Audit-Ready by Design

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Module 1: Foundations of Design V&V – Electrical Engineering Focus

Introduction to Design Verification & Validation in ISO 90

In any engineering discipline, design verification and design validation are core elements of a quality-driven design process. ISO 9001's design control principles require organizations to verify that design outputs meet input requirements and to validate that the finished product meets its intended purpose in the user's environment. In simpler terms, verification asks "Did we build the product right (according to specifications)?" while validation asks "Did we build the right product (meeting user needs)?"[1]. These complementary steps ensure that 70–80% of quality issues, which often originate in the design phase, are caught early – when they are cheapest to fix[2]. ISO 9001 encourages risk-based thinking at all stages, meaning engineers proactively consider potential failures or mismatches and address them before finalizing the design[3] [4].

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[1] https://www.youtube.com/watch?v=KaJrSNP_hlA

[2] https://www.youtube.com/watch?v=KaJrSNP_hlA

[3] https://asqrrd.org/wp-content/uploads/2021/02/Auditing-ISO-9001-Clause-8.3.pdf

[4] https://quality.eleapsoftware.com/fmea-in-qms-complete-implementation-guide/

1.1 Documented Information and V&V Artifacts

ISO 9001 emphasizes maintaining **documented information** (records, reports, checklists) as objective evidence of design control. For V&V, this means generating artifacts such as **test plans, review records,** analysis reports, and **qualification certificates** that demonstrate each requirement was verified and validated appropriately[5]. A **Design Verification Plan** might outline *who* performs each check, *how* it's done, and *what records* to keep[6]. Similarly, design validation often involves documented results of **user trials, simulations, or field tests** confirming the design fulfills its intended use[7]. These artifacts are vital not only for internal quality assurance but also to satisfy external audits or regulatory requirements that expect evidence of thorough design control.

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[5] https://maxicert.com/verification-validation-iso-9001/

[6] https://maxicert.com/verification-validation-iso-9001/

[7] https://maxicert.com/verification-validation-iso-9001/

1.2 Electrical Engineering Scenario – Designing a Power Supply Unit

Scenario: You're part of a team designing a new ***electrical power supply unit*** *(PSU) for an industrial control system.* The design requirements (inputs) include an output of 24 V DC ±5%, a maximum ripple of 50 mV, and compliance with safety standard XYZ. How do ISO 9001's V&V practices apply here?

1.2.1 Design Planning & Inputs:

Begin by clarifying requirements (e.g., output voltage tolerance, ripple spec, safety standards). Under ISO 9001's guidance, ensure requirements are documented and conflicts resolved. E.g., earlier PSUs had field issues with overheating; the team notes a risk related to thermal performance as part of planning (risk-based thinking).

1.2.2 Design Outputs:

The electrical engineers produce schematics and simulate the PSU circuit. The outputs include a **schematic diagram, Bill of Materials, and calculated performance** (voltage regulation, ripple, efficiency). Before releasing the design, **verification** activities are planned to check these outputs thoroughly.

1.2.3 Verification Activities:

Alternative Calculations:

An independent engineer cross-checks critical calculations, such as component stress margins, by performing simplified hand calculations or using a different simulation tool[8]. For instance, if the design simulation predicts 12°C temperature rise on a resistor, an independent calculation using power dissipation formula verifies it's consistent.

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[8] https://maxicert.com/verification-validation-iso-9001/

Design Review:

A formal design review meeting is held with a checklist. Peers and a quality representative assess whether the design meets all specified inputs (correct output voltage range, ripple limits, safety features). Action items are recorded for any discrepancies.

Testing & Prototyping:

A prototype PSU is built. The team conducts **verification tests** in the lab: measuring output voltage, ripple under various loads, and performing a safety insulation test. Results are logged in a verification test report.

Decision Matrix Example:

To decide on the best method for verifying electromagnetic compatibility (EMC) compliance, the team uses a **decision matrix** comparing options (Analytical modeling vs. Lab testing vs. Prior design comparison). Criteria include **accuracy, cost, and time**. For example, lab testing scores highest on accuracy but lowest on cost; after weighing, the team **chooses lab testing** for final EMC verification.

Verification Method Decision Matrix

	Simulation	Inspection	Lab Testing	Field Testing
Accuracy	4	3	5	4
Cost	3	4	2	5
Time	5	3	4	2
Complexity	3	2	4	3
Reliability	3	2	5	4
Total Score	18	14	16 ✓	12

1.2.4 Validation Activities:

Once design outputs are verified, **design validation** ensures the **product meets user needs** in real-world conditions[9]. For the PSU:

The team arranges a **field trial**: the PSU prototype is installed in the actual control system to observe performance over a week. Does it consistently deliver 24 V under site conditions? Does it integrate safely? If the PSU performs as expected (e.g. no overheating in enclosure, stable voltage), this usage **validates** that the design fulfills the intended purpose.

If a full field test is impractical at this stage, **customer witnessing** can serve as validation: showing the client a demo unit and getting written acceptance. Early user feedback – perhaps via a small batch release – may also be used. *(As per ISO 9001, even **customer acceptance of simulations or scaled models** can count as validation evidence if direct testing isn't feasible.)*

The outcomes are documented in a **validation report** or user acceptance sign-off.

1.2.5 Risk Mitigation Check (FMEA snippet): Throughout this scenario, risk-based thinking has been present. For instance, the team identified overheating as a potential **failure mode**. A simple **Design FMEA table** might list *overheating of PSU* as a risk, with causes (e.g., inadequate heat sink), effects (output drop or component damage), and mitigation (verification test at high ambient temperature). By conducting such an FMEA, the team ensures **design verification tests cover high-risk failure modes**[10].

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[10] https://quality.eleapsoftware.com/fmea-in-qms-complete-implementation-guide/

[10] https://maxicert.com/verification-validation-iso-9001/

1.3 Summary (Module 1):

In this module, we established a common **ISO 9001 design V&V framework** using an Electrical Engineering example. We saw how **verification** is planned and executed via reviews, calculations, and tests to ensure the design meets all specifications[11]. We also saw **validation** demonstrating the design's **fitness for use**, e.g. via field trials[12]. Key takeaways include the **importance of documented evidence** (artifacts) for each verification and validation action, and integrating **risk management** (like FMEA) in the design process to catch critical issues early[13]. This foundation applies to all engineering fields. Next, we'll adapt these concepts to Mechanical Engineering design scenarios, highlighting discipline-specific practices while maintaining the same quality principles.

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[11] https://maxicert.com/verification-validation-iso-9001/

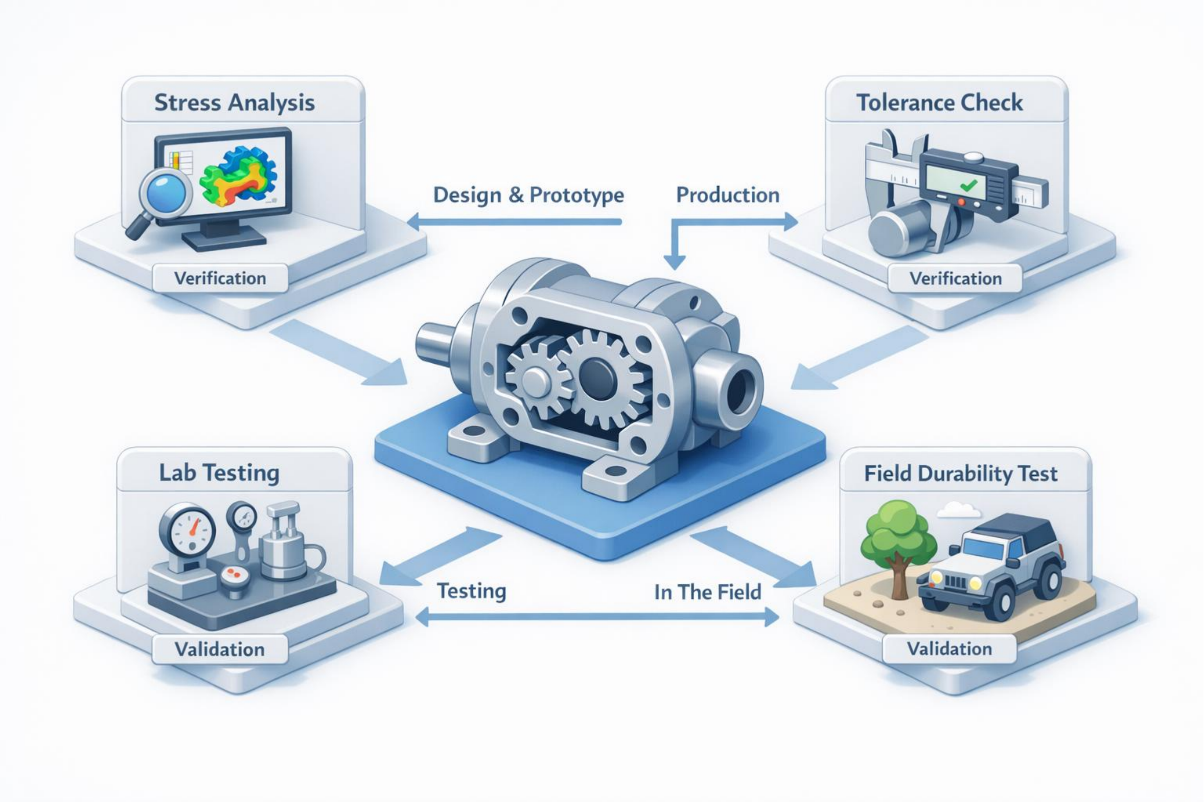
[12] https://maxicert.com/verification-validation-iso-9001/

[13] https://quality.eleapsoftware.com/fmea-in-qms-complete-implementation-guide/

Module 2: Verification & Validation in Mechanical Engineering Design

2.1 V&V in Mechanical Design – Overview

Mechanical engineering projects — whether designing a machine component, HVAC system, or an automotive part — follow a similar ISO 9001 design control approach: plan the design, verify outputs meet technical requirements, and validate the end result serves its intended function safely and effectively. **Verification in mechanical design** often emphasizes calculation checks (stress, load, performance margins), prototype testing, and drawing reviews. **Validation** might involve prototype field performance or user acceptance tests for the product in its operating environment. Both rely on **documented procedures** and results.



2.2. Mechanical Case Study – Designing a Structural Bracket

Scenario: A team is designing a ***load-bearing steel bracket*** *for use in a construction crane. The bracket must support 5,000 lb without permanent deformation and meet a* ***factor of safety (FoS)*** *of 2.0 under ultimate load.* Let’s step through the V&V process:

2.2.1 Requirements & Risk Planning: The design inputs specify material grade, load requirements (5,000 lb working load, FoS 2.0 meaning ultimate capacity 10,000 lb), and any **regulatory** references (e.g., *ASME or ASTM standards for structural steel*). During initial brainstorming, the team identifies a risk: fatigue failure under cyclic loading might be a concern if the bracket is used repeatedly. They add this to the **risk register/FMEA** to ensure it’s addressed.

2.2.2 Design Outputs: The mechanical engineer creates a 3D CAD model and detailed drawings of the bracket. The initial design's calculated **ultimate strength** is, for example, 12,000 lb, corresponding to FoS=2.4 which exceeds the requirement. The **design outputs** include drawings with dimensions/tolerances, material specs, and analysis results (e.g., finite element stress analysis images showing max stress).

2.2.3 Verification Activities:

- *Analytical Verification (Calculation Check):* Another engineer performs an **independent hand calculation** to verify the bracket's strength. Using a simplified model (treating the bracket as a cantilever, for instance), they compute bending stress and required section modulus. Suppose this check calculates an ultimate capacity ~11,000 lb; since it's close to the original analysis (12,000 lb) and still above 10,000 lb, it **confirms** the design likely meets FoS criteria. The calculation steps are documented in a **verification worksheet** for the project file[14].
- *Drawing and Specification Review:* A **design review** team inspects the drawings and material specs. They verify all critical dimensions have tolerances, materials meet standards, and load assumptions are clearly stated (catching issues like any **unnotated** welding requirement, which could be a quality gap). Review comments and resolutions are logged.
- *Prototype Test:* Based on risk considerations (like potential **fatigue**), the team decides to fabricate a **prototype bracket** for testing. In a controlled test (e.g., using a hydraulic press), they load the bracket incrementally up to 5,000 lb and then to failure. Results: the bracket withstands 5,000 lb without deformation and ultimately yields at ~11,500 lb. This destructive test verifies that the **actual performance aligns with calculations**, and no unforeseen weakness exists. All data (load vs. deflection curves, failure mode observations) are captured in a **test report**.
- *FMEA Spotlight:* The **Design FMEA** for the bracket includes failure modes like "weld failure" or "material defect." Suppose the FMEA rated fatigue as high risk (if the crane cycles loads often). To address this, the team adds a verification step: a **stress-life fatigue analysis** on the design, verifying at least a certain number of load cycles can be sustained. If the analysis shows adequacy, that result becomes another verification artifact proving the design's robustness under expected use.

2.2.4 Validation Activities:

- Once the bracket design is verified, **validation** ensures the design solves the real-world need. If possible, the bracket prototype is installed on a actual crane for a ***field trial***. Operators use the crane in typical operations for some period, and the bracket is inspected periodically for any cracks or loosening. A **successful field validation** is documented by noting that the bracket functioned as intended under actual conditions (and no operator complaints, functioning within safety limits).
- If an in-field test isn't feasible before production, a **customer or third-party witness test** might serve as validation. For instance, a representative from the client or a certifying agency witnesses the prototype load test. Their signed approval that "the bracket design meets the application requirements" serves as a validation record.
- Another aspect of design validation here could be **fit and integration**: confirming the bracket's hole pattern aligns properly with the crane structure (ensuring it "fits" in intended use). The team might use a **full-scale mock-up** or CAD integration to validate this fit.

2.2.5 Documentation: All through Module 2's scenario, each verification and validation step yields documentation: calculation sheets, review records, test reports, **material certifications**, and sign-off forms. By organizing these, the project compiles a **Design V&V file** for the bracket – a crucial part of ISO 9001's documented design outputs, demonstrating compliance with requirements and effective control of the process.

2.3 Decision Gates and Design Reviews in ISO 9001

In mechanical (and all) design processes, **design reviews** act as formal checkpoints. ISO 9001 expects you to conduct systematic reviews at appropriate stages to evaluate design progress and plan next actions[15] [16]. For example, after the bracket prototype test, a **post-test review meeting** might be held: if results were satisfactory, you document that verification is complete and proceed to validation/production. If issues were found (say the bracket twisted unexpectedly), the design would be **iterated** and re-verified. These reviews ensure accountability and that **verification/validation results feed back into design improvements** for continuous quality enhancement.

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[15] https://maxicert.com/verification-validation-iso-9001/

[16] https://maxicert.com/verification-validation-iso-9001/

[16] https://maxicert.com/verification-validation-iso-9001/

2.4 Summary (Module 2):

The mechanical engineering module applied ISO 9001 V&V principles to a structural bracket design. We saw multiple **verification techniques** – independent calculations, drawing checks, physical testing – used to prove the design met all technical specs. We also demonstrated **validation** in ensuring the bracket performs reliably in its intended real-world use. The scenario highlighted how risk (like fatigue) is addressed via targeted verification actions, and how **design reviews** govern the process to keep it effective and well-documented. The next module will extend these concepts to Civil Engineering, where design verification and validation have unique considerations such as regulatory code compliance and public safety.

Module 3: Verification & Validation in Civil Engineering Design

3.1 V&V Considerations in Civil/Structural Projects

Civil engineering designs — such as **infrastructure, buildings, or public works** — must adhere to strict codes and standards, making **verification** heavily focused on compliance checks (e.g., calculations vs. code requirements, peer reviews of drawings) and quality control in construction. **Validation** for civil projects often comes down to ensuring the built facility meets the intended **functional requirements and user needs** (e.g., capacity, serviceability, community acceptance). ISO 9001 design control still applies: even though final validation might be after construction, the design process must plan for how the final output will be validated and how interim verifications are documented.

3.2 Civil Case Study – Stormwater Management System Design

Scenario: An engineering firm is designing a ***stormwater detention basin*** *for a new commercial development, to manage runoff and prevent flooding.* Key requirements: it must hold a 100-year storm event volume, release water at a controlled outflow rate, and meet environmental regulations (water quality standards). Let's map the V&V:

3.2.1 Planning & Requirements: Design inputs include **hydrologic data** (rainfall intensity, runoff coefficients), local code criteria (e.g., pond volume must store the 6-inch rainfall event), and client needs (e.g., an aesthetically landscaped basin). Recognizing a **risk**: if calculations are off, the basin might flood or be undersized – with serious consequences. Thus, double-checking calculations will be critical in verification.

3.2.2 Design Outputs: The civil engineering team produces a **stormwater report and drawings**. The report has calculations for runoff volumes, basin sizing (dimensions, depth), an outflow structure design, and predicted water levels for design storms. The drawings detail the basin geometry, inlet/outlet structures, and cross-sections. There are also **maintenance plans** and landscaping details. These outputs need verification against the inputs and regulations.

3.2.3 Verification Activities:

- *Peer Review of Calculations:* Another engineer does a **peer review** of the stormwater management report. They independently verify a sample of the calculations (e.g., recompute the runoff volume using the rational method or unit hydrograph) and confirm that the **basin volume is adequate**. If the design calls for 50,000 cubic feet of storage, the reviewer might cross-check and get ~48,000 cu ft; the slight discrepancy leads to a discussion and a minor design adjustment for safety margin. This **review is documented** with mark-ups or a signed calculation check sheet.
- *Regulatory Compliance Check:* A **design checklist** ensures all relevant codes/regulations are addressed. For instance, does the design meet **EPA or state environmental** requirements for water quality (like including a forebay to trap sediment)? Does it follow municipal guidelines for maximum pond depth or safety slopes? Each item on the checklist is verified (with references to drawing sheets or report sections) and signed off by the responsible engineer.
- *Design Review Meeting:* A multi-disciplinary review (including civil designers, an environmental specialist, and perhaps the client's representative) is held. The team verifies that the design output will meet stakeholder needs: e.g., reviewing that the basin won't encroach on planned parking and that maintenance access is provided. **Minutes** record any required changes (such as adding a fence due to safety policy).

- *FMEA for Risk (Partial):* In infrastructure, formal FMEAs might not be as common, but risk evaluation is done. For example: potential failure mode – "outlet clog leading to overflow." Mitigation through design: include a trash rack and overflow spillway. The verification step here might be "Check hydraulic performance with outlet partially blocked" via a supporting calc or small physical model test. That result (showing the basin can safely overflow without dam breach) becomes an extra verification artifact ensuring robustness.

3.2.4 Validation Activities:

- In civil projects, **true validation often occurs upon project completion**, when the facility is operating. A key validation is **post-construction inspection and commissioning**. For the detention basin, validation includes **observing actual storm performance**: after a heavy rain, does the basin handle runoff as designed? The firm might simulate a heavy rain by filling the basin or simply rely on the first storm event to validate performance.
- Another validation aspect is **client acceptance** and functional testing: the client and possibly regulators will inspect the finished basin and sign off that it meets the intended purpose (no flooding observed, proper drainage). These **acceptance documents or operating permits** serve as validation evidence that the design works in practice.
- Additionally, in some cases **scale models or simulations** are used prior to construction as a form of design validation. For example, a computer simulation of a 100-year storm in the basin model can validate that it will perform as intended. If the simulation shows no overflow, it builds confidence in the design. Such results (e.g., screenshots of water depth over time) can be included as **pre-construction validation** evidence, acknowledging that final proof comes with actual performance.

3.2.5 Document Control: All through the civil design process, **documented information** is curated. The calculation check or peer review comments, compliance checklist, design review minutes, regulatory approvals, and eventual commissioning test reports are carefully maintained. ISO 9001's philosophy is that these **records demonstrate design due diligence** – from meeting technical specifications to satisfying user/regulatory needs – thereby fulfilling both **verification and validation** obligations in the quality management system.

3.3 Cross-Functional Collaboration

Civil engineering projects highlight the need for cross-functional input in V&V. Designers must work with **regulators, environmental scientists, contractors, and end-users** during the design process. For example, early consultation with environmental specialists can help validate that water quality objectives (user needs) are integrated in the design, not just verified later. Similarly, involving construction professionals in design reviews helps ensure the design can be realistically built (a kind of validation that the "product" can be realized as intended). ISO 9001 encourages involving appropriate **"interested parties"** (such as customers or experts) in design stages as needed[17] – which strengthens validation effectiveness.

3.4 Summary (Module 3):

In Module 3, we applied V&V to a civil engineering scenario. Verification took the form of rigorous calculation reviews and compliance checks to ensure the design output (stormwater basin plan) met all **specified requirements** (technical and regulatory). Validation was oriented toward **operational performance** – ultimately confirmed via post-construction inspection and acceptance. The scenario underscored the long timeline for validation in infrastructure projects and the importance of anticipating validation needs by planning early (e.g., computerized simulations as partial validation). Through comprehensive documentation and involvement of the right stakeholders, the civil engineering design process meets ISO 9001's standards for quality assurance and continuous improvement.

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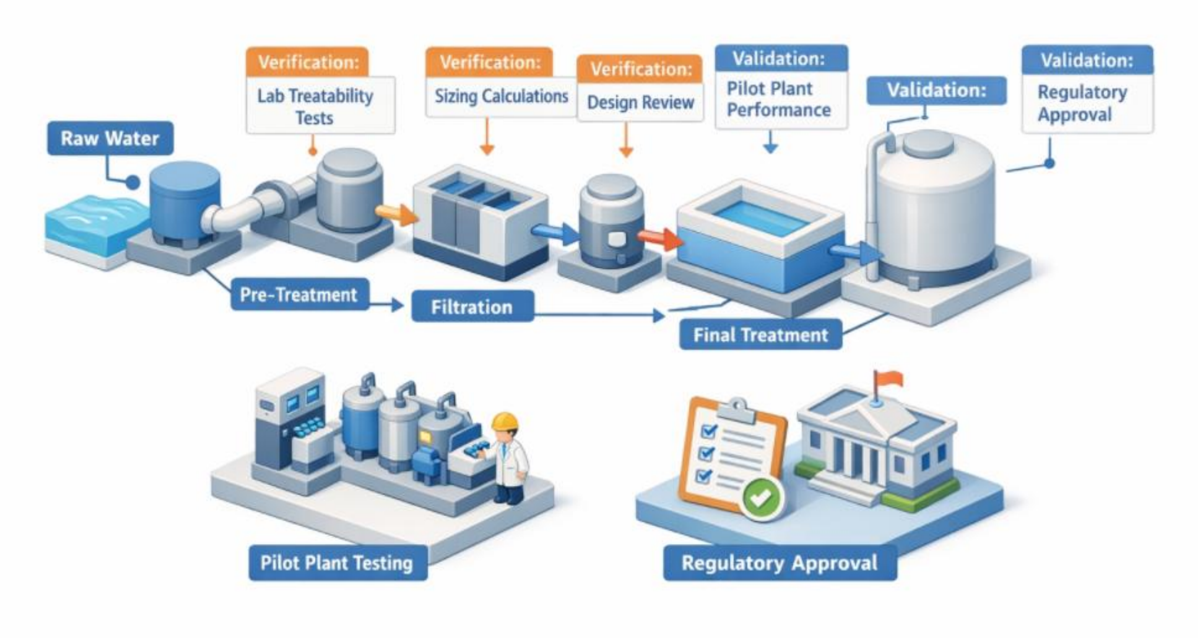
[17] https://maxicert.com/verification-validation-iso-9001/

Module 4: Verification & Validation in Environmental Engineering Design

4.1 V&V in Environmental Systems Design

Environmental engineering often deals with systems like **water/wastewater treatment, pollution control, or remediation systems**, where performance and regulatory compliance are paramount. ISO 9001's V&V framework again applies: you verify the design calculations, models, and components meet the environmental performance specs, and you validate that the system as a whole achieves the desired outcome (e.g., water quality improvement) under real conditions. There is significant overlap with civil engineering for built systems, but environmental projects may also involve **process engineering and scientific data** analysis (for example, verifying that treatment processes meet contaminant removal requirements through bench tests or pilot studies).



4.2 Environmental Case Study – Industrial Wastewater Treatment Design

Scenario: An engineering company is designing a ***wastewater treatment system*** *for a manufacturing plant. The goal is to remove contaminants so that the discharged water meets environmental permit limits (e.g., <10 mg/L nitrate, pH 6-9, etc.). The design includes a settling tank, a biofilter, and a UV disinfection unit.* Here's how V&V unfolds:

4.2.1 Requirements & Preliminary Analysis: The design inputs include the expected wastewater flow and contaminant levels, required **effluent quality**, and any site constraints. Risk brainstorming identifies a key concern: variability in wastewater composition might reduce treatment efficiency. The team plans a conservative design and adds **verification tests** to check performance across a range.

4.2.2 Design Outputs: The team develops a **process flow diagram and calculations** for each treatment stage (e.g., reactor volumes, retention times, chemical dosing). Detailed design outputs might include equipment specifications (pump sizes, UV reactor sizing), piping and instrumentation diagrams (P&IDs), and a control logic description. These are all subject to verification to ensure they meet the input requirements (like achieving <10 mg/L nitrate).

4.2.3 Verification Activities: Bench/Pilot Testing: Before finalizing design sizes, the team conducts bench-scale tests (in the lab) of the wastewater with proposed treatment methods. For example, they take a sample of the industrial wastewater and test a small biofilter setup to see how much nitrate reduction is achieved. The results (e.g., "90% nitrate removal achieved in lab at X retention time") verify the process concept works and inform design parameters. If lab results are promising, a pilot plant could be run on-site to further verify that scaling up will yield the required performance. These test reports serve as strong verification artifacts confirming design assumptions.

4.2.4 Calculation Verification: Engineers double-check process calculations. If the design calls for a 10,000-gallon settling tank to handle a certain flow, an independent check might verify the residence time is sufficient for settling, using Stokes' law or other equations. Similarly, verifying that the UV unit size and power meet disinfection criteria by comparing dose calculations with regulatory recommendations. Each significant calculation may be tabulated in a verification checklist to ensure none are missed.

4.2.5 Environmental Compliance Review: Like civil projects, regulatory compliance is critical. The design is reviewed to confirm it meets all permit conditions and relevant standards (e.g., Clean Water Act discharge limits). The team cross-references each effluent limit to the design guarantees. If the permit demands monthly reporting, the design includes sampling points and instrumentation – verifying that the design covers compliance monitoring needs too.

4.2.6 Design Review*:* A formal design review meeting includes the process engineers, plant operators (client's team), and a regulatory consultant. Beyond technical correctness, they verify practical aspects: can operators maintain the system easily? Are there fail-safes for power outages (like a backup generator)? Such a review might catch an issue (e.g., need an alarm on high effluent turbidity) which is then addressed in the design revision.

4.2.7 Validation Activities:

- **Commissioning and Performance Testing:** After construction and installation of the wastewater treatment system, a validation phase occurs where the **system is run and tested** with actual plant effluent. The team measures the water quality of the output over a trial period. If the system consistently meets the <10 mg/L nitrate and other criteria, this validates the design's effectiveness in its intended use. They compile a **commissioning report** showing actual performance vs. requirements (e.g., "Nitrate averaged 5 mg/L, pH held at 7.2–7.8, etc.").
- **Operator Feedback:** Validation also includes confirming the **system meets user/operator needs**. For example, plant operators provide feedback that the control interface is user-friendly, or maintenance is manageable. If the operators accept the system's operation and no unanticipated issues arise, it validates that the design not only works on paper but is acceptable in practice.
- **Regulatory Acceptance:** Usually, local environmental authorities will inspect or require a performance test of the new treatment system. Their issuance of a permit compliance letter or operating approval is effectively a **validation from a regulatory standpoint** that the final product meets the societal need (protecting environment) as intended.

4.2.8 Continuous Improvement Loop: ISO 9001 and professional practice encourage capturing lessons learned. Suppose during validation it was found that under extreme wastewater conditions (e.g., high contaminants during an upset), the system struggled. The team would then refine the design for future projects (or adjust operating procedures) – a feedback loop ensuring **continual improvement**. The **documented validation results** and any corrective actions become part of the project record, closing out the ISO 9001 design process for this project with full evidence of verification, validation, and adjustments made.

4.3. Summary (Module 4):

Our final module illustrated V&V in an environmental engineering context, emphasizing **process performance verification** (through lab/pilot testing and rigorous calculations) and final **system validation** with real operational trials. It demonstrated the importance of regulatory compliance as both a verification checkpoint and a validation outcome. By completing all four modules, you should appreciate that while **specific methods vary by discipline** – from hardware stress tests to environmental pilot studies – the underlying ISO 9001 framework remains consistent: carefully plan design activities, verify outputs against requirements, validate against needs, and record everything for accountability and improvement.

Course Conclusion and Final Examination

In summary, **ISO 9001's design verification & validation requirements** enforce a disciplined approach to engineering design across all fields. By **carefully planning, executing, and documenting V&V activities**, engineers ensure not only compliance with standards but also the delivery of safe, effective, and high-quality outcomes for clients and society. This course's four modules provided a **comprehensive, practical understanding** of how to implement verification and validation in **Electrical, Mechanical, Civil, and Environmental** engineering projects, using scenario-driven examples and light technical exercises to reinforce key concepts.