Exhibit E-2 – Compliance & Governance Breach Summary – Documentation Integrity Failure

Anderson v. Boston Scientific Corporation (NYSE: BSX) & Aaron Clark

Overview

This exhibit identifies the **governance-level implications** arising from a falsified performance-management document authored by a Boston Scientific manager and subsequently ***maintained, ratified, and relied upon*** within the company's internal-control environment. The incident converts a personnel-level dispute into a **documentation-integrity failure** affecting quality-system traceability, managerial oversight obligations, and SOX-aligned internal-control expectations.

The official performance document contained statements that were **materially inconsistent with the contemporaneous discussion** held during the employee's performance meeting on April 10, 2025. A verbatim audio recording of that meeting confirms that **key evaluative remarks and agreements were altered or omitted** in the written record, resulting in a description of performance and conduct that does **not accurately reflect the conversation or the employee's actual contributions**. The document was subsequently maintained and relied upon in later employment actions **without correction or addendum**, despite evidence establishing its inaccuracy.

In regulated environments, documentation used to characterize individual performance must remain accurate not only for employment decisions but also for leadership evaluation and organizational outcomes derived from those characterizations. The reliance on a disputed and inaccurate record within supervisory chains expands the risk profile from individual assessment error to governance-level decision contamination. The regulatory exposure does not arise from "HR conduct"—it arises from the falsification of a controlled record and subsequent executive inaction, which triggers internal-control, governance, and oversight obligations far beyond routine employment matters.

How an HR Document Becomes an ISO/SOX Control Failure

1. Nature of Control Failure

Category	Description of Failure	Governance/Reputation Impact
Record Accuracy	Official Resource Management Record (ISO 13485 §6.2) contains statements contradicted verbatim by contemporaneous audio.	Direct evidence of falsification in an official record relied upon for compensation, performance, and HR actions.

Record Reliance	Despite notice, the disputed document was retained, uncorrected, and used to justify an "Improvement Required" rating, raise denial, and adverse career impacts.	Establishes corporate ratification—the company adopted and operationalized a falsified record.
Traceability Failure (ISO 13485)	Employee performance management records form part of competence and personnel-qualification documentation required under ISO 13485 §6.2 and §4.2.5.	Falsified competence documentation constitutes an ISO-relevant nonconformance, impacting audit readiness.
SOX-Relevant Oversight Gap	HR records are part of the broader internal-control structure supporting executive certifications of accuracy in reporting, personnel-based risk assessments, and operational integrity.	Uncorrected falsification after notice signals a potential SOX 302/404 weakness in managerial review and escalation controls.
Leadership Escalation Failure	Executive leadership was notified on May 7, 2025, with supporting evidence, yet the record remained unchanged and continued to be used.	Converts a managerial lapse into an institutional governance failure with cascading liability.
Retaliatory Use of False Record	Fraudulent record deployed to justify performance rating, deny advancement, and support subsequent negative reviews.	Direct evidence of retaliation, willful disregard of corrected facts, and exposure to punitive damages.

2. Why This Constitutes a Governance Incident (Not HR Noise)

Because Boston Scientific operates under ISO 13485 and a SOX-governed internal-control environment, any falsification of records used in personnel qualification, performance evaluation, or managerial oversight becomes a system-level control failure once relied upon by the company.

The April 14 document is:

- Falsified
- Contradicted by audio evidence
- Relied upon in official employment actions
- Maintained after executive notice
- Integrated into ongoing performance documentation

This satisfies the criteria for a documentation-integrity breach with implications for:

- Internal Audit

- Compliance
- Executive reporting
- External regulatory audit readiness
- Litigation exposure
- Corporate oversight mechanisms

Once a falsified record enters a regulated documentation environment—and leadership knowingly relies on it—the issue is no longer personnel-based. It is an organization-level control exception.

3. Control-Impact Matrix

Impact Domain	Control Breakdown	Consequence
Quality System (ISO 13485)	Inaccurate personnel-competency documentation; failure of document control; unresolved nonconformance post-notice	Audit exposure, CAPA trigger, and traceability concerns
HR & Performance Management	Fraudulent record used to justify HR actions	Direct evidence supporting defamation, retaliation, and pretext
Internal Audit	Lack of corrective action post-notice	Indicates oversight gaps in managerial review and escalation
SOX Internal Controls	Maintenance of known-false documentation	Signals potential internal-control weakness affecting executive certifications
Board / Governance	Leadership inaction after C-suite notice	Converts isolated misconduct into ratified organizational behavior
Reputational Risk	Evidence of falsified internal documentation and retaliation	High-severity litigation & compromised reputation exposure

4. Chronology of Escalation (Control View)

1. **April 10** — Meeting occurs; audio captures actual discussion.
2. **April 14** — Written record authored containing materially inaccurate statements.

3. **April–May** —The falsified April 14 record did not influence the already-issued raise/bonus decisions but was subsequently used as a post hoc justification for adverse performance actions, including PIP initiation and follow-on evaluations. The timing demonstrates that the document functioned not as accurate contemporaneous notes but as a retroactive narrative device—a key indicator of pretext and retaliatory intent.
4. **May 7** — C-suite receives documented evidence of falsification, no corrective action.
5. **Mid-Year Review** — Further documentation incorporates and reinforces the disputed narrative.
6. **Current** — Falsified record remains in active use across multiple HR cycles.

This sequence demonstrates **initial falsification → internal reliance → HR containment →leadership ratification → systemic entrenchment**

5. Governance Implications

The Incident Establishes	Such Conditions Align with Criteria for
A validated falsification of an official record	Significant ***internal-control exceptions***
Failure of managerial review and accuracy controls	***Non-conformance*** under ISO 13485
Failure of HR validation controls	***SOX-relevant oversight gaps***
Failure of correction and escalation pathways	High-likelihood ***retaliation findings***
Leadership ratification after executive notice	Elevated ***punitive-damage exposure***
Use of falsified material in subsequent personnel decisions	Strong ***plaintiff leverage*** for pre-litigation resolution

6. Severity Rating

Overall Severity: HIGH
(Cross-functional impact: HR, Compliance, Legal, Internal Audit, Executive Leadership)

Likelihood of Adverse Finding in Litigation: HIGH
(Audio evidence + falsified record + corporate ratification)

Framework / Standard	Relevant Clauses / Controls	Obligation / Principle	Observed Conduct or Breach	Nature of Violation	Severity / Risk Level
ISO 13485:2016 (Medical Device QMS)	4.2.4, 5.6, 6.2.2, 7.3.2, 7.3.10, 8.2.2	Maintain integrity and traceability of quality records, including personnel competence documentation where applicable; ensure accuracy of management review inputs and competence documentation.	Performance documentation containing verified inconsistencies was retained without correction or addendum.	Non-conformance to documentation-integrity and management-responsibility requirements.	**High – Integrity Deviation**
ISO 9001:2015 (Corporate QMS)	5.1.1, 7.5.3, 10.2	Leadership is accountable for truthful documentation of all controlled records — HR, training, or quality. Clause 7.5.3 requires control of documented information and prompt correction of identified errors.	Incorrect performance record maintained in controlled system after validation evidence was available within a certified organization.	Breach of documentation-integrity and corrective-action requirements clause 7.5.3 ("control of documented information"). Breach of clause 5.1.1 ("leadership accountability") and corrective-action controls.	**High – Governance Failure**
Sarbanes–Oxley Act (SOX §302 & §404)	Management certification of internal controls and data accuracy.	Executives certify that internal information systems and personnel records reflect factual data.	Retention of disproven HR/performance data introduces internal-control deficiency affecting certification scope.	**Verified Control Failure**: Introduction of Corrupted IPE (Information Produced by Entity) into a Compensation Review Control under SOX 302/404 attestations (verbatim audio vs. text).	**High – Control Deficiency**

Corporate Code of Conduct / Global Business Practices	"Accurate and complete business records"; "Integrity in communications."	All records must be truthful, complete, and capable of audit verification.	Documented discrepancies brought to leadership attention and acknowledged but left unremediated.	Ethics-code violation indicating tone-at-the-top degradation.	**High - Integrity Misconduct**
Internal Quality Governance / Audit Systems	CAPA, Management Review, Internal Audit Procedures CAPA Management Review Internal Audit Procedures	Identified inaccuracies must trigger corrective-action traceability and escalation to management review.	No CAPA or corrective-action documentation initiated after confirmation of record inconsistency.	Systemic lapse in oversight and escalation protocol.	**High - Systemic Risk**

Interpretive Summary:

The observed record-keeping irregularities constitute verified non-conformances under ISO 13485/9001 documentation-integrity controls and create a potential SOX 302/404 internal-control weakness. The inaccuracy and subsequent ratification breach the fundamental integrity requirements of ISO 13485/9001, SOX certification duties, and Corporate Code of Conduct.

Once leadership notice has occurred, continued reliance on an uncorrected performance record transforms a documentation variance into a governance integrity issue, as the reliability of decisions derived from that record can no longer be presumed. The absence of corrective-action traceability following formal notification demonstrates a tone-at-the-top deficiency and governance failure inconsistent with the company's certified quality-management obligations and ethics framework, exposing the company to notified-body and audit scrutiny.

These findings elevate the matter from personnel conduct to governance-system exposure subject to external audit or regulatory review.