APPENDIX B-6: OPERATIONAL RELIANCE & PERFORMANCE ALIGNMENT

TO: Case File Memo – Anderson v. Boston Scientific (NYSE: BSX) & Aaron Clark
FROM: Narin Anderson
DATE: December 10, 2025
RE: Ranger 035 PDP – Townhall Update

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1. Purpose and Scope

This appendix provides an objective assessment of:

- **Operational dependence** on employee-authored technical deliverables, and
- **Variance** between those deliverables and the subsequent **performance documentation** referencing collaboration, planning, communication, and ***deliverable execution***.

Its purpose is to delineate the **operational reality**, the **record pathway**, and the **governance implications** associated with the unresolved variance and the **control environment**.. This appendix presents these facts without inference or characterization.

2. Operational Inputs and Reliance

The following employee-authored outputs were implemented during DV (Design Verification) and related program milestones:

- Packaging system configuration
- Coiling-plate architecture
- DV build documentation and drawings
- Specifications used to fabricate units
- Technical work product enabling successful development outcomes

Operational records confirm:

- These deliverables were **accepted**, **implemented**, and **relied upon** for DV execution.
- All DV (>8,500) units used for downstream activity incorporated these designs.
- DV testing passed nominal requirements, enabling **accelerated milestone timelines**.
- Leadership communications acknowledged DV outcomes as successful.
- On 10 Dec 2025, following the update on DV nominal-unit test results, the manager provided the following acknowledgment:

“Nice job Narin, awesome to hear and see that all the Ranger DV went well with acceptable results!!”
— Aaron Clark, 10 Dec 2025, 10:42 AM



Included solely as a factual artifact, this communication reflects real-time recognition of packaging-system performance during DV execution. These outcomes indicate that the employee's technical deliverables were both **implemented** and **relied upon** to meet program objectives establishing **actual operational reliance** during the period preceding and following creation of the falsified performance documentation.

3. Documentation-Integrity Variance

A performance-entry document dated **April 14, 2025** justified a previously issued '**Improvements Required**' (below expectations) in collaboration, planning, communication, **deliverable execution.**

A variance is present because:

- The April 14 entry was created **after** the deliverables had been fully implemented and used to achieve DV success.
- The performance characterization does **not align** with contemporaneous program outcomes or managerial acknowledgments of milestone achievement.
- The document reflects a managerial assessment **of *how* work was approached** rather than any deficiency in the underlying technical design.

From an ISO 13485 perspective, this represents:

- Non-Alignment of Documented Information (§4.2.4) - Performance documentation used in official review pathways must reflect accurate and complete operational context.
- Risk of Propagation of Nonconforming Records (§8.3) - If a performance document asserts below-expectation deliverable execution while the program concurrently relied on those deliverables to achieve DV success, downstream users may treat a misaligned record as authoritative.

- Inadequate Verification of Record Accuracy (§4.2.5) - Records must be traceable to validated evidence. The variance between DV results and the April 14 narrative indicates a need for verification or annotation.
- No corrective-action review or reconciliation was recorded.

4. Documentation Lifecycle & Downstream Utilization

Following the non-system, manually generated IPE (April 14 written summary) authored by the manager, the falsified performance record:

- Entered HR review pathways,
- Served as the basis for downstream HR processes.
- Informed subsequent evaluative processes,
- Shaped later managerial perception, and
- Was used as authoritative information ***without annotation reconciling its variance*** with the DV outcomes and program reliance.

This sequence constitutes **downstream reliance** on a potentially misaligned managerial record under:

- ISO 13485 §**8.2.2** (systematic internal audit review), and
- SOX-aligned expectations for reliability of management-generated information used in performance-based decisions.

5. Governance & Control-Environment Implications

The following observations arise strictly from the record pathway—not from interpretations:

- **Documentation-Integrity Risk:** A managerial record that diverges from operational outcomes and contradicted by contemporaneous evidence introduces the risk of **non-aligned IPE** propagating through official processes.
- **Absence of Corrective Action:** No verification, annotation, or corrective adjustment occurred after the variance was identified.
- **Multi-Party Reliance Chain:** The document propagated through multiple reviewers, creating a cross-functional reliance chain suggests system-level process exposure, not localized managerial deviation.
- **Record-Use Misalignment:** Records used in evaluative processes did not reflect the operational reality (DV pass and milestone acceleration) while asserting below-expectation **deliverable execution**, indicating **record-use misalignment**. When performance records diverge from operational evidence, downstream effects may include **misaligned compensation**, **promotion considerations**, and **HR investigative outcomes**—all of which depend on the accuracy of managerial IPE.
- **Organizational Level Exposure:** Because the document entered HR and managerial pathways without reconciliation, the variance represents a **systemic**, not localized, process exposure.

These observations align with typical internal-audit criteria under:

- **ISO 13485 documentation-control principles**, and

- **SOX 302/404 expectations for reliability of management-generated information** used in decision-making.

6. Summary

The program's reliance on the employee's technical outputs to meet key DV and launch-critical milestones stands in direct contrast to the April 14 evaluative documentation describing those same outputs as deficient related to collaboration, planning, communication, and **deliverable execution**.

This divergence creates:

- a **documentation-integrity variance**,
- a **potential internal-controls weakness**, and
- a **record-reliance risk** once the document entered managerial and HR review pathways.