Summary

As of 18th September 2016, Directive 2014/90/EU shall come into force and as a result Council Directive 96/98/EC will be repealed. ABS Europe Ltd have prepared the following information as a guide to assist MED clients assess the impact on current certification and future applications.
Certificate Validity through the transition period

Existing certificates issued under the Marine Equipment Directive 96/98/EC as amended will remain valid until either:

1. They reach their expiry date;
2. The conditions of the certificate’s validity are breached; or
3. Marine equipment meeting the specified standards within the existing certification is no longer accepted for being placed on board an EU ship in accordance with the “new implementation regulations”

Changes to note for manufacturers

Annex A.1

The current Annex A.1 that details the regulations and testing standards applicable to marine equipment within the scope of the MED shall be replaced by a set of new implementation acts.

The aforementioned implementation acts are yet to be published in the official European Journal and therefore are yet to be applied. Until the new implementation acts are published Directive amendment (EU) 559/2015 Annex A.1 shall be applied.

Notable amendments as a result of the new implementation acts

- For equipment currently listed in Annex A.1, the implementing acts will indicate the dates from which the requirements and testing standards are to apply via a “first date for placing on the market” column.
- For equipment currently listed in Annex A.1, the implementing acts will indicate the dates from which the outgoing requirements and testing standards are no longer applicable via a “last date for placing on-board” column.
- Annex A.2 shall be removed from the scope of the Directive and controlled at national level. The UK MCA have published MSN 1874 (M+F) which includes the national requirements for equipment previously within the scope of Annex A.2.
Authorised Representative

Directive 2014/90/EU Article 13 reinforces the previous requirement for an authorised representative. As of 18th September 2016 all manufacturers located outside of the EU are required to appoint an authorised representative to market the approved equipment. The details of the selected authorised representative shall be forwarded to ABS Europe Ltd.

The selection of an authorised representative is the responsibility of the manufacturer. The Authorised representative shall be a natural person or legal entity within an EU territory. As part of the module B or G application, contact details of the authorised representative shall be provided to ABS Europe Ltd. The mandate required by 2014/90/EU Article 13 shall be reviewed as part of the production conformity phase to verify that the written mandate meets the requirements of Directive.

The key task of the authorised representative’s appointment is to ensure the cooperation with competent national authorities based in EU. However, if an EU based manufacturer fulfils his obligations according to Article 12, then there is no need to appoint an authorised representative.

Adequate Analysis and Assessment of the risk(s)

Directive 2014/90/EU Annex II, Part I Module B: EC Type-Examination, point 3, third indent and Part V Module G: EC Unit Verification, point 2 requires that technical documentation, which is part of the application, shall also include “an adequate analysis and assessment of the risk(s)”.  

ABS Europe Ltd interpretation of the requirement for “an adequate analysis and assessment of the risk(s)” requires an assessment of risk against the equipment’s intended use. The manufacturer shall consider whether a combination of the type, production and installation testing adequately addresses the associated risk(s) for the approved equipment. In addition, the manufacturers shall consider whether any additional risk(s) as a result of the intended use or design require further mitigating measures.

Where a combination of the type, production and installation testing is considered by the manufacturer to fully address the risk(s) for the intended use of the equipment, the manufacturer may submit a declaration within the technical documentation. Where the assessment of risk(s) identifies additional risk(s), the manufacture shall provide details of the risk(s) and what measures have been taken to reduce the risk to an acceptable level.
Equipment Marking
Directive 2014/90/EU has introduced the provision for either 2 digit or 4 digit year reference on the mark of conformity. Both below examples are applicable.

Data Tagging
Directive 2014/90/EU has introduced the provision for electronic data tagging to complement the mark of conformity. The technology required to implement this system remains under development. Further details maybe given on request.

Changes to note for manufacturers, shipyards and owners

Declaration of conformity
The requirements and obligations of the manufacturer in relation to the declarations of conformity (DoC) have changed. The following now applies to the control and formatting of the DoC;

• State fulfilment with the requirements provided in the Directive 2014/90/EU and either Annex A.1 of (EU) 559/2015 or the new implementing acts (as applicable at the time of issue);
• Detail the approved conformity route as provided in Directive 2014/90/EU;
• Follow the model format as detailed in Annex III of the Decision 768/2008/EC;
• Be kept up to date;
• Be provided to the ship or end user. The DoC is to be kept on board until the equipment is removed;
• The DoC is to be translated by the manufacturer into language(s) required by the flag Member State;

If there any questions in relation to compliance with the MED, please contact the MED team via the following Email address - ABS-MED@eagle.org