Production quality systems, Product quality systems and Product verification for Marine Communication, Navigation, Fire protection and lifesaving Equipment

RD_041, Issue 22

This document describes in detail the procedures and requirements regarding Production quality systems, Product quality systems and Product verification as applicable under the Marine Equipment Directive 2014/90/EU.

Contents

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet

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1 Introduction

1.1 About Kiwa

Kiwa Nederland B.V. is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited Kiwa to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Kiwa is available in *RD_063, About Kiwa.*

1.2 About this document

This document lays down the procedures for the Economic operators (manufacturers, authorized representatives, importers and distributors) who want to apply for the services of Kiwa in order to place and making available of their marine communication, navigation, fire protection or lifesaving equipment on the market of the European Union. This with a view to place the equipment on board an EU ship.

It describes in detail the conformity assessment procedures regarding quality systems and those related to product verification. This document is supplementary to RD_040: *Conformity Assessment procedures for Marine Communication, Navigation, Fire protection and lifesaving equipment.*

These conformity assessment procedures are derived from the European Marine Equipment Directive (MED) 2014/90/EU.

2 Kiwa quality system assessment approach

The requirements for Production and Product quality systems, as laid down in this document, are derived from the Marine Equipment Directive 2014/90/EU. These quality system requirements are in principle based on the ISO standard 9001:2015 will be used as criteria. Some requirements imposed by the Directive are however not covered by ISO 9001, as visualised by the figure below.

Directive 2014/90/EU (1)	Module E (2)	Module D (3)

Legend: Part (1):Directive specific, non ISO9001:2015, quality system requirements.
Part (2):Directive quality system requirements where included some elements of ISO 9001:2015 criteria [Module E].
Part (3):Directive quality system requirements where included more elements of ISO 9001:2015 criteria [Module D]

Figure 1: Relationship between the Directive and ISO 9001:2015 requirements.

Kiwa performs an examination of the quality system of the manufacturer to verify compliance with the requirements of the Directive. This examination takes account of existing certificates, when available and acceptable. For remaining requirements an assessment program is arranged.

A *Production quality assurance certificate* or a *Product quality assurance certificate* will be issued when Kiwa has found that the quality system meets the requirements as laid down in Annex II of the MED directive.

Certified quality systems shall periodically (at least annually) be inspected to verify continuous compliance with the provisions of the Directive. Therefore Kiwa schedules an examination of surveillance audit results. If available the results of regularly performed follow-up audits under an existing quality system certificate are used (which should be made available by the manufacturer).

3 Application and ordering for quality system certification

By submitting the form: *Questionnaire for quality system approval* (RF_300) the applicant provides Kiwa with some basic information of his quality system. With this information the activities needed for assessment and certification of the quality system are determined and a quotation is prepared. If needs be, Kiwa will contact the applicant to request for further information.
This enquiry is without any obligation: detailed planning and assessments will begin after the applicant has accepted the quotation and returned the signed quotation to Kiwa.

Application for quality system certification is open to manufacturers or their authorized representatives. Such authorization must be shown by a written statement of the manufacturer indicating the scope of authorization.

The application shall include a written declaration that the same application has not been lodged with any other notified body.

4 Examination of quality systems

4.1 The examination program

After confirmation, an examination program will be made by Kiwa, detailing the activities necessary to determine whether the quality system of the manufacturer meets the requirements of the Directive. This program includes the verification of existing certificates (if available), a schedule and planning for additional assessments (if necessary) and the verification of the results by Kiwa. Kiwa will plan the assessments in consultation with the manufacturer.

4.2 Documentation examination and assessment

Following the examination program Kiwa will perform a document examination. In case of comments the manufacturer will be informed of determined non-compliances. During the audit MED questionnaire will be used (where included the auditplan and questionnaire). In case a non-conformity is found it will be drafted on a non-conformity report form. During the closing meeting non conformity reports will be read out and must be signed off by the company representative in case of acceptance. During the closing meeting findings will be communicated. In the assessment form a report summary will be reported including recommendations for certification. In case non-conformities are raised date of submission of the corrective/preventive action must be agreed. This document must also be signed off by the company representative. In the case of non-conformities , the client must indicate the cause, the extent of the non-conformity, solution and the result of the operational review.

After the audit has taken place Kiwa will issue an audit report. In case NCR(s) are drafted the corrective/preventive actions will be reviewed. If non-conformities still exist, re-assessments may be scheduled. The examination is closed when it is determined that the quality system meets all the requirements or when the applicant terminates the process without positive result.

All required data, including certificates and audit reports shall be made available by the applicant. Kiwa reserves the right to arrange additional assessments until full compliance with the MED has been determined.

5 Assessment of the production quality system

This chapter lays down all requirements quality systems have to comply with in order to gain approval by Kiwa. The quality system shall ensure that the products are in conformity with the type described in the EC type-examination certificate and 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 policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans manuals and records.
In section 5.1 the requirements regarding production quality systems and in section 5.2 the requirements for product quality systems are given.

5.1 Conformity to type based on quality assurance of the production process **(Module D)**

Annex II, article II, item 2 of Module D Directive 2014/90/EU.
The manufacturer shall operate an approved quality system for final product inspection and testing of the products. The quality system shall ensure compliance of the products with the type described in the EC type–examination certificate and that they apply with the applicable 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.

Production quality systems have to comply with all requirements of ISO 9001:2015 standard with exception of the following sections:

- 8.3.x Design and development;
- 8.2.3 Review of requirements related to the product;
- 8.5.3 Customer property;
- 9.1.2 Customer satisfaction .

The Directive specifically interprets some of the remaining ISO9001:2015 requirements. There are also some requirements that are not included in ISO9001:2015. These differences, sometimes indicated as supplementary requirements, are described in the following subsections. Where possible, reference is made to the corresponding ISO9001:2015 clauses.

In scheme plan of Kiwa are e.g. the related documents defined to conduct the Module D audits.

5.1.1 Quality management system (ISO 9001:2015: clause 4.4.1 & 4.4.2)

Annex II, article II, item: 3 of Module D Directive 2014/90/EU.
A quality scheme or equivalent documentation shall be available for each product or family of products. This scheme shall describe all relevant quality checks and inspections to ensure compliance with the relevant standards, regulations and requirements of the international instruments and conventions.

The quality system shall include written procedures with regard to:
- application for approval on the basis of an EC type-examination;
- drafting and signing of Declarations of Conformity;
- marine marking of approved products;
- communication with Kiwa;

Annex II, article II, item: 3 of Module D Directive 2014/90/EU.
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 shall keep Kiwa informed of any intended change to the quality system. Kiwa shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements as defined in this document 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.

Kiwa will take particular care to respect confidentiality and to give a prompt response to issues of a commercially sensitive nature.

Kiwa 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 Kiwa may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. Kiwa shall provide the manufacturer with a visit report and, if test have been carried out, with a test report.

The quality scheme or equivalent documentation shall be available in a language readily understood in the local working environment and in a language acceptable by Kiwa (for example: Dutch or English).

Kiwa 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.

5.1.2 Management responsibility (ISO 9001:2015: clause 5)

Annex II, article II, item: 3.2 of Module D Directive 2014/90/EU.
E.g. review of the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.

5.1.3 Data control / product identification and traceability (ISO 9001:2015: clause 7.5 and 8.5.2)

Annex II, article II, item 3.2 of Module D Directive 2014/90/EU.
E.g. All documents and data relating to production of terminal equipment must be traceable to the build status of the equipment as confirmed by the EC type-examination certificate and its annexes.
The quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned etc. The following records shall be kept for at least 10 years after the last product has been placed on the market:
- technical documentation of the approved type and a copy of the EC type-examination;
- the quality manual and quality schemes or equivalent documentation including design input and verification data;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;

- details of any amendments to the quality system documentation together with the notification of agreement from Kiwa where required;
- reports from Kiwa on all routine surveillance visits and unannounced visits, and any product tests arising from such visits.

5.1.4 Control of documents / records (ISO 9001:2015: clause 4.4.2 & 7.5.3)

Annex II, article II, item 3.2 of Module D Directive 2014/90/EU.
E.g. control of quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned etc.

5.1.5 Inspection and Testing (ISO 9001:2015: clause 8.1, 8.5, 8.6, 8.7 and 9.1.3)

Annex II, article II, item: 3.2 of Module D Directive 2014/90/EU.
Contain adequate description of manufacturing quality control and quality assurance techniques, processes and systematic actions that will be used.
E.g. the means of monitoring the achievement of the required product quality and the effective operation of the quality system. The examinations and test that will be carried out before, during and after manufacture, and the frequency with they will be carried out. The results of verifications, demonstrating that the mentioned facilities comply with the requirements (including e.g. measurement uncertainty), shall be recorded as part of the technical documentation file.

5.1.6 Internal Quality Audits & Management review (ISO 9001:2015: clause 9.2 & 9.3)

The effective implementation of the quality system, including the requirements of this document, shall be verified at least annually by means of internal audits. The audit results and follow up actions shall be formally documented and made available to Kiwa on request. The organisation's quality management system shall be reviewed at planned intervals.

5.1.7 Resources (ISO 9001:2015: clause 7.2)

The organisation shall determine the necessary competences as well that these persons are competent on the basis of the appropriate education, training or experience. Appropriate documentation to be in place as evidence of competence.

5.2 Conformity to type based on product quality assurance (**Module E**)

Annex II, article III, item 1 & 2 of Module E Directive 2014/90/EU.
The manufacturer shall operate an approved quality system for final product inspection and testing of the products. 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 quality programmes, plans manuals and records.

5.2.1 Management responsibility (ISO 9001:2015: clause 5)

Annex II, article III, item 3.2 of Module E Directive 2014/90/EU.

E.g. review of the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.

5.2.2 Inspection and testing (ISO 9001:2015: clause 8.1, 8.5.1, 9.9.1 and 8.6)

Annex II, article III, item 3.2 of Module E Directive 2014/90/EU
The manufacturer shall carry out final inspection and testing to each and every product to which the marine marking is to be applied to ensure that it has been manufactured in accordance with the EC type-examination certificate, its appendices and additions. These final inspections and testing shall be in accordance with the quality plan and documented procedures.

The manufacturer shall perform testing as follows:

1) *On all items bearing the marine marking*

   a) tests to ensure the product's safety;
   b) tests regarding spurious emissions of the transmitter (if applicable) including a functional test to confirm the basic operation of the product.

   Products that fail these tests are not allowed to be marketed.

   Where products are not fully assembled prior to dispatch, equivalent test shall be performed on the subassemblies or partly assembled products.

2) *Twice each year a full test shall be performed by the manufacturer or by an accredited laboratory on his behalf, to ensure that the products being produced still comply with the requirements of the Directives.*

   a) the tests shall be based on the requirements of the relevant test standards but shall not necessarily be the exact tests, which may not be suitable for the manufacturing environment;
   b) the tests shall be designed to cover, in particular, key points and parameters likely to be affected by variations in the manufacturing process.

The test results shall be documented and be available to Kiwa during any audit. The manufacturer shall inform Kiwa at once if a consistent non-compliance are determined.

5.2.3 Control of documents / records (ISO 9001:2015: clause 7.5)

Annex II, article III, item 3.2 & 4.2 of Module E Directive 2014/90/EU.
E.g. control of quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned etc.

5.2.4 Quality management system (ISO 9001:2015: clause 4.4)

Annex II, article IV, item 3.2 of Module E Directive 2014/90/EU.
E.g. the means of monitoring the effective operation of the quality system.

5.3 Conformity to type based on product verification (**Module F**)

Annex II, article IV, item 1 & 2 of Module F Directive 2014/90/EU
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the

EC type-examination certificate and with the requirements of the international instruments that apply to them.

Annex II, article IV, item 3 of Module F Directive 2014/90/EU
The Product verification procedure knows two forms. Testing of each individual product that is produced, or testing and applying statistical methods on batches of products produced. In either case, the manufacturer has to conclude a contract with Kiwa to ensure that the product verification is conducted in a consistent and acceptable manner. This chapter describes in more detail how this procedure should be implemented and what the conditions are.

5.3.1 Testing by the manufacturer

Following this procedure can be interesting when equipment is produced in small numbers or when the product is produced in irregular intervals.

Annex II, article IV, item 2 & 3 of Module F Directive 2014/90/EU.

This procedure implies that the manufacturer shall verify each product by a series of tests. These tests not necessarily need to include all tests that were carried out during the EC type-examination. What actual tests will have to be carried out will depend on the nature of the particular product, the potential risks involved and the test standards that are applicable to the product. In all cases the manufacturer has to lay down in a written procedure what tests he is going to perform on its finalised products. This testing scheme must be forwarded to Kiwa for endorsement. Kiwa will endorse or reject the proposed scheme, and inform the manufacturer accordingly. In case of rejection, Kiwa will also indicate what changes need to be made before it can be accepted.

In order to carry out the applicable tests under this procedure the manufacturer has two optional routes available.

5.3.2 Verification by testing at an accredited laboratory

In this case the test are carried out by an (third party) accredited laboratory. The accredited laboratory must be capable in carrying out all the tests as laid down in the testing scheme as approved by Kiwa. Kiwa will verify the accreditation status of the laboratory including its scope of testing capabilities and competence. When the information provided is to the satisfaction of Kiwa, the manufacturer will be send a contract stating the conditions and validity using the particular laboratory under this procedure including the obligations that lay upon the manufacturer.

The manufacturer has to forward the test results for each individual product to Kiwa for assessment. Kiwa will issue the manufacturer a certificate of conformity indicating that the test results were accepted and that the product may be marketed.

5.3.3 Verification by testing by the manufacturer (ISO 9001:2015: clause 8.1 and 8.5.1)

Annex II, article IV, item 3 & 4 of Module F Directive 2014/90/EU.
The possibility exists for the manufacturer to carry out the verification test himself. In such case Kiwa will verify the testing capabilities of the manufacturer and the testing and handling procedures that the manufacturer has put in place by means of an audit. In this case an overall quality system for final inspection and testing is not required, however certain quality aspects must be observed in line with ISO9001:2015 requirements clause 8.1 and 8.5.1.

When the audit results are to the satisfaction of Kiwa, the manufacturer will be send a contract stating the conditions and validity for testing by using its own testing facilities, including the obligations that lay upon the manufacturer.

The manufacturer has to forward the test results for each individual product or batch to Kiwa for assessment. Kiwa will issue the manufacturer a certificate of conformity indicating that the test results were accepted and that the product may be marketed.

During the audit Kiwa will check the following aspects in particular.
Product identification and traceability
All product related documents regarding shall be recorded and under control. This includes the documents under the EC type-examination, the Declaration of conformity and the test data obtained during final testing.

All products to which the marine marking is affixed shall be traceable by means of batch and/or serial numbers.

Inspection and testing

Written procedures must be in place regarding the tests the manufacturer is going to perform on its finalised products. The testing schemes require endorsement by Kiwa.

Control of inspection, measuring and test equipment

The manufacturer shall have a written procedure to control, calibrate and maintain final inspection, and have calibrated test equipment to demonstrate compliance.

Training and technical know how

Personal involved in the final testing and inspection shall have appropriate training and understanding about the test standards and the applicable requirements of the international instruments and conventions.

Communication with Kiwa

Kiwa shall be notified of all amendments to the testing scheme used by the manufacturer. Changes in testing schemes as well as new schemes shall be endorsed by Kiwa before they are implemented.

5.3.4 Verification by testing and application of statistical methods

Following this procedure can be interesting when equipment is produced in (small) batches. Production in batches is a condition for following this procedure.

Annex II, article IV, item 5 of Module F Directive 2014/90/EU
When products are produced in batches this procedure might be an interesting option. The method applied is verification by means of applying statistics. Effectively it means that a number of samples must be taken from each batch produced. Each of these samples will be tested according to a defined testing scheme. The final test results are evaluated by applying an objective statistical method.

The Marine Equipment Directive does not define what statistical method should be applied. Therefore there are various options. In the sections given below some examples are given as illustration.

5.3.5 Non-central T distribution

In cases where the actual measured value is known, the non-central T distribution[1] may be applied. The measurements shall be performed on an a-priori defined sample size. In those cases where the condition below is not satisfied, additional samples may be taken.

The following condition must be fulfilled:

$$\overline{X} \pm kS_n \leq L$$

$$\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

$$S_n^2 = \frac{\sum_{i=1}^{n}(X_i - \overline{X})^2}{n - 1}$$

Meaning of the symbols:

$\overline{X}$ = mean value of the interference level of the sample with size *n* of the items to be tested; $\overline{X}$ is known;
S_n = standard deviation of the sample with size *n* of the items to be tested; S_n is known;
X_i = measured value of the individual items; X_i is known;
k = constant to be determined in such a way that the above stated rule is satisfied; k is given in table 1;
L = the permitted limit; L is an upper limit;

Table 1: *The non-central T distribution factor k as a function of the sample size n*

n	3	4	5	6	7	8	9	10	11	12
k	2.04	1.69	1.52	1.42	1.35	1.30	1.27	1.24	1.21	1.20

A more detailed description can be found in: CISPR 16-4-3. Test based on the non-central t-distribution

5.3.6 Binomial distribution

In cases where the measured value is not known and determination of compliance is based on pass and fail criteria, the binomial distribution could be applied.

Binomial statistics can be applied using a number of different sampling plans. The selection of a suitable plan can depend on a number of different variables.

All results, on a single item, should be taken together to give an overall PASS/FAIL result per item.

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1 For general information, see CISPR 16-4-3 edition 2.0 : "Sampling procedures for inspection by attributes "

A detailed description of the sampling procedure is given in:
ISO 2859-1:2003: *Sampling procedures for inspection by attributes, Part 1, Sampling plans indexed by acceptable quality level ISO-2859 (AQL) for lot-by-lot inspection.*

5.4 Product verification (**Module G**)

Annex II, article V, item1 of Module G Directive 2014/90/EU
Unit verification is applicable in case equipment is produced individually or in extreme low volumes. This type of verification can also be used for prototypes of newly developed equipment for which series production is not visible yet. In this case each individual manufactured product must be assessed to ensure the compliance with the relevant requirements of the international instruments, no production (phase) requirements are applicable.

5.5 Technical documentation

Annex II, article V, item 2 of Module G Directive 2014/90/EU.
The manufacturer shall draw up the technical documentation and make it available to the notified body. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and shall cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the product;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with this Directive, together with a description of the solutions adopted to meet those requirements;
- results of design calculations made, examinations carried out; and
- test reports.

5.6 Manufacturing

Annex II, article V, item 3 of Module G Directive 2014/90/EU
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the international instruments.

6 Subcontracting (ISO 9001:2015: clause 8.4.x)

If subcontracted manufacturing is an issue then the requirements of ISO9001:2015 clause 8.4 are compulsory.

Subcontracted aspects and details of activities related to subcontracting shall be part of the manufacturer's documented quality system, including the procedures for overall control over subcontracted activities. Records demonstrating that this control is performed adequately should be available.

Subcontractors must be easily identifiable. Subcontracted work must be clearly specified by the manufacturer and carried out under a documented contract. This contract must especially enable Kiwa to perform assessments directly to the subcontractor's premises when deemed necessary.

Subcontracting must not entail the delegation of judgemental powers or responsibilities. In all cases the manufacturer has the responsibility that products comply with the essential requirements and remains fully liable.

7 Regulatory Marking and Labelling

Prior to packing it must be verified that the marking applied is the correct marking, applicable to that particular product.

Marine equipment the compliance of which with the requirements laid down in the MED has been demonstrated in accordance with the relevant conformity assessment procedures shall have the wheel mark affixed to it. More information about affixing the Wheel mark can be found in RD_104 “the affixing of marine markings”.

The marine marking in respect of the Directive shall be applied only to equipment which have been manufactured under control of the approved quality system and for which a valid Declaration of conformity to type exists (see section *Declarations of conformity to type*).

8 Declarations of conformity to type

Item 5.2 of Annex II, article II,III,IV of Module D/E/G and item 6.2 of Annex II, article V Module F Directive 2014/90/EU.
The procedure for drafting and signing of Declarations of conformity to type shall be applicable for all products that are produced under the certified Production quality assurance system. The procedure shall ensure that the Declaration of conformity is not completed before the provisions, tests and inspections included in the quality scheme are proven to be satisfactory for making products in full compliance with the applicable requirements, in conformity to the type for which an EC type-examination certificate was obtained. The authority for decision and for signing the Declaration of conformity to type shall be explicitly assigned in the manufacturers quality system.

The same authority to determine their effect on compliance to the applicable requirements shall examine all modifications to the certified product type. The considerations, which lead to the decision that the current EC type-examination certificate stays valid, shall be recorded as part of the technical documentation file.

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.

Declarations of conformity to type shall comply with the 768/2008/EC attachment III EC- Conformity Declaration. The declarations shall include references to the number of the *Production Quality System Certificate* issued by Kiwa and to the relevant requirements of the international instruments and conventions and test standards. A model of the Declaration of conformity to type can be found in RD_040 and in this document additional details are also shown in section 4.5.1

9 Record of complaints

The certificate holder (manufacturer, authorized representative or importer) shall keep a record of all complaints and remedial actions relative to the products covered by any certificate granted by

Kiwa and to make these records available to the certification body when requested. This record shall be part of the technical file. See also chapter 'The Technical File'.

In case such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification, appropriate action should be taken. The certificate holder should document the actions.

10 Communication with Kiwa

Kiwa shall be informed prior to any major amendment to the quality system of which the manufacturer may surmise that they will affect the approval of the Production quality system.
Examples of major amendments are:

- new production locations;
- production development or type testing locations;
- organisation or management structure;
- basics of subcontracting;
- basics of testing;
- authority or criteria for signing Declarations of conformity to type.

The quality system shall incorporate the duties for establishing needs for informing Kiwa and the responsibilities for communication with Kiwa.
Pending on the changes, Kiwa may impose an additional audit.

11 Quality system certification

11.1 The contract between the manufacturer and Kiwa

Upon establishing compliance with the Directive requirements, Kiwa will send a contract to the manufacturer. Contracts are valid without predefined time-limit, until:

- replaced by another contract between the same contracting partners, or;
- cancelled by one of the contracting partners.

After cancellation is announced the contract will terminate at the end of the second month following the date that the written announcement has been sent or received by Kiwa, unless otherwise agreed.

11.2 Application for modification

Modifications (e.g. adjustment of product groups or production/design locations) are handled as an addition to the original application. The manufacturer or his European representative may request for approval of such a modification, form RF_300 must be completed.

Kiwa performs an additional examination, only when an additional assessment is required. The need for this will depend on the nature of modification(s) and the existing experience from previously performed surveillance audits. Upon successful completion of the examination, the contract and the certificate will be updated.

11.3 Surveillance audits

The purpose of the surveillance is to take sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. The manufacturer shall, for assessment purposes, allow Kiwa 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 records and test data, calibration data, qualification reports on the personnel concerned etc.
At least annually, the quality system is subject to a re-examination. Kiwa will plan an audit at the manufacturer's facilities. Kiwa verifies audit results and corrective actions are requested if necessary. Kiwa may schedule extra surveillance audits if deemed to be necessary.

12 Report of granted approvals/certifications

In RQ_940 is incorporated the process of informing the relevant Authority regarding certificates and approvals granted by Certification.

13 Conditions and fees

The *General conditions of* Kiwa are applicable for all services of Kiwa.

Kiwa will charge fees for audits. These fees may be broken down into several categories. Costs are usually retrospective (based on fixed hourly rates), plus travel and accommodation expenses and where applicable the fees charged for technical experts.

An estimation of the fees will be included in the quotation for quality system approval upon request.

Clients may be required to make an advance payment to cover expenses to be incurred.

14 Annex A Additional information

For more information contact:

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