

1. GUIDING PRINCIPLES

Background

Mandating compliance with legal obligations is strictly outside the scope of ISO standards and other deliverables (TS, PAS, IWA, TR). Legislation, given that it is mandatory, will always take precedence over ISO standards, which are voluntary in nature. As is specified in the Foreword to all ISO standards, it is always understood that users of ISO standards will comply with the law.

In addition, including statements about the need to comply with the law in some standards, but not in others, could create the impression that there are two classes of standards advocating two different levels of compliance with the law. ISO deliverables can, however, be used to complement legal requirements and serve as useful tools for all related stakeholders (which can include government authorities and industry players).

Statements relating to contractual obligations, legal requirements and government regulations should only be used when deemed necessary by the experts in the technical committees and working groups, and not in a routine way, and editors may need to give a reminder of this.

NOTE In some ISO standards (e.g. those dealing with supply chain control), creating a system for ensuring legal compliance can be the most important part of the document.

The following **are not permitted** in ISO deliverables:

• statements that include an explicit requirement or recommendation to comply with laws, regulations or contracts.

The following **are permitted** in ISO deliverables:

- statements related to legal and regulatory requirements that do not include an explicit requirement or recommendation to comply with laws, regulations or contracts;
- factual examples of the content of specific laws or regulations for informative purposes.

ISO rules on references to legal requirements/statements

TMB Resolution 70/2018 states:

The Technical Management Board,

<u>Noting</u> the issues of interpretation related to Technical Management Board Resolution 8/2012 concerning the phrase "Further agrees that statements relating to contractual obligations or government regulation are also not permitted";

<u>Further</u> noting that

• text relating to compliance with contractual obligations, legal requirements and government regulations exists in many ISO standards; and

• ISO deliverables can be used to complement such requirements and serve as useful tools for all related stakeholders (which can include government authorities and industry players);

<u>Further noting</u> the responses received from the DMT consultation on this question;

<u>Clarifies</u> that, for all ISO deliverables:

a) Statements that include an explicit requirement or recommendation to comply with any specific law, regulation or contract (such as a normative reference to such requirements), or portion thereof, are not permitted;

b) Statements related to legal and regulatory requirements that do not violate point a) are permitted;c) Factual examples of the content of specific laws or regulations for informative purposes are permitted; and



d) No exceptions shall be granted to point a);(...)

The wording of the ISO/IEC Directives, Part 1, 2018, SR.1 and SR.3, and of the ISO/IEC Directives, Part 2, 2018, Clause 4, will be revised to align with TMB Resolution 70/2018.

The URL in the Foreword of all ISO standards, <u>www.iso.org/iso/foreword.html</u>, states:

ISO International Standards and other normative ISO deliverables (TS, PAS, IWA) are voluntary. They do not include contractual, legal or statutory requirements. Voluntary standards do not replace national laws, with which standards users are understood to comply and which take precedence.

2. ISO/CS APPLICATION OF THE RULES

Acceptable and non-acceptable wording

As stated in TMB Resolution 70/2018 bullet a), statements that include an explicit requirement or recommendation to comply with legal requirements **are not permitted** (whether the reference is to a specific legal requirement or to legal requirements in general).

NOTE Statements including a recommendation to comply with a legal requirement are particularly misleading, because compliance with the law is always mandatory and can never be simply recommended.

For example, the following wording is not permitted:

- "... shall/should... comply with... /respect... /adhere to... /follow... /conform to... /ensure compliance with... applicable laws/contracts/legislation/regulation/legal, regulatory, statutory requirements..."
- "this document is not intended to conflict with... /supersede... /replace... /contradict... applicable laws..."
- "national/international laws take precedence..."

However, statements in which compliance with legal requirements is only implied **are permitted** [see TMB Resolution 70/2018 bullet b)], including statements related to:

- being aware of legal requirements;
- identifying/listing/documenting/having access to applicable legal requirements;
- showing how applicable legal requirements are met/addressed;
- taking legal compliance into consideration;
- providing information on legal compliance;
- demonstrating or documenting legal compliance;
- documenting instances where applicable legal requirements differ from the requirements in the standard;
- providing/requesting evidence of legal compliance;
- showing that all necessary permits are in place;
- setting a policy that includes a commitment to fulfill legal requirements;
- examples and other informative text regarding legislation.

For example, the following statements are permissible:

- *"The organization shall be aware of applicable legal requirements."*
- *"Application of this document/this clause presupposes awareness of applicable legal requirements."*



• *"The organization shall document/show that it has access to all applicable legal requirements and how these legal requirements are met."*

NOTE With respect to practical implementation of a requirement in the context of conformity assessment, it is preferable to use the verb "presuppose" or a formulation that sets clear documentation/process requirements, because it is unrealistic to expect an auditor to be able to verify whether an organization is really aware of all applicable legal requirements.

- "The organization shall provide evidence of the legality of the material, e.g. permits from the applicable authority."
- "Control procedures (such as a due diligence system) shall be put in place to avoid illegal raw material entering the organization."
- *"Top management shall establish, implement and maintain a policy that includes a commitment to satisfy applicable safety requirements, including statutory and regulatory requirements."*
- "The economic operator shall identify legal requirements related to the relevant sustainability aspects described in Clause X, and shall document how these are addressed within the responses to the indicators of this document. An economic operator may also document instances where laws applicable to the economic operator establish different requirements compared to the sustainability aspects of this document."

These types of statements can be necessary, for example, in cases where an organization needs to demonstrate its awareness of the legal context (e.g. to auditors or procurers), or where a procedure needs to include identifying applicable laws. In order to minimize the risk of being seen to create two classes of standard, there should be a reason to include these types of implied statements, i.e. they should not be included simply to remind the user to follow the law.

In addition, informative references to legal requirements and factual examples of the content of specific laws or regulations [see TMB Resolution 70/2018 bullet c)] **are permitted**. For example:

- "Other characterization tests, such as those described in A.2 and A.3, might also be requested (e.g. in order to satisfy applicable national or regional regulation)."
- "Threshold values can be found in applicable legislation."
- "In the EU, Directive X sets requirements that govern whether product Y can be put on the market. Other countries or regions may have similar legislation with which the organization must comply."
- *"European legislation states that opaque eye protection must be worn in these environments."*

NOTE The use of the verbal form "must" indicates an external constraint defined outside of the document.

Beware: in some cases, there may not be obvious keywords indicating compliance with legal requirements. For example, the version of the *Rice Model* published in 2016 contained an implied legal requirement (which was superfluous because users are in all circumstances obliged to ensure that their product respects legal limits):

"The levels of additives and pesticide residues and other contaminants shall not exceed the maximum limits permitted in the country of destination."

This was corrected in the *Rice Model Amendment* published in 2017 as follows (to indicate that the user needs to demonstrate awareness of the legal context):



"There shall be a procedure to identify the maximum permissible levels for additives and pesticide residues and other contaminants in the country of destination."

NOTE In addition to the above wording, the following alternative wordings would also be acceptable:

- "Users shall be aware that the maximum permissible levels for additives and pesticide residues and other contaminants can vary from country to country."
- "It is presupposed that users are aware of the maximum permissible levels for additives and pesticide residues and other contaminants in the country of destination."
- "The organization shall provide evidence that the maximum permissible levels for additives and pesticide residues and other contaminants in the country of destination are not exceeded."

In all cases, the terminology used should be clear and unambiguous, e.g. stating "legal requirements" or "statutory and regulatory requirements". Ambiguous terms such as "national requirements", "external obligations" or "compliance obligations", which imply "the law" without saying so overtly, should be avoided. The user of the document should not be expected to infer meaning from vaguely worded statements.

Communicating to committees

The following note, or similar wording, can be provided to committees when prohibited text is identified and highlighted in the draft standard:

This text indicated is not in accordance with TMB Resolution 70/2018, which states the following: "Statements that include an explicit requirement or recommendation to comply with any specific law, regulation or contract (such as a normative reference to such requirements), or portion thereof, are not permitted."

Please reformulate the text accordingly in order to avoid its removal from the document. Please note that the URL in the fifth paragraph of the Foreword to ISO standards contains an explanation on the voluntary nature of standards and the relation between ISO standards and national law: <u>www.iso.org/iso/foreword.html</u>

3. EXAMPLES OF ACCEPTABLE AND UNACCEPTABLE WORDING

The examples in the table below are real-case examples taken from draft ISO standards. Statements relating to legal requirements are *italicized in red* in the column "Submitted text". In examples 1 to 17, the statements are considered unacceptable for the reasons given in the column "Acceptable or not?" and suggested permissible wording that could be used in ISO standards is *italicized in green*. In examples 18 to 33, the statements are considered acceptable for the reasons given in the column "Acceptable or not?".

	Submitted text	Acceptable or not?
1	<i>This document is not a substitute for legal requirements.</i>	NO – Statement that standard does not conflict with law
2	It is emphasized that the requirements specified in this document are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this document and applicable statutory or regulatory requirements, the latter shall take	NO – Statement that standard does not conflict with law



	precedence.	
3	The contents of a first aid equipment box shall comply with national legislation. () The firefighting equipment shall comply with national legislation.	NO – Explicit requirement to comply with law <u>Permissible wording (if needed):</u> "The required content of a first aid equipment box is given in national legislation. () The requirements for firefighting equipment are given in national legislation."
4	The organization should ensure that information is accurate, not misleading, verifiable and <i>in compliance</i> <i>with applicable statutory and regulatory requirements</i> , and that data collected are relevant.	NO – Explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "The organization should ensure that information is accurate, not misleading, verifiable and that data collected are relevant. <i>It is presupposed that the</i> <i>information is in compliance with</i> <i>applicable statutory and regulatory</i> <i>requirements.</i> "
5	In preparing the product, the organization should ensure that it can be effectively implemented <i>and that</i> <i>its provisions are not in violation of any statutory and</i> <i>regulatory requirements.</i>	NO – Explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "In preparing the product, the organization should ensure that it can be effectively implemented. <i>It is</i> <i>presupposed that its provisions are not in</i> <i>violation of any statutory and regulatory</i> <i>requirements.</i> "
6	Procedures should be developed in accordance with applicable statutory and regulatory requirements.	NO – Explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "It is presupposed that procedures are developed in accordance with applicable statutory and regulatory requirements."
7	<i>Records should be maintained consistent with</i> the organization's record retention policy and <i>applicable legal requirements</i> .	NO – Explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "Records should be maintained consistent with the organization's record retention policy. <i>It is presupposed that</i> <i>they are maintained consistent with</i> <i>applicable legal requirements.</i> "



8	The process <i>should be operated in accordance with applicable law and</i> with the agreement of the parties.	NO – Explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "The process should be operated with the agreement of the parties. <i>It is</i> <i>presupposed that it is operated in</i> <i>accordance with applicable law.</i> "
9	If characteristics of use (e.g. coupling to the grid) involve particular requirements from any other regulatory authority (e.g. inspecting and/or legislative authorities) those requirements have to be met.	NO – explicit recommendation to comply with law <u>Permissible wording (if needed):</u> "The user shall be aware of particular requirements from any other regulatory authority (e.g. inspecting and/or legislative authorities) related to characteristics of use (e.g. coupling to the grid)." or "It is presupposed that the user is aware of particular requirements from any other regulatory authority (e.g. inspecting and/or legislative authorities) related to characteristics of use (e.g. coupling to the
10	While following the guidance provided by this and other standards above is voluntary, suppliers must always maintain an awareness of, and comply with, the legislation and regulations pertaining to the exportation and importation of consumer products.	grid)." NO – Explicit requirement to comply with law. Permissible wording (if needed): "Suppliers shall be aware of legislation and regulations pertaining to the exportation and importation of consumer products." or "Application of this document presupposes that suppliers are aware of legislation and regulations pertaining to the exportation and importation of consumer products."
11	The method of calculation shall be approved by a notified body.	NO – Not an explicit requirement to comply with law, but not appropriate because concept of "notified bodies" is unique to Europe (where it is linked to regulation) and is not applicable to the rest of the world. <u>Change into a note:</u> "NOTE In the European Union, the



		calculation method needs to be approved by a notified body."
12	ISO 8100-20 does not supersede National Regulations. Users of ISO 8100-20 should comply with the National Regulations. ISO 8100-20 is intended to support national regulations on safety assessment of new lifts.	NO – The first two sentences are not permissible: statement that standard does not conflict with law + explicit recommendation to comply with law. However, the third sentence is permissible.
13	This document aims at providing industry recognized means of complying with Airworthiness Authorities general regulations applicable to load securing on board civil transport aircraft (see CCAR-25, JAS Part 3, 14 CFR Part 25 and EASA CS-25), and aircraft manufacturers Authority approved Weight and Balance Manuals for each aircraft type as specified therein. It is not the intent of this document to specify when restraint straps are used, but how they are used. It does not, under any circumstance, supersede the requirements of any of the above documents, which take precedence at all times.	NO – Statement that standard does not conflict with law. Voluntary standards are separate from regulations. The final sentence of the paragraph shall be deleted. However, the first sentence is permissible because it is simply informing the user that the standard provides a means to achieve compliance as an end result.
14	Clause 2, Normative referencesCAAC CCAR-25, Airworthiness Standards – TransportCategory AirplanesEuropean Aviation Safety Agency (EASA) CertificationSpecification CS-25, Airworthiness Standards: transportcategory aeroplanesEASA European Technical Standard Order ETSO-C172a– Cargo Restraint Strap AssembliesEASA European Technical Standard Order ETSO-C203 –Cargo Stopper DevicesEuropean Aviation Safety Agency (EASA) EU-OPS 1.035,Quality systemJapanese Airworthiness Standard Part 3 (CivilAeronautics Law Article 10 §U.S.A. Code of Federal Regulations (CFR) Title 14 Part25, Airworthiness Standards: transport categoryairplanesU.S.A. Federal Aviation Administration TechnicalStandard Order TSO-C172a – Cargo Restraint StrapAssembliesU.S.A. Federal Aviation Administration TechnicalStandard Order TSO-C203 – Cargo Stopper DevicesFederal Aviation Administration TechnicalStandard Order TSO-C203 – Cargo Stopper DevicesFederal Aviation Administration TechnicalStandard Order TSO-C203 – Cargo Stopper DevicesFederal Aviation Administration TechnicalStandard Order TSO-C203 – Cargo Stopper DevicesFederal Aviation Administration (FAA) AdvisoryCircular AC 120-59, Air Carriers Internal EvaluationPrograms	NO – Standard cannot cite regulatory documents normatively. These documents apply by default in the countries where the regulation comes from. They can be cited informatively and included in the Bibliography.



15	<pre>Ports and terminals must observe national, regional and local regulations. () Ports should take into account local, national or regional regulations and guidance that require ships to offload all, or part of, their waste prior to departure. () The port should also develop a periodic auditing system for review at regular intervals in line with national regulations or guidance. () A PWMP shall be transparent, auditable, include provisions for consultation with the stakeholders, and fulfil all legal requirements within the regulations concerning the port.</pre>	 NO – Explicit requirement to comply with law. In addition, throughout the document, the phrase "should take into account local, national or international legislation" (or similar) is repeated in various clauses. This repetition is not necessary as regulations shall always be followed. If it is stated in one clause and not another, it can imply that it is not relevant in the other clause. Rather than repeating throughout, such statements could be combined into one general statement covering an awareness of regulations. (If the local/national regulations are listed as a descriptive part of an analysis or a process/plan, they can be retained.)
16	<i>This document is not intended to be in conflict</i> with any organization's policies, procedures and standards or <i>with any national laws and regulations</i> . Any such conflict should be resolved before using this document.	NO – Statement that standard does not conflict with law.
17	The purpose of the ISO 15830 series is to document the design and specifications of this side-impact dummy <i>in a form suitable and intended for worldwide</i> <i>regulatory use.</i> In 1997, ISO/TC 22/SC 12 initiated the WorldSID 50th percentile adult male dummy development, with the aims of defining a global-consensus side-impact dummy, having a wider range of humanlike anthropometry, biofidelity, and injury monitoring capabilities <i>suitable for regulatory use</i> . Participating in the development were research institutes, dummy and instrumentation manufacturers, governments, and vehicle manufacturers from around the world. <i>With regard to potential regulatory, consumer</i> <i>information, or research and development use of the</i> <i>ISO 15830 series</i> , users will need to identify which of the permissive (i.e. optional) sensors and other elements defined in ISO 15830-3 are to be used in a given application.	NO – Not an explicit requirement to comply with law, but it could be seen to limit the applicability of the standard by suggesting it is for "regulatory use", which is not permissible. <u>Permissible text:</u> "The purpose of the ISO 15830 series is to document the design and specifications of this side-impact dummy <i>in a form suitable and intended for</i> <i>worldwide regulatory use.</i> In 1997, ISO/TC 22/SC 12 initiated the WorldSID 50th percentile adult male dummy development, with the aims of defining a global-consensus side-impact dummy, having a wider range of humanlike anthropometry, biofidelity, and injury monitoring capabilities, suitable for example for regulatory use. Participating in the development were research institutes, dummy and instrumentation manufacturers,



		governments, and vehicle manufacturers from around the world. <i>With regard to potential regulatory,</i> <i>consumer information, or research and</i> <i>development use of the ISO 15830 series,</i> Users of the ISO 15830 series will need to identify which of the permissive (i.e. optional) sensors and other elements defined in ISO 15830-3 are to be used in a given application."
18	 <i>The context of the quality plan can include</i>: a) external issues related to the specific case, such as <i>statutory and regulatory requirements</i>, competitive and market issues; 	OK – Factual statement
19	 The organization should determine the inputs to the quality plan, for example: a) customer requirements, statutory, regulatory and industry specifications; 	OK – Implied statement – taking legal compliance into consideration
20	 The quality plan should define what documented information should be retained. <i>Matters to be considered include</i>: a) <i>what the</i> customer, <i>statutory and regulatory requirements are, and how they will be applied</i>; 	OK – Implied statement – taking legal compliance into consideration
21	<i>The quality plan should take account of</i> applicable specifications, industry standards, quality characteristics, <i>statutory and regulatory requirements</i> .	OK – Implied statement – taking legal compliance into consideration
22	 The organization should revise the quality plan: a) to reflect any changes to quality plan inputs or risks, including: 1) statutory or regulatory requirements; 	OK – Implied statement – taking legal compliance into consideration
23	In conducting the review, the organization should include relevant information on: — changes in statutory and regulatory requirements,	OK – Implied statement – providing information on legal compliance
24	 The examples below highlight key areas where organizations can focus their attention, with suggestions for action in each. <i>Review applicable laws and regulations (e.g. consumer protection laws).</i> 	OK – Implied statement – taking legal compliance into consideration
25	Top management of the organization should review the complaints-handling process on a regular basis in order to:	OK – Implied statement – taking legal compliance into consideration



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	 identify and address instances of nonconformity with health, safety, environmental, customer, statutory, regulatory and other relevant requirements; 	
26	 Management reviews should consider information on: external factors, e.g. changes in statutory and regulatory requirements, practices of competitors or technological innovations; 	OK – Implied statement – taking legal compliance into consideration
27	The organization shall create, implement and maintain a service management plan. <i>The plan shall</i> <i>include or contain a reference to</i> : a) policies, standards, <i>legal and regulatory</i> <i>requirements and contractual obligations</i> ;	OK – Implied statement – taking legal compliance into consideration
28	When establishing policy and objectives, the organization shall be aware of any applicable statutory and legal requirements. or When establishing policy and objectives, it is presupposed that the organization is aware of any applicable statutory and legal requirements.	OK – Implied statement – being aware of legal requirements
29	WARNING — It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.	OK – Implied statement – determining applicability of legal requirements
30	The manufacturer of the sanitation system shall provide documentation concerning risks and instructions on proper use, handling and storage of any additives necessary for system function <i>and</i> <i>declare compliance with the relevant national</i> <i>regulations and laws.</i>	OK – Implied statement – presupposes compliance with legal requirements
31	The organization should consider factors such as: — any applicable statutory and regulatory requirements;	OK – Implied statement – taking legal compliance into consideration (although a superfluous statement)
32	NOTE Consent to participate can be subject to different statutory and regulatory requirements in different parts of the world.	OK – Statement of fact. (although a superfluous statement)
33	Recycled materials shall refer to those materials diverted from the waste stream, recovered and processed into new products <i>following local</i> <i>government permits and regulations</i> .	OK – Statement of fact. If the material has not been processed in accordance with the law, then it cannot be called recycled material; however, the text does not state the law shall be followed in order to recycle material.