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Determination of toxicity of a gas or gas mixture

Détermination de la toxicité d'un gaz ou d'un mélange de gaz

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10298 was prepared by Technical Committee ISO/TC 58, *Gas cylinders*, Subcommittee SC 2, *Cylinder fittings*.

This second edition cancels and replaces the first edition (ISO 10298:1995), which has been technically revised.

Introduction

ISO 5145 "*Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*" and similar standards establish practical criteria for the determination of outlet connections of cylinder valves. These criteria are based on certain physical and chemical properties of the gases, in particular, the acute toxicity of the gases.

One of the difficulties in the application of ISO 5145 resides in the fact that, in the case of single components, there are abundant data in the literature (although differences may be found, depending upon the test methods employed), but in the case of gas mixtures, data in the literature are often incomplete or even non-existent.

The aim of this International Standard is to eliminate the ambiguities in the case of differences in the literature, to supplement existing data and to give a calculation method for gas mixtures.

Since the publication of the first edition of ISO 10298, this International Standard has been used for other purposes than the selection of cylinder valve outlets, e.g. providing toxicity data for the classification of gas and gas mixtures according to the international transport regulations and dangerous substances regulations, which since 2003 is under the umbrella of the Globally Harmonized System (GHS).

Determination of toxicity of a gas or gas mixture

1 Scope

This International Standard lists the best available acute-toxicity data of gases from the literature to allow the classification of gases and gas mixtures.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
lethal concentration 50
LC_{50}
concentration of a gas (or a gas mixture) in air administered by a single exposure during a short period of time (24 h or less) to a group of young adult albino rats (males and females) which leads to the death of half of the animals in at least 14 days

2.2
toxicity level
level of toxicity of gases and gas mixtures

NOTE 1 In ISO 5145, the toxicity level is divided into three groups:

— Subdivision 1: non toxic [$LC_{50} > 5\ 000$ ppm (volume fraction)]

— Subdivision 2: toxic [200 ppm (volume fraction) $< LC_{50} \leqslant 5\ 000$ ppm (volume fraction)]

— Subdivision 3: very toxic [$LC_{50} \leqslant 200$ ppm (volume fraction)]

where

LC_{50} values	correspond to 1 h exposure to gas;
ppm (volume fraction)	indicates parts per million, by volume.

NOTE 2 In the GHS, the inhalation toxicity levels are:

Category 1: Fatal if inhaled	0 ppm $< LC_{50} \leqslant 100$ ppm (volume fraction)
Category 2: Fatal if inhaled	100 ppm (volume fraction) $< LC_{50} \leqslant 500$ ppm (volume fraction)
Category 3: Toxic if inhaled	500 ppm (volume fraction) $< LC_{50} \leqslant 2\ 500$ ppm (volume fraction)
Category 4: Harmful if inhaled	2 500 ppm (volume fraction) $< LC_{50} \leqslant 20\ 000$ ppm (volume fraction)

NOTE 3 In GHS, the LC_{50} values correspond to 4 h exposure. Consequently, the LC_{50} values given in Annex A (see 3.2.2) need to be divided by 2 (i.e. $\sqrt{4/1}$). The reasoning behind the division by 2 is given in Clause B.2.

3 Determination of toxicity

3.1 General

Toxicity may be determined through a test method (3.2) for gas mixtures where the data for the components exist, or through a calculation method (3.3).

For reasons of animal welfare, inhalation toxicity tests geared only for the classification of gas mixtures should be avoided if the toxicity of each of the components is available. In this case, toxicity is determined in accordance with 3.3.

3.2 Test method

3.2.1 Test procedure

When new toxicity data is being considered for inclusion in this International Standard, an internationally recognized test method such as OECD TG 403[43] should be used.

3.2.2 Results for pure gases

The toxicity of pure gases is listed in Annex A, in which LC_{50} values correspond to 1 h exposure. Some of these values have been estimated in accordance with Annex B.

3.3 Calculation method

The LC_{50} value of a gas mixture is calculated using the following equation:

$$LC_{50} = \frac{1}{\sum_i \frac{C_i}{LC_{50}}}$$

where

C_i is the mole fraction of the ith toxic component present in the gas mixture;

LC_{50i} is the lethal concentration of the ith toxic component [LC_{50} < 5 000 ppm (by volume)].

After the LC_{50} of the gas mixture has been calculated, this mixture is classified in accordance with 2.2.

NOTE Synergistic effects[1)] have not been considered in the above, due to a lack of scientific data.

1) For example, LEVIN, B.C. *et al*. Toxicological interactions between carbon monoxide and carbon dioxide. *Toxicol.*, **47**, 1987, pp. 135-164.

Annex A
(informative)

LC_{50} values for toxic gases and toxic vapours used in gas mixtures

Table A.1 lists for each gas the LC_{50} values and the literature references.

Table A.2 lists for each vapour the LC_{50} values and the literature references.

Table A.3 specifies the criteria for oxidizing gases.

Table A.1— List of toxic gases with their LC_{50} values and literature sources

Gases Common name	**CAS[a] No.**	**UN No.**	LC_{50}[b]/1 h ppm **(volume fraction)**	**Remarks**	**Literature reference** (see the Bibliography)
Ammonia	7664-41-7	1005	7 338		[1]
Arsine	7784-42-1	2188	178		[62]
Arsenic pentafluoride	7784-36-3	3308	178	By analogy with arsine	
Boron trichloride	10294-34-5	1741	2 541		[1]
Boron trifluoride	7637-07-2	1008	864		[44]
Bromine chloride	13863-41-7	2901	290	Estimated from chlorine	
Carbon monoxide	630-08-0	1016	3 760	Time-adjusted	[6]
Carbonyl fluoride	353-50-4	2417	360		[5]
Carbonyl sulfide	463-58-1	2204	1 700	Time-adjusted	[7]
Chlorine	7782-50-5	1017	293		[1]
Chlorine pentafluoride	13637-63-3	2548	122		[8]
Chlorine trifluoride	7790-91-2	1749	299		[8]
Chlorotrifluoroethylene	79-38-9	1082	2 000	Time-adjusted	[10]
Chloromethane	74-87-3	1063	5 133		[54]
Cyanogen	460-19-5	1026	350		[11]
Cyclopropane	75-19-4	1027	220 000	"Non toxic" – LC_{LO}[c] – Mouse – Time-adjusted	
Cyanogen chloride	506-77-4	1589	80	Time-adjusted	[12]
Deuterium chloride	7698-05-7	1789	3 120		
Deuterium selenide	13536-95-3	2202	51	Same as hydrogen selenide	
Deuterium sulfide	13536-94-2	1053	710	Similar to hydrogen sulfide	
Diborane	19287-45-7	1911	80	Time-adjusted	[13]
Dichlorosilane	4109-96-0	2189	314		[52]
Dimethylamine	124-40-3	1032	5 290	Time-adjusted	[67]
Dinitrogen trioxide	10544-73-7	2421	57	Calculated from decomposition into NO_2	
Ethylene oxide	75-21-8	1040	2 900	Time-adjusted	[18]
Fluorine	7782-41-4	1045	185		[19]
Germane	7782-65-2	2192	620		[55]
Hexafluoroacetone	684-16-2	2420	470	Time-adjusted	[56]
Hydrogen bromide	10035-10-6	1048	2 860		[51]
Hydrogen chloride	7647-01-0	1050	2 810		[45]

Table A.1 (*continued*)

Gases Common name	**CAS[a] No.**	**UN No.**	LC_{50}[b]/1 h ppm **(volume fraction)**	**Remarks**	**Literature reference** (see the Bibliography)
Hydrogen iodide	10034-85-2	2197	2 860	By analogy with hydrogen bromide	
Hydrogen selenide	07783-07-5	2 202	51		[57]
Hydrogen sulfide	07783-06-4	1053	712		[1]
Hydrogen telluride	07783-09-7	3160	51	By analogy with hydrogen selenide	
Methyl bromide	74-83-9	1062	850	Time-adjusted	[23]
Methyl mercaptan	74-93-1	1064	1 350	Time-adjusted	[24]
Methyl vinyl ether (inhibited)	107-25-5	1087	>40 000	Unverified source at 64 000 ppm	
Monoethylamine	75-04-7	1036	16 000	Time-adjusted	[25]
Monomethylamine	74-89-5	1061	7 110		[46]
Mustard gas			4	LC_{LO} – Human – Time-adjusted	[17]
Nitrogen monoxide	10102-43-9	1070	115	Same as nitrogen dioxide	
Nitrogen dioxide	10102-44-0	1067	115		[28]
Nitrogen trifluoride	7783-54-2	2451	6 700		[48]
Nitrosyl chloride	2696-92-6	1069	35	Time-adjusted – LC_{LO} – cat	[29]
Oxygen difluoride	7783-41-7	2190	2,6		[8]
Ozone	10028-15-6		9	Time-adjusted	[30]
Phosgene	75-44-5	1076	5	Time-adjusted	[32]
Phosphine	7803-51-2	2199	20	Time-adjusted	[64]
Phosphorus pentafluoride	07647-19-0	2198	261	Derived from decomposition to HF	—
Phosphorus trifluoride	7783-55-3	3308	436	Derived from decomposition to HF	—
Selenium hexafluoride	7783-79-1	2194	50	Time-adjusted	[39]
Silane	7803-62-5	2203	19 000	Time-adjusted	[1]
Silicon tetrafluoride	7783-61-1	1859	922		[5]
Stibine	7803-52-3	2676	178	By analogy with arsine	—
Sulfur dioxide	7446-09-5	1079	2 520		[35]
Sulfur tetrafluoride	7783-60-0	2418	40		[36]
Sulfuryl fluoride	2699-79-8	2191	3 020		[1]
Tellurium hexafluoride	7783-80-4	2195	25	Time-adjusted	[39]
Tetrafluoroethylene	116-14-3	1081	2 000		
Trifluoroacetyl chloride	354-32-5	3057	10	Similar to trichloroacetyl chloride	
Trifluoroethylene	359-11-5	1954	2 000	Time-adjusted - Taken from chlorotrifluoroethylene	
Trimethylamine	75-50-3	1083	7 000	LC_{LO} – Time-adjusted	[66]
Tungsten hexafluoride	7783-82-6	2196	218	Derived from decomposition to HF	
Vinyl bromide (inhibited)	593-60-2	1085	> 40 000		
Vinyl chloride (inhibited)	75-01-4	1086	150 000		[47]
Vinyl fluoride (inhibited)	75-02-5	1860	> 40 000		

a CAS = Chemical Abstract System.

b See 3.2.2.

c LC_{LO} = lethal concentration low value.

Table A.2 — List of toxic liquefiable vapours with their LC_{50} values and literature sources

Vapours Common name	**CAS[a] No.**	**UN No.**	LC_{50}[b]/1 h ppm **(volume fraction)**	**Remarks**	**Literature reference** (see the Bibliography)
Antimony pentafluoride	7783-70-2	1732	30	Mouse	[2]
Arsenic trifluoride	7784-35-2	1556	178	By analogy with arsine	
Bis(trifluoromethyl) peroxide	927-84-4		10	Assumed (conservative)	
Boron tribromide	10294-33-4	2692	950	Derived from HBr with BF_3	
Bromine chloride	13863-41-7	2901	290	Estimated from chlorine	
Bromine pentafluoride	7789-30-2	1745	25	Time- and effect-adjusted	[4]
Bromine trifluoride	7787-71-5	1746	180	Estimated from F_2	
Bromoacetone	598-31-2	1569	260	By analogy with chloroacetone	
Deuterium fluoride	14333-26-7		1 100		
Dibromodifluoro-methane	1868-53-7	1941	27 000	LC_{LO} – Time-adjusted	
Dichloro(2-chlorovinyl) arsine			8	Extrapolated from intravenous injection	[14]
Diethylamine	109-89-7	1154	8 000	Time adjusted	[67]
Diethylzinc	557-20-0	1366	non-toxic	Assumed (conservative)	[15]
Diphosgene	503-38-8	1076	2	Derived from phosgene (conservative)	
Ethyldichloroarsine	598-14-1	1892	7	LC_{LO} – Human – Time-adjusted	[17]
Heptafluorobutyronitrile	375-00-8		10	Assumed (conservative)	
Hydrogen cyanide	74-90-8	1613	144	Time-adjusted	[59]
Hydrogen fluoride	7664-39-3	1052	1 307	Median value of 5 studies	[61]
Iodine pentafluoride	7783-66-6	2495	120	Similar to ClF_5	
Methylchlorosilane	993-00-0	2534	2 810	Adjusted for HCl equivalent	[53]
Methyldichloroarsine	593-89-5	1556	7	By analogy with ethyldichloroarsine	
Methyldichlorosilane	75-54-7	1242	1 785		[49]
Nickel carbonyl	13463-39-3	1259	20	Time-adjusted	[27]
Pentaborane	19624-22-7	1380	10	Time-adjusted	[31]
Pentafluorobutyronitrile	None listed		10		
Pentafluoropropionitrile	422-04-8		10	Assumed (conservative)	
Perchloryl fluoride	7616-94-6		770	Time-adjusted	[12]
Perfluorobut-2-ene	360-89-4		12 000	“Non toxic” – LC_{LO} – Time-adjusted	[2]
Phenylcarbylamine chloride	622-44-6	1672	5	By analogy with phosgene	—
Propylene oxide	75-56-9	1951	7 140	Time-adjusted	[60]
Silicon tetrachloride	10026-04-7	1818	1 312		[49]

Table A.2 (*continued*)

Vapours Common name	**CAS[a] No.**	**UN No.**	LC_{50}[b]/1 h ppm **(volume fraction)**	**Remarks**	**Literature reference** (see the Bibliography)
Tellurium hexafluoride	7783-80-4	2195	25	Time-adjusted	[39]
Tetraethyl lead	78-00-2	1649	63		[37]
Tetrafluorohydrazine	10036-47-2		100	Time-adjusted	[38]
Tetramethyl lead	75-74-1		800	Time-adjusted	[65]
Thionyl chloride	7719-09-7	1836	500		[58]
Trichlorosilane	10025-78-2	1295	2 780		[50]
Triethylaluminium	97-93-8		non-toxic	Assumed (conservative)	
Triethylborane	97-94-9		1 400	Time-adjusted	[13]
Trifluoroacetonitrile	353-85-5		500	Time- and effect-adjusted; taken from trichloroacetonitrile	
Trimethylstibine			178	By analogy with stibine	
Uranium hexafluoride	7783-81-5	2978	25	By analogy with tellurium hexafluoride	

a CAS = Chemical Abstract System.

b See 3.2.2.

Table A.3 —Criteria for oxidizing gases

Category	**Criteria**
1	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23,5 % as determined by a method specified in ISO 10156:2010.

Annex B
(informative)

Selection of an LC_{50} value for a particular gas

B.1 General

When collecting data from the open literature on the acute inhalation toxicity of gases, some difficulties are experienced. For example, taking into account the very early years of publication, one can not expect to get results of standardized tests. Moreover, data from reporting sources have to be validated with respect to their details in handling and summarizing information. Furthermore, there is a lack of information on inhalation toxicity for several gases. Thus, particular attention is needed to incorporate all the available facts to complete the toxicological characteristics of gases.

B.2 Time adjustment

In inhalation toxicity tests, the dose-response relationship can be described by the equation

$$W = c \cdot t$$

where

W is a constant which is specific for any given effect, e.g. the deaths of 50 % of the animals exposed;

$c \cdot t$ is the applied dose expressed as the product of concentration and exposure time.

This equation, called Haber's rule, is applicable as long as the biological half-life of the substance in question is reasonably longer than the exposure time.

For gases and vapours with appreciable rates of detoxification or excretion over the time in question, it was found that the relationship between concentration and time is better described by

$$W = c \cdot t^{0,5}$$

When extrapolating from 4 h to 1 h, the equation $W = c \cdot t^{0,5}$ predicts lower LC_{50} values than does Haber's rule. To be on the safe side, this principle was applied by the UN Transport Recommendations in adopting the conversion factor 2 (i.e. $\sqrt{4/1}$) to allow classification of materials on the basis of 1-h LC_{50} data. On the other hand, Haber's rule predicts a lower LC_{50} when going from a 1-h to a 4-h LC_{50}. To make use of all the available data on acute inhalation toxicity under the different exposure schemes, a more generalized version was applied.

Using 1 h as the point of reference,

— going up from shorter periods, linear extrapolation was preferred;

— coming down from longer periods, the conversion factor $\sqrt{x\ \text{h}/1\ \text{h}}$ was used.

However, test results for a period less than 0,5 h were not used, as this was deemed unreliable.

B.3 Choice of animal

Since data on humans, if available, are usually not sufficient to derive any dose-response relationship, laboratory animals are used to investigate the toxicity of substances on warm-blooded animals.

Unless there are counter indications, such as extraordinarily high or low susceptibility of the rat compared to other animals or humans, the rat is the preferred species in the most common toxicity tests. Therefore, LC_{50} data in rats are the most likely to be found. If they are missing, data from animals close to the rat in body weight are evaluated.

B.4 Adjustment for effects

Instead of LC_{50}, often the term LC_{LO} is found in the reporting literature and in databases. The LC_{LO} (lethal concentration low value) is defined as the lowest concentration of a substance in air, other than the LC_{50}, which was reported in the original reference paper as having caused death in humans or animals.

Unfortunately, the use of this term is not consistent enough to make any assumptions as to whether the LC_{50} is below or above that value. Nevertheless, it seems reasonable to make the same use of the LC_{LO} as if it were information about an approximate lethal concentration (ALC). For the classification of gases, no higher precision is required, but the calculation formula for gas mixtures requires a definite LC_{50} value to be set. Another LC value has been taken as LC_{50} when additional information proved it plausible to do so.

B.5 Read across

Some substances had to be characterized as analogous to chemically related structures with known physiological properties. Structure-activity relationships have been taken into consideration as far as possible. Moreover, in several instances, the toxicological impact on the respiratory tract is based on fundamental reactions such as the hydrolysis of different gases in the presence of moisture leading to the same reactive principle.

B.6 Other routes of application

This route may only be used as a very last option.

Sometimes the inhalation toxicity of volatile liquids has to be assessed on the basis of other parenteral, especially intraperitoneal (i.p.), LD_{50} values. There is a good correlation between the LC_{50} and LD_{50} i.p. as far as systemically active substances are concerned. Taking toxic pesticides as an example, it could be shown that an LD_{50} i.p. corresponds in aerosol studies by far and large with the same body-weight-related dose inhaled by rats during a 4-h period. Actually, for instance, an LD_{50} i.p. of 100 mg/kg can be assumed to be equivalent to a 4 h-LC_{50} of about 1 mg/litre air.

B.7 Conclusion

The selection of an LC_{50} value for a particular gas follows the logic algorithm shown in Figure B.1. The preferred measurement standard is LC_{50} RAT for 1 h. Lacking good data for these exact parameters, LC_{50} RAT values for times different from, but closest to, 1 h were selected, eliminating all data for exposures less than 0,5 h. If no reliable LC_{50} data from RAT were available, the next animal of choice was MUS (mouse), then in the following order: rabbit, guinea pig, cat, dog, monkey and mammal. Data for 1 h exposures were preferred. If no reliable LC_{50} data were found for any animal, then a search was made for a reliable LC_{LO} value, utilizing the same hierarchy of animals.

If no reliable LC_{50} or LC_{LO} value was obtainable, a value was provisionally allocated based on any one, a combination, or all of the following:

a) reaction (decomposition) of the product in air;

b) analogy to similar products;

c) comparison to other published hazard levels; and

d) correlation to the LD_{50} i.p. value.

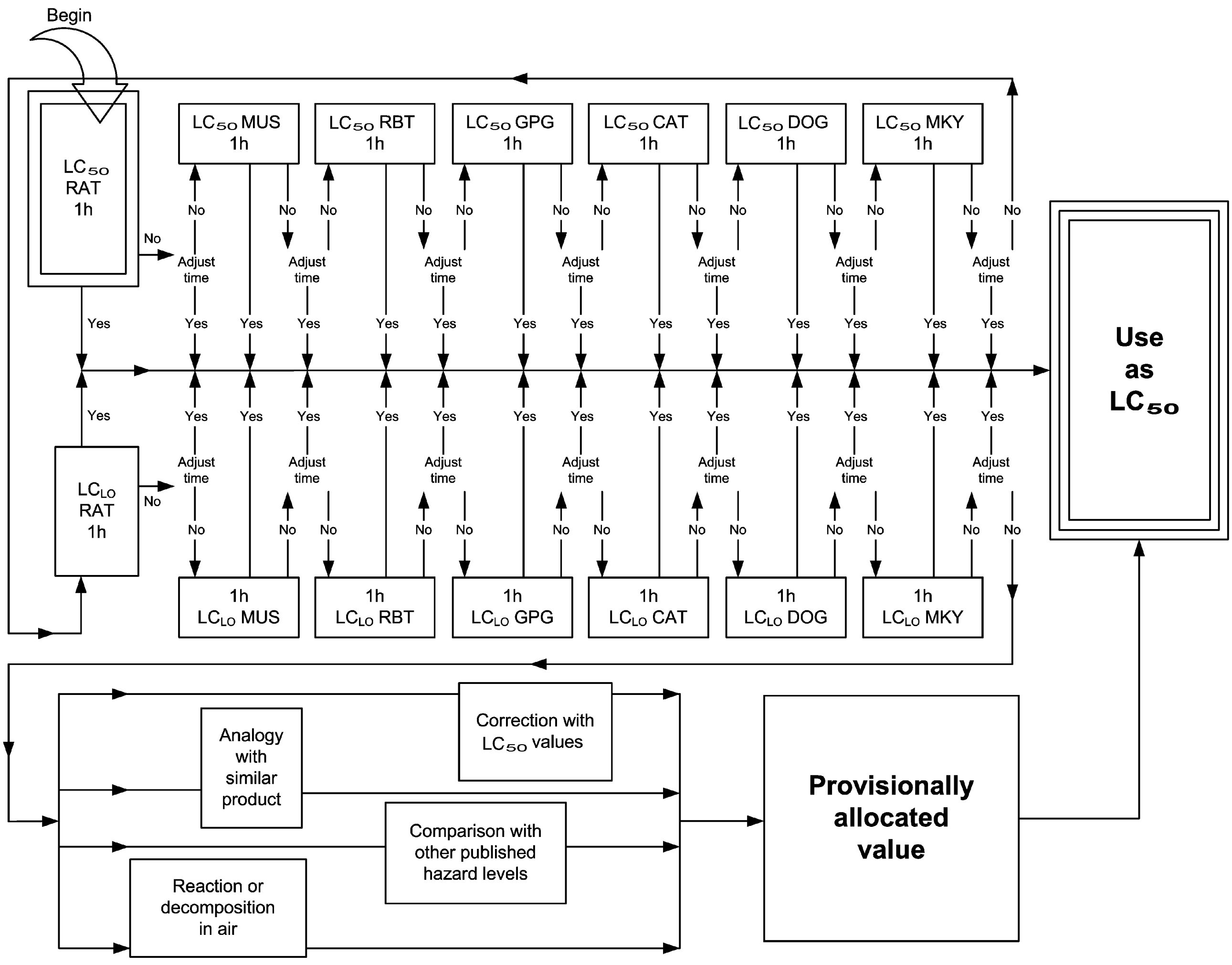

Figure B.1 — Selection algorithm

Bibliography

NOTE The references given below include all those which existed in the preceding version of ISO 10298, with the following modifications:

— some of them (References [3], [16], [21], [22], etc.) are no longer used in Tables A.1 and A.2 of this version and are superseded by new ones; the old references have however been kept for information;

— the new references used in Tables A.1 and A.2 are given at the end of this list (References [44] to [66]).

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