THE SUPPLY OF MACHINERY (SAFETY) REGULATIONS 1992 (AS AMENDED)

Guidelines on the Appointment of UK Notified Bodies to undertake inspection and certification for the purposes of the Conformity Assessment Procedures in the UK Regulations

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GUIDELINES ON THE APPOINTMENT OF UK NOTIFIED BODIES

ISSUED BY THE DEPARTMENT OF TRADE AND INDUSTRY (DTI) ON BEHALF OF THE SECRETARY OF STATE FOR TRADE AND INDUSTRY

1. PREFACE

1.1. These guidelines describe the requirements which apply in the United Kingdom for the assessment and appointment of Notified Bodies under the Supply of Machinery (Safety) Regulations 1992 (S.I. 1992/3073) as amended (S.I. 1994/2063), which implement the provisions of the EC Machinery Directive (98/37/EC) in UK law. A further S.I. will be issued to take account of the Commission’s codification of the Machinery Directive but it should be stressed that this will not mean any policy changes and will not affect the content of these Guidelines. Notified Bodies are appointed under and operate according to the law which transposes the provisions of the Directive. Please note that in these Regulations reference is made to “approved bodies”. The term “Notified Bodies” has been used in these Guidelines as all applicants successfully assessed are notified to the European Commission and are thus “notified” in accordance with the provisions of the Machinery Directive. The Directive applies in the European Economic Area (EEA).

2. INTRODUCTION

2.1. The European Community Directive on the approximation of the laws of the member States concerning machinery was transposed into UK law through the Supply of Machinery (Safety) Regulations 1992 which came into force on 1 January 1993 and were amended by the Supply of Machinery (Safety) (Amendment) Regulations 1994. All transitional periods have now expired. For ease of reference, this Directive was formerly 89/392/EEC as amended by 91/368/EEC, 93/44/EEC and 93/68/EEC. The Machinery Directive has since been codified into a single text - 98/37/EC which combined all these texts into a single document. A Statutory Instrument further amending the 1992 Regulations is being prepared to take this codification into account. The single codified text of the Directive was adopted by the European Parliament and the Council on 22 June 1998 and published in the Official Journal No. L 207 of 23 July 1998.

2.2 The Machinery Directive applies to both assemblies of machines and single products which fall within the definition as shown in regulation 4 as well as relevant safety components and interchangeable equipment. There is a specific list of products which may require third party examination in Schedule 4 to the Supply of Machinery (Safety) Regulations as amended (Annex IV of the Directive). In these cases, if a transposed harmonised standard has not been used in order to ensure compliance for the product, a third party is required to examine the product and to issue a type examination certificate before it can be placed on the market in the EEA.

2.3. The conformity assessment procedures under the Regulations consist of self-certification by the manufacturer of each product either directly in accordance with the technical requirements set out in the Regulations or against a specific transposed
harmonised European Standard (EN), or series of standards, which then gives that product a presumption of conformity with the relevant essential health and safety requirement of the Regulations. In these circumstances a manufacturer can self-certify his product and if appropriate affix the CE marking. If the product is listed in Schedule 4 to the Regulations as amended, either third party assessment is required or, if the product is wholly manufactured in accordance with transposed harmonised standards, the Technical File can be sent to a Notified Body either for retention or verification that the standards have been correctly applied with a certificate of adequacy being drawn up by the Notified Body. Where third party assessment is required, the Notified Body will perform the EC type examination and issue a certificate to the manufacturer once it has been assessed as being in conformity with the requirements of the Regulations as amended.

2.4. Third party assessment requires the involvement of Notified Bodies in the type approval process as outlined above. Subject to paragraph 7 (below), these are appointed by member/EEA States. In the United Kingdom, they are appointed under regulation 18 of the Supply of Machinery (Safety) Regulations 1992 as amended to either undertake the testing itself or be responsible for the retention/verification of the Technical File if the product has been wholly manufactured in accordance with transposed harmonised standards. These organisations, once assessed for their competence and appointed by the Secretary of State, are then notified to the European Commission and become “Notified Bodies” The scope of products within Schedule 4 to the Regulations which a Notified Body is authorised to type examine will be publicised and will also be specified in the letter of appointment. The Secretary of State for Trade and Industry at present has the responsibility for appointing Notified Bodies in the United Kingdom, to carry out the functions referred to above and for notifying the appointments to the European Commission and other member/EEA States.

3. CRITERIA, APPLICATION AND APPOINTMENT

3.1. An organisation wishing to be appointed as a notified body in the United Kingdom will need to be able to undertake EC type examination assessments in accordance with the relevant provisions of the Regulations which implement Annex VI of the Machinery Directive (reproduced here as Appendix I) and meet the minimum criteria set out in Annex VII of the Directive (reproduced here as Appendix 2 to these Guidelines). It should, however, be noted that meeting the minimum criteria for appointment will not automatically lead to appointment as appointment remains at the discretion of the Secretary of State. The requirements set out in paragraph 3.8 below must also be fulfilled. Reference should also be made to paragraph 4.13 regarding insurance arrangements.

3.2. Applicants will be required in the first instance, to make an application (for assessment) to the United Kingdom Accreditation Service (UKAS) which will undertake an assessment of the applicant against the criteria and report to the Secretary of State on that assessment. Applications should be submitted using UKAS form DF 101. The scope of any appointment will be defined by reference to the specific products set out in Schedule 4 to the Supply of Machinery (Safety) Regulations 1992 as amended and applicants should indicate, in the application, the particular product(s) (if not all) in respect of which the applicant wishes to be appointed. UKAS will quote and charge applicants against its standard scales of charges for its assessment.
activities under the provisions of these guidelines. UKAS has established procedures
to handle complaints or appeals associated with its assessment activities.

3.3. At the same time as it submits its application for assessment to UKAS, the applicant
will be required to send a copy to the DTI. This will represent the formal application
to the Secretary of State for appointment.

3.4. Once UKAS has submitted its report, the Secretary of State will then make a decision
on appointment on the basis of all the evidence. If satisfied that the applicant is fit for
appointment under the Supply of Machinery (Safety) Regulations 1992 as amended,
the Secretary of State will issue a letter of appointment.

3.5. The precise terms of appointment will be set out in the individual letters of appointment,
but they will include conditions that the applicant agrees:

to take part in co-ordination activities at both UK and European level;

to surveillance annually or at whatever intervals are thought appropriate by the DTI
(newly appointed Notified Bodies may be required to undergo an initial surveillance
after 6 months);

to a full reassessment every four years or at whatever intervals are thought appropriate
by the DTI.

Once acceptance of the conditions of the letter of appointment has been received,
receipt of that acceptance will be confirmed and the DTI will notify the European
Commission and the other member/EEA States of the appointment.

3.6. Reassessment and surveillance will be carried out on behalf of the Secretary of
State, normally by UKAS. A report on the reassessment and surveillance will be sent
to the Secretary of State. Reassessment and surveillance may also be carried out
by the Secretary of State. UKAS will advise the DTI of the outcome of annual
surveillance, four yearly reassessment and any other necessary monitoring in
intervening periods of Notified Bodies in order for the DTI to take any necessary
decisions about the continuation of a Notified Body’s appointment. The information
provided by UKAS to the DTI will include supporting documentation such as a copy
of the assessor’s visit report, details of identified deficiencies and any agreed remedial
action.

3.7. To be eligible for appointment as a United Kingdom Notified Body for the purposes
of the Regulations as amended, an applicant must be a legal entity in the United
Kingdom and carry out its assessment functions within the jurisdiction of the United
Kingdom. It may, where necessary, conduct tests, or have tests conducted on its
behalf, outside the jurisdiction of the United Kingdom.

3.8 Notified Bodies should ensure that they do not unreasonably restrict access of
manufacturers of products within the scope of the Regulations to their services. They
must not place undue financial or other conditions upon such manufacturers. The
procedures under which a Notified Body operates must be administered in a non-
discriminatory manner.
4. MEETING THE CRITERIA

Accreditation

4.1. Accreditation to the appropriate scope of one, or more, of the EN 45000 series of standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests, may be used as the basis for demonstrating conformity with the criteria set out in Appendices 1 & 2. Although accreditation to one of the EN 45000 series standards is encouraged, it is not mandatory and the relevant criteria may be satisfied in other ways. Applicants which are not accredited will normally be assessed by UKAS to the relevant requirements of the appropriate EN 45000 standard and will need to demonstrate equivalent levels of ability in terms of competence, resources, organisational arrangements, policies and all other relevant matters.

4.2. All applicants, whether accredited to one of the EN 45000 series of standards or not, will need to meet the additional requirements set out in these guidelines which may change from time to time. In particular, they will need to demonstrate:

- a thorough technical understanding of the products for which appointment is sought;
- the ability to undertake the conformity assessment activities laid down in the Regulations, as amended, in respect of which they seek appointment; and
- a thorough knowledge of the Machinery Directive and the implementing Regulations, as amended.

4.3. As indicated in paragraph 3.2 (above), applicants will therefore need to state for which products specified in Schedule 4 to the Regulations (as amended) they wish to be appointed. The scope of assessment and subsequent appointment will be determined by reference to the categories of product listed in Schedule 4 to those Regulations (Annex IV of the Machinery Directive - see Appendix 3). Applicants will be required to demonstrate the capability fully to undertake the EC type examination in accordance with the requirements of the Regulations (as amended) and satisfy the minimum criteria as shown in Appendix 2 to these Guidelines.

4.4. EN 45004 is the basic standard for assessing the suitability of applicants wishing to become Notified Bodies under the Regulations (as amended). The EN 45000 series of standards specify the general criteria for the competence of bodies performing inspection and the nature of third party assessment. Assessment of an applicant will be related to its ability to understand the Essential Health and Safety Requirements (EHSRs) and other relevant provisions of the Machinery Directive and the implementing Regulations relevant to its proposed scope of approval and to undertake the conformity assessment duties of a notified body in the required manner. Applicants who were initially assessed and appointed against the relevant requirements of the 1989 edition of EN 45011 and who wish to continue to work with this standard, should amend their systems to address the 1998 edition and be able to demonstrate compliance with the additional requirements of EN 45004 within 12 months of the date of publication of this document. Organisations who are amending their systems to adhere to EN 45004 in place of EN 45011 should also be able to demonstrate compliance within 12 months of the date of publication of these Guidelines.
4.5 All applicants will need to be able to demonstrate their professional ability and understanding of the Machinery Directive and implementing Regulations necessary to determine whether products offered for assessment satisfy the EHSRs and the other relevant provisions.

**Harmonised Standards**

4.6 The Machinery Directive also defines the role of harmonised standards, which are produced in response to a mandate from the European Commission to the European standards organisation, the Comite European de Normalisation (CEN). Products within the scope of the Machinery Directive/implementing Regulations (as amended) produced in accordance with such standards will enjoy a presumption of conformity with the relevant EHSRs (set out in Schedule 3 to the Regulations). Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the EHSRs and other relevant provisions direct. They will also need to be able to inspect against the CEN standards.

4.7 Where an applicant operates its own testing facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 45001 (General criteria for the operation of testing laboratories) though accreditation is not mandatory. Where testing is performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable of carrying out the tasks effectively and meets the relevant requirements of EN 45001 although accreditation is not mandatory.

4.8 Where an applicant operates its own inspection facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 45004 (General criteria for the operation of various types of bodies performing inspection) though accreditation is not mandatory. Although a Notified Body should normally carry out inspections which it contracts to undertake, where elements of the inspection will be performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable of carrying out the tasks effectively and meets the relevant requirements of EN 45004 although accreditation is not mandatory.

**Sub Contracting**

4.9 Where an applicant wishes to subcontract testing, the Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the subcontractors with the relevant requirements and to demonstrate that the subcontractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect to the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of subcontractors, and a list of subcontractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.

4.10 An applicant will need to have fully documented agreements with its subcontractors. A Register of all subcontractors which may be used by the applicant will need to be maintained; the Quality Manual will either contain the Register or will state where the
The Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose.

4.11. A Notified Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the implementing Regulations.

4.12. An applicant will need to have a Quality System, usually specified in a Quality Manual and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. The Quality System will need to ensure that all the relevant requirements of the appropriate standards in the EN 45000 series are met plus any further requirements for appointment and operation as a Notified Body.

4.13. All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to UKAS and to the DTI at the point at which a body makes an application to be appointed as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS. Such cover should extend to the whole of the Community, the European Economic Area (EEA), or, if the applicant intends to carry out work under the Machinery Directive outside these areas; world-wide. The Secretary of State will not in relation to any case or circumstance cover a Notified Body’s liability.

4.14. A Notified Body will be required to inform the Secretary of State for Trade and Industry and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status.

5. DUTIES OF NOTIFIED BODIES

5.1. It will be the duty of a Notified Body to assess the conformity of the products, which fall within the scope of its appointment, against the requirements of the Supply of Machinery (Safety) Regulations 1992 as amended. When a Notified Body assesses products as being in conformity with those Regulations, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations. This would include a type examination certificate stating that the product concerned complies with the terms of the Directive which apply to it and has been assessed as such.

5.2. It will be the duty of recognised third party organisations accurately to ensure that the staff responsible for inspection have sound technical and professional training, satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests, the ability to draw up the certificates records and reports required to authenticate the performance of the tests. In addition the staff should be impartial (see Annex VII of Directive 98/37/EC).

5.3. An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment activities for which it seeks approval.
On behalf of the Secretary of State, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant’s services. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant will be required to have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the Machinery Directive and the implementing Regulations are provided by the DTI, or through the national and European fora already in place for the exchange of views and discussion of interpretative issues in which prospective applicants are expected to fully participate.

5.4. A Notified Body will be required to maintain an up to date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of State for Trade and Industry, or such other person as may be authorised by the Secretary of State for Trade and Industry.

6. **MISUSE OF CERTIFICATES AND CONFORMITY NUMBERS**

6.1. The Quality Manual should state the Notified Body’s policy and procedure for controlling the use of its certificates and conformity numbers. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. must be dealt with by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

6.2. A Notified Body will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within the Quality Manual.

7. **MUTUAL RECOGNITION AGREEMENTS**

7.1. Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC Notified Bodies may be eligible to perform conformity assessments as required by the third country’s laws and, similarly, those trading partners’ equivalents to Notified Bodies may be eligible for appointment to perform conformity assessments under EC Directives. If an applicant organisation wishes to be considered for appointment under MRAs, it should inform the DTI.
8. CONTACT POINTS

8.1. Contact addresses are:

Richard Thompson
Department of Trade and Industry
Standards & Technical Regulations Directorate
151 Buckingham Palace Road
London SW1W 9SS

Tel: 0207-215 2913
Fax: 0207-215 1970

David Evans (or your usual accreditation manager)
United Kingdom Accreditation Service
21 - 47 High Street
Feltham
Middlesex
TW13 4UN

Tel: 0208 - 917 8400
Fax: 0208 - 917 8500

9. SOURCES OF RELEVANT DOCUMENTS

9.1. Copies of the Machinery Directive and the Supply of Machinery (Safety) Regulations 1992 (as amended) may be obtained from:

The Stationery Office Ltd
Nine Elms Lane
London
SW8 5DR

Tel: 0207- 873 9090
Fax: 0207- 873 8463

or from European Information Centres.

9.2. Information on the EN 45000 series of standards and the harmonised standards is available from:

BSI
389 Chiswick High Road
London
W4 4AL

Tel: 0208-996 9001
Fax: 0208-996 7048
Web: http://www.bsi.org.uk
ANNEX VI

EC TYPE-EXAMINATION

For the purposes of this Annex, 'machinery' means either 'machinery' or 'safety component' as defined in Article 1(2).

1. EC type-examination is the procedure by which a notified body ascertains and certifies that an example of machinery satisfies the provisions of this Directive which apply to it.

2. The application for EC type-examination shall be lodged by the manufacturer or by his authorised representative established in the Community, with a single notified body in respect of an example of the machinery.

The application shall include:

- the name and address of the manufacturer or his authorised representative established in the Community and the place of manufacture of the machinery,

- a technical file comprising at least:

  - an overall drawing of the machinery together with drawings of the control circuits,

  - full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,

  - a description of methods adopted to eliminate hazards presented by the machinery and a list of standards used,

  - a copy of the instructions for the machinery,

  - for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

It shall be accompanied by a machine representative of the production planned or, where appropriate, a statement of where the machine may be examined.

The documentation referred to above does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.
3. The notified body shall carry out the EC type-examination in the manner described below:

- it shall examine the technical construction file to verify its appropriateness and the machine supplied or made available to it,

- during the examination of the machine, the body shall:
  
  (a) ensure that it has been manufactured in conformity with the technical construction file and may safely be used under its intended working conditions;

  (b) check that standards, if used, have been properly applied;

  (c) perform appropriate examinations and tests to check that the machine complies with the essential health and safety requirements applicable to it.

4. If the example complies with the provisions applicable to it the body shall draw up an EC type-examination certificate which shall be forwarded to the applicant. That certificate shall state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved example.

The Commission, the Member States and the other approved bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical construction file and of the reports on the examinations and tests carried out.

5. The manufacturer or his authorised representative established in the Community shall inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machine to which the example relates. The notified body shall examine those modifications and inform the manufacturer or his authorised representative established in the Community whether the EC type-examination certificate remains valid.

6. A body which refuses to issue an EC type-examination certificate shall so inform the other notified bodies. A body which withdraws an EC type-examination certificate shall so inform the Member State which notified it. The latter shall inform the other Member States and the Commission thereof, giving the reasons for the decision.

7. The files and correspondence referring to the EC type-examination procedures shall be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.
ANNEX VII

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

For the purposes of this Annex, “machinery” means either “machinery” or “safety component” as defined in Article 1(2)

1 The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machinery which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of the machinery. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2 The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3 The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification it shall also have access to the equipment required for special verifications.

4 The staff responsible for inspection shall have:
   - sound technical and professional training,
   - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
   - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5 The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6 The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

7 The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

Machinery

1. Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials;
   1.1. Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed;
   1.2. Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage;
   1.3. Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
   1.4. Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.


3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.

4. Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.

5. Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.

6. Hand-fed tenoning machines with several tool holders for woodworking.


8. Portable chain saws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with a manual loading and/or unloading, whose movable working parts may have a travel exceeding 6mm and a speed exceeding 30mm/s.

10. Injection or compression plastics-moulding machines with manual loading or unloading.

11. Injection or compression rubber-moulding machines with manual loading or unloading.
12. Machinery for underground working of the following types;
   - machinery on rails: locomotive and brake vans;
   - hydraulic-powered roof supports;
   - internal combustion engines to be fitted to machinery for underground working.

13. Manually-loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Guards and detachable transmission shafts with universal joints as described in paragraph 3.4.7 (This is a reference to section 3.4.7 of the Essential Health and Safety Requirements set out in Schedule 3 to the Regulations, as amended/Annex I of the Machinery Directive).

15. Vehicles servicing lifts.

16. Devices for the lifting of persons involving a risk of falling from a vertical height of more than three metres.

17. Machines for the manufacture of pyrotechnics.

Safety Components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.)

2. Logic units which ensure the safety functions of bi-manual controls.

3. Automatic movable screens to protect the presses referred to in 9, 10, and 11.

4. Roll-over protection structures (ROPS).

5. Falling-object protective structures (FOPS)