Enabling product manufacturers to demonstrate SIL compliance

### IEC 61508 PRODUCT SIL COMPLIANCE PROGRAMME

**Overview:**

Having performed over 150 assessments for a great variety of equipment suppliers, we realise that most organisations have similar requirements.

This information sheet outlines a typical work programme that enables product reliability data and the necessary functional safety processes to be established in order to make a claim of compliance to **IEC 61508** for use in automated safety functions up to a specified **Safety Integrity Level** (SIL).

The scope covers the two main requirements from IEC 61508 that need to be addressed:

- **Random (probabilistic) failures**
  
  This involves a detailed design analysis of the unit and creating a reliability model in order to quantify the likelihood of random hardware failures.

- **Systematic failure mechanisms**
  
  This involves an evaluation of the qualitative processes used in realisation (design and manufacture) and the product documentation.

**Typical Products:**

Instruments for measuring temperature, pressure, flow, level, position, speed, weight, radiation; signal conditioning units, monitors, alarms, relays, contactors, controllers, valves, actuators, contactors, isolators, etc.

**Our service:**

Silmetric can either provide direct assistance (consultancy) or an independent assessment to IEC 61508-1 clause 8. (Assessments are not available to clients for whom Silmetric has provided a consultancy service on the same product or process).

**Software:**

For products that contain software that performs or can affect the critical functions, an additional scope of work is required. (Contact Silmetric for details).

### WHAT YOU WILL GAIN FROM THIS PROGRAMME

**Benefits:**

Once the reliability data and systematic integrity are established, the product(s) can be used in safety functions up to a specified SIL.

- An assisted route to market for claiming ‘SIL-capability’.
- Detailed guidance on how to augment the ISO 9001 processes with the necessary functional safety processes.
- Creation of a full and complete Technical Construction File supporting the use of the product(s) in SIL applications or with a machinery Performance Level (PL).
- Independent assessment reports (where consultancy is not used).
- A deep learning experience.
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### A TYPICAL WORK PROGRAMME

The work typically follows the stages described below, depending on the agreed strategy at the initial meeting. Some clients only need some of the work stages, or for more complex projects further work may be required.

1. **Initial meeting:**
   - We meet you to understand your requirements, conduct briefings and propose a strategy that suits your needs and is designed to achieve a successful outcome.

2. **Create or verify the reliability model:**
   - Silmetric can either create a hardware reliability model (e.g., a failure mode, effects and diagnostics analysis – FMEDA) or verify an existing one. Clients may also opt to perform this analysis on their own with supervision or training from Silmetric as required. During this stage, the correct reliability data is established, for example $\lambda_{SD}$, $\lambda_{SU}$, $\lambda_{SO}$, $\lambda_{DU}$, $\lambda_{NP}$, DC, SFF, PFDavg.

3. **Review of qualitative processes:**
   - The existing quality management system can provide a foundation on which to build any additional processes needed to meet IEC 61508 for product realisation and functional safety management, as applicable to the product. During this stage we identify any shortcomings and can provide support to remediate. This work establishes the product’s Systematic Capability (SC 1-3).

4. **Review of the product literature:**
   - In this stage we ensure that the correct functional safety information from the hardware analysis and supporting documentation is identified and included in the published specification and the mandatory ‘Safety Manual’ for the user.

5. **Conclusion and final report:**
   - Once any remediation work is done, we can provide a final review to verify that all the requirements of IEC 61508 are fully satisfied and mapped to an appropriate source. We can advise how to publish a claim of compliance and use in safety functions at a specified SIL, including any restrictions or boundaries in application, backed up with a detailed independent assessment report.

### WHY USE SILMETRIC?

Silmetric assessors have performed independent assessments of numerous products that cover a large range of technologies and complexities, for use in various applications up to SIL 3.

**Reasons:**

- Silmetric assessors have worked on at least 150 successful compliance projects, mostly subject to UKAS scrutiny, in the UK, Canada, USA, France, Germany, Norway, Holland, Israel, Russia, Middle East, India and South Korea
- Assessors meet the strict CASS competence criteria (www.cass.uk.net)
- We use the CASS templates for maximum transparency and credibility when compiling evidence of compliance or for conducting assessments

### FOR MORE INFORMATION PLEASE CONTACT SILMETRIC

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