61508 Association Policy document: Proven in Use

In a SIL rated safety loop there are occasions when it is thought desirable to use an instrument or a component well known to the user that has not been assessed under the IEC61508 group of standards e.g. by an FMEDA\(^1\). The Functional Safety standards allow the use of such equipment only on the basis that it has been “proven in use” (61508) or has a history of “prior use” (61511).

It is the end user who must ensure that the Safety Instrumented System (SIS) meets the requirements of the standard. He can do that by assessing the SIS himself or by devolving the assessment to a supplier or system integrator. However, the user retains overall responsibility.

The prior use argument may appear an attractive solution, especially in the following situations:

- To a user having to provide safety related information on components already in use
- To a user seeking to replace old equipment with new
- To designers of new plant who cannot find devices that have been assessed for compliance with IEC 61508

The requirements of 61508 and 61511 for “proven in use” are very demanding. The user is required to have appropriate evidence that the components and subsystems are suitable for use in the SIS. This means that as a minimum the user must have:

- a formal system for gathering reliability data that differentiates between safe and dangerous failures
- means of assessing the recorded data to determine the safety integrity of the device / equipment, and its suitability for the intended use.
- evidence that the application is clearly comparable
- recorded historical evidence of device hours in use
- evidence of the manufacturer’s management, quality and configuration manufacturing systems
- device firmware revision records
- proof that reliability data records are updated and reviewed regularly

Users are cautioned to closely scrutinise the relevant clauses of both standards before embarking on this solution.

DISCLAIMER: The Association would welcome any comments on this publication, see http://www.61508.org/contact.htm. Whilst every effort has been made to ensure the accuracy of the information contained in this document, neither The 61508 Association nor any of its members will assume liability for any use made thereof.