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INLAND TRANSPORT COMMITTEE

Working Party on the Transport of Dangerous Goods

Joint Meeting of the RID Committee of Experts and the
Working Party on the Transport of Dangerous Goods

Geneva, 11-21 September 2007

Item 6(a) of the provisional agenda

PROPOSALS FOR AMENDMENTS TO RID/ADR/ADN

Pending issues

Inspection body of type C

Transmitted by the Government of Sweden

SUMMARY

Executive summary: The document 2007/48 from the United Kingdom contains a proposal to adopt a modification of the type B bodies into the RID/ADR.

If the proposal from UK is adopted into the RID/ADR, the RID/ADR will have a unique type of body deviating from the rest of the world.

Action to be taken: To preserve the existing types of bodies in the EN ISO/IEC 17020:2004 applied in the rest of the world, in all other industrial areas performing inspection.

Proposal: Please see ECE/TRANS/WP.15/AC.1/2007/46 as this is only an informal document.

Related documents: ECE/TRANS/WP.15/AC.1/2007/46
ECE/TRANS/WP.15/AC.1/2007/48

Introduction

Part 1

The United Kingdom has in document 2007/48 supported the principle that type C bodies are not included in the Directive 99/36/EC (TPED) and should therefore be deleted from the RID/ADR, which is fully in line with document 2007/46 from Sweden which makes us very pleased.

The document 2007/48 from the UK also contains a proposal to adopt a modification of the description of bodies of type B into the RID/ADR.

Sweden would like to draw the attention of Joint Meeting, to that there exist an international covering guidance document on the application of the standard EN ISO/IEC 17020:2004. In this guidance document the different types of bodies are described in part 4, please see Annex 1.

The Guidance document ILAC/IAF A4: Guidance on the Application of ISO/IEC 17020, is accepted by the: European Co-operation for Accreditations (EA), International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum, Inc (IAF).

Since the standard EN ISO/IEC 17020:2004 and the developed guidance document ILAC/IAF A4 is accepted and applied in the rest of the world and in all other industrial areas performing inspection, Sweden finds the proposal from United Kingdom very inappropriate.

The only logical action to take in this question is to adopt and use the existing international accepted definitions.

If the proposal from the UK is adopted into the RID/ADR, the RID/ADR will have a unique type of inspection body deviating from the rest of the world.

This modified inspection body will not fulfil the requirements of EN ISO/IEC 17020:2004 as a body of type B.

But it will correspond with the requirements of the type C body according to EN ISO/IEC 17020:2004. The type C bodies are not included in the TPED.

Part 2

As the UK have illustrated, there are differences between the texts in TPED and EN ISO/IEC 17020:2004 (which is a carbon copy of the earlier EN 45004:1995) for the type B bodies.

We would like to point out that these differences also exist in Annex I (Minimum criteria to be met by notified or approved bodies) and Annex II (Supplementary Criteria to be met by Notified Bodies) of the TPED compared with the text in the standard EN ISO/IEC 17020:2004.

In Annex II to this informal document a broader table comparing the Annex I, II and III of the TPED with the standard EN ISO/IEC 17020:2004 is presented. (In 2007/48 only Annex II is compared with standard EN ISO/IEC 17020:2004.)

The European Commission submitted on 9 January 1997 The Proposal for a Council Directive on transportable pressure equipment (97/C95/02) COM(96) 674 final - 97/0011(SYN). This proposal comprised the type C bodies, which later were removed by the Council; please see INF.4 to this Joint Meeting. In the text of the proposal it is clearer how the Commission pointed out these three types of bodies.

But the adopted TPED comprises only two types of bodies.

In Annex III to this informal document the differences between the Commissions proposal from 9 January 1997 and the adopted TPED are illustrated.

Part 3

Under point 9 (a) and (b) in document 2007/48, the UK have described problems with bodies not conforming to type B.

If these bodies form a demonstrably separate and identifiable part of an organisation, which should be possible to achieve without considerable problems and another part of the organisation is involved in the design, manufacture, supply, installation, use or maintenance of items that they inspect, for example filling of the pressure receptacle, the inspection body should be able to conform to type B and also be in line with the Guidance document ILAC/IAF A4, see first part of 4.2.2a also inserted below.

4.2.2a The two characteristics by which inspection bodies can be identified as Type B inspection bodies are the following:

- Type B inspection bodies form a demonstrably separate and identifiable part of an organisation that is involved in the design, manufacture, supply, installation, use or maintenance of items that they inspect;

Sweden cannot therefore understand the problem described by UK.

Justification

Please see ECE/TRANS/WP.15/AC.1/2007/46.

Proposal

Please see ECE/TRANS/WP.15/AC.1/2007/46 as this is only an informal document.

This information comes from the EA, European Co-operation for Accreditations webpage, <http://www.european-accreditation.org>. On their webpage a number of publications are to be found and they are categorised to give an indication on how to apply the document.

The Category 2 is the EA MLA support documents. EA MLA support documents are documents of a horizontal nature that support the application of the standards used for accreditation. These documents must be implemented by EA member accreditation bodies for use in their accreditation systems. Their implementation will be assessed as part of the EA MLA peer evaluation process. At <http://www.european-accreditation.org/content/publications/pub.htm> the Application documents for Inspection Series 5 is to be found.

The document EA 5/01 (rev03) Category 2 has been withdrawn. The EA Guidance on the Application on the EN 45004 is replaced by ILAC/IAF A4: Guidance on the Application of ISO/IEC 17020. Please download the document at www.ilac.org or at iaf.nu.

ILAC/IAF A4: Guidance on the Application of ISO/IEC 17020 is to be found at;

ILAC, International Laboratory Accreditation Cooperation,
http://www.ilac.org/documents/IAF-ILAC-A4_2004_guidance_on_the_application_of_ISO-IEC_17020.pdf or at IAF, International Accreditation Forum, Inc.
http://www.compad.com.au/cms/iaf/workstation/upFiles/600630.IAF-ILAC-A4_2004_guidance_on_the_application_of_ISO-IEC_17020_2007-04.pdf

The following text is from the IAF/ILAC-A4:2004, Guidance on the Application of ISO/IEC 17020.

4. Independence, Impartiality and Integrity

- 4.1a Procedures should be documented to assure inspection body staff are free from commercial, financial or other pressures which might affect their judgement.
- 4.2a The categorisation of inspection bodies as Type A, B or C is essentially a measure of their independence. Demonstrable independence of an inspection body may strengthen the confidence of the inspection body's customers in the body's ability to carry out inspection work with impartiality and objectivity. The terms *first party* and *second party*, as defined in ISO/IEC Guide 2, are not used in ISO/IEC 17020, because application of them would not be helpful. However, since conventional thinking has been in terms of first, second or third parties for many years, it is necessary to offer some explanation on the relationship between the two sets of categories, as included below.
 - 4.2.1 a A Type A Inspection Body, to claim to be independent of the parties involved, shall demonstrate that it is not linked to a party directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items by

- common ownership (except where the owners have no ability to influence the outcome of an inspection), *Note 1*
- common ownership appointees on the boards (or equivalent) of the organisations (except where these have functions that have no influence on the outcome of an inspection) *Note 2*
- directly reporting to the same higher level of management
- contractual arrangements, informal understandings or other means that may have an ability to influence the outcome of an inspection

In addition to the above, an Inspection Body shall not become a Type A Inspection Body if another part of the same organisation is directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items, when such other parts of the organisation do not have a separate legal identity.

The Chief Executive of the legal entity of which the Inspection Body is a part shall define and document its policy for maintaining the Type A status of the Inspection Body. The Accreditation Body will examine the evidence of implementation of this policy in respect of ownership interests, constitution of board of directors, means of financing, decision making methods and other such factors that may have an influence on the impartiality, independence and integrity of a Type A Inspection Body.

Note 1: An example of this is a cooperative type of structure where there are large numbers of stakeholders but they (individually or as a group) have no formal means of influencing the policies, strategies or operation of the inspection body.

Note 2: An example of this is where a bank financing a company may insist on an appointee to the board to overview how the company is managed but will not be involved in any decision-making.

4.2.2a The two characteristics by which inspection bodies can be identified as Type B inspection bodies are the following:

- Type B inspection bodies form a demonstrably separate and identifiable part of an organisation that is involved in the design, manufacture, supply, installation, use or maintenance of items that they inspect;
- Type B inspection bodies supply inspection services only to their parent organisation.

A Type B inspection body may form a part of a *user* organisation or of a *supplier* organisation.

When a Type B inspection body that forms a part of a supplier organisation inspects items that are manufactured by or for its parent organisation and are to be supplied to the market or to any other party, it carries out first party inspection.

When a Type B inspection body that forms a part of a user organisation inspects items to be supplied for use by its parent organisation by a supplier organisation that is not its parent organisation and not related to it, it carries out second party inspection.

- 4.2.3a Type C inspection bodies are involved, in the design, manufacture, supply, installation, use or maintenance of items that they inspect. Inspections carried out by them may include first party inspections and second party inspections of the same type as carried out by Type B bodies. However, Type C inspection bodies are distinct from Type B inspection bodies for the following reasons:

A Type C inspection body need not be a separate part but shall be identifiable within the organisation. A Type C body may itself be the designer, manufacturer, supplier, installer, user or maintainer of items that it inspects.

A Type C inspection body may offer its inspection service on the open market or to any other party and supply inspection service to external organisations. For example, it may inspect products supplied by it or by its parent organisation and used by another organisation. It may also supply other organisations with inspection of items that are similar to those designed, manufactured, supplied, installed, used or maintained by it or by its parent organisation, and which may therefore be regarded as competitive.

Inspections carried out by Type C inspection bodies cannot be classified as third party inspections because they do not meet the requirements of independence of operations as stipulated for Type A inspection bodies in Annex A of ISO/IEC 17020. Type C inspection bodies may conform to some of the criteria concerning independence of other economic operators, non-involvement in ‘conflicting’ activities and non-discriminatory operations that characterise Type A and Type B inspection bodies. Yet they remain Type C inspection bodies as long as they do not meet *all* of the requirements applicable to Type A or Type B inspection bodies.

The design/manufacture/supply/installation/servicing/maintenance and the inspection of an entity carried out by a Type C inspection body should not be undertaken by the same person. An exception to this is where a regulatory or other authoritative requirement explicitly allows an individual person from a Type C inspection body to undertake both the design/manufacture/supply/installation/servicing/maintenance and the inspection of an entity.

Annex II

There are differences in the annexes of the TPED compared with the text in the EN ISO/IEC 17020:2004 not only in Annex III regarding the approved bodies (type B). See the following table, which covers Annex I, II and III of the TPED.

Annex I Minimum criteria to be met by notified or approved bodies	Requirements in ISO 17020:2005
<p>1. A notified inspection body or an approved inspection body that is part of an organisation involved in functions other than inspection must be identifiable within that organisation.</p>	<p>3.2 An inspection body that is part of an organisation involved in functions other than inspection shall be identifiable within that organisation.</p>
<p>2. The inspection body and its staff must not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities.</p> <p>In particular the staff of the inspection body must be free from any commercial, financial and other pressures which might affect their judgment, particularly from persons or organisations external to the inspection body with an interest in the results of inspections carried out.</p> <p>The impartiality of the inspection staff of the body must be guaranteed.</p>	<p>A2 & B.2 (first sentence) The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspections activities.</p> <p>4.1 The personal of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgment.</p> <p>Procedures shall be implemented to ensure that persons or organizations external to the inspection body, cannot influence the result of inspections carried out.</p>
<p>3. The inspection body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform the technical and administrative tasks connected with the inspection and verification operations properly. It must also have access to the equipment required to perform special verifications.</p>	<p>9.1 The inspection body shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out.</p>
<p>4. The staff of the inspection body who are responsible for inspection must have appropriate qualifications, sound technical and vocational training and a satisfactory knowledge of the requirements of the inspections to be carried out and adequate experience of such operations.</p>	<p>8.2 (first sentence) The staff responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out.</p>

<p>In order to guarantee a high level of safety the inspection body must be in a position to provide expertise in the field of safety of transportable pressure equipment.</p> <p>The staff must have the ability to make professional judgments as to conformity with general requirements using examination results and to report thereon.</p> <p>They must also have the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.</p>	<p>8.1 The inspection body shall have a sufficient numbers of permanent personnel with the range of expertise to carry out its normal functions.</p> <p>8.2 (second sentence) They shall have the ability to make professional judgments as to conformity with general requirements using examination results and to report thereon.</p> <p>8.1 The inspection body shall have a sufficient numbers of permanent personnel with the range of expertise to carry out its normal functions.</p>
<p>5. They must also have relevant knowledge of the technology used for the manufacturing of the transportable pressure equipment, including accessories, which they inspect, of the way in which the equipment submitted to their inspections is used or is intended to be used, and of the defects which may occur during use or in service.</p>	<p>8.2 (third sentence) They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service.</p>
<p>6. The inspection body and its staff must carry out the assessments and verifications with the highest degree of professional integrity and technical competence.</p> <p>The inspection body must ensure the confidentiality of information obtained in the course of its inspection activities.</p> <p>Proprietary rights must be protected.</p>	<p>8.1 The inspection body shall have a sufficient numbers of permanent personnel with the range of expertise to carry out its normal functions.</p> <p>5 The inspection body shall ensure confidentiality of information obtained in the course of its inspection activities.</p> <p>Proprietary rights shall be protected.</p>
<p>7. The remuneration of persons engaged in inspection activities must not directly depend on the number of inspections carried out and in no case on the results of such inspections.</p>	<p>8.6 The remuneration of persons engaged in inspection activities shall not directly depend on the number of inspections carried out and in no case on the results of such inspections.</p>
<p>8. The inspection body must have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organisation of which it forms a part.</p>	<p>3.4 The inspection body shall have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organization of which it forms a part.</p>

<p>9. The inspection body must itself normally perform the inspections which it contracts to undertake.</p> <p>When a inspection body sub-contracts any part of the inspection, it must ensure and be able to demonstrate that its sub-contractor is competent to perform the service in question and must take full responsibility for that sub-contracting.</p>	<p>14.1 The inspection body shall itself normally perform the inspections which it contracts to undertake.</p> <p>14.2 When an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that its subcontractor is competent to perform the service in question and where applicable complies with the criteria stipulated in the relevant standard of the EN 45000 series. The subcontractor shall be acceptable to the client.</p>
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<p>TPED Annex II: Supplementary Criteria to be met by Notified Bodies referred to in Article 8</p>	<p>Requirements in ISO 17020 for Type A bodies; Clause 4.2.1 and Annex A</p>
<p>1. A notified body must be independent of the parties involved and therefore provide ‘third party’ inspection services.</p> <p>The notified body and its staff responsible for carrying out the inspection must not be the designer, manufacturer, supplier, purchaser, owner, holder, user or maintainer of the transportable pressure equipment, including accessories, which that body inspects, nor the authorised representative of any of these parties.</p> <p>They must not be directly involved in the design, manufacture, marketing or maintenance of the transportable pressure equipment, including accessories, nor represent the parties engaged in these activities.</p> <p>This does not preclude the possibility of exchanges of technical information between the manufacturer of transportable pressure equipment and the inspection body.</p>	<p>4.2.1 The inspection body providing “third party” shall meet the criteria of annex A (normative).</p> <p>A.1 The inspection body shall be independent of the parties involved.</p> <p>The notified body, and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they inspect, nor the authorised representative of any of these parties.</p> <p>A2. The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspections activities.</p> <p>In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.</p>

<p>2. All interested parties must have access to the services of the inspection body. There must be no undue financial or other conditions. The procedures under which the body operates must be administered in a non-discriminatory manner.</p>	<p>A.3 All interested parties shall have access to the services of the inspection body. There shall not be undue financial or other conditions. The procedures under which the body operates shall be administered in a non-discriminatory manner.</p>
<p>TPED Annex III: Supplementary Criteria to be met by Approved Bodies referred to in Article 9</p>	<p>Requirements in ISO 17020:2005 for Type B bodies; Clause 4.2.2 and Annex B</p>
<p>1. The approved body must form a separate and identifiable part of an organisation involved in the design, manufacture, supply, use or maintenance of the items it inspects.</p>	<p>4.2.2 The inspection body which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organization shall meet the criteria of annex B (normative).</p>
<p>2. The approved body must not become directly involved in the design, manufacture, supply or use of the transportable pressure equipment, including accessories inspected, or similar competitive items.</p>	<p>B.2 The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.</p>
<p>3. There must be a clear separation of the responsibilities of the inspection staff from those of the staff employed in other functions, which must be established by organisational identification and the reporting methods of the inspection body within the parent organisation.</p>	<p>B.1 A clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization.</p>
	<p>B.3 Inspection services shall only be supplied to the organization of which the inspection body forms a part.</p>

Annex III

The following text shows the existing TPED compared with “The Proposal for a Council Directive on transportable pressure equipment” submitted by the European Commission on 9 January 1997.

The COMMON POSITION adopted by the Council on the 30 November 1998 deleted bodies of type C.

Council Directive on transportable pressure equipment 99/36/EC	Proposal for a Council Directive on transportable pressure equipment (97/C95/02) COM(96) 674 final - 97/0011(SYN) (Submitted by the Commission on 9 January 1997)
Article 2 Definitions For the purposes of this Directive:	Article 2 For the purposes of this Directive:
1. ‘transportable pressure equipment’ means:.....	- ‘transportable pressure equipment` shall mean.....
5. ‘notified body’ means an inspection body designated by the national competent authority of a Member State in accordance with Article 8 and meeting the criteria of Annexes I and II;	- ‘notified body or type A inspection body` shall mean a body designated by the national competent authority of a Member State in conformity with Article 5 and meeting the criteria of Annexes I and II,
6. ‘approved body’ means an inspection body designated by the national competent authority of a Member State in accordance with Article 9 and meeting the criteria of Annexes I and III.	- ‘type B inspection body` shall mean a body designated by the national competent authority of a Member State in conformity with Article 6 and meeting the criteria of Annexes I and III,
	- ‘type C inspection body` shall mean a body designated by the national competent authority of a Member State in conformity with Article 7 and meeting the criteria of Annexes I and IV.