IEC 61508 Functional Safety Assessment

Project:

Safety Rated Valves

Customer:

Velan

Montreal, QC

Canada

Contract Number: Q21/05-063 & Q22/08-117

Report No.: VEL 14-05-020 R003

Version V2, Revision R3, October 28, 2022

Oluwatobi Falomo

Management Summary

This report summarizes the results of the functional safety assessment according to IEC 61508 carried out on the Safety Rated Valves including the following valve families:

- TORQSEAL Butterfly Valve
- Resilient Seated Ball Valve
- Metal Seated Ball Valve
- Coker Ball Valve
- Cast Steel Gate Valve
- Pressure Seal Gate Valve
- API 623 Globe Valve

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

- *exida* assessed the development process used by Velan through an audit and review of a detailed safety case against the *exida* certification scheme which includes the relevant requirements of IEC 61508. The investigation was executed using subsets of the IEC 61508 requirements tailored to the work scope of the development team.
- *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 verify the accuracy of the FMEDA analysis.
- *exida* reviewed the manufacturing quality system in use at Velan.

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* Safety Case tool 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.

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

The audited development process as tailored and implemented by the Velan Safety Rated Valves development project, complies with the relevant safety management requirements of IEC 61508 SIL 3, **SC 3 (SIL 3 Capable).**

The assessment of the FMEDA, done to the requirements of IEC 61508, has shown that the Safety Rated Valves can be used in a low demand safety related system in a manner where the PFD_{avg} meets the requirements of table 2 or table 3 of IEC 61508-1.

The assessment of the FMEDA also shows that the Safety Rated Valves meets the requirements for architectural constraints of an element such that it can be used to implement a SIL 2 safety function (with HFT = 0) or a SIL 3 safety function (with HFT = 1).

This means that the Safety Rated Valves is capable for use in SIL 3 applications in Low DEMAND mode, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual and when using the versions specified in section 3 of this document.

The manufacturer will be entitled to use the Functional Safety Logo.


CERTIFIED
exida
IEC 61508
SIL 3 CAPABLE

Table of Contents

1 Purpose and Scope

This document shall describe the results of the IEC 61508 functional safety assessment of the Velan Safety Rated Valves including the following valve families:

- TORQSEAL Butterfly Valve
- Resilient Seated Ball Valve
- Metal Seated Ball Valve
- Coker Ball Valve
- Cast Steel Gate Valve
- Pressure Seal Gate Valve
- API 623 Globe Valve

by *exida* according to accredited *exida* certification scheme which includes the requirements of IEC 61508: ed2, 2010.

The assessment has been carried out based on the quality procedures and scope definitions of *exida*.

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.

1.1 Tools and Methods used for the assessment

This assessment was carried out by using the *exida* Safety Case tool. The Safety Case tool contains the *exida* scheme which includes all the relevant requirements of IEC 61508.

For the fulfillment of the objectives, expectations are defined which builds the acceptance level for the assessment. The expectations are reviewed to verify that each single requirement is covered. Because of this methodology, comparable assessments in multiple projects with different assessors are achieved. The arguments for the positive judgment of the assessor are documented within this tool and summarized within this report.

The assessment was planned by *exida* agreed with Velan.

All assessment steps were continuously documented by *exida* (see [R16] to [R18])

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 500 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 based on 350 billion hours of field failure data.

2.2 Roles of the parties involved

Velan	Manufacturer of the Safety Rated Valves
exida	Performed the hardware assessment
exida	Performed the IEC 61508 Functional Safety Assessment per the accredited *exida* scheme.

Velan contracted *exida* in August 2022 for the IEC 61508 Functional Safety Assessment of the above-mentioned devices.

2.3 Standards and literature used

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

[N1]	IEC 61508 (Parts 1 - 7): 2010	Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems

2.4 Reference documents

2.4.1 Documentation provided by Velan

[D1]	QC-900-I; Rev 19, 1/25/2021	Quality Manual
[D2]	QAM Procedure; Rev 24, 3/10/2022	QM for Nuclear Valves
[D3]	ISO 9001:2015; 3/7/2024	ISO 9001 Cert from Bureau Veritas
[D4]	ISO 9001:2015; 3/7/2024	ISO 9001 UKAS
[D5]	QMS Artifact; Rev 17, 1/26/2022	Quality Audit Schedule
[D6]	QMS Monitoring results, 07/2022	QMS Report on the results and Tables
[D7]	QC-700-1; Rev 21, 4/04/2022	Calibration Procedure Manual

[D8]	QC-714; 11/7/2005	Verification and Calibration of Assembly and Test Fixtures
[D9]	QCI-560; Rev 8, 07/17/2018	Reporting of Defects and Nonconformances per the NRC
[D10]	QCI-945; Rev 9; 8/8/2013	Control of Returned Items
[D11]	Training record and requirements; 6/28/2021	Employee Training requirements
[D12]	Des File; N/A; 9/6/2011	Design File Checklist Screen Capture
[D13]	Design Input Checklist	Design Input Checklist
[D14]	Design File	Torqseal Design File Contents Page
[D15]	Design Files	Design Files - Drawings and BOMs
[D16]	DF-T-002-1; 1/19/2011	Independent Design Review Checklist 8" 150# Lug TOV
[D17]	DF-T-009-1; 2/14/2011	Independent Design Review Check List 28" 150# Flanged B16.5 TOV
[D18]	DS-TOV2-07-21; 2021	Torqseal Triple-offset Butterfly Valves Product Catalogue
[D19]	VEL-CRYO-2001a	Cryogenic Brochure
[D20]	BRO-CBV-03-17 – Coker IOM; 2013	Coker Ball Valve Brochure
[D21]	VEL-BVMS2_98a; 2/2020	Securaseal Metal-seated Ball Valve Brochure
[D22]	QS-MSSM-03-22	Securaseal Splitbody Ball Valve
[D23]	DS-MSBVR-04-22	Securaseal Splitbody Ball Valve, Type R
[D24]	DS-MSBVN-05-20	Securaseal Splitbody Ball Valve, Type N
[D25]	CAT-CSV-09-18c	Cast Stainless Steel Valves – Gate, Globe, and Check Valves Product Catalogue
[D26]	DS-PSFLEXASME	Pressure Seal & Bolted Bonnet – Gate, Globe, and Check Valves Product Catalogue
[D27]	VEL-QCI-1123; Rev 20, 11/14/2017	Commercial Grade Dedication Procedure
[D28]	VEL-QCI-1299; Rev 9, 8/11/2020	Supplier Approval ISO 9000
[D29]	Fire Test; 21058; 1/28/2020	API 607 Rev 4 Fire test Report (8", 150# Metal Seated Butterfly Valve)
[D30]	Fire Test; 20158; 1/28/2020	API 607 Rev 4 Fire test Report - 8", 150#Prefered Flow direction.
[D31]	Test 690206-006-RA; Rev 0; 8/21/2006	Functional Testing Procedure & Results
[D32]	API Qualification Test; 2/18/2002	API and Exxon Qualification Tests
[D33]	Pre Production MoM; 6/14/2000	MoM for the Butterfly Valves

[D34]	Catalog Approval Form	Product Catalog Approval Form
[D35]	IOM-BFVM-02-16; 2016	Torqseal Valves IOM Maintenance manual
[D36]	IOM-CBVM-04-16; 2016	Delayed Coker Metal-Seated Ball Valves Maintenance manual
[D37]	VEL_BVEP-97a	EP 2000 Memory Seal Ball Valves Maintenance manual
[D38]	VEL-BVHB-98a	HB 2000 Memory Seal Ball Valves Maintenance manual
[D39]	VEL-BVUB3_01a	Memory Seal Ball Valves 1/2 - 1 1/2 Inch Maintenance manual
[D40]	VEL-BVUB4-2001b	Memory Seal Ball Valves 2 - 12 Inch Maintenance manual
[D41]	IOM-BVEE-03-11; 2010	EE 1000 Memory Seal Ball Valves Maintenance manual
[D42]	IOM-BVSB1-10-16	Memory Seal Ball Valve Split Body 1/2 - 1 1/2 Inch Maintenance manual
[D43]	IOM-BVSB2-07-14; 2014	Memory Seal Ball Valve Split Body 2 - 10 Inch Maintenance manual
[D44]	IOM-BVSB3A-10-12; 2012	Memory Seal Ball Valve NPS 2 – 24 Maintenance manual
[D45]	BVMS2-98	Metal Seated Ball Valves Top Entry 1/2 - 2 Inch
[D46]	Maintenance Manual	Metal Seated Ball Valve 2 - 12 Inch
[D47]	IOM-MSBVC-03-10 -Type C; 2010	Securaseal Metal Seated Ball Valve Type C 4 - 6 Inch Maintenance manual
[D48]	IOM-MSBVNR-10-15 – Type N & R; 2010	Secure Seal Ball Valve Type N & Type R Maintenance manual
[D49]	IOM-MSBVU-03-14; 2014	Secure Seal Ball Valve Type U Maintenance manual
[D50]	IOM-CSVM-02-16; 2014	Cast Steel Valves Maintenance manual
[D51]	IOM-FPSM-03-12; 2012	Pressure Seal Valves Maintenance manual
[D52]	Form	Valve Automation Data Multi Turn
[D53]	Valve Automation Data form	Valve Automation Data Quarter Turn
[D54]	Quarter- Turn Valve Automation Specification	Quarter-Turn Valve Form- Customer Requirements
[D55]	SIL-BF-01-16_11a17; 2012	TORQSEAL Safety Manual
[D56]	SIL-MTV-09-22draft; 2022	Safety Manual for Multi-turn Valves
[D57]	SIL-MS-02-18; 2014	Safety Manual for Metal Seated Ball Valves
[D58]	SIL-BV-04-16; 2014	Safety Manual for Resilient Seated Ball Valves
[D59]	EWI-0010; 7/22/2009	Engineering Change Request - ECR

[D60]	EWI-0011; 11/6/2009	Engineering Change Order - ECO
[D61]	EWI-0012; ECR025-10; 7/21/2009	Sample Engineering Change Report
[D62]	VEL-QCI-1316; Rev 12, 4/17/2018	Completion of Deviation Reports
[D63]	CAR Form; n/a; 7/12/2021	Corrective Action Form
[D64]	DR 100002778-2022-01-17; 1/13/2022	Deviation report
[D65]	4F-2074C-02TS-02; Rev J; 07/27/2018	Globe Valve Drawing

2.4.2 Documentation generated by *exida*

[R1]	VEL 10-10-021 R001 V1R1 – Torqseal Butterfly Valve FMEDA Report, June 5, 2011	FMEDA Report, Triple-Offset Butterfly Valve
[R2]	VEL 10-10-021 R002 V1R1 – Torqseal Butterfly Valve – Cryogenic FMEDA Report, June 7, 2011	FMEDA Report, Triple-Offset Cryogenic Butterfly Valve
[R3]	VEL 10-10-021 R003 V1R1 – Torqseal Butterfly Valve with Seat Insert FMEDA Report,	FMEDA Report, Torqseal Triple-Offset Butterfly Valve with Seat Insert, June 13, 2011
[R4]	VEL 13-04-029 R001 V1R2 – Split Body Ball Valve FMEDA Report, May 30, 2013	FMEDA Report, Memoryseal Split Body Ball Valve
[R5]	VEL 13-04-029 R002 V1R2 – Top Entry Ball Valve FMEDA Report, July 2, 2013	FMEDA Report, Memoryseal Top-Entry Ball Valve
[R6]	VEL 13-04-029 R003 V1R2 – Unibody Ball Valve FMEDA Report, July 2, 2103	FMEDA Report, Memoryseal Unibody Ball Valve
[R7]	VEL 13-04-029 R004 V1R2 – EE, EP, and HB Ball Valve FMEDA Report, July 2, 2103	FMEDA Report, Memoryseal EE, EP, and HB Ball Valves
[R8]	VEL 13-05-091 R001 V1R2 – Top Entry Ball Valve FMEDA Report, February 14, 2014	FMEDA Report, Securaseal Top-Entry Ball Valve
[R9]	VEL 13-05-091 R002 V1R2 – Split Body Ball Valve FMEDA Report, February 14, 2014	FMEDA Report, Securaseal Split-Body Valve
[R10]	VEL 13-05-091 R003 V1R2 – Securaseal Type Ball Valve FMEDA Report, February 14, 2014	FMEDA Report, Securaseal Type Ball Valve
[R11]	VEL 13-05-091 R001 V1R2 – Coker Ball Valve FMEDA Report, February 14, 2014	FMEDA Report, Coker Ball Valve

[R12]	VEL 14-05-020 R001 V1R1 FMEDA Cast Gate Valve, September 24, 2014	FMEDA Report, Cast Steel Wedge Gate Valves
[R13]	VEL 14-05-020 R002 V1R1 FMEDA Pressure Seal Gate Valve, September 24, 2014	FMEDA Report, Pressure Seal Flexible Wedge Gate Valves
[R14]	VEL 22-08-117 R001, V1R1, 20-Oct-22	FMEDA Report, Globe Valve
[R15]	VEL Safety Rated Valves FFA R1; 22-Sep-2022	Field Failure Analysis
[R16]	VEL Q10-10-021 Velan Torqseal initial SafetyCaseDB IEC61508 R2	IEC 61508 SafetyCaseDB for Safety Rated Valves
[R17]	Q21-05-063 Velan Renewal PM Workbook	Certification Renewal Workbook
[R18]	VEL 14-05-020 Assessment Report R003 V2R3 Safety Valves IEC 61508 Assessment.docx, October 28, 2022	IEC 61508 Functional Safety Assessment, Velan Safety Rated Valves (this report)

2.5 Assessment Approach

The certification audit was closely driven by requirements of the *exida* scheme which includes subsets filtered from IEC 61508.

The assessment was planned by *exida* and agreed upon by Velan.

The following IEC 61508 objectives were subject to detailed auditing at Velan:

- FSM planning, including
  - Safety Life Cycle definition
  - Scope of the FSM activities
  - Documentation
  - Activities and Responsibilities (Training and competence)
  - Configuration management
- Safety Requirement Specification
- Change and modification management
- Hardware architecture design - process, techniques and documentation
- Hardware design / probabilistic modeling
- Hardware and system related V&V activities including documentation, verification
  - Integration and fault insertion test strategy
- Hardware-related operation, installation and maintenance requirements

3 Product Descriptions

The following valve families are included in this assessment:

- TORQSEAL Buttery Valve
- Resilient Seated Ball Valve
- Metal Seated Ball Valve
- Coker Ball Valve
- Cast Steel Gate Valve
- Pressure Seal Gate Valve
- API 623 Globe Valve

TORQSEAL Safety Rated Valves description:

Valve Family	Specifications	Description
Triple-Offset metal seated butterfly valve	Valve Sizes: 3” through 48” Pressure Ratings: ANSI Class 150 to ANSI Class 600	The Torqseal’s design features three-way eccentricity and unique elliptical seat geometry ensuring compressive sealing around the entire seat. It is offered with flanged, butt-weld, lug, and wafer connections. This analysis includes the following packing designs; Standard Low Emissions, “0” Helium Bubbles, Lantern Ring, and TA-LUFT.

Resilient Seated Ball Valve Safety Rated Valves description:

Valve Family	Specifications	Description
Memoryseal Split Body Ball Valve	Valve Sizes: ¼" through 24" Pressure Ratings: ANSI Class 150, 300, and 600 Full and regular port design Floating and Trunnion Ball designs Flange body style	The Memoryseal Split Body ball valves meet the requirements of oils and gas pipeline service and can be supplied as NACE compliant. The valves handle a variety of fluids, slurries, semi-solid, and corrosive material. Design for the chemical, oil, petrochemical, gas, pulp, paper processing, and other industries.
Memoryseal Top-Entry Ball Valve	Valve Sizes: ½" through 6" Pressure Ratings: ANSI Class 150, 300, and 600 Socket weld, butt weld, and flanged body styles Full and regular port design	The valves handle a variety of fluids, slurries, semi-solid, and corrosive material. Design for the chemical, oil, petrochemical, gas, pulp, paper processing, and other industries.
Memoryseal Unibody Ball Valve	Valve Sizes: ½" through 12" Pressure Ratings: ANSI Class 150 and 300 Regular port design Flanged body style	The valves handle a variety of fluids, slurries, semi-solid, and corrosive material. Design for the chemical, oil, petrochemical, gas, pulp, paper processing, and other industries.
Memoryseal EE Ball Valve	Valve Sizes: ¼" through 2" Full port design Threaded connection	Stainless steel construction for corrosive applications.
Memoryseal EP Ball Valve	Valve Sizes: ½" through 2" Regular port design Threaded connection	Larger port heavy duty valve for oilfields, chemical, and general purpose.
Memoryseal HB Ball Valve	Valve Sizes: ¼" through 2" Threaded connection	Rugged valve design for industrial, commercial and original equipment manufacturers.

Metal Seated Safety Rated Valves description:

Valve Family	Specifications	Description
Securaseal Top-Entry Ball Valve Type T	Valve Sizes: ½" through 6" Pressure Ratings: ANSI Class 150, 300, and 600 Threaded, socket weld, butt weld, and flanged body styles Full and regular port design	The valves handle a variety of fluids, slurries, semi-solid, and corrosive material. Design for the chemical, oil, petrochemical, gas, pulp, paper processing, and other industries.
Securaseal Split-Body Ball Valve	Valve Sizes: 2" through 24" Pressure Ratings: ANSI Class 150, 300, and 600 Flanged body styles Full and regular port design	The valves handle a variety of fluids, slurries, semi-solid, and corrosive material. Design for the chemical, oil, petrochemical, gas, pulp, paper processing, and other industries.
Securaseal Split-Body Ball Valve, Type R	Valve Sizes: 1/2" through 48" Pressure Ratings: ANSI Class 150, 300, 600, 900, 1500, 2500, and 4500 Flanged, Butt Weld, Socket Weld, and Clamp body styles Full and regular port design	Severe service cast and forged metal-seated ball valves
Securaseal Split-Body Ball Valve, Type N	Valve Sizes: 1/2" through 24" Pressure Ratings: ANSI Class 150, 300, 600, 900, 1500, 2500, and 4500 Flanged, Butt Weld, Socket Weld, Threaded, and Clamp body styles Full and regular port design	Severe service forged metal-seated ball valves, external thrust bearing
Securaseal Split-Body Ball Valve, Type L	Valve Sizes: 4" through 24" Pressure Ratings: ANSI Class 150, and 300 Flanged body styles Full and regular port design	High temperature metal-seated ball valves

Securaseal Split-Body Ball Valve, Type P	Valve Sizes: 1/2” through 24” Pressure Ratings: ANSI Class 150, 300, 600, 900, 1500, 2500, and 4500 Flanged, Butt Weld, Socket Weld, Threaded, and Clamp body styles Full and regular port design	Severe service integral flow-thru jacketed design metal-seated ball valves
Securaseal Split-Body Ball Valve, Type U	Valve Sizes: 2” through 24” Pressure Ratings: ANSI Class 150, 300, 600, 900, 1500, 2500, and 4500 Flanged, Butt Weld, Socket Weld, Threaded, and Clamp body styles Full and regular port design	Severe service trunnion mounted metal-seated top entry ball valve, with seat inserts
Securaseal Split-Body Ball Valve, Type C	Valve Sizes: 2” through 24” Pressure Ratings: ANSI Class 150, 300, 600, 900, 1500, 2500, and 4500 Flanged, Butt Weld, Socket Weld, Threaded, and Clamp body styles Full and regular port design	Severe service split body metal-seated ball valve with graphite sprung seating
Securaseal Split-Body Ball Valve, Type T	Valve Sizes: 2” through 24” Pressure Ratings: ANSI Class 150, 300, and 600 Flanged body styles Full and regular port design	Trunnion mounted metal-seated top entry ball valve

Coker Safety Rated Valves description:

Valve Family	Specifications	Description
Coker Ball Valve, Type K	Valve Sizes: 2” through 12” Pressure Ratings: ANSI Class 150, 300, 600, and 900 Flanged and Butt Welded body style Full port design	Forged body
Coker Ball Valve, Type K , T Head Coupling	Valve Sizes: 6” through 36” Pressure Ratings: ANSI Class 150, 300, 600, and 900 Flanged body style Full port design	Two piece ball and stem design, T Head coupling
Coker Ball Valve, Type K , Key Coupling	Valve Sizes: 6” through 36” Pressure Ratings: ANSI Class 150, 300, 600, and 900 Flanged body style Full port design	Two piece ball and stem design, Key coupling
Coker Ball Valve, Type K , One Piece Ball and Stem	Valve Sizes: 6” through 36” Pressure Ratings: ANSI Class 150, 300, 600, and 900 Flanged body style Full port design	One piece ball and stem design
Coker Ball Valve, Type D	Valve Sizes: 2” through 36” Pressure Ratings: ANSI Class 150, 300, 600, and 900 Flanged body styles Full port design	Trunnion mounted, one piece ball and stem design
Coker Ball Valve, Type F	Valve Sizes: 2” through 24” Pressure Ratings: ANSI Class 300, 600, and 900 Flanged body styles Full port design	Three or Four-way diverter valve

Cast Gate Safety Rated Valves description:

Valve Family	Specifications	Description
Cast Steel Wedge Gate Valves	Valve Sizes: NPS 2 – 64 ASME Class 150 - 1500	Bolted bonnet cast steel gate valve in a broad range of carbon, alloy and stainless steel materials. NPS 2–64 (DN 50–1600), ASME CLASSES: 150– 1500. Conforms to API 600. Low fugitive emissions design. Broad range of trims, including API 600 trims and others. Flexible wedge with low center stem-wedge contact. Seating surfaces including CA15/13 Cr and cobalt-chrome alloy hardfacing. Multiple actuation options, including gear actuator and electric or fluid powered actuator. Non-rotating stem with ACME thread in multiple pitch options. Body-bonnet joint in accordance with API 600 and ASME B16.34. Low fugitive emissions body-bonnet gasket. Multiple body connection options including flanged and butt weld.

Pressure Seal Gate Safety Rated Valves description:

Valve Family	Specifications	Description
Cast and Forged Pressure Seal Wedge Gate Valves	Valve Sizes: NPS 2 – 36 ASME Class 150 – 1500	Pressure seal bonnet gate valve in a broad range of carbon, alloy and stainless steel materials. NPS 2–36 (DN 50–900), ASME CLASSES: 150– 4500. Conforms to ASME B16.34. One-piece die formed forgings. Multi-piece fabricated forged designs available. Broad range of trims. Hardfaced seating surfaces. Velan pressure seal design. Graphite pressure seal gasket standard. Other materials available. Broad range of trims, including API 600 trims and others. Conventional flexible wedge standard. Ultraflex® wedge available to avoid thermal binding. Low fugitive emissions capable. Optional live-loading of packing. Non-rotating stem. Multiple actuation options, including gear actuator and electric or fluid powered actuator. Multiple body connection options.

API 623 Globe Valve Safety Rated Valves description:

The API 623 Cast Steel Globe Valve is used primarily for throttling and regulating flow of liquid or gas in a pipeline. It comes in different size ranges from NPS 2 - 24 with pressure class of 150 – 1500. Some of the features include.

- Unique non-rotating stem
- Universal trim suitable for service up to 850^0F
- Precision machined body and bonnet castings
- Torque arm to reduce wear on packing rings and better sealing

Application	Pressure Class	WCB	Cast Stainless
Non-rotating rising stem	150	NPS 12 to 14	N/A
	300	NPS 8 to 14	
	600	NPS 6 to 8	
	900	NPS 2 to 4	
	1500	NPS 2 to 4	
Non-rotating rising stem	150	NPS 8	N/A
	300	NPS 6	
Rotating rising stem	150	NPS 2 to 10	NPS ½ to 6
	300	NPS 2 to 6	NPS ½ to 6
	600	NPS 2 to 4	N/A

4 IEC 61508 Functional Safety Assessment Scheme

exida assessed the development process used by Velan for this development project against the objectives of the *exida* certification scheme which includes subsets of IEC 61508 -1 to 3. The results of the assessment are documented in [R16] and [R17].

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 5.2.

4.2 Assessment level

The Safety Rated Valves has 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 (SIL 3) according to IEC 61508.

5 Results of the IEC 61508 Functional Safety Assessment

exida assessed the development process used by Velan for these products against the objectives of the *exida* certification scheme which includes IEC 61508 parts 1, 2, & 3 see [N1]. The development of the Safety Rated Valves was done per this IEC 61508 SIL 3 compliant development process. The Safety Case was updated with project specific design documents.

5.1 Lifecycle Activities and Fault Avoidance Measures

Velan has a defined product lifecycle process in place. This is documented in the Quality Management System Manual [D1] and various Quality Procedures. A design file is created for every unique valve configuration. A documented modification process is also covered in the Quality Manual. 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 the *exida* certification scheme which includes subsets of IEC 61508 requirements tailored to the SIL 3 work scope of the development team. The result of the assessment can be summarized by the following observations:

The audited Velan design and development process complies with the relevant managerial requirements of IEC 61508 SIL 3 .

5.1.1 Functional Safety Management

The valves manufactured by Velan are not built for inventory. These valves are built-to-order. The basic designs are standardized, but each order can have trim and materials variations or specific customer requested proof tests. Due to the specialized nature of each valve, documentation that defines all of the requirements is generated for every order as part of the process.

FSM Planning

Velan has a defined process in place for product design and development. Required activities are specified along with review and approval requirements. This is primarily documented in VEL-QC-900-3 of their Quality Management System Manual [D1] and in greater detail in work instructions EWI-0010 [D60] and EWI-0011 [D61]. Templates and sample documents were reviews and found to be sufficient. 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

VEL-QC-900-3 Section 4.9 of [D1] requires that all documents be under document control. Use of this to control revisions was evident during the audit.

Training, Competency recording

VEL-QC-900-16 of [D1] requires the Human Resource department to maintain 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. The procedures and records were examined and found up-to-date and sufficient. Velan hired *exida* to be the independent assessor per IEC 61508 and to provide specific IEC 61508 knowledge.

5.1.2 Safety Requirements Specification and Architecture Design

For the Safety Rated Valves, the simple primary functionality of the valve is the same as the safety functionality of the product (Valve changes position, Close / Open). Therefore, no special Safety Requirements Specification was needed. The normal functional requirements were sufficient. As the Safety Rated Valves designs are simple and are 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.

5.1.3 Hardware Design

The design process is documented in VEL-QC-900-3 of [D1]. VEL-QC-900-3, Section 4.4.2 specifies that a Design File will be created for all engineering projects. 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, modularization, use of well-tried components / materials, and computer-aided design tools. This meets SIL 3.

5.1.4 Validation

According to VEL-QC-900-3, Section 4.7, Validation Testing is conducted on new designs to ensure that the designs meet the requirements. Test results are documented and recorded. As the Safety Rated Valves are purely mechanical devices with a simple safety function, there is no separate integration testing necessary. The Safety Rated Valves performs only 1 Safety Function, which is extensively tested under various conditions during validation testing.

Items from IEC **61508-2, Table B.3** include functional testing, project management, documentation, and black-box testing (for the considered devices this is similar to functional testing). Field experience and statistical testing via regression testing are not applicable. This meets SIL 3.

Items from IEC **61508-2, Table B.5** included functional testing and functional testing under environmental conditions, project management, documentation, failure analysis (analysis on products that failed), expanded functional testing, black-box testing, and fault insertion testing. This meets SIL 3.

5.1.5 Verification

The development and verification activities are defined in VEL-QC-900-3, section 4.6 of [D1]. For each design phase the objectives are stated, required input and output documents and review activities. This meets SIL 3.

5.1.6 Proven In Use

In addition to the Design Fault avoidance techniques listed above, a Proven in Use evaluation was carried out on the Velan Safety Rated Valves. Shipment records were used to determine that the all Safety Rated Valve families have >300 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.

5.1.7 Modifications

The modification procedure is described in VEL-QC-900-3 Section 4.8 of [D1]. Modifications are initiated per an Engineering Change Order (ECO) and are released on an Engineering Change Notice Engineering Master. 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.

The modification process has been successfully assessed and audited, so Velan may make modifications to this product as needed.

- As part of the *exida* scheme a surveillance audit is conducted every 3 years. The modification documentation listed below is submitted as part of the surveillance audit. *exida* will review 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

This meets SIL 3.

5.1.8 User documentation

Velan creates the following user documentation: product catalogs [D18 – D26] and Safety Manuals [D55 – D58]. The Safety Manuals were found to contain all of the required information given the simplicity of the products. The Safety Manuals reference 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 (Safety Rated 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.

5.2 Hardware Assessment

To evaluate the hardware design of the Safety Rated Valves Failure Modes, Effects, and Diagnostic Analysis's were performed by *exida*. These are documented in [R1] through [R14].

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. Tables in the FMEDA report list these failure rates for the Safety Rated Valves under a variety of applications. The failure rates listed are valid for the useful life of the devices.

According to IEC 61508 the architectural constraints of an element must be determined. This can be done by following the 1_H approach according to 7.4.4.2 of IEC 61508-2 or the 2_H approach according to 7.4.4.3 of IEC 61508-2.

The 1_H approach involves calculating the Safe Failure Fraction for the entire element.

The 2_H approach involves assessment of the reliability data for the entire element according to 7.4.4.3.3 of IEC 61508-2.

The failure rate data used for this analysis meets the *exida* criteria for Route 2_H. Therefore, the Safety Rated Valves can be classified as a 2_H device. When 2_H data is used for all of the devices in an element, the element meets the hardware architectural constraints up to SIL 2 at HFT=0 (or SIL 3 @ HFT=1) per Route 2_H.

If Route 2_H is not applicable for the entire final element, the architectural constraints will need to be evaluated per Route 1_H.

Note, as the Safety Rated 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_{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 user's 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 Safety Rated Valves can meet the hardware requirements of IEC 61508, SIL 3 for the Safety Rated Valves depending on the complete final element design. The Hardware Fault Tolerance and PFD_{avg} requirements of IEC 61508 must be verified for each specific design.

6 2022 IEC 61508 Functional Safety Surveillance Audit

6.1 Roles of the parties involved

Velan	Manufacturer of the Safety Rated Valves
exida	Performed the hardware assessment review
exida	Performed the IEC 61508 Functional Safety Surveillance Audit per the accredited *exida* scheme.

Velan contracted *exida* in August 2022 for the certification renewal of the Safety Rated Valves. The surveillance audit was conducted onsite at the Velan's facility in Montreal QC, Canada on October 11, 2022.

6.2 Surveillance Methodology

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

- Procedure Changes – Changes to relevant procedures since the last audit are reviewed to determine that the modified procedures meet the requirements of the *exida* certification scheme.
- Engineering Changes – The engineering change list is reviewed to determine if any of the changes could affect the safety function of the Safety Rated Valves.
- Impact Analysis – If changes were made to the product design, the impact analysis associated with the change will be reviewed to see that the functional safety requirements for an impact analysis have been met.
- Field History – Shipping and field returns during the certification period will be reviewed to determine if any systematic failures have occurred. If systematic failures have occurred during the certification period, the corrective action that was taken to eliminate the systematic failure(s) will be reviewed to determine that said action followed the approved processes and was effective.
- Safety Manual – The latest version of the safety manual will be reviewed to determine that it meets the IEC 61508 requirements for a safety manual.
- FMEDA Update – If required or requested the FMEDA will be updated. This is typically done if there are changes to the IEC 61508 standard and/or changes to the *exida* failure rate database.
- Evaluate use of the certificate and/or certification mark - Conduct a search of the applicant's web site and document any misuse of the certificate and/or certification mark. Report any misuse of the certificate and/or certification mark to the exida Managing Director.
- Recommendations from Previous Audits – If there are recommendations from the previous audit, these are reviewed to see if the recommendations have been implemented properly.

6.2.1 Documentation provided by Velan

Note: See section 2.4.1 for documents that have been revised or added since the previous audits (highlighted in grey)

6.3 Surveillance Results

6.3.1 Procedure Changes

All procedures were reviewed for changes. All change made were found to be consistent with the requirements of IEC 61508.

6.3.2 Engineering Changes

There were no significant design changes to these products during the previous certification period. An ECN for a minor enhancement was reviewed and all documentation was found to be acceptable.

6.3.3 Impact Analysis

There were no safety-related design changes during the previous certification period.

6.3.4 Field History

The field histories of these products were analyzed and found to be consistent with the failure rates predicted by the FMEDA.

6.3.5 Safety Manual

The safety manual was reviewed and found to be compliant with IEC 61508:2010.

6.3.6 FMEDA Update

No update to the FMEDA was needed.

6.3.7 Evaluate use of certificate and/or certification mark

The Velan website was searched and no misleading or misuse of the certification or certification marks was found.

6.3.8 Previous Recommendations

There were no previous recommendations to be assessed at this audit.

7 Terms and Definitions

Architectural Constraint	The SIL limit imposed by the combination of SFF and HFT for Route 1_H or by the HFT and Diagnostic Coverage (DC applies to Type B only) for Route 2_H
exida criteria	A conservative approach to arriving at failure rates suitable for use in hardware evaluations utilizing the 2_H Route in IEC 61508-2.
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 demand interval for operation made on a safety-related system is greater than twice the proof test interval.
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.
Random Capability	The SIL limit imposed by the PFD_{avg} for each element.
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).
Systematic Capability	The SIL limit imposed by the capability of the products manufacturer.
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

8 Status of the Document

8.1 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.

8.2 Version History

Contract Number	Report Number	Revision Notes
Q21/05-063 & Q22/08-117	VEL 14-05-020 R003 V2, R3	Certification Renewal and added Globe Valve, October 28, 2022
Q17/10-124	VEL 14-05-020 R003 V2, R2	Minor updates, July 10, 2018
Q17/10-124	VEL 14-05-020 R003 V2, R1	Released to Velan, June 21, 2018
Q14/05-020	VEL 14-05-020 R003 V1, R1	Released to Velan, November 19, 2014
Q14/05-020	VEL 14-05-020 R003 V1, R0	Draft; November 16, 2014

Reviewer: Bob Gavin, *exida*, October 28, 2022
Status: Released

8.3 Future Enhancements

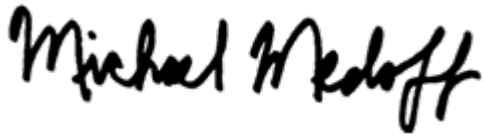
At request of client.

8.4 Release Signatures

Oluwatobi Falomo, Safety Engineer

Chris O'Brien, CFSE, Partner, Evaluating Assessor

Bob Gavin, Safety Engineer, Certifying Assessor



Michael Medoff, CFSE, CACE, OEM Certification Director