U.S. FOOD & DRUG ADMINISTRATION

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Today's Topic:

Biocompatibility Town Hall #3: Toxicological Risk Assessments

October 7, 2026

Biocompatibility Town Hall #3: Toxicological Risk Assessment Approaches for Addressing Biocompatibility Endpoints

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Background

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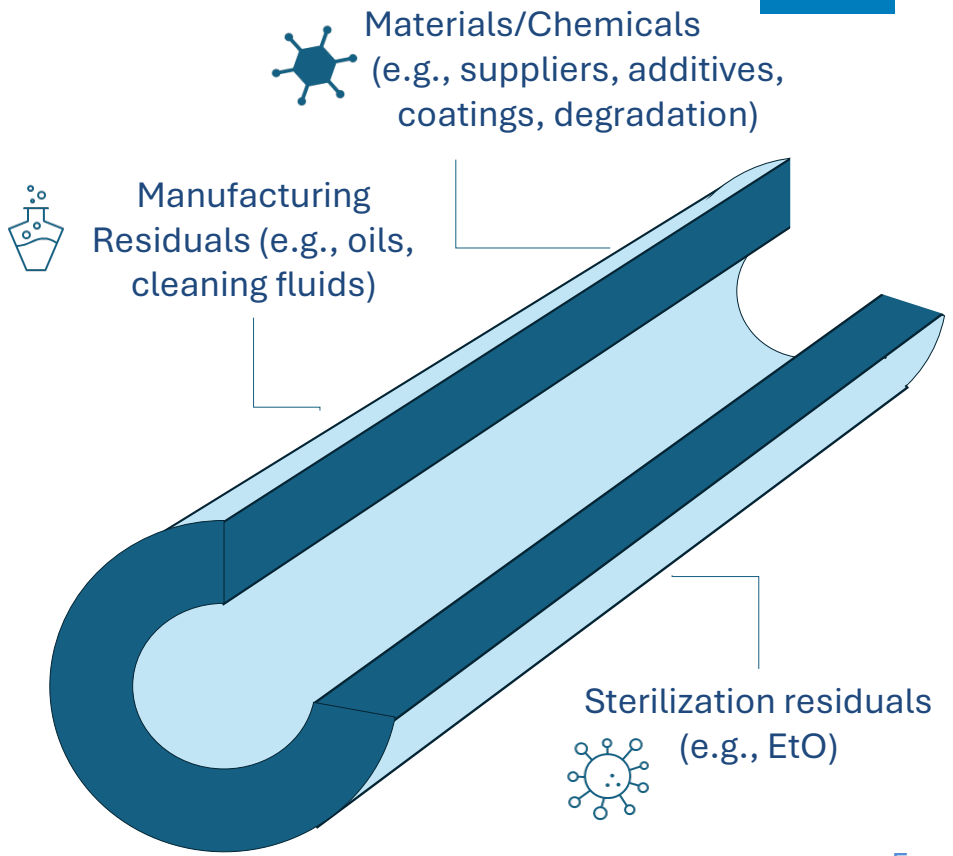
Learning Objectives

- Introduce ISO 10993-17:2023 and ISO TS 21726:2019
- Share key considerations in the application of chemical toxicological risk assessment (TRA)
- Present common TRA issues and considerations

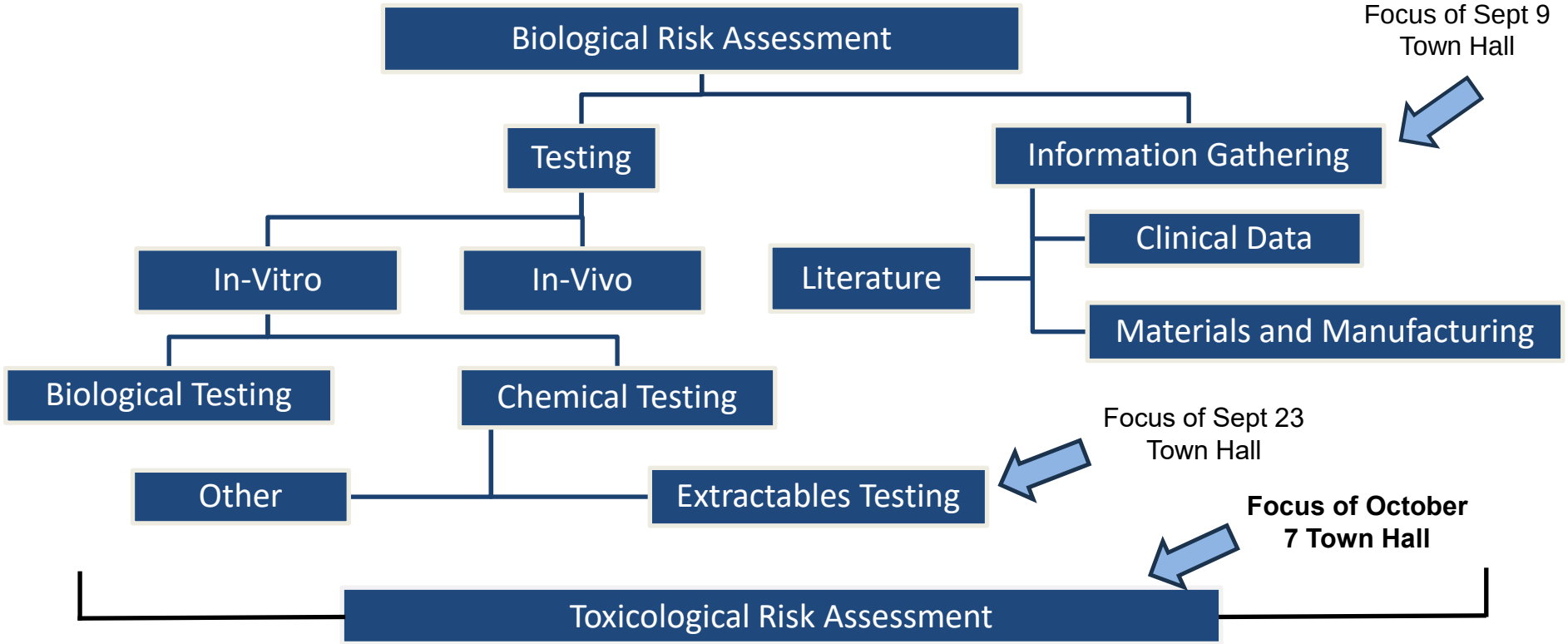
Biological Risk

Potential biocompatibility risks include:

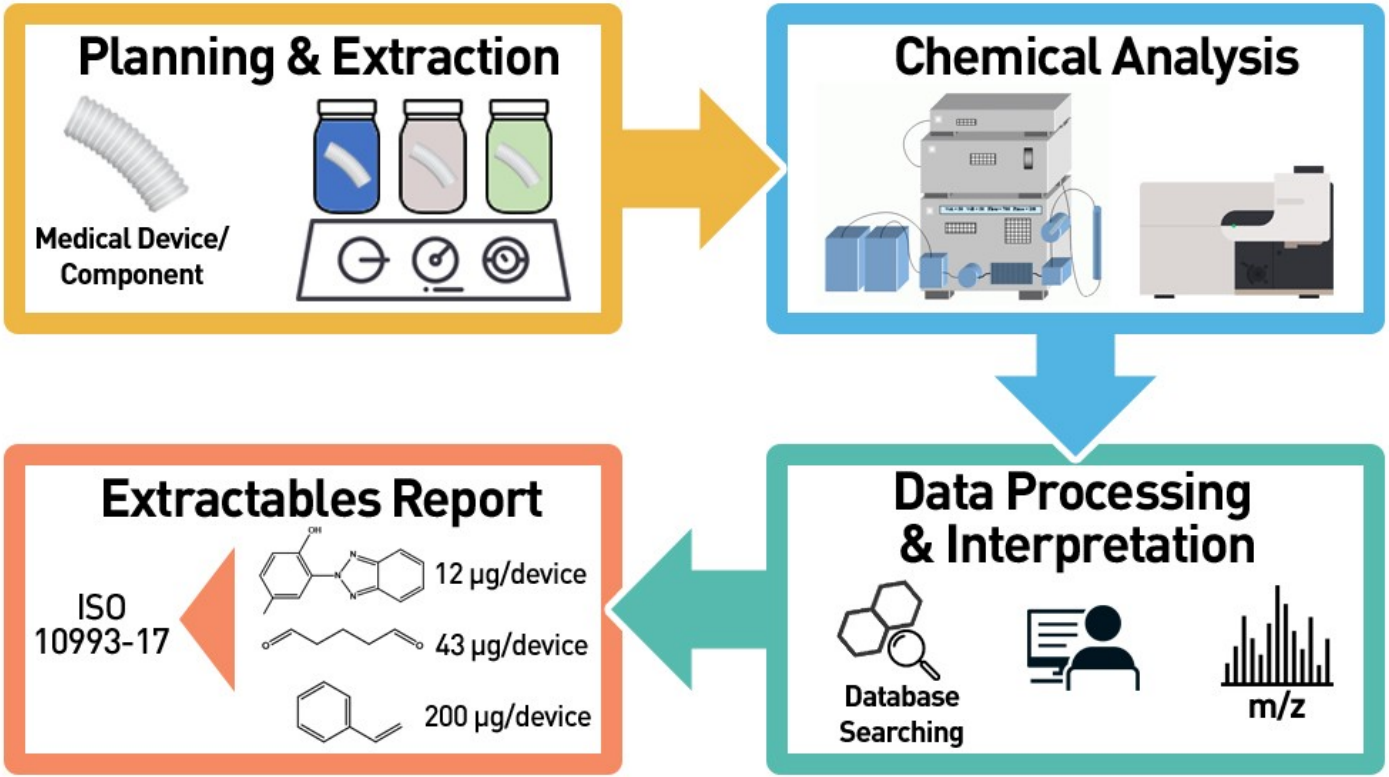
- Material or chemical toxicity
- Unacceptable biological response to physical characteristics of the device
- Aspects of manufacturing and processing that could alter the physicochemical characteristics of the device, resulting in an unacceptable risk



Biological Risk Assessment



Analysis Process



Sussman et al. ACS Biomater. Sci. Eng. 2022, 8, 3, 939–963

Toxicological Risk Assessment

- TRA is a systematic, exposure-based safety evaluation used to determine whether the chemical constituents identified in, or released from, a medical device pose a negligible or tolerable risk for the applicable exposure scenario.
- Relevant standards:
  - ISO 10993-17:2023 *Toxicological risk assessment of medical device constituents* (FDA SIS; partial recognition)
  - ISO TS 21726:2019 *Application of Threshold for Toxicological Concern (TTC) for assessing biocompatibility of medical devices* (FDA SIS; complete recognition)

Table A.1: Biocompatibility Evaluation Endpoints

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – long term (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity#	Degradation@
Category	Contact														
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	X	O	X		X					
		C	X	X	X	X	O	X	X	X		X			
	Breached or compromised surface	A	X	X	X	X	X								
		B	X	X	X	X	X	X		X					
		C	X	X	X	X	X	X	X	X		X	X		
External communicating device	Blood path, indirect	A	X	X	X	X	X				X				
		B	X	X	X	X	X	X			X				
		C	X	X	X	X	X	X	X	X	X	X	X		
	Tissue+/bone/ dentin	A	X	X	X	X	X								
		B	X	X	X	X	X	X	X	X					
		C	X	X	X	X	X	X	X	X		X	X		
	Circulating blood	A	X	X	X	X	X		X		X				
		B	X	X	X	X	X	X	X	X	X				
		C	X	X	X	X	X	X	X	X	X	X	X		
Implant device	Tissue+/bone	A	X	X	X	X	X								
		B	X	X	X	X	X	X	X	X					
		C	X	X	X	X	X	X	X	X		X	X		
	Blood	A	X	X	X	X	X		X	X	X				
		B	X	X	X	X	X	X	X	X	X				
		C	X	X	X	X	X	X	X	X	X	X	X		

Extractables testing and TRA are often leveraged to address certain biological endpoints (e.g., systemic toxicity, genotoxicity, carcinogenicity, and reproductive/ development toxicity).

May be used in combination with risk assessment and/or biological testing.

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff

Introduction to ISO 10993-17:2023 and ISO/TS 21726:2019

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Abbreviations

- **TRA** – Toxicological Risk Assessment [1]
- **CoC** – Cohort of Concern [2]
- **TTC** – Threshold of Toxicological Concern [1,2]
- **TI** – Tolerable Intake [1]
- **MoS** – Margin of Safety [1]
- **EED_{max}** – Estimated Exposure Dose (Maximum) [1]
- **TSL** – Toxicological Screening Limit [1]
- **TQ** – Total Quantity [1]
- **TQ_{max}** - Total Quantity (Maximum) [1]
- **MRL** – Minimal Risk Level [*]
- **RfD** – Reference Dose [*]
- **NSRL** - No Significant Risk Level [*]
- **PoD** – Point of Departure [1]
- **ECHA** – European Chemicals Agency [*]
- **MADL** – Maximum Allowable Dose Level [*]
- **LOAEL** – Lowest Observed Adverse Effect Level [1]
- **LD_{50}** – Lethal Dose, 50% [*]
- **CRSD** – Cancer Risk Specific Dose [1]
- **TD_{50}** – Tumorigenic Dose, 50% [1]
- **LADD** – Life-Average Daily Dose [*]
- **$HQ_{r.k}$** - Highest Quantity (Release Kinetics) [1]
- **MF** – Modifying Factor [1]
- **PDE** – Permitted Daily Exposure
- **AET** – Analytical Evaluation Threshold

[1] Sourced from ISO 10993-17:2023
[2] Sourced from ISO TS 21726
[*] Not a medical device toxicological risk assessment recognized abbreviation/term

Purpose of TRA

- Address biological endpoints that are not addressed by conducting the applicable biological test.
- Contact with tissue can result in exposure to extractable substances.
- Toxicity is an inherent property of extractable substances.
- Understanding extractable toxicity and estimating toxicological risk can demonstrate that exposure is at tolerable level or can identify a hazardous situation.
- Following a common toxicological risk assessment approach facilitates consistent outcomes and decisions.

Consensus Standards Overview

ISO 10993-17:2023 Toxicological risk assessment of medical device constituents	ISO TS 21726:2019 Application of the TTC for assessing biocompatibility of medical device constituents
• Describes the process and requirements for the TRA of medical device constituents. • Includes the methods and criteria that can be used to assess whether exposure to a constituent is without appreciable harm to health. • Supports the biological evaluation of the final product, as described in ISO 10993-1.	• Describes the basis for, selection of, and general applicability of a threshold of toxicological concern (TTC) value for a constituent present in/on a medical device or released from a medical device.
DOES NOT APPLY TO: • Constituents in or extracted from a medical device that fall below a toxicologically-based reporting threshold (excluding cohort of concern (CoC) substances). • A new or changed medical device shown to be chemically or biologically equivalent to an already biocompatible or US marketed medical device.	**DOES NOT APPLY TO:** • Constituents with adequate toxicity data for deriving a tolerable intake (TI) value. • Potential exposure via gas pathways of medical devices, see ISO 18562 series. • Cohort of Concern compounds.

What's new in ISO 10993-17:2023

What’s new compared to version 2002?

- When to conduct a toxicological risk assessment;
- Application of toxicological screening limit (TSL) approach;
- How to calculate a worst-case estimated exposure dose for a constituent;
- When to address toxicological risk by other means. For example:
  - Refinement of a worst-case estimated exposure dose (EEDmax);
  - Additional constituent and harm-specific dose-response data;
  - Application of risk management principles per ISO 10993-1 and ISO 14971.

Extent of Recognition for ISO 10993-17:2023

Partial recognition as described in FDA's Supplementary Information Sheet (SIS):

- Table E.2 in Clause E2 of Annex E
- Phrase "e.g. the largest surface area of device which can be in contact with the body is not the same as the surface area of the device which is in contact with the solution during extraction" in the paragraph before formula E.2 of Clause E2 and in the paragraph before formula E.4 of Clause E3.1.

Key Considerations for TRA

- Analytical Evaluation Threshold (AET)
- General Concepts
- Expressing constituent quantity in µg/device
- Total constituent quantity per ISO 10993-17:2023
- Toxicological Screening Limit (TSL)
- Worst-Case Estimated Exposure Dose (EED_{max})
- Margin of Safety (MoS)

Analytical Evaluation Threshold

The Analytical Evaluation Threshold (AET) is at the heart of the design of an extractables study and determines the concentration at which a substance is identified and (semi-)quantified if present.

AET: Analytical Evaluation Threshold: µg/ml
DBT: Dose-Based Threshold: µg/day
- Typically equal to Threshold of Toxicological Concern (TTC) per ISO TS 21726

A: number of medical devices extracted
B: extract volume
C: number of medical devices that contact the body
D (optional): if diluted (D>1); if concentrated (D<1); if not diluted (D=1)
UF = uncertainty factor of analytical methods (UF >=1)

$$\mathrm{AET} = \frac{\mathrm{DBT} \times \frac{A}{B \times C \times D}}{UF}$$

Formula per ISO 10993-18:2020 Annex E (partial recognition; SIS).

Analytical Evaluation Threshold

$$\mathrm{AET} = \frac{\mathrm{DBT} \times \frac{A}{B \times C \times D}}{UF}$$

DBT: Dose-Based Threshold: µg/day

- Typically equal to Threshold of Toxicological Concern (TTC) per ISO TS 21726 (table copied below)
- Selection of DBT, a potency value, is based on the intended use. For example, a higher DBT than 1.5 µg/d for a long-term (>10 year) implant may apply when shorter constituent exposure duration is reasonably expected.

Contact Category	Limited (<24h)	Prolonged (24h-30d)	Long-term (>30d)		
Duration of body contact	1 mo		> 1 mo to 12 mo	>1 yr to 10 yr	>10 yr to lifetime
Daily intake (µg/d of any one constituent)	120		20	10	1.5

General Concepts of TRA

- Per ISO 10993-17, TRA begins with a known or **estimated** quantity (in µg/device) of a constituent(s);
- Total quantity (in µg/device) of a constituent is **intended to be** representative of a short-term (limited or prolonged contact with tissue) or long-term (long-term contact with tissue) release;
- Worst-case exposure dose is based on **clinical use factors**;
- Constituent Margin of Safety (MoS) is an **inherent outcome** of the medical device and its intended use.

Reporting Constituent Quantity in µg/device

Key Consideration

A constituent quantity reported in µg/device may not represent a clinically relevant maximum total quantity (TQ_{max}) that could be released from a medical device during its intended use.

Explanation of units

	µg	/	device
Meaning	A specified quantity	from	a single or multiple devices

Reporting Constituent Total Quantity in µg/device

TQ_{max} (in µg) in µg/device can represent a maximum amount that could be released when calculated in accordance with ISO 10993-17:2023, Formulas B.2 and B.3.

Illustrative Examples

Example	TQ [1,2]	$MD_{b.c.}$ [2]	SF [3]	TQ_{max} [4]	Calculation (TQ_{max} x SF) [5]	Reporting
A	50	1	0.5	25	50 x 0.5	The total quantity of the constituent from one medical device that contacts the body is 25 µg.
B	50	1	1	50	50 x 1	The total quantity of the constituent from one medical device that contacts the body is 50 µg.
C	50	2	1	50	50 x 1	The total quantity of the constituent from two medical devices that contacts the body is 50 µg.
D	50	2	2	100	50 x 2	The total quantity of the constituent from two medical devices that contacts the body is 100 µg.

[1] Total quantity (TQ) in µg/device from Formula B.2; [2] Maximum number of medical devices that contacts the body from Formula B.3; [3] Scaling factor (SF) from Formula B.2; [4] Maximum total quantity (TQ_{max}) from Formula B.2; [5] Formula B.2 in ISO 10993-17:2023, Clause B.3.

Total Constituent Quantity (in µg/device)

Relative to →
- The duration and frequency of exposure;
- The size of the medical device;
- The number or quantity of medical device that contacts tissue.

Based on →
- Method used to extract constituents from the medical device;
- Impacted by post-extraction processing steps;
- Analytical chemistry test quantification.

Useful for →
- Application of toxicological screening limit (TSL);
- Calculation of EED_{max} based on maximum release, see E.3 in ISO 10993-17:2023.

Maximum Total Constituent Quantity (in µg)

When constituent quantity (in µg/device) may not be a reasonable estimate of a Tq_{max} (in µg) for a specified time-period, such as:

- The constituent is present at a very low level; OR
- The source of the constituent is unrelated to the medical device material of construction.

For these constituents, toxicological risk can be addressed in accordance with ISO 10993-17:2023

For example, calculation of the EED_{max} per Clause E.3.2.

Maximum Total Constituent Quantity (in µg)

Source:

- *Known constituent quantity*: For material of construction, it can be obtained by calculating the percent composition from a material supplier document, see Clause 5.2.2 in ISO 10993-18:2020, by the quantity of the material present in the medical device;
- *Estimated constituent quantity*: For materials of construction or manufacturing materials, can be obtained from chemical analysis of a device extract, see Clause 5.6 in ISO 10993-18:2020.

Reporting:

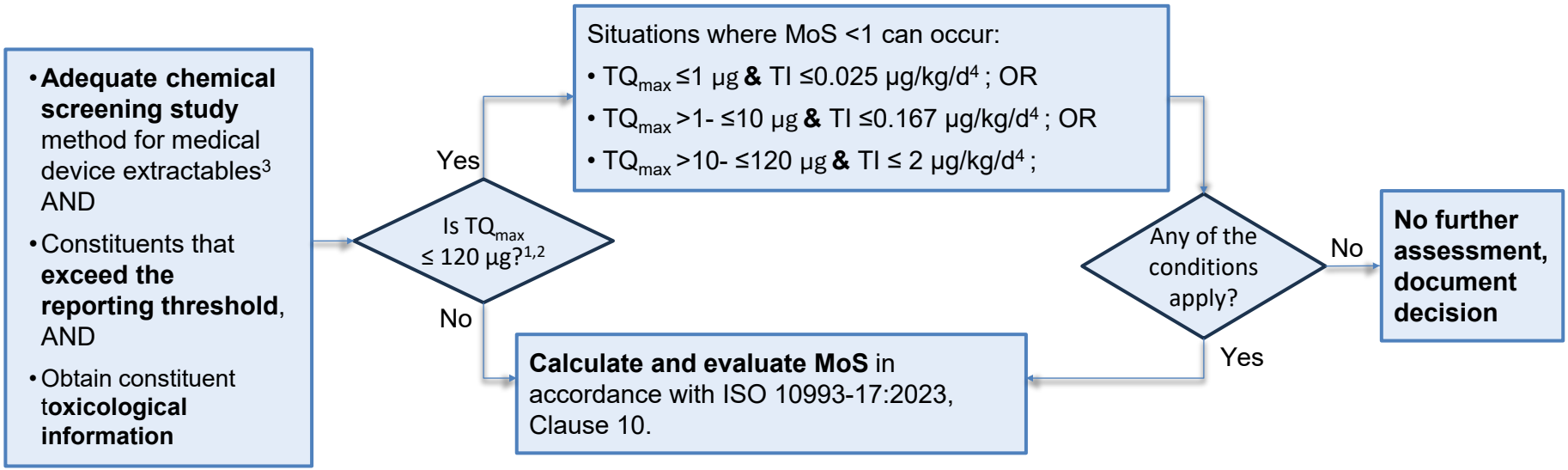
- Expressing constituent quantity in µg/device or µg/(cm^2, g, mL) is necessary for estimating a worst-case exposure dose per ISO 10993-17:2023, Clause 8, in the chemical toxicological risk assessment.

Toxicological Screening Limit (TSL)

What is TSL used for?

- The TSL applies to identified constituents that has been evaluated in accordance with ISO 10993-17:2023, 6.2.2, and
- The TSL (in µg) determines whether a constituent TQ_{max} (in µg) is too low to pose a short-term or long-term risk for genotoxicity, cancer, systemic toxicity, or reproductive harm AND the applicable subpopulation does not include very young infants or neonates, including preterm, see ISO 10993-17:2023, Annex B.
- The applicable TSL value (e.g. short-term 120 µg, long-term 600 µg) is compared against the TQ_{max} of a constituent, see ISO 10993-17:2023, Annex B.

Toxicological Screening Limit (TSL)



[1] Calculation of TSL and maximum total quantity (TQ_{max}) is explained in ISO 10993-17:2023, B.3 Application of toxicological screening limits
[2] The TQ_{max} shown applies to a single medical device or the medical device(s) used for extraction is equal to the medical devices that contact the body. The TQ_{max} is proportionally decreased or increased when the ratio of medical devices used for extraction to the medical devices that contact the body is >1 or <1, respectively.
[3] When quantity does not represent an extractable total, toxicological risk can be estimated per ISO 10993-17:2023, Clauses 7-10 and E.3.2.
[4] In accordance with ISO 10993-17:2023, B.1 (4th bullet, excludes highly potent constituents).

Worst-Case Estimated Exposure Dose (EED_{max})

Applies to:

- Constituent quantity;
- Specific time-period (1d, 2- 30d, 31- 365d, 366d);
- Needs to be a conservative estimate.

Based on clinical factors, such as:

- Sensitivity of the patient;
- The duration and frequency of exposure that applies to the EED_{max};
- The number or quantity of medical device(s) that contact tissue.

Margin of Safety (MoS)

Acceptance Criteria:

- MoS >1 OR
- MoS <1 with ***root cause analysis*** and adequate ***risk management***.

Root Cause Analysis*:*

- *Source of the constituent is identified; AND*
- *Exposure at the EED_{max} for the entire duration is feasible (e.g., based on reasonably estimated total constituent quantity that is present in/on the device).*

Risk Management:

- *Risk evaluation and Risk mitigation (if practical); otherwise*
- *Applications of benefit-risk factors.*

Common TRA Issues and Considerations

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Common TRA Issues

- General observations
- Challenges when applying ISO 10993-17:2023:
  - Tolerable intake (TI)
  - Estimated exposure dose (EED_{max})
- Challenges when applying ISO/TS 21726:2019
  - Threshold of Toxicological Concern (TTC)
- Margin of Safety (MoS) considerations

General Observations

? For chemical screening studies, the adequacy of the chemical data reported for chemical TRA is not clearly stated.

Consideration: Clearly state the adequacy for TRA, such as:

i. The reported quantity represents, based on the extraction method, the worst-case amounts released in a single day for one or more time-period(s) that apply to the medical device intended use OR

ii. The reported quantity represents, based on the extraction method, a total amount that could be released for the longest time-period applicable to the medical device intended use

Challenges when applying ISO 10993-17:2023

Tolerable Intake

- Calculation of TI value is not in accordance with C.2.2 Determination of Uncertainty Factors in ISO 10993-17:2023.
- For example:

  Some applicable sources of uncertainty (i.e., modifying factor (MF) is lower than expected or absent) are not included.

Considerations: Apply the approach described in Annex C.2.2.

Challenges when applying ISO 10993-17:2023

Tolerable Intake

- When deriving the TI value from chemical analogue using read-across approach, no detailed information is provided to state what type of criteria are selected to identify an analogue.

Consideration: Apply Clause 6.2.4 Selection of the point of departure (PoD) that is used in the derivation of the TI value.

Challenges when applying ISO 10993-17:2023

Tolerable Intake

Issue	Solution
Chemical specific non-medical device threshold (e.g., MRL, RfD, NSRL, MADL) is obtained from a public database summary only (e.g., ECHA) instead of searching published literature for chemical specific point of departure (PoD). The detailed study information on how the PoD was obtained is not provided.	Identify the PoD used, review its source, and assess whether the PoD aligns with ISO 10993-17. Apply (if necessary) the applicable uncertainty factors in ISO 10993-17:2023, Annex C. This approach is necessary to establish that the constituent tolerable intake value will be protective for the specific medical device intended use.
Use LD_{50} data from acute systemic toxicity study is used to derive the short-term and long-term TI limit.	Use the relevant POD value for the chemical or its analog, otherwise apply the recommended TTC value per ISO/TS 21726:2019.

Challenges when applying ISO 10993-17:2023

Tolerable Intake

- Not reporting a CRSD and MoS cancer values for a carcinogen with a reported slope-factor or TD_{50} value.

Consideration: Provide an assessment per Clause C.3 of ISO 10993-17:2023, for devices that contain a human carcinogen or a suspected human carcinogen.

Challenges when applying ISO 10993-17:2023

Estimated Exposure Dose

Calculation of EED_{max} is not in accordance with Clause 8 Exposure Dose Estimation and Annex E.3 in ISO 10993-17:2023, for example:

- The estimated daily exposure dose is adjusted by applying a proportional factor (e.g., based on frequency of use) for some intermittent exposure device (e.g., a proportional factor of 3/7 based on 3 treatments per week from a 24 h extraction study for hemodialysis device), OR
- Lifetime Average Daily Dose (LADD) is calculated, which results in a less conservative long-term estimated exposure dose and conflicts with the second bullet in 10.1 of ISO 10993-17:2023.

Consideration: Calculate EEDmax in accordance with Clause 8 and Annex E.3, and apply 10.2 if necessary.

Challenges when applying ISO 10993-17:2023

Estimated Exposure Dose

The selected total quantity (TQ) does not represent a cumulative exposure dose based on the extraction methods and is not adequate for calculating a worst-case estimated exposure dose (EED_{max}) in accordance with E.3.1.

- Example, the TQ obtained from exaggerated extraction (e.g., 50C for 72 h), instead of exhaustive extraction is used to calculate the EED_{max} for a long-term contacting device by dividing it with 366 days.

Consideration: Calculate EED_{max} in accordance with Annex E.3.2 in ISO 10993-17:2023. For example, when the device contacts tissue for more than 1 year, repeat the chemical screening study under exhaustive conditions and calculate EED_{max} in accordance with Annex E.3.

Challenges when applying ISO 10993-17:2023

Estimated Exposure Dose

The EED_{max} is not selected based on the highest measured quantity (HQr.k.) of compounds released during a day due to the incomplete release kinetics study

- Example: The selection of the number of time points is not sufficient to represent the exposure period of device from the release kinetic study as stated in Note 2 of Clause E.2 in Annex E or only non-targeted analysis is used for quantification.

Consideration: Consider consultation with FDA via the Q-submission process prior to conducting the release kinetics study. Otherwise, the minimum information for the TRA is typically a traditional chemical screening study that generates a total quantity representative of the medical device's cumulative prolonged exposure duration with extractables quantified by non-targeted analysis.

Challenges when applying ISO 10993-17:2023

? *Estimated Exposure Dose*

Formula E.3 (Worst-case exposure dose estimation based on maximum release) is used for a medical device with limited (24 h) tissue contact, and extraction temperature and duration are not representative of worst-case intended use, see ISO 10993-17:2023, E.2 and E.3.1.

✓ Consideration: Recalculate the worst-case estimated exposure dose using Formulas E.1 and E.2 for each reportable constituent. Consider repeating the extraction study based on the adequacy of the extraction method and toxicity of the reported extractables to address false negative and false positive TRA outcomes, respectively.

Challenges when applying ISO 10993-17:2023

Other

Issue	Solution
TSL is applied to an excessive number of extractables, such as extractables other than an identified constituent (i.e., unknown, incomplete identity, metals, CoC compounds, or other excluded substances).	**Solution:** Apply TSL in accordance with Clause 6.2.2 and Annex B of ISO 10993-17:2023. Apply Clauses 7, 8, 9, and 10 in ISO 10993-17:2023 to extractables that exceed the TSL or excluded from application of the TSL approach.
The toxicological risk assessment is used to address all biocompatibility endpoints or establish the biological equivalence between two devices to waive all biological testing. However, the TRA is acceptable to address some endpoints only (i.e., systemic toxicity, genotoxicity, carcinogenicity) instead of all endpoints as stated in the standard).	**Solution:** Use other approach in accordance with ISO 10993-1, otherwise consult with FDA through the Q-submission process.

Challenges when applying ISO TS 21726:2019

Other

Issue	Solution
TTC is applied to all chemicals without consideration of a chemical TI value that is available.	Follow ISO 10993-17:2023 to derive a TI when a PoD is available for more accurate risk assessment and prevent false toxicological risk concerns.
Apply noncancer TTC value (e.g., Cramer Classification threshold) to unknown/unidentified compounds.	Identify the chemical structures to apply the non-cancer TTC. Otherwise, apply mutagenicity/ cancer TTC values per ISO/TS 21726:2019.
TTC is applied in an unexpected and novel way without providing sufficient toxicological evidence that the resulting value will be adequately protective. For example, non-cancer TTC 30d = non-cancer TTC>30d x (lifetime Ôdevice tissue contact duration) x safety factor.	Follow ISO 10993-17:2023 for general recommendations in how to apply TTC.

MoS Considerations

? *Further risk analysis or risk evaluation or risk mitigation (i.e., MoS <1)*
The lowest toxic dose that the extractable is capable of eliciting harm is not included in the TRA report, see 10.2 in ISO 10993-17:2023.

Consideration 1a: When the lowest toxic dose is available (e.g. LOAEL), apply the UFs for Exposure Route, Exposure Duration, Data Applicability, and Data Quality in accordance with Annex C and compare to the EEDmax to evaluate whether toxicological risk could be at a higher plausible level.

Consideration 1b: Apply risk mitigation in accordance with ISO 14971 based on the probability of occurrence (e.g., possible or plausible) and severity of the harm (e.g., non-serious or serious). If risk mitigation is not practical, then benefit-risk analysis in accordance with FDA Benefit-Risk guidance documents may result in an acceptable risk outcome.

MoS Considerations

Margin of safety reporting

Reporting of MoS values without indicating the applicable time-period

- Not preferred
- Indicates that Clause E.3.2 (necessary when chemistry data does not align with exposure assessment principles) is applicable instead of E.3.1 (preferred when chemistry data aligns with exposure assessment principles).

Consideration: Report time-based MoS values, e.g., MoS 1d, MoS2-30d, MoS31- 365d, MoS 366d

Summary

- Application of ISO 10993-17:2023 and ISO TS 21726 has been widely cited in submissions
- Occurrence of challenges when applying ISO 10993-17:2023 or ISO TS 21726 is frequent and varied.
- Verification of submitted chemistry data and TRA outcomes is necessary.

Summary (cont.)

- Conduct the TRA in accordance with ISO 10993-17:2023 and ISO TS 21726:2019 unless a strong science-based justification is provided that includes relevant evidence.
- To address a risk, apply risk management principles, which can include TRA outcomes based on chemical screening data, such as:
  - Root cause analysis
  - Risk notification (i.e., for non-serious harms)
  - Risk reduction (i.e., for serious harms)
  - Benefit-risk analysis (i.e., when risk reduction is not practical)
- If challenges occur when applying the consensus standard(s) or proposing risk management principles, consider consultation with FDA/CDRH (e.g., Q-Submission process) for feedback regarding the approach.

Resources

Slide Number	Cited Resource	URL
7	Sussman, et al. “Chemical Characterization and Non-targeted Analysis of Medical Device Extracts: A Review of Current Approaches, Gaps, and Emerging Practices”. ACS Biomater. Sci. Eng. (2022) 8 (3): 939–963.	https://doi.org/10.1021/acsbiomaterials.1c01119
8, 16	ISO 10993-17:2023 *Toxicological risk assessment of medical device constituents* - Supplementary Information Sheet	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=44811
8	ISO TS 21726:2019 *Application of TTC for assessing biocompatibility of medical devices* - Supplementary Information Sheet	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=39076

Resources

Slide Number	Cited Resource	URL
9	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and FDA Staff	www.fda.gov/media/142959/download
17	ISO 10993-18:2020 *Chemical characterization of medical device materials within a risk management process* - Supplementary Information Sheet	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=47373
Question	[Regulatory Scient Tool] TSL/EED/MOS (TEEM) Calculator | Center for Devices and Radiological Health	https://cdrh-rst.fda.gov/tsleedmos-teem-calculator


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Additional Panelist

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Previously Submitted Questions

Thanks for Joining Today!

- **Presentation, Slides and Transcript will be available at CDRH Learn**
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- **Additional questions about today's topic**
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