For use only if the UK has left the EU without a deal

THE NOISE EMISSION IN THE ENVIRONMENT BY EQUIPMENT FOR USE OUTDOORS REGULATIONS 2001, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

September 2019
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1. Introduction

The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001 set out the essential requirements which must be met before products can be placed on the UK market. The purpose of the legislation is to ensure that only equipment that does not exceed permissible sound power levels are placed on the market or put into service by requiring “responsible persons” to ensure the equipment meets the relevant requirements.

This guidance is designed to help you understand the Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001, now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

2. Legislative Background

The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001 (the 2001 Regulations) implemented Directive 2000/14/EC. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU. Accordingly, the 2019 Amendment Regulations fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market.

3. Scope

The 2001 Regulations (as amended) apply to equipment listed in Schedules 1 and 2 of the Regulations. A full list of equipment to which the 2001 Regulations apply can be found in Annex A to this guidance.

The 2001 Regulations do not apply to the following equipment:

(a) non-powered attachments separately placed on the market or put into service except for hand-held concrete breakers and picks and those for hydraulic hammers;
(b) all equipment primarily intended for the transport of goods or persons by road or rail or by air or on waterways; or
(c) equipment specially designed and constructed for military and police purposes and for emergency services.

The 2001 Regulations do not apply to equipment placed on the market before July 2001, and there was a further limited exemption up to 2 January 2002.

4. Requirements

The 2001 Regulations detail the requirements which must be met by a responsible person (defined, and the definition has been amended by the 2019 Amendment Regulations - see below) before placing on the market or putting into service any equipment to which the Regulations apply.

The requirements concerning noise emission in the environment of equipment to which the 2001 Regulations apply are that the guaranteed sound power level does not exceed the applicable permissible sound power level as laid out in the table below, and the guaranteed sound power level is to be marked on the equipment.
The responsible person must ensure that the appropriate conformity assessment procedure has been completed. The equipment must be accompanied by a declaration of conformity. Please see transitional arrangements for conformity marking in section 8.

5. Obligations of manufacturers

Under the 2001 Regulations, the onus to comply lies with the responsible person, being the manufacturer or their authorised representative. Where neither the manufacturer nor their authorised representative is established in the UK (previously this was in the EU but has been amended by the 2019 Amendment Regulations), the obligations of the 2001 Regulations shall apply to any person placing the equipment on the market or putting it into service in the UK.

Equipment subject to noise limits

Before placing on the market or putting into service any equipment subject to noise emission limits, the manufacturer, or his authorised representative shall subject each type of equipment to one of the following conformity assessment procedures:

- either the internal control of production with assessment of technical documentation and periodical checking procedure referred to in Annex E of this guidance,
- or the unit verification procedure referred to in Annex F,
- or the full quality assurance procedure referred to in Annex G.

All three of the above will require the involvement of approved bodies (UK based conformity assessment bodies - for more detail see below).

Equipment subject to noise marking only

Before placing on the market or putting into service any equipment subject to noise marking only, the manufacturer, or their authorised representative, shall subject each type of equipment to:

- the internal control of production procedure referred to in Annex D.

The procedure under Annex D will not require the involvement of ‘approved bodies’.

Noise Limits:

The guaranteed sound power level of the equipment shall not exceed the permissible sound power level as laid down in the table below.

<table>
<thead>
<tr>
<th>Type of equipment</th>
<th>Net installed power $P$ in kW</th>
<th>Electric power $P_{el}$ in kW</th>
<th>Mass of appliance $m$ in kg</th>
<th>Cutting width $L$ in cm</th>
<th>Permissible sound power level $L_{A}$ in dB/1 pW</th>
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<td></td>
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<td></td>
<td></td>
<td>as from Stage I 3 January 2002</td>
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<tr>
<td>Compaction machines (vibrating rollers, vibratory plates, vibratory rammers)</td>
<td>$P \leq 8$</td>
<td>$8 &lt; P \leq 70$</td>
<td>$P &gt; 70$</td>
<td>$L$</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>$P \leq 55$</td>
<td>$P &gt; 55$</td>
<td></td>
<td></td>
<td>109</td>
</tr>
<tr>
<td>Tracked dozers, tracked loaders, tracked excavator-loaders</td>
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<td></td>
<td></td>
<td>106</td>
</tr>
</tbody>
</table>

This will only apply if the EU leaves the UK without a deal.
<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>$P \leq 55$</th>
<th>$P &gt; 55$</th>
<th>$P_{el} \leq 2$</th>
<th>$2 &lt; P_{el} \leq 10$</th>
<th>$P_{el} &gt; 10$</th>
<th>$L \leq 50$</th>
<th>$50 &lt; L \leq 70$</th>
<th>$70 &lt; L \leq 120$</th>
<th>$L &gt; 120$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheeled dozers, wheeled loaders, wheeled</td>
<td>$104$</td>
<td>$82 + 11\ g\ P$</td>
<td>$97 + 1\ g\ P_{el}$</td>
<td>$98 + 1\ g\ P_{el}$</td>
<td>$96 + 1\ g\ P_{el}$</td>
<td>$96$</td>
<td>$100$</td>
<td>$100$</td>
<td>$105$</td>
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<td>excavator-loaders, dumpers, graders, loader-type</td>
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<td>landfi l compactors,</td>
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<td>combustion-engine driven counterbalanced lift</td>
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<tr>
<td>trucks, mobile cranes, compaction machines (non-</td>
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<td>vibrating rollers), paver-finishers, hydraulic</td>
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<td>power packs</td>
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<td>Mobile Cranes</td>
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<td>$P_{el} \leq 2$</td>
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<td>Excavators, builders’ hoists for the transport of</td>
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<td>goods, construction winches, motor hoes</td>
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<td>Hand-held concrete-breakers and picks</td>
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<td>Tower cranes</td>
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<tr>
<td>Lawnmowers, lawn trimmers/lawn edge trimmers</td>
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The permissible sound power level shall be rounded up or down to the nearest integer number (less than 0.5, user lower number; greater than or equal to 0.5, user higher number)

a $P_{el}$ for welding generators: conventional welding current multiplied by the conventional load voltage for the lowest value of the duty factor given by the manufacturer

b For power generators: prime power according to ISO 8528-1:1993, clause 13.3.2

c For the following types of equipment for the figures for Stage I will continue to apply for Stage II:

- Walk-behind vibrating rollers;
- Vibratory plates (>3 kW);
- Vibratory rammers;
- Dozers (steel tracked);
- Loaders (steel tracked >55 kW);
- Combustion-engine driven counterbalanced lift trucks;
- Compacting screed paver-finishers; and
- Hand-held internal combustion-engine concrete-breakers and picks (15 < m < 30).

c For single engine mobile cranes the figures for Stage I shall continue to apply until 3rd January 2008. After that date Stage II figures shall apply
6. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives and where they do so, those authorised representatives will be “responsible persons” within the meaning of the Regulations.

Mandated authorised representatives established in the EEA prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the legislation. However, any authorised representatives appointed and mandated after the UK left the EU to act in the UK must be established in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in an EU Member State, can therefore continue to use the same authorised representative.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer’s behalf for equipment being placed on the EU market. Therefore, a manufacturer exporting equipment to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative based in the EU.

The obligations of authorised representatives include the following:

1. An authorised representative must comply with all the duties imposed on the responsible person under the Regulations.

2. As far as those duties are concerned as well as penalties for failure to comply with those duties any references in the Regulations to the responsible person are to be taken as a reference to the authorised representative.

7. Transitional arrangements

‘Deeming’ provision

Equipment which has undergone full conformity assessment under the equivalent EU requirements, and which bears the CE conformity mark, is deemed compliant with the UK legislation and can be placed on the UK market as if it had been UK conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess products for the UK market. Equipment assessed by an EU recognised notified body prior to the UK leaving the EU does not need reassessment before being placed on the UK market. Furthermore, for a time-limited period, equipment assessed by an EU recognised notified body can continue to be placed on the UK market. (For the status of UK notified bodies please see section 10 below).

This ‘deeming provision’ is available for a time-limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.
8. **UK Conformity Mark**

**Assessment through third-party organisations:**

The UKCA conformity mark will replace the CE marking for equipment placed on the UK market which has been assessed by a UK approved body. In all other cases, responsible persons will be able to continue using the CE marking for equipment being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking.

**Self-assessment:**

CE marking based on self-declaration of conformity by the responsible person is still possible in the same way it was pre-exit, including when exporting to the EU.

Responsible persons selling equipment on the UK market can alternatively affix the new UKCA conformity marking before placing a product on the UK market. It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration. When exporting to the EU, the CE marking remains mandatory.

**Placing CE marked goods on the UK market:**

Equipment that meets EU regulatory requirements, including those with a CE marking, which has been assessed by an EU recognised conformity assessment body or which has been self-declared can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had their equipment assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.


Equipment exported to the EU Single Market must comply with EU Directive 2001/14/EC.

9. **Approved Bodies**

The UK has established a new framework for UK based bodies to assess equipment against UK rules. Existing UK Notified Bodies have been granted new UK ‘approved body’ status and are listed on a new UK database. There is no need for existing UK notified bodies to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit approved body number.

Approved bodies can assess equipment for the UK market against UK requirements (which are substantially the same as EU requirements).

Approved Bodies are conformity assessment bodies which were UK notified bodies before the UK left the EU, or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the UK market.

UK Approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of the product to assess the adequacy of the technical design.
Where an approved body finds that essential safety requirements have not been met by a manufacturer, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A list of UK approved bodies can be found [link to be added].

10. Enforcement

These Regulations are enforced by the Office for Product Safety and Standards on behalf of the Secretary of State for Business, Energy and Industrial Strategy.

Regulators’ Code

Market surveillance authorities must continue to have regard to the Regulators’ Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators’ Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators’ Code can be found here:

Penalties

A person committing an offence under the Regulations may be liable to a penalty. Penalties can include a fine or a prison sentence of up to three months for the most serious offences. It is matter for the enforcement authority to decide what action is appropriate in each case taking into account the circumstances of the case and the enforcement authorities’ own policies, operational procedures and practices in line with the Regulators Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

11. Where to find guidance about Directive 2000/14/EC

You can find further and more detailed guidance on Directive 2000/14/EC, now incorporated into UK law, here:

12. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a UK ‘Notified Body’ prior to the UK leaving the EU.

- **Authorised Representative** – A person appointed by a manufacturer to perform specific tasks for the manufacturer.
• **Declaration of conformity** – A document prepared by the manufacturer which must detail the following:
  o The specific product to which the declaration is referring;
  o The name and address of the manufacturer and, where applicable, their authorised representative.

This must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the market. This declaration must be made available to the enforcing authority upon request.

**Responsible person** – The manufacturer or their authorised representative, or if neither are in the UK then the person placing on the market or putting into service in the UK.

• **UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.
13. ANNEXES

Annex A – Equipment to which the 2001 Regulations as amended apply:

Equipment subject to noise limits:

- Builders’ hoists for the transport of goods (combustion-engine driven)
- Compaction machines (only vibrating and non-vibrating rollers, vibratory plates and vibratory rammers)
- Compressors (<350 kW)
- Concrete-breakers and picks, hand-held
- Construction winches (combustion-engine driven)
- Dozers (<500 kW)
- Dumpers (<500 kW)
- Excavators, hydraulic or rope-operated (<500 kW)
- Excavator-loaders (<500 kW)
- Graders (<500 kW)
- Hydraulic power packs
- Landfill compactors, loader-type with bucket (<500 kW)
- Lawnmowers (excluding agricultural and forestry equipment, and multi-purpose devices, the main motorised component of which has an installed power of more than 20 kW)
- Lawn trimmers/lawn edge trimmers
- Lift trucks, combustion-engine driven, counterbalanced (excluding 'other counterbalanced lift trucks' with a rated capacity of not more than 10 tonnes)
- Loaders (<500 kW)
- Mobile cranes
- Motor hoes (<3 kW)
- Paver-finishers (excluding paver-finishers equipped with a high-compaction screed)
- Power generators (<400 kW)
- Tower cranes
- Welding generators

Equipment subject to noise marking only:

- Aerial access platforms with combustion engine
- Brush cutters
- Builders’ hoists for the transport of goods (with electric motor)
- Building site band saw machines
- Building site circular saw benches
- Chain saws, portable
- Combined high pressure flushers and suction vehicles
- Compaction machines (explosion rammers only)
- Concrete or mortar mixers
- Construction winches (with electric motor)
- Conveying and spraying machines for concrete and mortar
- Conveyor belts
- Cooling equipment on vehicles
- Drill rigs
- Equipment for loading and unloading tanks or silos on trucks
- Glass recycling containers
- Grass trimmers /grass edge trimmers
- Hedge trimmers
High pressure flushers
High pressure water jet machines
Hydraulic hammers
Joint cutters
Leaf blowers
Leaf collectors
Lift trucks, combustion-engine driven, counterbalanced (only 'other counterbalanced lift trucks' with a rated capacity of not more than 10 tonnes)
Mobile waste containers
Paver finishers (equipped with a high-compaction screed)
Piling equipment
Pipelayes
Piste caterpillars
Power generators (< 400 kW)
Power sweepers
Refuse collection vehicles
Road milling machines
Scarifiers
Shredders/chippers
Snow-removing machines with rotating tools (self-propelled, excluding attachments)
Suction vehicles
Trenchers
Truck mixers
Water pump units (not for use under water)

*Definitions for each type of equipment can be found in Schedule 4 of the Regulations.
Annex B – Declaration of Conformity

The declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorised representative established in the UK;
- name and address of the person who keeps the technical documentation;
- description of the equipment;
- conformity assessment procedure followed, and, where appropriate, name and address of the approved body involved;
- measured sound power level on an equipment representative for this type;
- guaranteed sound power level for this equipment;
- a reference to the 2001 Regulations as amended;
- the declaration that the equipment conforms to the requirements of the 2001 Regulations as amended;
- where appropriate, the declaration of conformity and references of other enactments applied;
- the place and date of the declaration; and
- particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative.
Annex C - Models of the UK Marking of Conformity and of the Indication of the Guaranteed Sound Power Level

The UK conformity marking must consist of the initials 'UKCA' taking the following form:

If the UK marking is reduced or enlarged according to the size of the equipment the proportions given in the above drawing must be respected. The various components of the UK marking must have substantially the same vertical dimension which may not be less than 5 mm.

The indication of the guaranteed sound power level must consist of the single-number of the guaranteed sound power in dB, the sign $L_{WA}$ and a pictogram taking the following form:

If the indication is reduced or enlarged according to the size of the equipment the proportions given in the above drawing must be respected. However, the vertical dimension of the indication should, if possible, not be less than 40 mm.
Annex D - Internal Control of Production

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, who carries out the obligations laid down in point 2, ensures and declares that the equipment concerned satisfies the requirements of the 2001 Regulations as amended. The manufacturer, or their authorised representative, must affix the UKCA marking, or, for a time limited period, the CE marking of conformity and the indication of the guaranteed sound power level as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations as amended to each piece of equipment and draw up a written declaration of conformity as required in Regulation 7(2)(d) and Schedule 5.

2. The manufacturer, or their authorised representative, must draw up the technical documentation described in point 3 and they must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant authorities for inspection purposes. The manufacturer, or their authorised representative, may entrust another person to keep the technical documentation. In this case they have to include the name and address of this person in the declaration of conformity.

3. The technical documentation must enable the conformity of the equipment with the requirements of the 2001 Regulations as amended to be assessed. It must contain at least the following information:
   • name and address of the manufacturer or their authorised representative;
   • a description of the equipment;
   • make;
   • trade name;
   • type, series and numbers;
   • 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;
   • the reference to the 2001 Regulations as amended;
   • the technical report of noise measurements carried out in accordance with the provisions of the 2001 Regulations as amended; and
   • 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.

4. The manufacturer must take all measures necessary in order that the manufacturing process ensures continuing compliance of the manufactured equipment with the technical documentation referred to in points 2 and 3 and with the requirements of the 2001 Regulations as amended.
Annex E - Internal Control of Production with Assessment of Technical Documentation and Periodical Checking

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, who carries out the obligations laid down in points 2, 5 and 6 ensures and declares that the equipment concerned satisfies the requirements of these Regulations. The manufacturer, or their authorised representative, must affix the UKCA marking, or, for a time limited period, the CE marking of conformity and the indication of the guaranteed sound power level as required in Regulation 7(2)(c), 11 and Schedule 7 of the 2001 Regulations as amended to each equipment and draw up a written declaration of conformity as required in Regulation 7 (2)(d) and Schedule 5.

2. The manufacturer, or their authorised representative, must draw up the technical documentation described in point 3 and he must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes. The manufacturer, or their authorised representative, may entrust another person to keep the technical documentation. In this case he has to include the name and address of this person in the declaration of conformity.

3. The technical documentation must enable the conformity of the equipment with the requirements of the 2001 Regulations as amended to be assessed. It must contain at least the following information:
   - name and address of the manufacturer or their authorised representative;
   - a description of the equipment;
   - make;
   - trade name;
   - type, series and numbers;
   - 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;
   - the reference to the 2001 Regulations as amended;
   - the technical report of noise measurements carried out in accordance with the provisions of these Regulations; and
   - 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.

4. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured equipment with the technical documentation referred to in points 2 and 3 and with the requirements of the 2001 Regulations as amended.

Evaluation by the approved body prior to placing on the market

5. The manufacturer, or their authorised representative, shall present a copy of his technical documentation to an approved body of their choice before the first item of equipment is placed on the market or put into service.
6. If there are doubts about the plausibility of the technical documentation the approved body shall inform accordingly the manufacturer or their authorised representative in the UK, and, if need be, carry out, or have carried out, modifications of the technical documentation, or possibly, tests deemed necessary.

7. After the approved body has issued a report confirming that the technical documentation satisfies the provisions of the 2001 Regulations as amended, the manufacturer or their authorised representative established in the UK may affix the UKCA marking, or, for a time limited period, the CE marking to the equipment and issue an declaration of conformity in accordance with Regulations 7(2)(c) and (d), 11 and schedule 7 of the 2001 Regulations as amended, for which he will bear complete responsibility.

Evaluation by the approved body during production

8. The manufacturer, or their authorised representative established in the UK, shall further involve the approved body in the production phase according to one of the following procedures to be chosen by the manufacturer or his authorised representative:

9. The approved body shall carry out periodical checks in order to verify continuing compliance of the manufactured equipment with the technical documentation and with the requirements of the 2001 Regulations as amended; in particular the approved body shall concentrate on:

   a. the correct and complete marking of the equipment according to Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations as amended;
   
   b. issuing of the declaration of conformity according to Regulation 7(2)(d) and schedule 5 of the 2001 Regulations as amended; and
   
   c. 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.

10. The manufacturer, or their authorised representative established in the UK, shall give the approved body free access to all the internal documentation supporting these procedures, the actual results of the internal audits and the corrective actions which have been taken, if any.

11. Only if the above checks give unsatisfactory results shall the approved body carry out noise tests, which, upon its own judgement and experience, may be simplified or completely carried out according to the provisions laid down in Annex III of the 2001 Regulations as amended for the relevant type of equipment.

12. The approved body shall carry out or have carried out product checks at random intervals. An adequate sample of the final equipment, chosen by the approved body, must be examined and appropriate noise tests as set out in Annex III of the 2001 Regulations as amended, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of the Regulations. The product checking must include the following aspects:

   a. the correct and complete marking of the equipment according to Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations as amended;
   
   b. issuing of the declaration of conformity according to Regulation 7(2)(d) and schedule 5 of the 2001 Regulations as amended.
13. In both procedures, the frequency of the checks shall be defined by the approved body according to the results of previous evaluations, the need to monitor corrective actions and further guidance for the frequency of the checks that may be given by the yearly production and the general reliability of the manufacturer to maintain the guaranteed values; however a check shall be carried out at least once every 3 years.

14. If there are doubts about the plausibility of the technical documentation or the adherence during production, the approved body shall inform accordingly the manufacturer, or their authorised representative.
Annex F – Unit Verification

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, ensures and declares that the equipment which has been issued with the certificate referred to in point 4 conforms to the requirements of 2001 Regulations as amended. The manufacturer, or their authorised representative, must affix the UKCA marking, or for a time limited period, the CE marking supplemented by the information as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations as amended to the equipment and draw up the declaration of conformity referred to in Regulation 7(2)(d) and Schedule 5 of the Regulations.

2. The application for a unit verification must be lodged by the manufacturer or their authorised representative with an approved body chosen by them.

3. This application must include:
   - the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;
   - a written declaration that the same application has not been lodged with any other approved body;
   - a technical documentation conforming to the requirements set below:
     - a description of the equipment;
     - trade name;
     - type, series and number;
     - 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; and
     - the reference to the 2001 Regulations as amended.

4. The approved body must:
   - examine whether the equipment has been manufactured in conformity with the technical documentation;
   - agree with the applicant the location where, in accordance with the 2001 Regulations as amended, the noise tests will be carried out; and
   - in accordance with the 2001 Regulations as amended, carry out or have carried out the necessary noise tests.

5. Where the equipment meets the provisions of the 2001 Regulations as amended, the approved body must issue a certificate of conformity to the applicant as described in Schedule 12.

6. The manufacturer, or their authorised representative, must keep with the technical documentation copies of the certificate of conformity for a period of 10 years from the date on which the equipment is placed on the UK market.
Annex G – Full Quality Assurance

1. This Annex describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the equipment concerned satisfies the requirements of the 2001 Regulations as amended. The manufacturer, or their authorised representative, must affix the UKCA marking, or, for a time limited period, the CE marking supplemented by the information as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations as amended to each product and draw up the written declaration of conformity referred to in Regulation 7(1)(d) and Schedule 5 of the Regulations.

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

Quality assurance system

3. The manufacturer must lodge an application for assessment of his quality assurance system with an approved body of their choice.

4. The application must include:
   - all relevant information for the product category envisaged, including technical documentations of all equipment already in phase of design or production that must contain at least the following information:
     - name and address of the manufacturer or their authorised representative;
     - a description of the equipment;
     - make;
     - trade name;
     - type, series and numbers;
     - 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;
     - the reference to the 2001 Regulations as amended;
     - the technical report of noise measurements carried out in accordance with the provisions of the 2001 Regulations as amended; and
     - 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.
   - a copy of the declaration of conformity.
   - the documentation concerning the quality assurance system.

5. The quality assurance system must ensure compliance of the product with the requirements of the Regulations that apply to it.

6. 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 assurance system documentation must permit a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.
7. It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical documentation to be drawn up for each product, containing at least the information indicated in point 3.1 for the technical documentations mentioned there;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the equipment category covered;
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality assurance system.

8. The approved body must assess the quality assurance system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality assurance systems that implement EN ISO 9001.

9. The auditing team must have at least one member with experience as an assessor in the equipment technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.

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

11. The manufacturer must undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it in an adequate and efficient manner.

12. The manufacturer or their authorised representative shall keep the approved body that has approved the quality assurance system informed of any intended updating of the quality assurance system.

13. The approved body must evaluate the modifications proposed and decide whether the modified quality assurance system will still satisfy the requirements referred to in point 3.2 or whether a re-assessment is required.

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

**Surveillance under the responsibility of the approved body**

15. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.
16. The manufacturer must allow the approved body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

- the quality assurance system documentation;
- the quality records as foreseen by the design part of the quality assurance system, such as results of analyses, calculations, tests, etc.; and
- the quality records as foreseen by the manufacturing part of the quality assurance system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned etc.

17. The approved body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality assurance system and must provide an audit report to the manufacturer.

18. Additionally, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The approved body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

19. The manufacturer must, for a period ending at least 10 years after the last equipment has been manufactured, keep at the disposal of the relevant authorities:

- the documentation referred to in the second indent of point 3.1 of this Annex;
- the updating referred to in the second paragraph of point 3.4; and
- the decisions and reports from the approved body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

20. Each approved body must give the other approved bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.