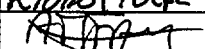
### 4. PROCEDURE

#### 4.1 GENERAL

When serialized product is processed through receiving, a Production Order Tag is attached 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 Configuration Discrepancy Tracking Checklists 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 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 off ( or initialed) at pre-defined process stages. Each person authorized to "Stamp Off" a process shall be assigned a unique personal stamp. The issuing and use of the stamp shall be in

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>



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accordance with the Quality Procedure QPM 12.1. The stamp (or initials) shall identify the person.

### 4.3 INSPECTION STATUS TAGS

#### 4.3.1 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 also be attached to the part:

- 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

Personnel in Receiving will "Stamp Off" the appropriate box on the tag, open a Batch Inspection Report and process parts to Receiving Inspection. Following acceptance of the item by Receiving Inspection, the results are entered in the computer data base and the Inspector will "Stamp Off" the appropriate box on the tag.

The parts that do not require serialization shall be processed through Receiving and Receiving Inspection using the Batch Inspection 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.

#### 4.3.2 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 Request (MRR), and the assembly will be segregated and processed by the Material Review Board (MRB) per QAM 13.2.

#### 4.3.3 CUSTOMER SERVICE

All return items will be issued to the Customer Service 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 is determined to be not repairable, it will be

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identified with a "RED TAG" and the assembly will be segregated and processed by the MRB (QAM 13.2).

#### 4.4 LOGS/CHECKLISTS

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.

##### 4.4.1 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.

##### 4.4.2 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 and the manufacture's code, the daily rework activity.

##### 4.4.3 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.

##### 4.4.4 PRE-TEST SYSTEM CHECKLIST

A system level inspection is performed on every system prior to System Test. The "System Check List : Pre Test" is used to document the inspection status of the system prior to System Test.

##### 4.4.5 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 Test by the Quality Inspector. Any changes made on the System Configuration Sheet are recorded on the System Configuration Discrepancy Tracking Sheet.

# TRICONEX CORPORATION

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#### 4.4.6 SYSTEM CONFIGURATION DISCREPANCY TRACKING SHEET

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

#### 4.4.7 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.

#### 4.4.8 PRE-SHIP CHECKLIST

A Pre-Ship inspection is performed on each system prior to delivery of the completed system. The "System Check List: Pre-Ship" identifies the inspection status of the system prior to packaging for delivery.

#### 4.4.9 SYSTEM INTEGRATION CHECKLIST

When the system is issued to the manufacturing floor for the assembly into cabinets and integration, a System Integration Checklist is issued. This traveler identifies both the manufacturing and inspection operations required to be performed to complete the integration process. This identifies by operation what has been completed. The Sales Order number is used as the designator to tie the System Integration Checklist to the correct hardware on the floor.

### 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 19.1:	Return Material Authorization System
TGM D-1	System Integration Process
TGM D-6	System Integration Testing

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

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**1. PURPOSE**

This procedure describes the system used by Triconex Corporation to ensure that product which does not conform to specified requirements is prevented from inadvertent use or installation.

**2. DEPARTMENTS AFFECTED**

- Manufacturing
- Product Assurance
- Engineering
- Finance
- Customer Satisfaction
- Systems Integration

**3. SCOPE**

This procedure applies to all manufacturing, production, and integration areas of the Triconex Irvine facility. This procedure covers the identification, documentation, evaluation, segregation, and disposition of non-conforming material and product. 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**

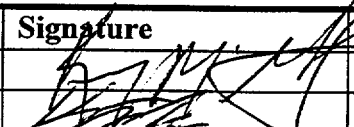
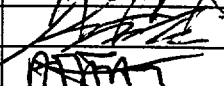

**4.1. GENERAL**

**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. 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).

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION

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### 4.1.3. PRODUCT FAILURE DURING SYSTEM INTEGRATION PROCESS

Failures in Triconex Products which have been inspected, tested, and transferred to the Systems Integration area are documented on the System Integration Discrepancy Report.

If rework can be done in accordance with MDM 9.6, the rework activities will be recorded on the W.O. Tag. Items which cannot be routinely reworked shall be dispositioned on an MRR in accordance with this procedure.

### 4.1.4. PRODUCT NOT MEETING CUSTOMER REQUIREMENTS

Product or integrated 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 QC 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

### 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 Work Order Tag and are not in the process of being shipped, or that do not have a serial number.
- 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.
- 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 Manager, Quality Assurance.

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### 4.2.2. DOCUMENTATION

Nonconforming items, with exception for those that can be reworked in-house, shall be documented on a Material Review Request (MRR) form.

### 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(s) 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 the Work Order Tag (if applicable) and Quality Assurance Inspector shall not stamp off the work 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 Service 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. 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 Corporation without a written waiver from the customer.

## 4.3. RECORDS

Material Review Request files and 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
MDM 9.6	Board Level Test and Rework
MDM 13.2	Review and Disposition of Non-Conforming Product
TGM C-7	Beta Program

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## QUALITY ASSURANCE MANUAL

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**1. PURPOSE**

This procedure describes the responsibility to review and authority for disposition of non-conforming product within Triconex Corporation.

**2. DEPARTMENTS AFFECTED**

- Manufacturing
- Product Assurance
- Customer Satisfaction
- Engineering
- Finance

**3. SCOPE**

The Non-Conforming product 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.

**4. PROCEDURE**

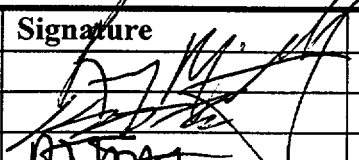
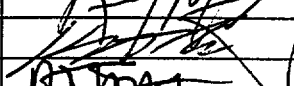
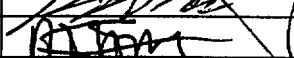
**4.1. GENERAL**

Non-Conforming Product Review and disposition is attained by the Material Review Board (MRB) as described below.

**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

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance



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## QUALITY ASSURANCE MANUAL

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Return to Vendor and Rework disposition can be made by the Manufacturing Representative and do not require a Material Review Request form to be completed. For Repair, Use As Is and Scrap dispositions the MRB shall complete the Material Review Request (MRR) form, organize and monitor the disposition of the material.

#### 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.

#### 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 Director, Product Assurance can decide to recall these products from the field. The Vice President, Customer Satisfaction (VP CS) 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 VP CS shall notify the customer and 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 VP CS shall maintain separate records of recalled product. 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 Director, Product Assurance shall also determine if the nonconforming product is reportable for 10CFR Part 21 requirements. See QAM 13.3.

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## 4.7. RECORDS

The Material Review Board (MRB) shall maintain records of all Material Review Request forms. The MRR is stamped with an "MRB Action Closed" stamp when all actions have been completed and placed in MRR files. 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 16.0	Quality Records
QAM 19.0	Servicing
MDM 13.2	Review and Disposition of Non-conforming Product

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## QUALITY ASSURANCE MANUAL

<b>Section:</b>	QAM 13.3	<b>Subject:</b>	10CFR Part 21 Reporting 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. DEPARTMENTS AFFECTED

Product Assurance  
Customer Satisfaction

### 3. SCOPE

This procedure applies to TRICONEX products developed for and supplied to nuclear customers.

### 4. PROCEDURE

#### 4.1 RESPONSIBILITY

The Vice President, Development is responsible for reviewing nonconformance data, evaluating the data, and reporting to the NRC any identified defect and/or deviation which could affect the safety function of TRICONEX equipment used in a nuclear facility. The Director, Product Assurance will forward information regarding potentially reportable defects to the VP Development for final determination of reportability.

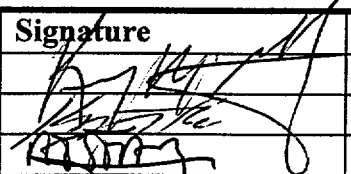


#### 4.2 DEFINITIONS (As used in 10CFR Part 21)

##### **Defect**

A deviation in a basic component delivered to a customer for use in a nuclear facility or activity; the installation, use, or operation of a basic component containing a defect; or a condition or circumstance involving a basic component that could affect nuclear safety.

##### **Deviation**

A departure from the technical requirements included in a procurement document which was used to purchase the basic component.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>

# TRICONEX CORPORATION

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### Basic Component (Nuclear)

A structure, system, or component or part thereof that affects the safety functions necessary to assure integrity of the reactor system, the capability to shut down the reactor, or mitigate the consequences of an accident. This includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services associated with the component hardware whether these services are performed by the component supplier or others.

### Commercial Grade Item

A structure, system, or component that affects the safety function of a nuclear power plant, but was not designed and manufactured as a basic component.

### Dedication

Dedication of a commercial grade item occurs after receipt, when that item is designated for use as a basic component.

## 4.3 DATA SCREENING AND EVALUATION

The Quality Assurance Review Board (QARB) reviews deficiencies and/or deviations reported on Action Request Reports (ARR), Quality Discrepancy Reports (QDR), and Product Discrepancy Reports (PDR). During 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 defect or noncompliance safety related? If answer is yes, continue to next question.
- 2) Was the item supplied to a nuclear facility? If yes, continue to next question.
- 3) Is this condition outside the bounds of the FMEA analysis (i.e., unexpected failure mode, higher than normal failure rates, etc.) If yes, go to next question.
- 4) Will 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)? If yes, notify the NRC and initiate 10CFR Part 21 report.

Evaluate deviations and nonconformances 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.

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Ensure that the Vice President, Development is informed as soon as practical, and in all cases, within 5 working days after completion of the evaluation if the deviation or noncompliance:

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

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 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 VP, Development. 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 a defect or noncompliance, to the extent known.

#### 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 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.
- 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.

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- 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 Vice President Customer Satisfaction. See QPM 13.2.

### 4.8 RECORDS

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

- 1) Retain evaluations of all deviations and noncompliance for a minimum of 5 years after the date of the evaluation;
- 2) Retain 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.

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

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## 5. REFERENCES AND RELATED DOCUMENTS

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 13.2 Product Discrepancies

QPM 14.0 Quality Assurance Review Board

TGM D-4 System Integration Material Control



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# ■ TRICONEX CORPORATION

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### 1. 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 Corporation vendor supplied materials and processes as well as Triconex Corporation manufactured materials and processes.

### 2. DEPARTMENTS AFFECTED

Manufacturing  
 Product Assurance  
 Customer Satisfaction  
 Engineering

### 3. SCOPE

This procedure applies to all corrective or preventive action taken with the objective to eliminate actual or potential non-conformities. Any such action shall be to a degree appropriate to magnitude of the problems and encountered risk.

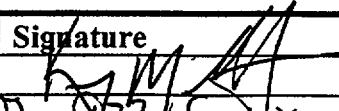
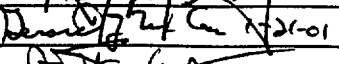
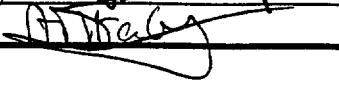
### 4. PROCEDURE

#### 4.1 GENERAL

All Corrective and Preventive Actions will be reported and controlled using one of the methods described in paragraph 4.4 of this procedure. The reports described in this paragraph shall be regarded as Quality Records as per QAM 16.0. A Corrective or Preventive Action shall not be closed until the effectiveness of the action taken has been reviewed. In general, the Quality Assurance Review Board (QARB) shall review the effectiveness of the corrective actions reported.

#### 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 records of it occurring. Typically Corrective Actions would be generated as a result of Customer Complaints or the identification or analysis of nonconforming material.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION

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### 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 Non-conforming material disposition.

### 4.4 IDENTIFICATION

The need for Corrective or Preventive action can be revealed by analysis of the following:

- Inspection records
- Test Results
- Material Review Requests
- Customer Complaints
- Field Failure Data

Furthermore, the need for Preventive or Corrective Action can be identified 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. The ARR targets corrective action for internal deficiencies that are not related to specific products or vendors. The ARR is used to report discrepancies observed during internal audits and third party audits conducted at the Triconex facility.

ARRs will be logged in by the Product Assurance department and effectiveness of the action taken will be reviewed by the QARB.

#### 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.

#### 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 Customer Satisfaction engineers or Product Assurance test engineers. However anyone may initiate a PDR.

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PDRs will be logged in by the Customer Satisfaction department 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 Assurance department's test engineers.

QDRs will be logged in by the Product Assurance department 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 person actioned 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 out.

### 5. REFERENCES AND RELATED DOCUMENTS

- QAM 16.0 Quality Records
- QPM 14.2 Corrective Action Document Processing

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# ■ TRICONEX CORPORATION

## QUALITY ASSURANCE MANUAL

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### 1. 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.

### 2. DEPARTMENTS AFFECTED

Manufacturing  
Product Assurance  
Customer Satisfaction

### 3. SCOPE

This procedure applies to the handling and packaging of all Triconex material throughout the manufacturing, 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. PROCEDURE

#### 4.1. GENERAL

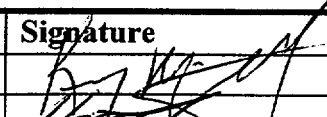
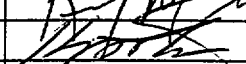

During all stages of the process, Triconex personnel shall follow all existing procedures on handling, storage and packaging in order to prevent deterioration or damage of material used, and to ensure the intended quality level for the final product.

#### 4.2. CUSTOMER SUPPLIED ITEMS AND MATERIALS

Customer supplied items and materials shall be inspected in accordance with QPM 10.2 and handled and stored in accordance with MDM 15.2 and MDM 15.2.3.

#### 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. Such material will be returned to the vendor without further inspection.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

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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.

#### 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.

### 4.5 PACKAGING

The method of packaging used to ship all Triconex product 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.

### 4.6 PRESERVATION

Triconex products and systems are appropriately packaged to prevent damage and deterioration. There are 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.

## 5. 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

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**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

All Departments

**3. 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.

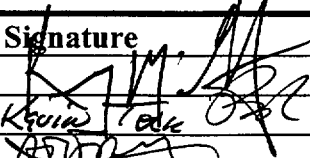
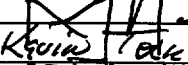
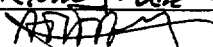
**4. PROCEDURE**

**4.1 RECORDS**

**4.1.1 GENERAL**

The Quality records shall be all those documents necessary to maintain the product quality 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. The Director, Product Assurance or his designate shall maintain a master list of all identified Quality Records. This list shall include, but is not limited to the following records:

- Management Review Minutes
- Contract Reviews
- Design Reviews
- Quality Plans
- Quality Improvement Plans
- Product Specifications
- Audit Reports
- Vendor Surveys
- Rework Logs
- Burn-In Data
- Calibration Records
- Material Review Requests
- Production Order Tags
- System Configuration Files
- Inspection Reports
- QA Stamp Control Log
- Corrective/Preventive Action Reports
- Inspection Logs

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance



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- Training Records and Procedures
- 10CFR 21 Reports to the NRC and Nuclear Customers
- Customer Contact Data
- Nonconformances

### 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 Files 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.

### 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
- Register the date the change was made

Correction fluid ("White Out") or correction tape should not be used for any Quality Record.

### 4.2 RETENTION TIME

All Quality records as described in ISO 9001, will be retained for a period of 10 (ten) years. 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 files and Product Design Documentation will not be destroyed. Other records (such as nuclear equipment qualification) may be designated "permanent" where required by contract or regulation. Applicable procedures will address special retention requirements or any exceptions to the above.

### 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 Product Assurance department.

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#### 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 Director, Product Assurance.

#### 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 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.

### 5. REFERENCES AND RELATED DOCUMENTS

- EDM 22.00 Engineering Document Control
- TGM D-2 System Integration Document and Data Control

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**1. PURPOSE**

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

**2. DEPARTMENTS AFFECTED**

All Departments

**3. SCOPE**

It is the policy of the Triconex Corporation 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 the current working practice is reflected in the company procedures, and to ensure that the current working practice is in accordance with the requirements of ISO 9001 and 10CFR50 Appendix B.

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

**4. PROCEDURE**

**4.1. GENERAL**

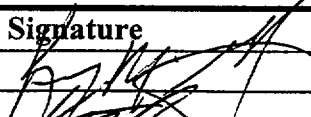
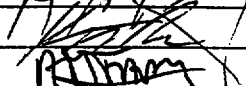
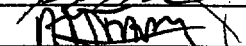
All areas of activity which impact the Triconex quality process shall be audited under the direction of the Director, Product Assurance. These audits will be conducted on a scheduled basis and will be documented in formal reports.

Trained auditors will be assigned to conduct the audits. Auditors will be certified in accordance with QAM 18.0 and will 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 App. B (nuclear), and the existing Triconex procedures. The Internal Audit Schedule is approved by the Director, Product Assurance and the Quality Assurance Review Board (QARB).

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		<b>President Triconex Corporation</b>
	Kevin Tock		<b>VP Development</b>
	Aad Faber		<b>Director, Product Assurance</b>

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### 4.3. VENDOR AUDITS

Product Assurance will perform vendor 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.

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

An annual Vendor Audit Schedule will be developed and approved by the Director, Product Assurance and the QARB.

### 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 to the Vice President of Development and to responsible management in the area audited, as a minimum.

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 Manager, Quality Assurance on deficiencies noted in internal audits. Corrective Action Reports (CARs) are written to document problems noted in vendor 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. A Surveillance Report 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. Surveillance Reports may be used to document QA verification of actions taken in response to a corrective action document. Surveillance Reports may support, but not take the place of, scheduled quality program audits.

A surveillance may be assigned at the discretion of the Director, Product Assurance, or his designee, 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 on the Surveillance Report.

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### 4.6. AUDIT PROGRAM REVIEW

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

## 5. 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

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

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**1. PURPOSE**

The purpose of this procedure is to describe the requirements for training and certification of Triconex personnel.

**2. DEPARTMENTS AFFECTED**

All Departments

**3. SCOPE**

This procedure applies to all personnel performing activities affecting the quality of the product. It describes the identification of positions or processes that require the assignment of certified personnel, the company policy on training, the identification of training needs, and the requirement for training records. It also includes the training that is provided to the customers for operation and maintenance of the TRICON Systems

**4. PROCEDURE**

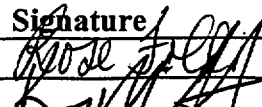
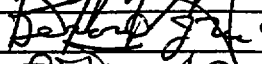
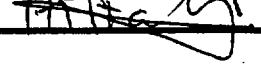

**4.1 COMPANY POLICY**

It is the policy of the Triconex Corporation to assign tasks to qualified personnel on the basis of appropriate education, training, and/or experience. The objective of this policy is to improve the quality of the product, services offered and the quality of the overall work performed. Furthermore, Triconex understands the importance of continuously training and educating all levels of personnel and the positive impact on the overall quality system that it provides. As such, Triconex will provide all reasonable resources to achieve this goal.

**4.2 QUALIFICATION REQUIREMENTS**

The Human Resources Department is responsible for managing the overall employee training program. Each Department supervisor is responsible for ensuring that their employees, both permanent and temporary, are appropriately trained and qualified to perform the functions described on the specific job descriptions.

The Human Resources Department documents each employee's job description and the qualifications for that position, including education and any special training needed (see TGM A-1). This document is signed by the responsible supervisor to certify that the employee is qualified to perform the duties described.

	Name	Signature	Title
<b>Author:</b>	Rose Folli		VP Human Resources
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Jerry McCann		VP Research & Development
	Aad Faber		Director, Product Assurance



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The basis for the qualification by the supervisor shall be (1) evidence of education, experience, and training in the employee's file and (2) knowledge of the person's capability through interview or other knowledge of work performance.

Qualification records shall be in place for all regular and temporary employees, with the exception of new employees in OJT or consultants working under the direct supervision of another qualified employee.

### 4.3 TRAINING REQUIREMENTS

Determining the training requirements for each employee shall be the responsibility of his/her respective supervisor. This is a continuous process to identify the training needs of the employees in order to improve productivity and the quality of the product. The minimum training requirements are established on the employee job description. The supervisor shall also review employee performance annually to identify further training requirements and to ensure that all appropriate training records are in the employee's training file. After the training needs have been identified they shall be given to the Human Resources Department who will organize and schedule the training. Safety training shall be conducted in accordance with TGM A-2.

As a minimum, a training attendance sheet shall be used to document all training. At the completion of any training, the training instructor or responsible supervisor shall forward all training records, such as attendance sheets, certificates, etc., to Human Resources for filing in the employee training file.

When appropriate, Triconex will issue a certificate at the successful completion of internal training. A certificate or other appropriate document will be used to record the successful completion of externally conducted training.

#### 4.3.1 ORIENTATION

Orientation training will be provided to all Triconex personnel. This training will include, but is not limited to, a review of the Triconex quality assurance program and management expectations for program implementation.

#### 4.3.2 QUALITY PROGRAM/PROCEDURE REVISIONS

Periodically, changes are made to the Quality Assurance Manual (QAM) and/or Department procedures. Each department Supervisor shall review the changes, as applicable, to determine the impact of the change on their activity. For any changes that affect the way the department performs their activities, the Supervisor shall provide training to the affected employees to ensure that the changes are understood and implemented. The training shall be documented.

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### 4.4 TRAINING RECORDS

Records of education, training and certifications will be maintained for all personnel who are assigned activities affecting the quality of the product. These records will contain, where possible, copies of diplomas, training certificates, descriptions of "on-the-job" training, and experience. Each Department supervisor shall be responsible for ensuring that all applicable training records are in the respective employee training files.

An electronic database may serve as an alternative method to store education, training, and certification records. These records will contain information pertaining to personnel qualifications.

### 4.5 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 filed and handled as Quality Records per QAM 16.0.

An electronic database may serve as an alternative method to store certification data. The database will contain all relevant information about the training received including a class description, source of the training, and the certification expiration date.

#### 4.5.1 AUDITOR CERTIFICATION

Personnel 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 audit personnel shall be certified based on evidence of formal training, previous auditor certification or experience, and/or other demonstrated skills. Auditor certification shall consist of a job description for Auditor/Lead Auditor signed by the Director, Product Assurance.

#### 4.5.2 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 annually. Inspector certification shall consist of a job description for Inspector signed by the Director, Product Assurance.

#### 4.5.3 PROCESSES REQUIRING CERTIFICATION

Personnel assigned tasks related to one or more of the following processes require training and certification:

- a) Handling of Electrostatic Discharge sensitive product
- b) Soldering

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### 4.6 QUALITY RECORDS

Training and certification records (including inspector eye exams) are regarded as Quality Records and will be handled in accordance with QAM 16.0. For audit purposes, these records shall be retained as follows:

- a) Permanent employee records will be retained during employment and for a minimum of two years after the date of termination.
- b) Temporary employee records will be retained during employment and for a minimum of one year after the date of termination.

### 5. REFERENCES AND RELATED DOCUMENTS

QAM 16.0	Quality Records
TGM A-1	Job Description
TGM A-2	Injury and Illness Prevention Program

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## QUALITY ASSURANCE MANUAL

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**1. PURPOSE**

This procedure describes the customer service operation in use by the Triconex Corporation.

**2. DEPARTMENTS AFFECTED**

Customer Satisfaction

**3. SCOPE**

This procedure describes the Triconex customer service operation which includes the customer Technical Support group and the Customer Service group within the Customer Satisfaction Department. This procedure does not address the details of the various service and warranty programs that Triconex Corporation offers to its customers. These programs are described in the System Log Book that is provided to the Customers.

**4. PROCEDURE**

**4.1. STRUCTURE**

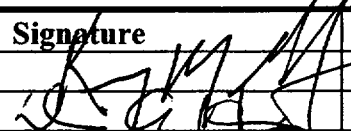
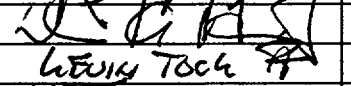
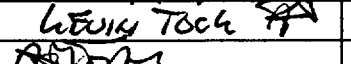

All Technical Support Engineers report directly to the Manager, Technical Support in Irvine, CA. Technical Support Engineers provide technical product support to the worldwide Triconex Service Centers and to individual customers.

**4.2. CUSTOMER TECHNICAL SUPPORT AVAILABILITY**

Triconex Corporation shall provide a 24 hours per day, 7 days per week telephone support for all its customers. This system is described in the System Log Book.

**4.3. SERVICE AND WARRANTY PROGRAMS**

The service provided by the technical support group is based on, although not limited to, the service, warranty and support programs described in the System Log Book. These programs include technical product support, system trouble shooting, diagnostic evaluations, Ship Ahead, On Site Support, Software/Firmware/Hardware Upgrades, Training and other services. Where appropriate and deemed necessary the Vice President (VP) Customer Satisfaction (CS) can deviate from these programs in order to satisfy the customer.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Dennis Harris		VP Customer Satisfaction
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance

# TRICONEX CORPORATION QUALITY ASSURANCE MANUAL

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## 4.4. TECHNICAL SUPPORT TASKS

The Triconex Corporation technical support engineers have, among other, the following tasks:

- a) To 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.
- 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 organize customer requests for Return Material Authorizations.
- e) To respond to all customer queries and complaints in a timely manner with the objective to satisfy the customers requirements (QAM 14.0).
- f) To document customer queries and complaints in the computer database system. A summary is provided to the VP CS in Irvine for review in the Quality Assurance Review Board. Customer complaints, as determined by the VP CS, will be handled from the Irvine office only.
- g) To maintain records of all customer queries and complaints. Records shall be organized by customer.
- h) To refer the customer to his direct supervisor or to VP CS in case there is an indication that the customer is not satisfied with the service offered.

## 4.5. CUSTOMER TRAINING

In addition, Triconex Corporation 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, Triconex offers their Customers extensive courses on the Operation and Maintenance of the Triconex Products.

## 4.6. AUTHORIZATION

The Customer Service group in Irvine is the only authorized location to perform repair work on any Triconex Corporation triple modular redundant (TMR) product. The Triconex Texas facility is authorized to repair turbomachinery products.

# TRICONEX CORPORATION

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### 4.7. 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.

### 4.8. SOFTWARE / FIRMWARE UPGRADES

Depending on the customer selected service program the customer service groups will perform upgrades of hardware, software and firmware. These upgrades will be made strictly in compliance with the applicable Product Release Notice. The Triconex Corporation customer service groups are 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).

### 4.9. PRODUCT TRACEABILITY

The Customer Service group in Irvine shall maintain a product traceability system which meets the following minimum requirements:

- a) Complete records of systems shipped to the customer as described in QAM 8.0
- b) Product traceability data by part number and serial number of all serialized product for the life cycle of the product with references to original customer and where possible end user.
- c) Complete documented Return Material Authorization (RMA) system with the ability to authorize, track and document customer returns.
- d) Documented procedures for the RMA and product traceability system including procedures for the transfer of data between Irvine customer service group and other Triconex Corporation organizations.

## 5. REFERENCES AND RELATED DOCUMENTS

QAM 4.0	Design control
QAM 8.0	Product Identification and Traceability
QAM 14.0	Corrective and Preventive Action

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

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**1. PURPOSE**

This procedure describes the guideline for the use of statistical techniques required for verifying the acceptability of process capabilities and product characteristics.

**2. DEPARTMENTS AFFECTED**

- Product 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 require the usage of statistical techniques:

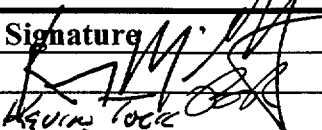
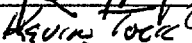

- Sample Inspection
- Reliability Calculations
- Product Test Sampling

**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 Corporation shall be based upon parts count methods described in MIL-HDBK-217 or on actual field return data.

	Name	Signature	Title
<b>Approvals:</b>	Kevin McGlensey		President Triconex Corporation
	Kevin Tock		VP Development
	Aad Faber		Director, Product Assurance



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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