Comparison table between COUNCIL DIRECTIVE 96/98/EC on marine equipment (current MED) and DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on marine equipment and repealing Council Directive 96/98/EC (new MED) regarding changes of the requirements to Modules D and E

	COUNCIL DIRECTIVE 96/98/EC on marine equipment	DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on marine equipment and repealing Council Directive 96/98/EC	
Comments	PRODUCTION-QUALITY ASSURANCE (MODULE D)	II. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS	Comments
	1. A manufacturer who satisfies the obligations of point 2 must ensure and declare that the products concerned conform to type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.	1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EC type- examination certificate and that it satisfies the requirements of the international instruments that apply to it.	See also 5.1 and 5.2
	2. The manufacturer must operate an approved quality system for production, final-product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.	2. Manufacturing The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.	
	3. Quality system	3. Quality system	
	3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice for the products concerned. The application must include:	3.1. The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned. The application shall include: — the name and address of the manufacturer and, if the	

		application is lodged by the authorised representative, its name and address as well; — a written declaration that the same application has not been lodged with any other notified body;	
	— all relevant information for the product category envisaged, — the documentation concerning the quality system, — the technical documentation of the approved type and a copy of the EC type-examination certificate.	— all relevant information for the marine equipment category envisaged; — the documentation concerning the quality system; — the technical documentation of the approved type and a copy of the EC type-examination certificate.	
	3.2. The quality system must ensure that the products conform to type as described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality-system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records. It must, in particular, include an adequate description of: — the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,	3.2. The quality system shall ensure that the products are in conformity with the type described in the EC type- examination certificate and that they comply with the requirements of the international instruments that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;	

	— the manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used, — the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, — the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc., — the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; — the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and — the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	
	3.3. The notified body must assess the quality system to determine whether it satisfies the requirements laid down in point 3.2. It must presume compliance with those requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team must have at least one member with experience of assessment in the product technology concerned. The assessment procedure must include a visit to the manufacturer's premises.	3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer’s premises. The auditing team shall review the technical documentation referred to in the fifth indent of point 3.1 in order to verify the manufacturer’s ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.	

	The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.	The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.	
	3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.	3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient	
	The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality system. The notified body must assess the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required. The manufacturer must be notified of its decision. The notification must include the conclusions of the examination and the reasoned assessment decision.	3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	
	4. Surveillance under the responsibility of the notified body	4. Surveillance under the responsibility of the notified body	
	4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	
	4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:	4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:	

	— the quality-system documentation, — the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	— the quality system documentation; — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.	
	4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with audit reports.	4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system, and shall provide the manufacturer with an audit report.	
	4.4. In addition, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or cause tests to be carried out to check that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.	4.4. In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	
		5. Conformity marking and declaration of conformity	
This is extract from para 1	*The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.*	5.1. The manufacturer shall affix the wheel mark referred to in Article 9, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC type-examination certificate and that satisfies the applicable requirements of the international instruments.	Information about the wheelmark (See also para 1 of the 96/98/EC)
This is extract from para 1	*The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.*	5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned. The declaration of conformity shall identify the marine equipment model for which it has been drawn up.	Information about the DoC (See also para 1 of the 96/98/EC)

		A copy of the declaration of conformity shall be made available to the relevant authorities upon request.	
	5. The manufacturer must, for at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities: — the documentation referred to in the second indent of the second paragraph of point 3.1, — the updating referred to in the second paragraph of point 3.4, — the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.	6. The manufacturer shall keep at the disposal of the competent authorities, for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned: — the documentation referred to in point 3.1; — the change referred to in point 3.5, as approved; — the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.	
	6. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.	7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.	
		8. Authorised representative The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.	
	PRODUCT-QUALITY ASSURANCE (MODULE E)	III. MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT	

		QUALITY ASSURANCE	
	1. A manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned conform to type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.	1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EC type-examination certificate and that it satisfies the requirements of the international instruments that apply to it.	
	2. The manufacturer must operate an approved quality system for final inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.	2. Manufacturing The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.	
	3. Quality system	3. Quality system	
	3.1. The manufacturer must lodge an application for assessment of his quality system for the products concerned with a notified body of his choice. The application must include: — all relevant information for the product category envisaged,	3.1. The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned. The application shall include: — the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well; — a written declaration that the same application has not been lodged with any other notified body; — all relevant information for the marine equipment category envisaged;	

	— documentation concerning the quality system, — the technical documentation of the approved type and a copy of the EC type-examination certificate.	— the documentation concerning the quality system; and — the technical documentation of the approved type and a copy of the EC type-examination certificate.	
	3.2. Under the quality system, each product must be examined and appropriate tests must be carried out in order to ensure its compliance with the relevant requirements of the international instruments. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality-system documentation must ensure common understanding of the quality programmes, plans, manuals and records. It must, in particular, include an adequate description of: — the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality, — the examinations and tests that will be carried out after manufacture, — the means of monitoring the effective operation of the quality system, — the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	3.2. The quality system shall ensure compliance of the products with the type described in the EC type-examination certificate and with the applicable requirements of the international instruments. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality; — the examinations and tests that will be carried out after manufacture; — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; — the means of monitoring the effective operation of the quality system.	

	3.3 The notified body must assess the quality system to determine whether it satisfies the requirements laid down in point 3.2. It must presume compliance with the requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team must have at least one member with experience as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises. The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.	3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in the fifth indent of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.	
	3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it in an appropriate and efficient manner.	3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	
	The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality	3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	

	system. The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required. The manufacturer must be notified of its decisions. The notification must include the conclusions of the examination and the reasoned assessment decision.	The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	
	4. Surveillance under the responsibility of the notified body	4. Surveillance under the responsibility of the notified body	
	4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	
	4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and must provide it with all necessary information, in particular: — the quality-system documentation, — the technical documentation, — the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc	4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular: — the quality system documentation; — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.	
	4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with audit reports.	4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system, and shall provide the manufacturer with an audit report.	
	4.4. In addition, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or cause tests to be carried out	4.4. In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During	

	to check that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.	such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	
		5. Conformity marking and declaration of conformity	
This an extract from para 1	*The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.*	5.1. The manufacturer shall affix the wheel mark referred to in Article 9, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC type-examination certificate and that satisfies the applicable requirements of the international instruments.	Information about the wheelmark (See also para 1 of the 96/98/EC)
This an extract from para 1	*The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.*	5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned. The declaration of conformity shall identify the marine equipment model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the relevant authorities upon request.	Information about the wheelmark (See also para 1 of the 96/98/EC)
	5. The manufacturer must, for at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities: — the documentation referred to in the third indent of the second paragraph of point 3.1, — the updating referred to in the second paragraph of point 3.4,	6. The manufacturer shall keep at the disposal of the competent authorities, for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned: — the documentation referred to in point 3.1; — the change referred to in point 3.5, as approved;	

	— the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.	— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.	
	6. Each notified body must on request provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.	7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.	
		8. Authorised representative The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.	