




AMERICAN SOCIETY OF SAFETY PROFESSIONALS

OFFICIAL REQUEST - LETTER OF INTERPRETATION (LOI) ANSI/ASSP STANDARD

Read Appendix C of the ANSI-ASSP Standards Procedures addressing LOI preparation and complete the form below in its entirety. The form must be submitted as a Word file and sent to the following e-mail address: admin.workspace@assp.org. All requests must be typed and submitted in a professional and legible format. Please expand the applicable sections to include necessary material/text. We suggest that an LOI not be more than four pages long.

I have read and understand the attached accredited procedures including the specific section and directions addressing an LOI request, (Appendix C). I understand that if the request is not consistent with the accredited procedures the LOI request will be returned to my attention without any action.	 ASSP Standards Procedures (July 2021)
Your initials here:	EM

Please fill out the form below and note there are 10 specific areas requiring your review and response before submission.

1. Organization Requesting the LOI:	Terumo BCT, Inc.
-------------------------------------	------------------

2. Your Name (Point of Contact):	Ed Matthews
----------------------------------	-------------

3. Complete Contact Information including US postal mail address:

Street:	10810 W. Collins Ave.
City	Lakewood
State:	Colorado
Zip Code:	80215
Email:	edward.matthews@terumobct.com

4. I have read and understand the statement below, your initials here:	EM
-------------------------------------------------------------------------------	----

An American National Standard (ANS) implies a consensus of those substantially concerned with its scope and provisions. An ANS is intended as a guide to aid the manufacturer, the consumer, and the general public. The existence of an ANS does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. ANS's are subject to periodic review and users are cautioned to obtain the latest editions.

5. I have read and understand the statement below, your initials here:	EM
-------------------------------------------------------------------------------	----

The information and materials contained in ANSI/ASSP publications have been developed from sources believed to be reliable. However, the American Society of Safety Professionals (ASSP) as secretariat of ANSI accredited standards committees or individual committee members accept no legal responsibility for the correctness or completeness of this material or its application to specific factual situations. By publication of these standards, ASSP or the impacted committee do not ensure that adherence to these recommendations will protect the safety or health of any persons or preserve property.



AMERICAN SOCIETY OF SAFETY PROFESSIONALS

6. The complete title and designation of the standard including the year:	
ANSI/ASSP/ISO 45001:2018 Occupational health and safety management systems - Requirements with guidance for use	

7. The section and subsection impacted by the request:	Clause 5.1 m) and Clause 10.2 of ISO 45001:2018
--------------------------------------------------------	-------------------------------------------------

8. My specific LOI request.

(All requests detailed below must be clearly worded to solicit a "Yes" or "No" answer from the committee, as detailed in the accredited procedures.)

Submitter Question	Committee Response		
	Yes	No	No Interpretation Given*
LOI Question #1			
Under Leadership and commitment, is Clause 5.1 m) <i>"supporting the establishment and functioning of health and safety committees, [see 5.4 e) 1])."</i> of the standard interpreted as a requirement that an organization must have a health and safety committee to be in conformance with ISO 45001:2018?		XXX	
<p>Additional Response Language from the U.S. TAG: Clause 5.1.m is not a strict requirement for the establishment of health and safety committees. Rather, the standard in 5.1 (m) requires Top Management to demonstrate its support for S&H Committees as a means to promote non-managerial worker participation in the OSHMS and related activities per Clause 5.4.e.1. A health and safety committee can be used to satisfy this requirement. An organization might also choose to take a path other than a formal health and safety committee as long as it is equivalent in purpose, promoting workers (non-managerial, especially) participation, and with demonstrated support from Top Management.</p> <p>ISO 45002 provides guidance for implementation of ISO 45001 and gives examples that include ideas of how top management can demonstrate their commitment to non-managerial participation through formal safety and health committees, as well as other methods. One example includes a small business that is looking to reduce near misses and incidents through a systems approach; the owner held meetings where the workers were presented the ISO 45001 standard. This information helped them realize how their consultation and participation was key to achieving established OSH management goals (ISO 45002 Section 5.1 Example 5).</p> <p>Another example describes regular meetings to ensure that knowledge and ideas are exchanged, and that information is not lost as part of a brainstorming meeting with workers (ISO 45002 Section 5.4 Example 3).</p>			
LOI Question #2: Clause 10.2 of ISO 45001:2018	Yes	No	No Interpretation Given*



AMERICAN SOCIETY OF SAFETY PROFESSIONALS

<p>Under Incident, nonconformity and corrective action, is Clause 10.2 a) <i>“react in a timely manner to the incident or nonconformity and, as applicable:</i></p> <p>1) <i>take action to control and correct it;</i></p> <p>2) <i>deal with the consequences;” of the standard a requirement that an organization must have all actions that they have identified to address a nonconformity completely closed within a specific time frame, for example: 3 months, 6 months, or less than a year, etc. to be in conformance with ISO 45001:2018?</i></p>		XXX	
<p>Additional Response Language from the U.S. TAG: Clause 10.2 of ISO 45001:2018 does not spell out a specific time frame for reacting “in a timely manner and taking action to deal with the consequences.” There are practical reasons for this. Incidents and non-conformities vary in the complexity of their causes and development of solutions and the subsequent time it takes for implementation. Accordingly, the Standard doesn’t specify time frames, only that it is done in a timely manner, because it depends on the situation concerning the incident or nonconformity.</p> <p>The reaction and control of any incident requires prompt action, particularly where the consequence has a significant potential for life threatening or life altering injuries. That is something an organization needs to determine. The Annex to ISO 45001:2018, Section A.10.2, which provides additional interpretation of requirements, is also silent regarding specific time frames, such as three or six months, but emphasizes the effectiveness of the corrective actions taken.</p> <p>What the standard requires in clause 10.2 relative to timeliness is taking action to control and correct the immediate identified issue or incident that occurred. This means that an organization needs to determine the timeframe for correction relative to the potential consequences that must be dealt with. You can think of this as a sound plan for preventing further injury and illness which can include temporary mitigation measures.</p> <p>To help understand what timeliness means, it may be helpful to refer to U.S. OSHA’s guidance to its field inspectors. The term “timeliness” is used in assessing compliance with process hazard analysis action completion under the process safety management Standard (see below).</p> <p>https://www.osha.gov/enforcement/directives/cpl-2-245a-ch-1</p> <p>“(e)(5) Timeliness</p>			



AMERICAN SOCIETY OF SAFETY PROFESSIONALS

Employers must "promptly" address the problems identified in the PHA in a "timely manner," and complete actions "as soon as possible." What time frame did OSHA intend here?			
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	--

The standard's intent is for the employer to take corrective action as soon as possible. As soon as possible means that the employer shall proceed with all due speed, considering the complexity of the recommendation and the difficulty of implementation. U.S. OSHA expects employers to develop a schedule for completion of corrective actions, to document what actions are to be taken, and to document the completion of those actions as they occur."

Additional Commentary: This interpretation only addresses the adoption of ISO 45001 as a Nationally Adopted American National Standard, [NAIS]. This interpretation does not extend past ISO 45001 as an NAIS. If an interpretation of this standard is needed beyond that of an American National Standard, then a request should be directed to the leadership of the ISO Technical Committee 283. Nothing in this response constitutes an official position or policy of ISO Technical Committee 283.

*A request for an interpretation shall not be processed if it involves:

1. a determination of compliance of a design, installation, or product or equivalency of protection;
2. requests interpretation of non-current versions of the document in question
3. a review of plans or specifications or requires judgment or knowledge that can only be acquired as result of an inspection;
4. text that clearly and decisively provides the requested information;
5. subjects that were not previously considered by the committee or that are not addressed in the standard;
6. product evaluation judgment concerning safe work practices; or
7. issues in litigation.
8. is deemed commercial in nature such as asking for an endorsement of a product

9. Any comments or rationale you would like to include:

"Notes to entry" used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

Note to entry 1 to both 3.4 participation and 3.5 consultation: adds the qualification "*where they exist*", which implies that health and safety committees are not specifically required.

10. Please type your name which signifies your electronic signature for the purposes of submitting your LOI Request.

Your name here:	Ed Matthews
------------------------	-------------

Below reserved for the impacted committee

LOI Committee Response

Subgroup Coordinator: Vic Toy



AMERICAN SOCIETY OF SAFETY PROFESSIONALS

ASSP as the TAG Administrator to ANSI for ISO TC283 verifies via the release of this LOI that it was reviewed, processed, and approved per the accredited procedures.

Release of this LOI Authorized by:

- Ken Clayman, Chair U.S. TAG to ANSI for ISO TC283
- Tim Fisher, TAG Administrator, U.S. TAG to ANSI for ISO TC283

Date: March 15, 2024

Applicable Responding Secretariat Staff Member:

Tim Fisher
TAG Administrator
U.S. TAG to ANSI for ISO TC283