IEC 61508 Functional Safety Assessment

Project:
377 Series Trip Valves

Customer:
Fisher Controls International, LLC
Marshalltown, IA
USA

Contract Number: Q11/08-109
Report No.: EPM 11/08-109 R002
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Jack Gao
Management summary

This report summarizes the results of the functional safety assessment according to IEC 61508 carried out on the 377 Series Trip Valves.

The functional safety assessment performed by exida consisted of the following activities:

- exida assessed the development process used by Fisher Controls International, LLC by an on-site audit and creation of a safety case against the requirements of IEC 61508.
- exida performed a detailed Failure Modes, Effects, and Diagnostic Analysis (FMEDA) of the devices to document the hardware architecture and failure behavior.
- exida reviewed field failure data to ensure that the FMEDA analysis was complete.
- exida reviewed the manufacturing quality system in use at Fisher Controls International, LLC.

The functional safety assessment was performed to the requirements of IEC 61508: ed2, 2010, SIL 3 for mechanical components. A full IEC 61508 Safety Case was prepared, using the exida SafetyCaseDB™ tool, and used as the primary audit tool. Hardware process requirements and all associated documentation were reviewed. Environmental test reports were reviewed. Also the user documentation (safety manual) was reviewed.

Some areas of improvement were identified in the design process and the design procedures were upgraded during the project. However because of the low complexity of the products and the proven in use design, Fisher Controls International, LLC was able to demonstrate that the objectives of the standard have been met.

The results of the Functional Safety Assessment can be summarized as:

The Fisher Controls International, LLC 377 Series Trip Valves were found to meet the requirements of IEC 61508 for up to SIL 3 (SIL 3 Capable). The PFD_{AVG} and architectural constraint requirements of the standard must be verified for each element of the safety function.

The manufacturer will be entitled to use the Functional Safety Logo.
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1 Purpose and Scope

This document shall describe the results of the IEC 61508 functional safety assessment of the Fisher Controls International, LLC:

- 377 Series Trip Valves

by exida according to the requirements of IEC 61508: ed2, 2010.

The results of this provides the safety instrumentation engineer with the required failure data as per IEC 61508 / IEC 61511 and confidence that sufficient attention has been given to systematic failures during the development process of the device.
2 Project management

2.1 exida

exida is one of the world’s leading accredited Certification Bodies and knowledge companies specializing in automation system safety and availability with over 300 years of cumulative experience in functional safety. Founded by several of the world’s top reliability and safety experts from assessment organizations and manufacturers, exida is a global company with offices around the world. exida offers training, coaching, project oriented system consulting services, safety lifecycle engineering tools, detailed product assurance, cyber-security and functional safety certification, and a collection of on-line safety and reliability resources. exida maintains a comprehensive failure rate and failure mode database on process equipment.

2.2 Roles of the parties involved

Fisher Controls International, LLC  Manufacturer of the 377 Series Trip Valves

exida  Performed the hardware assessment

exida  Performed the IEC 61508 Functional Safety Assessment according.

Fisher Controls International, LLC contracted exida in June 2012 for the IEC 61508 Functional Safety Assessment of the above mentioned devices.

2.3 Standards / Literature used

The services delivered by exida were performed based on the following standards / literature.


2.4 Reference documents

2.4.1 Documentation provided by Fisher Controls International, LLC

<p>| [D1] | 15B15.8; Issue 2 Rev D; 1/3/2009 | 15B15.8 Internal Audit - Internal Audit Procedure |
| [D2] | 15B84; Rev C; 24/8/2012 | 15B84 Auditor / Lead Auditor Qualification |
| [D5] | 4.05A; Rev 0; 25/8/1998 | 4.05A - Corporate Quality System Document Control |
| [D6] | 48a1042_g_1i_e; n/a; | 48a1042_g_1i_e - Finalised version of Example markup |</p>
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### 2.4.2 Documentation generated by *exida*

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<td>[R2] PIU; 1/7/2012</td>
<td>PIU - Proven In Use Analysis 377 Trip Valve</td>
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3 Product Descriptions

377 Series Trip Valves description: The 377 Series pressure-sensing trip valves are for control applications where a specific valve/actuator action is required when supply pressure falls below a specific point. When supply pressure falls below the trip point the trip valve causes the actuator to fail up (377U), lock in the last position (377L), or fail down (377D). When the supply pressure rises above the trip point, the 377 Series trip valve automatically resets, allowing the system to return to normal operation.

Figure 1 shows the 377U Configuration.

![Figure 1 377U Configuration](image_url)
Figure 2 shows the 377D Configuration.
Figure 3 shows the 377L Configuration.

Figure 3 377L Configuration

The safety function of the trip valve is to move the associated actuator to the safe position within the safety time.
4 IEC 61508 Functional Safety Assessment

The IEC 61508 Functional Safety Assessment was performed based on the information received from Fisher Controls International, LLC and is documented in this report.

4.1 Methodology

The full functional safety assessment includes an assessment of all fault avoidance and fault control measures during hardware development and demonstrates full compliance with IEC 61508 to the end-user. The assessment considers all requirements of IEC 61508. Any requirements that have been deemed not applicable have been marked as such in the full Safety Case report, e.g. software development requirements for a product with no software. The assessment also includes a review of existing manufacturing quality procedures to ensure compliance to the quality requirements of IEC 61508.

As part of the IEC 61508 functional safety assessment the following aspects have been reviewed:

- Development process, including:
  - Functional Safety Management, including training and competence recording, FSM planning, and configuration management
  - Specification process, techniques and documentation
  - Design process, techniques and documentation, including tools used
  - Validation activities, including development test procedures, test plans and reports, production test procedures and documentation
  - Verification activities and documentation
  - Modification process and documentation
  - Installation, operation, and maintenance requirements, including user documentation
  - Manufacturing Quality System

- Product design
  - Hardware architecture and failure behavior, documented in a FMEDA

The review of the development procedures is described in section 5. The review of the product design is described in section 5.3.

4.2 Assessment level

The 377 Series Trip Valves have been assessed per IEC 61508 to the following levels:

- SIL 3 capability

The development procedures have been assessed as suitable for use in applications with a maximum Safety Integrity Level of 3 (SIL3) according to IEC 61508.
4.3 Product Modifications

Fisher Controls International, LLC may make modifications to this product as needed. Modifications shall be classified into two types:

Type 1 Modification: Changes requiring re-certification, which includes the re-design of safety functions or safety integrity functions.

Type 2 Modification: Changes allowed to be made by Fisher Controls International, LLC provided that:

- A competent person from Fisher Controls International, LLC approves the modifications.
- The modification documentation listed below is submitted prior to a renewal of the certification to exida for review of the decisions made by the competent person in respect to the modifications made.
  - List of all anomalies reported
  - List of all modifications completed
  - Safety impact analysis which shall indicate with respect to the modification:
    - The initiating problem (e.g. results of root cause analysis)
    - The effect on the product / system
    - The elements/components that are subject to the modification
    - The extent of any re-testing
  - List of modified documentation
  - Regression test plans
5 Results of the IEC 61508 Functional Safety Assessment

exida assessed the development process used by Fisher Controls International, LLC for these products against the objectives of IEC 61508 parts 1 - 7. The assessment was done on-site at the Shenzhen facility on December 11-12, 2012 and documented in the SafetyCase [R4].

5.1 Open Issues

The overall process is strong and the designs have extensive proven field experience, sufficient for SIL 3 capability. Some areas of improvement were identified in the design process and some of the design procedures and forms were upgraded during the project. All of the improvements were evaluated and included in the final version of the SafetyCase.

5.2 Lifecycle Activities and Fault Avoidance Measures

Fisher Controls International, LLC has a defined product lifecycle process in place. This is documented in the Quality Management System Manual [D47] and various Quality Procedures. Products are typically ordered by a product code or model designation. A documented modification process is covered in the Design Change Procedure [D23]. No software is part of the design and therefore any requirements specific from IEC 61508 to software and software development do not apply.

The assessment investigated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for product design and development. The investigation was executed using subsets of the IEC 61508 requirements tailored to the SIL 3 work scope of the development team. The defined product lifecycle process was modified as a result of the audit which showed some areas for improvement. However, given the simple nature of the safety function and the extensive proven field experience for existing products Fisher Controls International, LLC was able to demonstrate that the objectives of the standard have been met. The result of the assessment can be summarized by the following observations:

The audited Fisher Controls International, LLC design and development process complies with the relevant managerial requirements of IEC 61508 SIL 3.

5.2.1 Functional Safety Management

The valves manufactured by Fisher Controls International, LLC are typically built per the model designation code. The basic designs are standardized, but each order can have materials variations.
FSM Planning

Fisher Controls International, LLC has a defined process in place for product design and development. Required activities are specified along with review and approval requirements. This is documented in detail in procedure ES 269, “Product Development Process for Safety Instrumented Systems”. In addition project management is defined by procedure EP 42, “Project Management Process Description”. EP 42 describes the project management responsibilities, which include the creation of a “Project Management Plan (PMP)”. The PMP is a roadmap for the project. The 377 Series Trip Valves were designed at least 30 years ago and therefore did not go through the same procedures that exist today at Fisher Controls International, LLC Therefore, templates and sample documents were not part of this review. The modification process is described in ES 192, “Engineering Change Request Procedure”. This process and the procedures referenced therein fulfill the requirements of IEC 61508 with respect to functional safety management for a product with simple complexity and well defined safety functionality.

Version Control

ES 269 requires that design documentation be maintained under version control. The PMP includes the configuration management plan. In addition procedure 4.05A, “Corporate Quality System Document Control” describes the revision control of the quality system documents.

Training, Competency recording

Section 6.2 of the Quality Manual addresses Resource Management. The Human Resource department maintains training records of education, experience, training and qualifications for all personnel. Department heads are responsible for identifying and providing the training needs for their department as well as proficiency evaluations. PeopleSoft is used to track performance reviews and training needs. The procedures and records were examined and found up-to-date and sufficient. Fisher Controls International, LLC hired exida Consulting to be the independent assessor per IEC 61508 and to provide specific IEC 61508 knowledge.

5.2.2 Safety Requirements Specification and Architecture Design

A Safety Requirements Specification was developed for the 377 Series Trip Valves, 377 SRS, Rev 0.1. The SRS defines the Functional Safety requirements as well as the Environmental Conditions. The primary functionality of the trip valve is for control applications where a specific valve/ actuator action required when supply pressure falls below a specific point. When supply pressure falls below the trip point, the trip valve cause the actuator to fail up, lock in the last position, or fail down. When the supply pressure rises above the trip point, the 377 trip valve automatically resets, allowing the system to return to normal operation. As the 377 Series Trip Valves’ designs is simple and is based upon standard designs with extensive field history, no semi-formal methods are needed. General Design and testing methodology is documented and required as part of the design process. This meets SIL 3.

5.2.3 Hardware Design

The design process is documented in ES 269, “Product Development Process for Safety Instrumented Systems”. Items from IEC 61508-2, Table B.2 include observance of guidelines and standards, project management, documentation (design outputs are documented per quality procedures), structured design, use of well-tried components / materials, and computer-aided design tools. This meets SIL 3.
5.2.4 Validation
Since the 377 Series Trip Valves were developed over 30 years ago, it was determined through the Proven in Use calculation that the 377 Series Trip Valves are suitable for use in SIL 3 applications. Since the Proven in Use calculation was used to validate the 377 Series Trip Valves, actual development validation documentation was not examined. A production Assembly and Test Plan, FGS 12G5, Rev D was reviewed. All 377 Series Trip Valves are subject to this test procedure before shipping. As the 377 Series Trip Valves is a purely mechanical device with a simple safety function, there is no separate integration testing necessary. The 377 Series Trip Valves perform only 1 Safety Function, which is extensively tested under various conditions during validation testing.

5.2.5 Verification
The development and verification activities are defined in ES 269, “Product Development Process for Safety Instrumented Systems”. For each design phase the objectives are stated, required input and output documents and review activities. This meets SIL 3.

5.2.6 Proven In Use
In addition to the Design Fault avoidance techniques listed above, a Proven in Use evaluation was carried out on the Fisher Controls International, LLC 377 Series Trip Valves. Shipment records were used to determine that the 377 Series Trip Valves have >200 million operating hours and they have demonstrated a field failure rate less than the failure rates indicated in the FMEDA reports. This meets the requirements for Proven In Use for SIL 3.

5.2.7 Modifications
Modifications are initiated per ES 192, Engineering Change Request Procedure. Engineering changes are entered and tracked through “FISHWEB/Engineering & Technology/ECRN System”. All changes are first reviewed and analyzed for impact before being approved. Measures to verify and validate the change are developed following the normal design process. This meets SIL 3.

5.2.8 User documentation
Fisher Controls International, LLC creates the following user documentation: Installation, Operation, Maintenance and Safety Manuals. The IOM was found to contain all of the required information for normal installation and maintenance. The Safety Manual provides all the necessary information for Safety System Installations. The Safety Manual references the FMEDA reports which are available and contain the required failure rates, failure modes, useful life, and suggested proof test information.

Items from IEC 61508-2, Table B.4 include operation and maintenance instructions, user friendliness, maintenance friendliness, project management, documentation, limited operation possibilities (377 Series Trip Valves perform well-defined actions) and operation only by skilled operators (operators familiar with type of valve, although this is partly the responsibility of the end-user). This meets SIL 3.

5.3 Hardware Assessment
To evaluate the hardware design of the 377 Series Trip Valves Failure Modes, Effects, and Diagnostic Analysis’s were performed by exida. These are documented in [R1].
A Failure Modes and Effects Analysis (FMEA) is a systematic way to identify and evaluate the effects of different component failure modes, to determine what could eliminate or reduce the chance of failure, and to document the system in consideration. An FMEDA (Failure Mode Effect and Diagnostic Analysis) is an FMEA extension. It combines standard FMEA techniques with extension to identify online diagnostics techniques and the failure modes relevant to safety instrumented system design.

From the FMEDA, failure rates are derived for each important failure category. All failure rate analysis results and useful life limitations are listed in the FMEDA report [R1]. Tables in the FMEDA report list these failure rates for the 377 Series Trip Valves under a variety of applications. The failure rates listed are valid for the useful life of the devices.

Note, as the 377 Series Trip Valves are only one part of a (sub)system, the SFF should be calculated for the entire final element combination.

These results must be considered in combination with PFD\textsubscript{AVG} values of other devices of a Safety Instrumented Function (SIF) in order to determine suitability for a specific Safety Integrity Level (SIL). The architectural constraints requirements of IEC 61508-2, Table 2 also need to be evaluated for each final element application. It is the end users responsibility to confirm this for each particular application and to include all components of the final element in the calculations.

The analysis shows that the design of the 377 Series Trip Valves can meet the hardware requirements of IEC 61508, SIL 3 depending on the complete final element design. The Hardware Fault Tolerance, PFD\textsubscript{AVG}, and Safe Failure Fraction requirements of IEC 61508 must be verified for each specific design.
6 Terms and Definitions

Fault tolerance  Ability of a functional unit to continue to perform a required function in the presence of faults or errors (IEC 61508-4, 3.6.3)

FIT  Failure In Time (1x10⁻⁹ failures per hour)

FMEDA  Failure Mode Effect and Diagnostic Analysis

HFT  Hardware Fault Tolerance

Low demand mode  Mode, where the frequency of demands for operation made on a safety-related system is no greater than twice the proof test frequency.

PFD_avg  Average Probability of Failure on Demand

PVST  Partial Valve Stroke Test
It is assumed that the Partial Stroke Testing, when performed, is automatically performed at least an order of magnitude more frequent than the proof test, therefore the test can be assumed an automatic diagnostic. Because of the automatic diagnostic assumption the Partial Valve Stroke Testing also has an impact on the Safe Failure Fraction.

SFF  Safe Failure Fraction summarizes the fraction of failures, which lead to a safe state and the fraction of failures which will be detected by diagnostic measures and lead to a defined safety action.

SIF  Safety Instrumented Function

SIL  Safety Integrity Level

SIS  Safety Instrumented System – Implementation of one or more Safety Instrumented Functions. A SIS is composed of any combination of sensor(s), logic solver(s), and final element(s).

Type A element  “Non-Complex” element (using discrete components); for details see 7.4.4.1.2 of IEC 61508-2

Type B element  “Complex” element (using complex components such as micro controllers or programmable logic); for details see 7.4.4.1.3 of IEC 61508-2
7 Status of the Document

7.1 Liability

*exida* prepares reports based on methods advocated in International standards. *exida* accepts no liability whatsoever for the use of this report or for the correctness of the standards on which the general calculation methods are based.

7.2 Releases

Version: V1
Revision: R1
Version History: V1, R1: Released, July 3, 2013
V0, R1: Draft; February 5, 2013
Authors: Jack Gao
Review: V0, R1: Steven Close; April 30, 2013
Release status: Released

7.3 Future Enhancements

At request of client.

7.4 Release Signatures

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