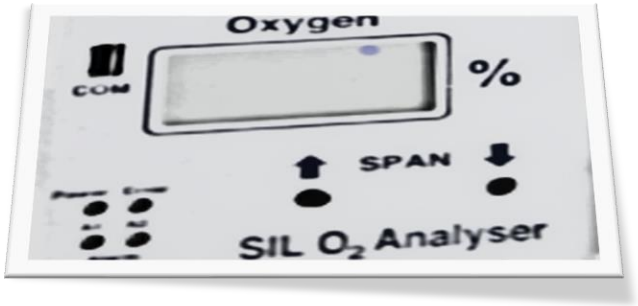
EN:50402 Certification for SIL1 O2 Analyzer

Client

Our client is part of the Process Sensing Technologies (PST) Group, which allows customers to benefit from a wider product range as well as an extensive distribution network through a collection of trusted brands to provide an unmatched suite of instruments, analyzers, and sensors for precision measurements and monitoring in highly demanding end markets

So, our client state-of-the-art, technology-led, and SIL (safety integrity level) approved oxygen analyzers and transmitters help customers from segments as diverse as pharmaceutical, life sciences, food and beverage, industrial and specialty gases, O&G, and additive manufacturing.



Problem statement and challenges

Our client contacted SQAConsultant to help them achieve EN:50402 certification including IEC:61508 SIL1. The main task was to bring the software to meet the requirements as set out in the EN-50402:2017 standard with a minimal set of changes. At the same time, we were given the job of generating the necessary documentation to meet the requirements of IEC:61508 SIL 1.

The biggest challenge here was that the certification agency had not specified any list of documents/checklists that they were looking for.

Also, the changes in the software were to be restricted to a minimum so that the instrument performance, experienced by the end users, was not compromised.

Moreover, the certification agency demanded detailed test reports to show extensive testing carried out on the instruments.

Solution Strategy

We tackled this project by first dividing the project into three main phases.

- The first phase was the scope definition in which we defined the deliverables for the project after a thorough analysis of the EN:50402 requirements.
- In 2nd phase, we developed an SRS (System requirement specification) took the assessor on board, and reviewed it in detail (what is the source of the safety requirements, their applicability, and how to realize these in the system with proper evidence/proof)
- We designated the 3rd phase as the testing phase in which we tested the O2 Analyzer comprehensively.
- The last phase was reserved for certification in which we prepared a complete documentation package for submission to the assessor for assessment.

In the first phase, we defined the project scope and the list of deliverables that we would present to the safety certification agency. We reviewed the requirements as set out in the EN:50402 standard and performed a gap analysis to identify areas where the gas monitors fell short. Using our experience in safety certifications, we referred back and forth to the parent standard IEC:61508 and extracted the requirements that were needed to be

updated in the instrument software. Subsequently, we prepared a complete list of requirements that required validation for EN:50402 certification. To make sure we were on the right track, we put together a list of documents that we thought would be sufficient for certification. We reviewed this list with the assessor and got a green light straight away.

Furthermore, in this phase, we prepared plan documents that included the Software Quality Assurance Plan including all the processes and procedures to be followed as per requirements of the certification standards. Verification and Validation plans were prepared next to direct the verification and validation activities for the SIL1 O2 Analyzer.

The 2nd phase involved developing an SRS (System requirement specification) with the coordination of the client; took the assessor on board and reviewed each requirement including standard related clauses in detail.
We developed a checklist that was recoding and addressing the source of the safety requirements, their description, applicability, and realization in the system under development with proper evidence/proof)

The 3rd phase involved the actual testing of the O2 Analyzer. We performed functional testing based on the functional test cases written meeting safety standard criteria. These included the boundary values analysis and performance tests. Simultaneously, we carried out static code analysis on the instrument's software to ensure that the software adhered to the restrictions EN:50402 enforces. At this stage, we were in constant contact with our client to ensure that the changes resulting in the instrument software were localized and were not affecting the instrument performance in any way. We prepared comprehensive test reports to document all the testing activities.

The last phase was the finalization of the documentation as specified in the first phase. We prepared a comprehensive validation report that showed the verification and validation of all the safety requirements of EN:50402 as per the verification and validation plans drafted in the first phase. Subsequently, we packaged all the documentation into a structured form as demanded by the certification agency and submitted it to the assessor for evaluation.

Ultimately, our clients were awarded with the EN:50402 certification compliance certificate without any further iterations.

Highlights

To summarize, these were the key highlights for this project:

- Getting approval for a list of deliverables for EN: 50402 certification including IEC:61508 SIL1
- Preparing detailed test specifications and corresponding test reports verifying the functional behavior of the gas monitors
- Drafting V&V plans and reports validating the safety requirements
- Receiving EN:50402 certification without any iterations from the certification agency

Outcomes

This project provided us with the valuable experience of working with one of the world's leading process sensing technology clients plus a certification agency and proved to be a big stepping stone in the expansion of our portfolio. Our name spread out further and we got clients from areas of the world we had not imagined before.

Contact Us

Explore ways to use our expertise in growing your business while establishing a valuable partnership with us.

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