ASME V&V 40 · NASA-STD-7009B · ISO 42001 · OPEN SOURCE · APACHE-2.0

# Unit of *Assurance* (UofA)

An open-source way to package *model credibility evidence* so a reviewer can verify it without reading 200 pages of prose.

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## THE PROBLEM

Reviewers don't reject your simulation. They reject your evidence package. Standards tell you *what* to assess. Your tools capture *what ran*. Neither captures *why you believe it*, and that's where submissions stall.

C1 · PACKAGES

### Decisions as artifacts

Your credibility evidence becomes a portable, signed object you hand a reviewer. Ed25519 + SHA-256. Tool-independent. Tamper-evident.

C2 · DETECTS GAPS

### A rule engine for weakeners

Forward-chaining rules catch missing UQ and unsupported claims. Surfaces compound risks no standalone SPARQL query can find.

C3 · COMPARES

### Records, side by side

Score two published records under one catalog version and compare what evidence each one carries. Page 3 does this.

## WHAT A PACKAGE BINDS

| | | | |
|---|---|---|---|
| **Requirement** `bindsRequirement` | **Claim** `bindsClaim` | **Model** `bindsModel` | **Datasets** 2 `bindsDataset` |
| **Context of use** `hasContextOfUse` | **Credibility factors** 13 `hasCredibilityFactor` | **Validation results** 6 `hasValidationResult` | **Decision record** `hasDecisionRecord` |

A package binds all of these in one signed object. The counts above are this record's, and page 2 sets them out in full.

## WHAT FOLLOWS

PAGE 2 — **The record.** Source paper, context of use, model risk, and how the 13 V&V 40 factors were assessed.

PAGE 3 — **The findings.** What the rule engine flagged, the decision as encoded, integrity, and a comparison.

This document applies the tool to one published paper. It reports what that record contains. It is not an assessment of the modeling work, and it takes no position on regulatory review.

## WHY IT MIGHT FIT YOU

Works in medical device (ASME V&V 40), aerospace (NASA-STD-7009B), and AI management systems (ISO 42001) today. Runs locally, so evidence never leaves your environment. Sits alongside your PLM, SPDM, or model registry, and it doesn't replace them.

ZERO INSTALL

```
codespaces.new/
cloudronin/uofa
```

ON YOUR MACHINE

```
pip install uofa
uofa setup
```

WORKED EXAMPLE

```
uofa.net/demo
```

**The ask:** Run it on one of your own models, even a small one. Email me what breaks or what's missing.

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uofa.net · github.com/cloudronin/uofa

ASME V&V 40 · CASE RECORD · CATALOG CORE@0.5.0 + VV40@0.5.0

# Pedicle screw FEA *credibility record*

The Nagaraja et al. (2024) assessment, encoded as a signed Unit of Assurance package and scored by the weakener rule engine.

## SOURCE RECORD

Nagaraja S, Loughran G, Baumann AP, Kartikeya K, Horner M. “Establishing finite element model credibility of a pedicle screw system under compression-bending: An end-to-end example of the ASME V&V 40 standard.” *Methods* 225 (2024) 74–88.

https://doi.org/10.1016/j.ymeth.2024.03.003

## CONTEXT OF USE, AS ENCODED

FEA predicts construct stiffness, yield force, and force at 40 mm displacement for the non-cannulated 7.5 mm pedicle screw design under ASTM F1717 static compression-bending. Validated by direct comparison to bench testing (N=11 constructs across two laboratories). Model influence MEDIUM (testing confirms results); decision consequence MEDIUM (pedicle screw fracture leads to revision surgery, not death).

PACKAGE NODE nagaraja/cou/cou1-noncannulated

## MODEL RISK, AS ENCODED

| MODEL INFLUENCE | DECISION CONSEQUENCE | MODEL RISK LEVEL | ASSURANCE LEVEL | DEVICE CLASS |
|---|---|---|---|---|
| Medium | Medium | 3 | Medium | Class II |

Model influence and decision consequence are the two components the record gives as drivers of model risk. Both are recorded at Medium.

## FACTOR COVERAGE, 13 OF 13 ASSESSED

The published record reports every factor in the ASME V&V 40 Table 5-1 set. 12 factors reach their required level. Values show achieved level against required level.

| | | | |
|---|---|---|---|
| Software quality assurance | 3 / 3 | Test samples | 2 / 2 |
| Numerical code verification | 3 / 3 | Test conditions | 1 / 3 |
| Discretization error | 2 / 2 | Equivalency of input parameters | 3 / 3 |
| Numerical solver error | 3 / 3 | Output comparison | 3 / 3 |
| Use error | 3 / 3 | Relevance of the quantities of interest | 3 / 3 |
| Model form | 2 / 2 | Relevance of the validation activities to the COU | 3 / 3 |
| Model inputs | 2 / 2 | | |

uofa check --build nagaraja/cou1

```
$ uofa check --build packs/vv40/examples/nagaraja/cou1/uofa-nagaraja-cou1.jsonld
== C2: SHACL profile validation ==
  ✓ SHACL validation  Conforms
== C1: Integrity verification (hash + signature) ==
  ✓ Hash match
  ✓ Signature valid
== C3: Jena rule engine ==
  SUMMARY: 19 weakener(s) detected
  ──────────────────────────────────

    High:  19
⚠ W-AL-01     [High]  6 hits
⚠ W-AR-05     [High]  6 hits
⚠ W-EP-02     [High]  6 hits
⚠ W-ON-02     [High]  1 hit
```

## WEAKENERS DETECTED

A weakener is a condition under which stated evidence does not support the claim it is offered for. It is a property of the record as published. It is not a defect in the modeling work.

| PATTERN | NAME | SEVERITY | HITS | ATTACHES TO | FINDING |
|---|---|---|---|---|---|
| W-AL-01 | Aleatory uncertainty uncharacterized | High | 6 | 6 validation results | No uncertainty quantification is linked to the validation result node. |
| W-AR-05 | Comparator source absent | High | 6 | 6 validation results | No comparator data source is linked from the validation result node. |
| W-EP-02 | Generation activity missing | High | 6 | 6 validation results | No generating activity is recorded for the validation result node. |
| W-ON-02 | Validity boundary undocumented | High | 1 | cou1-noncannulated | The context of use carries no applicability constraint and no operating envelope. |

The package records uncertainty quantification and sensitivity analysis at the package level, and it carries validation results for both. W-AL-01 fires on all six validation results because no uncertainty quantification is linked from the individual validation result nodes. The rule reads the link rather than the package flag.

## DECISION RECORD, AS ENCODED

**Accepted**. Model accuracy met pre-established criterion of <10% difference between FEA and experiment for all three QoIs (stiffness 1.5% E/D, yield load 1.1% E/D, force at 40 mm 1.3% E/D). Critical stress location (rod midshaft) matched experimental failure mode. Test-conditions factor shortfall (achievedLevel 1 vs requiredLevel 3) is acknowledged and offset by N=11 sample size which exceeds typical spinal-device testing recommendations.

Credibility assessment team · decided 2024-03-08

## OFFSET RATIONALE, TEST CONDITIONS

Test-conditions factor shortfall (achievedLevel 1 vs requiredLevel 3) — single ASTM F1717 static compression-bending condition — is offset by N=11 experimental constructs across two laboratories, which exceeds the typical spinal-device testing sample size convention. Nagaraja et al. (2024) §4 acknowledges the limitation explicitly and treats the larger sample size as compensating evidence for the narrow loading-condition coverage.

PACKAGE NODE nagaraja/decision/cou1-overall/offset/test-conditions

## COMPARISON AT THE SAME CATALOG VERSION

Two published records scored under catalog core@0.5.0 + vv40@0.5.0. The counts describe how completely each record documents its evidence. They do not rank the papers or the teams.

| RECORD | FACTORS | FIRINGS | PATTERNS | SEVERITY |
|---|---|---|---|---|
| Nagaraja COU1 | 13 / 13 | 19 | 4 | High 19 |
| Morrison COU1 | 13 / 13 | 11 | 5 | High 10, Medium 1 |
| Morrison COU2 | 13 / 13 | 18 | 6 | Critical 9, High 7, Medium 2 |

SHACL PROFILE
✓ Conforms · ProfileComplete

HASH
✓ Match · SHA-256

SIGNATURE
✓ Valid · Ed25519

PACKAGE HASH
sha256:c0c3c30b766833b5581cea440871dfeae07e4745dbd6d55fd47797fff27e2727

## REPRODUCE EVERY NUMBER ON THESE PAGES

```
$ uofa check --build packs/vv40/examples/nagaraja/cou1/uofa-nagaraja-cou1.jsonld
```



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