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From the Blog

ISO 10993-1:2025: Changes for Your Chemical Characterization and E&L Program

March 2nd 2026

At Medistri, we have been working through the 2025 revision of ISO 10993-1 with clients since it was published in November. The question we hear most often is some version of the same thing: do we need to redo our chemical characterization study and toxicological risk assessment? The honest answer is that it depends — and more often than manufacturers expect, the answer is no, or not yet. What usually needs to change is how existing work is documented and positioned within the biological evaluation file. This article sets out where the real differences lie.

Chemical Data First — That Is Now Explicit
Clause 6.3 of the 2025 edition makes something official that was already good practice: gathering physical and chemical information is the required first step before any biological testing decisions are made. The 2018 edition listed chemical characterization as a line item in Table A.1. The 2025 edition removes it from the evaluation tables entirely and positions it as the prerequisite that drives everything downstream.

It is worth being precise about scope here. Chemical characterization under ISO 10993-18 is not limited to extractables and leachables testing. It covers material composition, manufacturing process residues, surface properties, and degradation behavior alongside E&L analysis. Manufacturers who have invested in thorough compositional work often find they need less E&L testing than those who went straight to extraction studies — and the 2025 standard makes that logic explicit and defensible.

There is also a direction of travel that does not always get highlighted: for devices with well-characterized materials and an established safety history, 2025 can reduce testing burden. If biological risk estimation can be completed on the basis of existing information, the standard does not require you to generate new analytical data. This is one of the more useful aspects of the revision.

Contact Category Restructuring
The elimination of the 'externally communicating' category is the change most likely to catch manufacturers off guard. Devices previously classified under blood path indirect, tissue/bone/dentin communicating, or circulating blood contact need to be re-mapped under the 2025 four-table structure: intact skin, intact mucosal membranes, breached or compromised surfaces and internal tissues, and circulating blood. This is not just an administrative update. The biological effects required under each new category are not always the same as under the old classification. Where the scope shifts, the E&L program and TRA may need to be revisited. This is the first check we run in any gap analysis.

Exposure Duration: The Calculation Has Changed
For reusable and repeatedly-used devices, the 2025 rules for calculating cumulative exposure differ from 2018. Intermittent contact is now counted in calendar days from first to last use, not cumulative contact hours. A new bioaccumulation rule also applies: if any constituent bioaccumulates, the device is treated as long-term exposure regardless of actual contact duration.
For single-use devices this changes nothing. For devices like endoscopes, dialysis circuits, or multi-session monitoring systems, the recalculation can push a device from prolonged to long-term contact — with everything that implies for TRA scope. We recommend working through this before finalizing the characterization report, not after.

Our position: for clients with EU submissions or technical file renewals due in 2026, we recommend structuring your Biological Evaluation Plan to the 2025 framework now — even where the underlying testing was conducted under 2018. Notified bodies are already applying 2025 expectations in audits, and building your BEP around the 2018 structure creates avoidable rework later. We are tracking recognition updates across all markets and flag changes to clients as they happen.

Key structural changes in ISO 10993-1:2025:

- Clause 6.3: Physical and chemical information is the explicit first step — removed from Tables 1–4 and elevated to a normative prerequisite.
- Biological Evaluation Plan (BEP): Now a normative Clause 5 requirement. Chemical characterization scope and rationale must be explicitly addressed.
- Biological Evaluation Report (BER): Normative Clause 9. TRA conclusions must be traceable to specific biological risk control decisions.
- ISO 14971:2019 alignment: Biological harm, hazard, and risk terminology is now formally aligned with the risk management standard.
- ISO 10993-17:2023/Amd 1:2025: A 3-page amendment published alongside 10993-1:2025. Update your references accordingly.

Genotoxicity and Carcinogenicity: Who Is Now in Scope
These two changes generate the most genuine surprise in our client reviews. Genotoxicity is now required for prolonged contact (greater than 24 hours up to 30 days) with mucosal membranes, breached surfaces, and indirect blood contact — categories that were not in scope under 2018. Carcinogenicity moves into scope for long-term mucosal contact, which previously only applied to implants. For devices in these categories, the TRA must address these endpoints directly. In most cases the extractables data is already available — it is a matter of completing the genotoxicity-specific risk calculation and documenting the conclusion. Where extractables profiles are incomplete, targeted additional work may be needed. Single-use, limited-duration devices of 24 hours or less are not affected.

What Does Not Change
Because a lot of the commentary around this revision overstates the disruption: the analytical methodology under ISO 10993-18 is unchanged. AET calculations, extraction conditions, TSL values, TTC-based TRA approaches — all remain valid. Re-testing is not required for devices with an acceptable safety history under Clause 6.6.2. A gap review and documentation update is sufficient for most existing compliant files. ISO 10993-1:2025 is not more demanding across the board — it is more precise. It requires you to demonstrate that you actually understand your device's chemical hazard profile, not just that you ran the right tests. For manufacturers who have been doing rigorous chemical characterization all along, this transition is largely a documentation exercise. For those who have been working from a checklist, it is a more substantive project.

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How We Can Support You
At Medistri, we support clients through every stage of this transition — whether you are preparing a new submission, renewing an existing technical file, or simply trying to understand what the 2025 revision means for a specific device. Most projects start with a gap analysis: what documentation exists, what the 2025 framework requires for that device category, and what can be carried forward versus what needs to be updated.

Our work in this area includes:
ISO 10993-1:2025 gap analyses for existing technical files:

- Chemical characterization reports and E&L studies under ISO 10993-18:
- Toxicological risk assessments structured to ISO 10993-17:2023/Amd 1:2025:
- BEP and BER drafting aligned to the 2025 framework:
- Genotoxicity and carcinogenicity testing for devices newly in scope:
- Device re-categorization review under the 2025 contact category structure

Learn more about our laboratory services at our website here. To ensure your products meet the highest quality and safety standards, contact our dedicated team at contact@medistri.com.

— The Medistri Team

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A Note on Regulatory Recognition
As of February 2026, FDA has not recognized the 2025 edition — US submissions should continue referencing 10993-1:2018. In the EU, 2025 is not yet harmonized but notified bodies are treating it as state of the art under MDR 2017/745; check with your notified body before your next technical file renewal. Swissmedic follows the EU line. MHRA, Health Canada, TGA, and PMDA are monitoring but have not yet published updated guidance.