SCHEDULE 5 Regulation 9(1)

(ANNEX V TO THE CABLEWAY INSTALLATIONS DIRECTIVE)

SAFETY COMPONENTS : ASSESSMENT OF CONFORMITY

1. Scope

This Annex applies to safety components with a view to checking compliance with the essential requirements referred to in Article 3(1) of this Directive and defined in Annex II. It concerns the assessment by one or more notified bodies of the intrinsic conformity of a component, considered in isolation, with the prescribed technical specifications.

2. Procedures

The assessment procedures implemented by the notified bodies both at the design and production stage are based on the modules defined in Council Decision 93/465/EEC along the lines indicated in the following table. The solutions in this table are considered to be equivalent and can be used at the manufacturer's discretion.

ASSESSMENT OF THE CONFORMITY OF SAFETY COMPONENTS

Design	*Production*
1. EC type-examination Module "B"	**1(a).** Production quality assurance Module "D"
	1(b). Product verification Module "F"
2. Full quality assurance Module "H"	**2.** Full quality assurance Module "H"
3. Unit verification Module "G"	**3.** Unit verification Module "G"

Modules must be applied taking into account the specific supplementary conditions in each module.

MODULE B: EC TYPE-EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of this Directive.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community with a notified body of his choice.

The application must include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— the technical documentation, as described in point 3.

The applicant must place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called "type". The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation must enable the conformity of the component with the requirements of this Directive to be assessed. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the component.

The documentation must contain as far as is relevant to assessment:

— a general type-description,

— conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the product,

— the list of the European specifications referred to in Article 2(2) of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the European specifications referred to in Article 2(2) of this Directive do not exist,

— the results of design calculations made, examinations carried out, etc.,

— test reports.

It must also indicate the field of use of the component.

4. The notified body:

4.1. must examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the European specifications referred to in Article 2(2) of this Directive as well as those which have been designed without applying the relevant provisions of those European specifications;

4.2. must perform or have performed the appropriate examinations and necessary tests to check whether, where the European specifications referred to in Article 2(2) of this Directive have not been applied, the solutions adopted by the manufacturer meet the essential requirements of this Directive;

4.3. must perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant European specifications, these have actually been applied;

4.4. must agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the provisions of this Directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must state the name and address of the manufacturer, the conclusions of the examination, the conditions for its validity, the duration thereof and give the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body. If the notified body refuses to issue an EC-type certificate to the manufacturer, the former must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications of the approved component which must receive additional approval where such changes may affect the conformity of the component with the essential requirements for the prescribed conditions for its use. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 30 years after the last component has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the component on the Community market.

MODULE D: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the components concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to each component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for monitoring as specified in point 4.

2. The manufacturer must operate an approved quality system for production, final component inspection and testing as specified in point 3, and is subject to monitoring as specified in section 4.

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 components concerned.

The application must include:

— all relevant information for the component category envisaged,

— the documentation concerning the quality system,

— if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. The quality system must ensure compliance with the type as described in the EC type-examination certificate and with the requirements of this Directive.

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, plans, manuals and records.

It must in particular contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to competent 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 to monitor the achievement of the required component 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 referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonised standards.

The auditing team must have at least one member with experience of evaluating in the component technology concerned. The evaluation procedure must include an inspection visit to the manufacturer’s premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner at a proper and efficient level.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

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.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the places of manufacture, inspection and testing, and storage, and must 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.

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 an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out or cause to be carried out, tests to verify 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, a test report.

5. The manufacturer must, for period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning all quality system approvals issued and withdrawn.

MODULE F: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorised representative established within the Community checks and attests that the components subject to the provisions of point 3 are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of this Directive.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the components with the type as described in the EC type-examination certificate and with the requirements of this Directive. He shall affix the CE marking to each component and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the components to the requirements of this Directive either by examination and testing of every component as specified in point 4 or by examination and testing of components on a statistical basis, as specified in point 5, at the choice of the manufacturer.

The manufacturer or his authorised representative resident within the Community must keep a copy of the declaration of conformity for a period ending at least 30 years after the last component has been manufactured.

4. Verification by examination and testing of every component

4.1. All components must be individually examined and appropriate tests as set out in the relevant European specification(s) referred to in Article 2 or equivalent tests shall be carried out in order to verify their conformity with the type described in the EC type-examination certificate and to the requirements of this Directive.

4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved component and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

5. Statistical verification

5.1. The manufacturer must present his components in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All components must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot. Components in a sample must be individually examined and appropriate tests as set out in the European specification(s) referred to in Article 2(2) of this Directive, or equivalent tests, shall be carried out to ensure their conformity with the requirements of this Directive and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure must use the following elements:

— a statistical method,

— a sampling plan with its operational characteristics.

5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification number to each component, and shall draw up a written certificate of conformity relating to the tests carried out. All components in the lot may be put on the market, except those components from the sample which were found not to be in conformity.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent the putting on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

MODULE G: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the component concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a declaration of conformity.

2. The notified body must examine the component and must carry out the appropriate tests as set out in the relevant European specifications referred to in Article 2(2) of this Directive, or equivalent tests, to ensure its conformity with the relevant requirements of this Directive.

The notified body must affix, or cause to be affixed, its identification number on the approved component and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the component to be understood.

For the purposes of assessment, the documentation must include the following:

— a general description of the type,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the component,

— a list of the relevant European specifications applied in total or partially referred to in Article 2(2) of this Directive, as well as a description of the solutions adopted by the manufacturer to meet the essential requirements of the Directive, where the European specifications referred to in Article 2(2) have not been applied,

— the results of the design calculations made, examinations carried out, etc.,

— test reports,

— fields of use of components.

MODULE H: FULL QUALITY ASSURANCE

1. This module describes the procedure whereby a manufacturer who satisfies the obligations of paragraph 2 must ensure and declare that the components concerned satisfy the relevant requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for design, manufacture and final component inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— all relevant information for the category of component envisaged,

— the documentation relating to the quality system.

3.2. The quality system must ensure compliance of the components with the relevant requirements of this Directive.

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. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must in particular include an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and component quality,

— the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive, that will be applied and, where the European specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the components pertaining to the category of components covered,

— 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 of the personnel concerned, etc.,

— the means to monitor the achievement of the required design and component quality and the effective operation of the quality assurance system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

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.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the places of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of 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 shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

7. Supplementary requirements; design examination

7.1. The manufacturer must lodge an application for examination of the design with a single notified body.

7.2. The application must enable the design, manufacture and operation of the component to be understood, and shall enable conformity with the requirements of this Directive to be assessed.

It must include:

— the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive that have been applied,

— the necessary supporting evidence for their adequacy, in particular where the European specifications referred to in Article 2(2) of this Directive have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

7.3. The notified body must examine the application and where the design meets the provisions of this Directive, must issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the component's functioning.

7.4. The applicant must keep the notified body that issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect conformity to the essential requirements referred to in Article 3(1) of this Directive or the prescribed conditions for use of the component. This additional approval is given in the form of an addition to the original EC design examination certificate.

7.5. The notified bodies must forward to the other notified bodies the relevant information concerning:

— the EC design examination certificates and additions issued,

— the EC design approvals and additional approvals withdrawn,

— the EC design examination certificates and additions refused.