Exhibit E-3 – Documentation Integrity Failure Summary –

ISO 13485 Documentation-Control Requirements &

SOX 302/404 Internal-Control Obligations

Overview

The April 14, 2025 performance record was a manually generated, non-system IPE (Information Provided by Entity) residing only within the manager's and employee's email accounts. Despite its informal origin, it was retrospectively used to justify a previously issued performance appraisal, compensation outcome, and subsequent managerial actions. Because it was relied upon for formal personnel decisions, it constitutes a controlled managerial record under ISO 13485 documentation-control duties and SOX 302/404 internal-control obligations—not an informal note or HR convenience document.

Boston Scientific is:

- **ISO 13485–certified** (voluntarily, but binding once certified)
- **SOX-compliant and publicly traded**, making SOX 302/404 **mandatory federal requirements**

Therefore:

ISO 13485 = Certification Obligations

Once certified, the organization must **fulfill all documentation-control requirements** (ISO 13485 §4.2). A falsified controlled record is, therefore, a **nonconformity** under a binding standard.

SOX 302/404 = Federal Compliance Obligations

These sections require:

- Controls ensuring accuracy of records used in financial or compensation-relevant decisions
- Disclosure of material weaknesses
- Attestation of internal controls integrity

Performance documentation used in compensation determinations **falls squarely within the SOX-controls environment.**

Why ISO 13485 / SOX Apply In This Matter

Regulatory and Internal-Control Implications of a Manually Generated IPE Used for Personnel Decisions

Although the disputed April 14 document originated within an HR workflow, its inaccuracies constitute a **documentation-integrity failure** governed by the company's **internal-control environment**, not solely by HR policies. Under **ISO 13485 documentation-control requirements** and **SOX 302/404 internal-control obligations**, any management-generated record that is relied upon for compensation, performance appraisal, promotion gating, or formal personnel decisions is categorized as a **controlled managerial record**.

This includes, but is not limited to:

- performance reviews
- competency assessments
- promotion/advancement documentation
- compensation and merit decisions
- disciplinary records
- any document used to justify or support managerial action

Classification of the April 14 Record

The April 14 document was a **manually generated, non-system IPE (Information Provided by Entity)** residing only within the manager's and employee's email accounts. Despite its informal origin, it was later **relied upon to justify**:

- a previously issued performance appraisal,
- corresponding compensation outcomes, and
- subsequent managerial actions.

Because it was **used in formal decision-making**, the April 14 document is treated as a **controlled managerial record** under ISO 13485 and SOX 302/404 obligations—not as an informal note or HR convenience document. This classification is not discretionary; it follows directly from the record's use in compensation and appraisal workflows.

Why This Matters (Internal-Control Perspective)

The documentation-integrity failure is significant because the April 14 record was:

- authored by a manager,
- relied upon by HR for official personnel actions,
- directly contested with contemporaneous evidence, and
- maintained uncorrected after formal notice.

In an internal-control environment operating under ISO 13485 and SOX 302/404, these conditions elevate the issue from an HR disagreement to a **system-level control weakness**.

ISO 13485 and SOX do not regulate "HR matters."
They regulate the integrity of the internal-control environment.

A falsified or inaccurate controlled record—irrespective of department of origin—represents a **controls breach** because it:

- bypasses established documentation-integrity requirements,
- creates an unvalidated managerial data source (manual IPE),
- introduces an unmitigated risk to downstream decision-making, and
- undermines the reliability of the organization's internal records.

Any such record inside a validated internal-control system is a breach—whether intentional or inadvertent.

Escalation & Governance Implications

When notified of a documentation-integrity failure involving a controlled record, the expected internal-control response is:

1. examination of the disputed record,
2. evaluation of the contemporaneous evidence,
3. correction of inaccuracies, and
4. remediation to prevent recurrence.

In this matter, despite receipt of **audio-verified evidence**, the April 14 record remained **uncorrected** and continued to be used as a basis for personnel actions. This outcome creates exposure in the areas of:

- documentation control compliance (ISO 13485)
- internal-control reliability (SOX 302/404)
- executive attestation accuracy
- governance oversight and escalation handling

Summary

The April 14th document is not a routine HR record. It is a controlled managerial IPE containing verified inaccuracies, relied upon for personnel decisions, and maintained after notice. Under ISO 13485 and SOX internal-control obligations, this constitutes a documentation-integrity breach and a potential system-level control weakness, irrespective of intent.