

The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (SI 2001/1701 as amended)

A Guide for Manufacturers to the Contents of Technical Documentation

First Edition

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This guide is intended to assist manufacturers of outdoor equipment to comply with the requirements for technical documentation in the Regulations. It is not an authoritative interpretation of the Regulations, which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations for technical documentation only and does not attempt to address all requirements of the Regulations. You should refer to the Regulations themselves (SI 2001/1701 as amended by S.I. 2001/3958) for a full statement of the requirements. Whilst every effort has been made to ensure that the information in this guide is accurate, the Department of Trade and Industry cannot accept liability for any errors, omissions or misleading statements in that information, whether caused by negligence or otherwise.

1. INTRODUCTION

The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (SI 2001/1701 as amended by S.I. 2001/3958) (the Regulations) implement in the UK the Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors (the Directive).

The Regulations implement the requirement in Annexes V to VIII to the Directive, that the equipment manufacturer or his authorised representative established in the Community must provide technical documentation. In the case of Schedule 8 (Internal control of production), the technical documentation must enable the conformity of the equipment to be assessed against the requirements of the Directive and must contain at least certain information. In the case of Schedule 9 (Internal control of production with assessment of technical documentation and periodical checking), Schedule 10 (Unit Verification) and Schedule 11 (Full quality assurance), certain information must be included in the technical documentation submitted in the application to the notified body for the relevant conformity assessment procedure to be effected.

In addition, manufacturers and their authorised representatives should note that their equipment may be subject to other Directives, for example, Machinery, Electromagnetic Compatibility, Low Voltage, etc., that may also require the production of technical files or documentation. The technical documentation referred to in this guide may be integrated into the overall technical documentation requirements of the equipment.

This guide provides three lists of items that should be considered for inclusion in technical documentation. The lists may not be exhaustive but they contain the basic elements that are required and can be considered as a guide to the production of technical documentation.

2. INITIAL CONSIDERATIONS

When assessing what items relating to noise emission measurements should be included in technical documentation, for the purposes of complying with the requirements of the Regulations/Directive, there are three areas that must be considered:

- conformity assessment requirements of the Regulations (contained in Schedules 8 to 11) which implement Annexes V to VIII of the Directive,
- quality requirements (for example EN ISO 17025, "General requirements for the competence of testing and calibration laboratories"), and
- standards requirements (for example the basic noise emission standard EN ISO 3744).

To some extent the requirements of these three areas tend to overlap even though they approach the technical documentation from three different aspects. In the UK, the Regulations provide the overall basic requirement and it is this that must be satisfied.

The quality requirements are primarily concerned with the production of written records, relating to the competence of procedures and their implementation, and to their retention. The standards requirement is to ensure that it can be demonstrated that measurement procedures have been followed and that environmental conditions conform to basic requirements.

It should also be noted that type-examination certificates issued and measurements of certain equipment under the previous noise emission legislation may be used in drawing up the technical documentation, provided that they fulfil the test methods in Schedule 6 of the Regulations (see regulation 7(5)).

Before compiling a list of items that need to be included in technical documentation, it is necessary to establish some terminology (for the purposes of this guide).

Equipment

the item (within the scope of the Regulations/Directive) which is under test and is produced by the equipment manufacturer.

Noise measurement testing equipment

all items (except the equipment defined above) that are used in the test.

Tester

the organisation performing the tests (this may be the equipment manufacturer).

3. RETENTION OF TECHNICAL DOCUMENTATION AND EC DECLARATION OF CONFORMITY

The Regulations/Directive require the manufacturer or his authorised representative to keep a specimen of the EC declaration of conformity for 10 years from the date on which the equipment was last manufactured, together with the technical documentation [see regulation 7(4)/Article 8(3)]. In addition, in the case of Unit Verification (Schedule 10/Annex VII), the manufacturer or his authorised representative must keep with the technical documentation copies of the certificate of conformity (issued by the notified body in the form described in Schedule 12/Annex X) for a period of 10 years from the date on which the equipment is placed on the market.

The requirements for the contents of the EC declaration of conformity (contained in Schedule 5 of the Regulations and Annex II of the Directive) are reproduced at Annex D to this guide with some additional comments by way of guidance for consideration. It should be noted that, when equipment is placed on the market or put into service, it must be accompanied by an EC declaration of conformity (which is a separate document from the EC Conformity Certificate required by Schedule 10/Annex VII as part of the Unit Verification conformity assessment procedure).

4. DTI PUBLICATIONS

The following DTI publications relating to the Regulations are available in Adobe Acrobat format from our website at http://www.dti.gov.uk/strd

- Noise emission in the environment by equipment for use outdoors: Guidance notes on the UK Regulations URN 01/774
- The Noise emission in the environment by equipment for use outdoors Directive 2000/14/EC: A Guide for Manufacturers to the Evaluation of Uncertainties – URN 00/605
- The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001- Guidelines for Organisations seeking Notified Body status to Undertake Noise Emission Testing, Inspection and Certification - URN 01/753
- The Noise Emission in the Environment by Equipment for Use Outdoors Directive 2000/14/EC - UK Notified Bodies - URN 01/1407 (available only via our website. No printed equivalent is available)

Where available, printed copies of these and all other DTI publications can be ordered from the DTI Publications Orderline:

Tel: 0870 1502 500 (national rate)

Fax: 0870 1502 333 Minicom: 0870 1502 100

E-mail: publications@dti.gsi.gov.uk

On-line: http://www.dti.gov.uk/publications

REQUIREMENTS OF THE REGULATIONS/DIRECTIVE RELATING TO TECHNICAL DOCUMENTATION

With the exception of certain items in respect of Unit Verification (Schedule 10 to the Regulations), the technical documentation must include some basic items of information, which are required by the Regulations/Directive. These are listed below:

- name and address of the equipment manufacturer or his authorised representative established in the Community
- a description of the equipment
- make of the equipment
- trade name of the equipment
- type, series and serial numbers of the equipment
- the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding.
- reference to the Directive
- the technical report of noise measurements carried out in accordance with the provisions of the Directive to include the measured sound power level and the guaranteed sound power level
- the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.

The last two bullet points above require some further comment, for consideration by the manufacturer, which is provided in the next two Annexes.

Additionally, a copy of the EC declaration of conformity should be retained with the technical documentation and, in the case of Full Quality Assurance (Schedule 11), forms part of the technical documentation to be submitted to the notified body.

The following may also be included with the technical documentation:

• a sample of the labels

ANNEX B

BASIC REQUIREMENTS FOR PRODUCTION OF A TECHNICAL REPORT

In addition to the requirements of the Regulations/Directive regarding a unique description of the equipment under test, as indicated in Annex A, the basic specified requirement for production of a technical report (that shall form part of the technical documentation), other than in the case of Unit Verification, appears to require by way of implication that it shall contain the elements in the list below.

- name and address of the Tester
- unique identifier for the technical report
- on each page of the technical report a unique form of identifier (such as the unique identifier of the technical report with a unique page number in the form "page -- of pages")
- date of receipt of equipment and the date(s) of the performance of the test(s)
- date of the technical report
- signature and legible name of person taking responsibility for the technical report
- signature and legible name of person(s) that performed the test
- any abnormalities or departures from a standard equipment that will affect its running conditions and sound power level
- reference to the test method and procedures used
- any standard or other specification relevant to the test method and deviations additions to or exclusions from the specifications concerned.
- where relevant to the validity or application of the test results, details of any sampling, equipment preparation or data analysis
- test results
- any design or performance specifications met or failed
- estimation of uncertainty in the test results¹

¹ See 'A Guide for Manufacturers to the Evaluation of Uncertainties' – URN 00/605

In addition to the basic requirements for a technical report as listed above, the following technical details would be appropriate for inclusion in the technical report.

- dimensions of the equipment
- actual operating conditions during the test stating whether in accordance with a specific noise test code for the equipment or according to the manufacturer's instructions
- mounting conditions during the test stating whether in accordance with a specific noise test code for the equipment or according to manufacturers instructions etc.
- the acoustic environment
 - place where the test was performed
 - if indoors, description of the physical treatment of walls ceiling and floor with a sketch showing the location of the equipment and room contents
 - if outdoors, a sketch showing the location of the equipment with respect to the surrounding terrain, and a physical description of the test environment.
- indication of the meteorological environment when applicable
 - air temperature in degrees Celsius
 - barometric pressure in pascals
 - relative humidity
 - wind speed
 - wind direction in relation to the equipment
- any abnormalities or departures from "normal" meteorological operating that will affect the running of the equipment and its sound power level
- method used for checking the calibration of the microphones, calibrator and other system components with the date, place and result of the calibration
- acoustical data
 - A-weighted sound power level
 - the shape of the enveloping surface
 - measurement distance or radius
 - location and orientation of microphone positions
 - area of the measurement surface
 - the A-weighted background noise correction for the sound pressure levels
 - the A-weighted environmental correction factor and the method by which it was determined
 - the A-weighted sound pressure levels at each measurement position
 - the A-weighted surface sound pressure level
 - the guaranteed sound power level²

² See 'A Guide for Manufacturers to the Evaluation of Uncertainties' – URN 00/605

RECORDS OF THE NOISE MEASUREMENT TESTING EQUIPMENT

The contents of the technical documentation shall be supported (except in the case of Unit Verification, where an EC Conformity Certificate from a notified body is required) by records that shall be maintained for each item of noise measurement testing equipment used in the noise test significant to the tests performed. Each record shall be retained for a period of at least ten years after the last piece of equipment has been manufactured and shall be available for inspection. Each record shall include at least the items listed below.

- name of all of the items of noise measurement testing equipment used in the test
- name of the noise measurement testing equipment manufacturer(s) and any model or type identification
- any serial number allocated by the noise measurement testing equipment manufacturer
- any serial number or other identifier allocated by the Tester
- where available, date when noise measurement testing equipment received by the Tester
- condition when received by the Tester (i.e. new, used reconditioned)
- details of any checks made for compliance with relevant calibration or test standard specification
- date when noise measurement testing equipment placed in service with the Tester
- current location of the noise measurement testing equipment, if appropriate
- copy of the noise measurement testing equipment manufacturer's operating instructions, where available
- details of maintenance carried out to any item of noise measurement testing equipment used in the test together with a history of any damage, malfunction, lapses of validity, re-commissioning, modification or repair

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EC DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following particulars given in bold. Additional guidance is given in italics:

Name and address of the manufacturer or his authorised representative established in the Community

Name and address of the person who keeps the technical documentation:

when the technical documentation is entrusted to a different person to the one indicated above

Description of the equipment: for example

- type of equipment taken from the list in either Schedule 1/Article 12 or Schedule 2/Article 13 of the Regulations/Directive
- type (model no./name), serial number (optional), etc.
- the net installed power or any other noise related value

Conformity assessment procedure followed, and, where appropriate, name and address of the notified body involved

For equipment listed in Schedule 2/Article 13;

• Internal control of production (Schedule8/Annex V) should be used/specified here.

For equipment listed in Schedule 1/Article 12, the chosen conformity assessment route of one of the following together with details of the Notified Body used:

- Internal control of production with assessment of technical documentation and periodical checking (Schedule 9/Annex VI);
- Unit verification (Schedule 10/Annex VII); or
- Full quality assurance (Schedule 11/Annex VIII).

Measured sound power level on an equipment representative for this type

this shall be reported to the nearest whole number (less than 0.5 use the lower number; greater than or equal to 0.5 use the higher number)

Guaranteed sound power level for this equipment

this shall be rounded to the nearest whole number (less than 0.5 use the lower number; greater than or equal to 0.5 use the higher number)

A reference to this Directive

Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors

The declaration that the equipment conforms to the requirements of this Directive

Where appropriate, the declaration(s)of conformity and references of the other Community Directives applied

This EC declaration of conformity may be combined with the declaration(s) of conformity required by other applicable Directive(s) such as the Machinery Directive 98/37/EC and the Electromagnetic Compatibility Directive 89/336/EEC, etc.

The place and date of the declaration

Particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative established in the Community. The signature may be printed