Build It Right: Quality-Driven Component & Material Choices

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1. Introduction: Risk-Based Thinking in Engineering Quality

In modern engineering practice, especially under **ISO 9001 Quality Management Systems**, **risk-based thinking** plays a pivotal role in ensuring that products and projects meet their requirements for safety, reliability, and performance. ISO 9001:2015 (and later versions) introduced a **shift from reactive problem-solving to proactive risk management** in all processes[1]. Rather than waiting for failures or non-conformities to occur and then fixing them, engineers and managers are encouraged to **anticipate potential issues early** – during design, component selection, material procurement, and other stages – and take preventive action. This philosophy is embedded throughout the standard (in planning, operations, design control, etc.) as a means of **building quality into the design from the start**.

What is risk-based thinking? In simple terms, it means **incorporating risk-awareness into every decision**. A "risk" in this context is commonly defined as *the combination of the probability of an event and its consequences* (which can be negative or positive)[2]. For engineering decisions, risk-based thinking involves asking: *"What could go wrong with this design choice, and how severe would the outcome be?"* and *"How likely is that to happen?"* By considering those questions, engineers can make choices that minimize the chances of failure or underperformance and maximize opportunities for success (in ISO terms, "risks and opportunities"). In essence, **risk-based component and material selection** means **choosing parts and materials not just on upfront cost or performance, but also on reliability, safety margins, supplier quality, environmental impact, and other risk factors** that could affect the project or product lifecycle.

ISO 9001's guidance doesn't prescribe a specific risk management process or require formal risk management documents for every decision. Instead, it expects organizations to **identify and address risks and opportunities** appropriate to their context. For engineers, this translates to practices like conducting risk assessments during design reviews, using checklists of potential failure modes, relying on standards/codes that build in safety factors, and generally being able to show that **important decisions were made with due consideration of what could go wrong**. This proactive mindset supports continuous improvement and more resilient designs[3].

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[1] https://www.qmii.com/comprehensive-guide-to-risk-based-thinking-in-iso-90012015-transition/

[2] https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf

[3] https://www.qmii.com/comprehensive-guide-to-risk-based-thinking-in-iso-90012015-transition/

1.1 Course Approach and Overview

This course focuses on applying risk-based thinking to the **selection of components and materials**, a critical part of engineering design across disciplines:

- Choosing an electrical component (like a circuit breaker or a microprocessor) involves weighing risks of failure, electrical hazards, supplier reliability, etc., alongside functionality and cost.
- Selecting a mechanical component or material (like a pump, a type of bearing, or an alloy for a machine part) requires considering failure modes (wear, fatigue, corrosion), maintenance needs, safety factors, and compliance with quality standards.
- Civil engineering decisions (e.g., what piping material to use in a water system, or which structural material for a bridge) must factor in environmental conditions, durability, safety codes, and public safety risks.
- Environmental engineering choices (e.g., the material for a tank liner, or choosing a treatment process) involve risks related to containment failure, regulatory compliance, and long-term sustainability.

Throughout this manual, we will **integrate examples from Electrical, Mechanical, Civil, and Environmental engineering** to demonstrate universal principles. The approach is **practical and documentation-focused**: you will see how to **identify risks**, assess them qualitatively and quantitatively (with *lightweight calculations* like risk scoring, decision matrices, etc.), decide on the best option, and then **document that decision** so that it's traceable and defensible. Documentation and traceability are important not only for ISO 9001 compliance but also for professional engineering ethics – they show that due diligence was done.

Finally, the course provides a short multiple-choice assessment to test your understanding, ensuring the material meets **NCEES Continuing Professional Competency** criteria (e.g., clear objectives, relevance to professional practice, and assessment of knowledge gained).

🔍 Proactive Over Reactive

ISO 9001 prioritizes prevention. Don't wait for failures – anticipate and address risks from the start. This mindset shifts engineers from reacting to problems to building robust designs that avoid them.

🎯 Quality by Design

Risk-based decisions ensure quality. By factoring in reliability, safety, and compliance in component and material choices, engineers embed quality into the design process, not as an afterthought.

🗂️ Documented Decisions

Traceability is critical. ISO 9001 doesn't require piles of paperwork, but you should document your rationale – think design notes, risk registers, and meeting minutes – so decisions can be reviewed and justified.

🌐 Across All Disciplines

Universal principles, local context. Electrical, Mechanical, Civil, or Environmental – whatever your field, the core risk-based approach is similar, but the specific risks and best practices will vary with context.

2. Risk Identification in Component & Material Selection

The first step in risk-based decision making is **identifying potential risks** associated with each component or material option. In engineering projects, risks can arise from many sources: technical limitations, environmental conditions, human factors, lifecycle issues, and beyond. It's important to brainstorm **"What might go wrong if we choose this component/material?"** or **"What uncertainties do we have about this choice?"**. At this stage, we are not yet solving the risks – just listing them.

Key considerations for identifying risks in selection include:

- **Functional Risks:** Will the component/material perform its intended function under all design conditions? (e.g., an electronic part not working at extreme temperatures, or a structural material losing strength over time)
- **Reliability Risks:** What is the probability of failure or malfunction? (e.g., a bearing that might wear out sooner than expected, or a sensor that has a known failure rate)
- **Safety Risks:** Could this choice endanger people or the environment if it fails? (e.g., a chemical storage material that could leak toxins, or an electrical component that could overheat and cause fire)
- **Compliance Risks:** Does it meet required standards, codes, or regulations? (e.g., building code compliance for materials in construction, environmental regulations for materials in contact with drinking water)
- **Supply Chain Risks:** Are there uncertainties in sourcing or supply? (e.g., a supplier's quality control issues, long lead times, risk of component obsolescence or a vendor going out of business)
- **Environmental Exposure Risks:** Will environmental conditions (weather, corrosion, UV, chemicals) affect the performance or durability? (e.g., material brittle in cold climates, or electronics failing in humid conditions)
- **Operational/Use Risks:** Might the end-users misuse or overstress the component? (e.g., an electrical circuit used beyond its rated load, or a machine part subjected to loads it wasn't designed for)
- **Lifecycle & Maintenance Risks:** What are the long-term considerations? (e.g., maintenance challenges, difficulty in inspection or replacement, compatibility with future upgrades)

Brainstorming and information sources: To identify risks thoroughly, engineers often draw on past experience and data. This can include **historical failure data**, consultation with subject matter experts, reviewing standards and literature, or using formal methods like checklists and **Risk Breakdown Structures (RBS)**. An RBS is essentially a categorization of possible risk sources (e.g., technical, logistical, environmental, etc.) that can prompt you to think of risks you might otherwise miss. For example, an electric utility project might define categories such as licensing, site conditions, technical problems, equipment issues, contractor performance, and personnel issues[4] – each category then sparks specific risk questions (like "Have we considered the risk of supplier delays?" under equipment issues).

[4]https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf

Different engineering **disciplines focus on different risk areas**, though there is overlap. Below are examples of risk identification in component/material selection for each discipline:

- **Electrical Engineering:** Risks might include component electrical ratings being insufficient (voltage or current too low, leading to overload failure), electromagnetic interference between components, heat dissipation issues, short-circuits or arc flash hazards, and software/firmware reliability for smart components. For instance, selecting a power supply module involves asking: *What if the actual load is higher than estimated? What if the input power quality is poor? What if the cooling is inadequate causing it to overheat?*
- **Mechanical Engineering:** Common risks are material failure modes (fatigue cracking, yielding under overload, excessive wear), incorrect tolerances or fits, vibrations, thermal expansion issues, or lubrication failures. For example, when choosing a bearing material, an engineer considers: *What if the load spikes occasionally above the design load? What if the operating temperature causes the lubricant to degrade? Could corrosion occur over time?*
- **Civil/Structural Engineering:** Material selection risks might involve environmental degradation (corrosion of steel, rot in wood, freeze-thaw damage in concrete), unexpected loads (seismic events, flooding, wind gusts beyond code assumptions), or construction quality issues. As an example, picking a pipe material for a water distribution network raises questions like: *What if soil conditions cause the pipe to corrode or shift? What if water pressure surges cause joint leakage? Are there earthquake considerations for this pipe material?*
- **Environmental Engineering:** Risks often relate to containment and treatment efficacy. When selecting materials for environmental protection (liners, filters, treatment chemicals), one must ask: *What if this material fails to contain a contaminant (leakage risk)? What if it degrades and releases harmful by-products over time?* Also, regulatory compliance is key: using a certain chemical might carry the risk of not meeting discharge standards or creating waste that's hard to dispose of.

Tip: It can be helpful to use a structured form such as a **risk register or a table** during identification. Simply list the potential risk (uncertain event or condition) and the possible consequence if it happens. At this stage, keep the list broad. For example:

Option	Identified Potential Risks
High-strength steel bolts	- Risk of hydrogen embrittlement causing crack/failure under stress- Supplier has long lead time (schedule risk)- Need for special corrosion coating (added cost/risk if omitted)
Composite material panels	- Unproven long-term durability (risk of delamination)- Expensive to replace if damaged (maintenance risk)- Installation crew unfamiliar – risk of errors in installation
PVC piping for chemical line	- Vulnerable to UV sunlight (brittle over time outdoors)- Could crack under high pressure spikes (burst risk)- Not compatible with certain chemicals (may cause softening)

(Table: Example fragment of an identification table showing different options and some of their potential risks.)

This kind of table is not yet evaluating or solving anything – it's just gathering information. Once we have a clear list of possible risks for the options at hand, we can move to analyzing them in more detail.

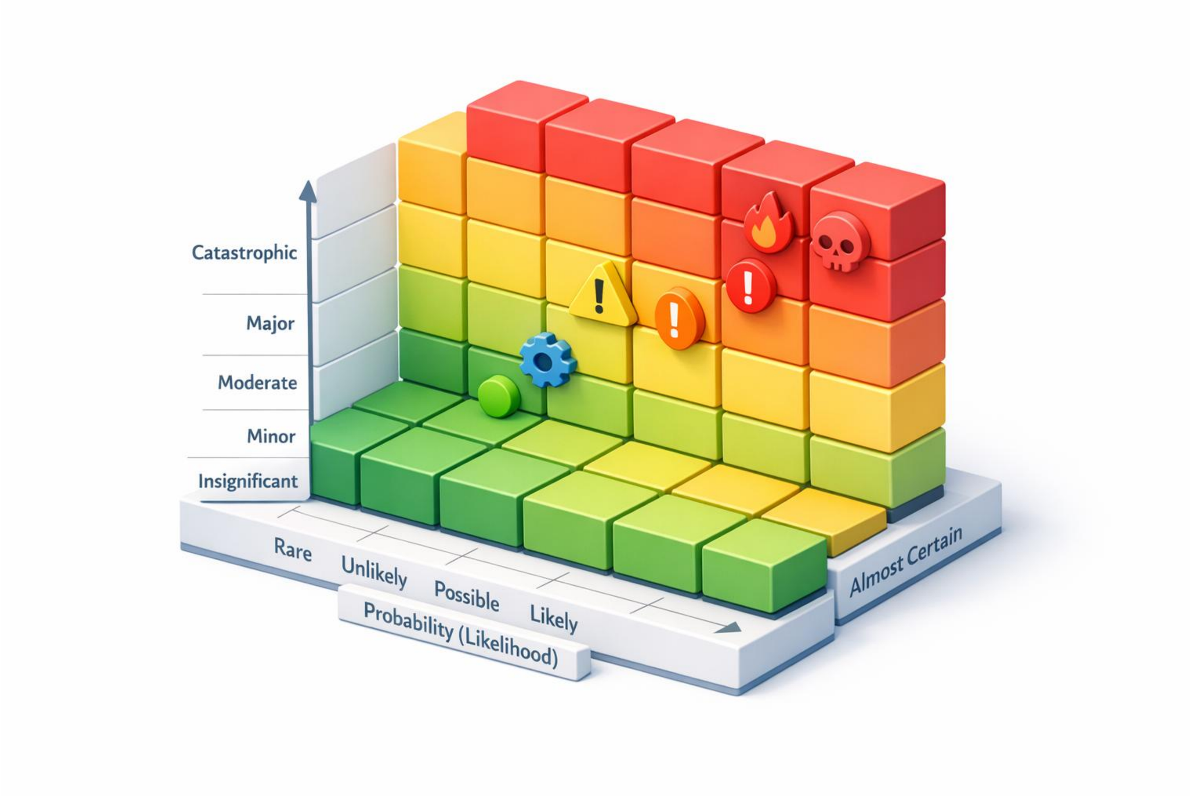
3. Risk Analysis and Evaluation

After identifying a variety of risks, the next step is to **analyze these risks** to understand their significance. Not all risks are equal: some are very unlikely to happen or have minor effects, while others could cause serious problems or have a high chance of occurring. Risk analysis typically involves assessing two primary dimensions:

- **Likelihood** (Probability) – How likely is it that this risk will materialize?
- **Consequence** (Impact or Severity) – How severe would the outcome be if it does happen?

By estimating these, engineers can evaluate the **level of risk** for each identified scenario. A common approach is using a **Risk Matrix** to qualitatively rank risk levels. In a risk matrix, one axis (e.g., horizontal) represents likelihood (ranging from Rare to Frequent) and the other axis (vertical) represents severity (ranging from Negligible to Catastrophic). Each risk can be plotted on this grid to determine if it falls into a **Low**, **Medium**, or **High-risk** zone depending on the combination of probability and impact[5]. High-probability & high-impact events are obviously high risk; low-probability & low-impact are low risk; the mixed cases fall in between. This provides a visual and intuitive way to prioritize risks by criticality.

[5]https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf



Using the risk matrix qualitatively helps to **screen which risks deserve the most attention**. For instance, in a material selection for a bridge:

- The risk of **cosmetic paint fade** (fading paint) might be *likely* but the impact is *minor* (aesthetic only) – that would plot as Low risk (no serious action needed beyond maybe routine maintenance).
- The risk of **steel fatigue crack** under repeated heavy loads might be *unlikely in the short term*, but the impact is *catastrophic* (structural failure) – that plots as High risk (we must address it, perhaps by using a higher grade steel or more frequent inspections).
- A **moderate risk** example: say the risk of **construction delay due to late material delivery** – if it's moderately likely and would have a moderate cost impact, it sits in the Medium (yellow) zone, meaning we should monitor it and possibly mitigate it (e.g. order early or have backup suppliers), but it's not as critical as life-safety issues.

3.1 Qualitative vs. Quantitative Analysis

In many cases, especially during early design, engineers use **qualitative judgement** (High/Med/Low scales, or 1–5 rating scales) because precise data might not be available. **Expert opinion** and past experience play a big role. For example, an experienced civil engineer might judge the likelihood of foundation problems as "low" based on similar past projects and soil surveys, and the impact as "high" if it were to happen; thus, labeling it a medium risk overall with a note that geotechnical review is needed.

When data *is* available, you can add **light quantitative analysis** to support decisions:

- You might calculate an expected cost of a risk: *Probability* × *Impact (cost)*. For example, if a certain electronic component has a 5% chance of failing within a year and the failure would cost $100,000 (in repairs, downtime, etc.), the *annual risk cost* can be estimated as 0.05 × $100,000 = $5,000. This can be thought of as the budget you'd logically be willing to spend (per year) to mitigate that risk. In one real scenario, the probability of two redundant power lines failing simultaneously was 0.1%, and the business loss would have been $500 million; multiplying gives an expected risk cost of $500,000[6]. While no one actually "pays" this cost directly, it helps compare and prioritize – $500k/year risk is very significant.
- You can also compute reliability metrics. For instance, if Supplier A's part has a documented failure rate of 1 in 1,000 (0.1%) and Supplier B's similar part is 1 in 10,000 (0.01%), and the impact of failure is critical (say it causes a major shutdown), you might lean towards Supplier B despite higher cost, because the risk reduction (tenfold reliability improvement) is worth it.

However, **be cautious with quantitative precision**. Often the numbers we plug in (probabilities, costs) are rough estimates. ISO 9001 does **not** require a full quantitative risk analysis; a qualitative sense of high/medium/low with justification is usually sufficient as evidence of "risk-based thinking." Use quantitative estimates to augment your understanding where you have solid data (e.g., historical failure rates, supplier stats, known probabilities), but avoid false precision.

[6]https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf

3.2 Failure Modes and Effects Analysis (FMEA)

One proven method to systematically identify and analyze risks in engineering designs is **Failure Modes and Effects Analysis (FMEA)**[7]. FMEA is *especially useful for component and material selection* because it prompts you to think of **failure modes** (the ways a component or material could fail or not meet requirements) and their **effects** (the consequences of those failures). It's a formalized extension of the thought process we've been discussing, often done in table form. ISO 9001's emphasis on proactive risk management has made FMEA even more prominent in quality-conscious organizations[8].

In an FMEA, for each potential failure mode, you typically estimate:

- **Severity (S):** How bad would the effect of this failure be? (Usually rated on a scale, e.g. 1 = no impact, up to 10 = catastrophic impact like safety hazard or mission failure.)
- **Occurrence (O):** How likely is this failure mode? (1 = extremely unlikely, 10 = almost certain or frequently occurring.)
- **Detection (D):** How likely is it that this failure would *not* be detected before it causes impact? (1 = almost certain to catch it in time with controls/tests, 10 = very unlikely to detect it before it hits the user or operation.)

These three numbers are then multiplied to give a **Risk Priority Number (RPN)** = $S \times O \times D$[9]. The RPN is a quantitative score (ranging typically from 1 to 1000 if each factor is 1–10) indicating overall risk priority – higher RPN means a more critical risk that should get attention first[10].

[7] https://the9000store.com/articles/using-fmea-to-manage-risk/

[8] https://the9000store.com/articles/using-fmea-to-manage-risk/

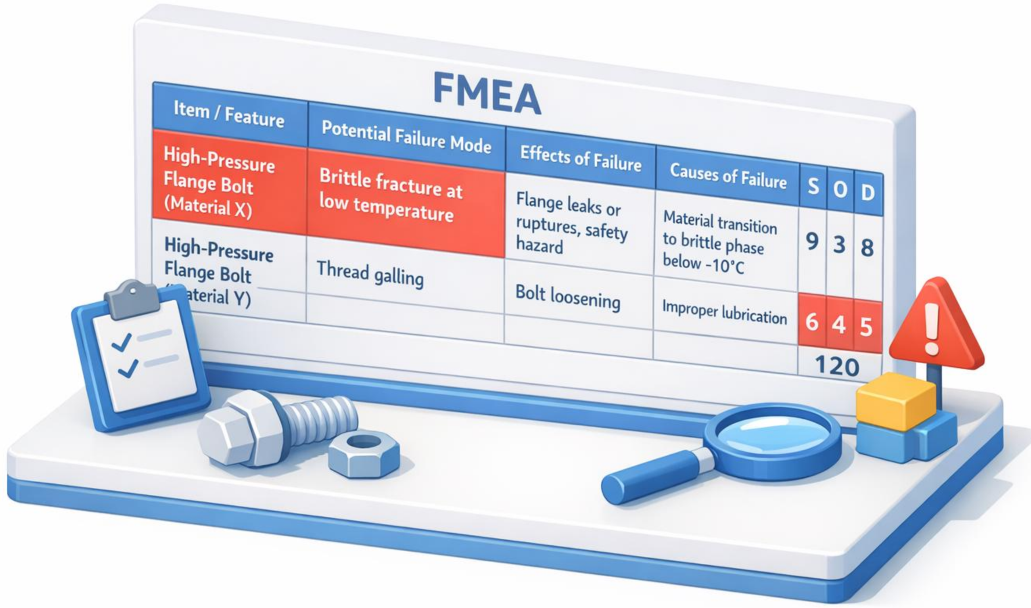
[9] https://visuresolutions.com/alm-guide/fmea-risk-matrix/

[10] https://visuresolutions.com/alm-guide/fmea-risk-matrix/

For example, suppose a mechanical engineer is evaluating two different bolt materials for a high-pressure flange:

- For **Material X** (a high-carbon steel): One failure mode might be *brittle fracture in cold temperatures*. If that happened, the flange could leak or burst, which might be a severe safety hazard (S = 9 on a 10-point scale). How likely is brittle fracture? Perhaps rare if the material is normally tough, but if the temperature can drop very low, maybe O = 3 (rare but not impossible). And detection could be difficult because you might not know the bolt is brittle until it breaks (D = 8, since regular maintenance might not catch this). The RPN = 9×3×8 = 216.
- For **Material Y** (a stainless alloy): A potential issue might be *chloride stress corrosion cracking* in a marine environment. Severity if it cracks could also be high (S = 8, causing leaks), the likelihood might be moderate (O = 5, since chlorides are present and this alloy is somewhat susceptible), and detection could be moderate (D = 5, perhaps periodic inspections could catch early cracks). RPN = 8×5×5 = 200.
- Another failure mode for **Material Y** could be *galling of threads when tightened* (a more minor mode): S might be 3 (just makes assembly harder, not a field failure), O perhaps 4 (somewhat likely during installation), D = 4 (would be detected during assembly testing). RPN = 3×4×4 = 48.

These numbers help prioritize which issues need action. Both materials have a high RPN risk (~200) – brittle fracture and stress corrosion were high – so both need mitigation plans. The galling risk (48) is much lower – it might be acceptable or handled by using a lubricant during installation.



Interpreting FMEA results: An FMEA by itself doesn't solve risks; it points out where you should act. Generally, you set a threshold (or use engineering judgment) to decide which RPNs are "too high." For those, you brainstorm and implement **risk mitigation actions** (which we'll cover in the next section). You also document the actions and recalculate RPN if actions are taken. FMEA provides a clear, documented trail of your thought process, which is excellent for both ISO audits and design reviews – it shows you didn't pick a component or material blindly, but analyzed potential failure modes and took steps to prevent them.

3.3 Decision Matrices for Selecting Among Alternatives

Another helpful tool in the evaluation phase is a **decision matrix** (also known as a **weighted scoring matrix**). When you have multiple competing options for a component or material, and several factors to consider (performance, cost, risk, etc.), a decision matrix provides a structured way to compare options against consistent criteria.

How a weighted decision matrix works:

1. **List your criteria.** These should cover the important factors, including risk-related ones. For example, criteria for selecting a material might include *Strength, Weight, Cost, Corrosion Resistance, and Supplier Reliability*.
2. **Assign weights** to each criterion based on importance. The weights are usually numerical values that sum up to 1 (or 100%). Higher weight = more important to the decision. For instance, if safety is paramount, the criterion related to safety (maybe "Strength" or "Fire Resistance") would get a high weight. Less critical aspects (like aesthetics perhaps) get lower weight.
3. **Score each option** on each criterion, typically on a common scale (say 1 to 5 or 1 to 10, where a higher score means better performance on that criterion). These scores can come from testing data, analysis, or expert judgment.
4. **Calculate weighted scores** by multiplying each score by the criterion's weight. Then sum up the weighted scores for each option. The option with the highest total score might be the best-balanced choice.
5. **Consider the result with a critical eye** – the matrix informs your decision, it doesn't make it automatically. You should review whether the highest scoring option makes practical sense, and ensure no high risks were obscured by the averaging effect of the scores.

Let's illustrate a simple decision matrix. Suppose an **environmental engineer** is choosing a lining material for a wastewater treatment tank. They have three candidates: **Option A: High-density polyethylene (HDPE) liner**, **Option B: Epoxy coating**, **Option C: PVC liner**. They decide on key criteria and weights as follows: *Chemical Resistance (30% weight), Installation Cost (25%), Longevity (20%), Ease of Repair (15%), and Supplier Reliability (10%)*. They then rate each option on a scale of 1 (poor) to 5 (excellent) for each criterion:

Criterion (Weight)	Option A: HDPE Liner	Option B: Epoxy Coating	Option C: PVC Liner
Chemical Resistance (0.30)	5 (excellent resistance)	4 (good, but some solvents issue)	3 (adequate)
Installation Cost (0.25)	3 (moderate)	4 (low labor cost)	5 (lowest cost)
Longevity (0.20)	4 (20+ years)	3 (10-15 years average)	3 (10-15 years)
Ease of Repair (0.15)	4 (weldable patches)	2 (difficult to recoat)	3 (patch kits available)
Supplier Reliability (0.10)	4 (established vendor)	3 (local contractors)	3 (commodity product)
Total Weighted Score	**4.15**	**3.45**	**3.65**

(Table: Simplified decision matrix for choosing a tank lining material. Each option is scored on key criteria; scores are multiplied by weights and summed to yield a total score.)

From the above matrix, **Option A (HDPE liner)** scores highest (4.15) because it excels in critical areas like chemical resistance and longevity, and its slightly higher installation cost is outweighed by those benefits. **Option C (PVC)** is cheapest and easy to install (highest in cost criterion), but has lower chemical resistance and longevity, resulting in a lower overall score. **Option B (Epoxy)** falls behind due to repair difficulty and moderate longevity.

The matrix provides a **quantitative audit trail** for why Option A might be selected, which is great for documentation. However, an engineer would also double-check specific concerns: for example, if the downside of HDPE is slightly higher cost, is that cost difference acceptable? If yes, the decision is clear. If the cost difference were huge, the team might revisit the weights or consider if cost should have been given more weight. The strength of the decision matrix is in structuring discussions and ensuring all factors (including risk-related ones like reliability and safety) are considered explicitly.

Note: Simpler forms of decision matrices include un-weighted scoring (all criteria considered equal) or **"pros and cons" lists** for each option. Any method that systematically evaluates options against relevant factors can be acceptable. The key, in the spirit of ISO 9001, is that you **document the considerations and rationale**. For example, you might write a short design note or report: "Option A was chosen for the tank liner due to its superior chemical resistance and longevity, which outweighed its higher upfront cost. An FMEA was conducted which identified the risk of installation problems with HDPE (mitigated by using certified installers) and the risk of leaks over time as low given HDPE's performance history. See attached decision matrix and FMEA worksheet for details." A statement like that, backed by the kind of analysis we've described, would demonstrate compliance with risk-based thinking and provide a clear justification for the decision.

4. Risk Mitigation and Planning

After analyzing and prioritizing risks, the crucial next step is **deciding what to do about them**. In risk management, there are four classic strategies for addressing risks[11] [12]:

1. **Avoid the risk** – Change your plan or choice to eliminate the risk entirely.
2. **Mitigate (Reduce) the risk** – Take action to reduce the likelihood or impact (or both) of the risk.
3. **Transfer (or Share) the risk** – Shift the risk's impact to a third party who is better able to handle it.
4. **Accept the risk** – Acknowledge the risk and proceed without additional action, usually because it's low enough that the benefits outweigh the potential downsides.

Let's discuss these in the context of component and material selection, with examples from different disciplines:

- **Avoidance:** If a particular component or material carries high risk, one option is to simply *choose a different approach* that doesn't have that risk. For example, suppose an electrical engineer is considering using a cutting-edge new battery technology for a backup power system, but it has a risk of thermal runaway (fire/explosion) that can't be fully mitigated yet. By opting for a more proven battery chemistry or a different backup power design (like a generator), the engineer avoids that safety risk altogether. In civil engineering, if building on a floodplain poses too much risk of flood damage, the project might be relocated to higher ground – avoiding the flood risk rather than trying to fight it. Avoidance often means making a significant change to the design concept or requirements to eliminate a hazard. It's the most effective way to deal with a risk, but not always feasible if the risky approach is essential for other reasons.
- **Mitigation:** This is the most common strategy. You keep the same component or material but find ways to **reduce its risk** to an acceptable level. Mitigation can target the probability of failure, the impact of failure, or improve detection controls. For instance, a mechanical engineer selecting a certain grade of aluminum for a machine part might worry about fatigue cracking (risk: part could fail after many load cycles). Mitigations could include: increasing the part's safety factor (so it's stronger than strictly needed), adding a protective coating to prevent corrosion that could exacerbate fatigue, or scheduling regular inspections (to detect cracks early, reducing impact). In an environmental engineering scenario, if using a particular water treatment chemical has the risk of leaving a harmful

[11] https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf

[12] https://www.cedengineering.com/userfiles/B02-013%20-%20Risk%20Management%20for%20Engineers%20-%20US.pdf

byproduct at trace levels, a mitigation could be adding a secondary treatment step (like a carbon filter) to remove that byproduct. Mitigation measures often show up as **design changes, additional components, process changes, or testing/inspection regimes**. It's essentially *engineering risk controls* into the project.

- **Transfer/Share:** Some risks can be transferred to another party, usually via contracts or insurance. In component selection, an example is **supplier warranties or guarantees** – if a vendor guarantees their part will meet certain reliability and will cover damages if it fails, you've transferred some risk to the supplier. For a civil project, hiring a specialist subcontractor for a tricky material installation could transfer risk – they take on responsibility (and liability) for that portion of the work being done right, because they have the expertise. *Insurance* is another transfer mechanism: e.g., an environmental engineer might insure a project against environmental cleanup costs, effectively transferring some of the financial risk of a containment failure to the insurer. In all cases, remember that transfer doesn't make the risk go away; it just ensures **if something goes wrong, the impact (usually financial impact) is borne by someone else** (who is presumably compensated for taking on that risk).
- **Acceptance:** After all the above, you will likely still have some residual risks. To "accept" a risk means you consciously decide to **take no further action** beyond perhaps monitoring. This is reasonable for **low-level risks** – those that are unlikely and/or would have minor impact. It may also be the only choice for certain risks that are impractical to avoid or mitigate (sometimes called "residual risk"). For example, an electrical engineer might accept the risk that a power surge above design levels could damage a device once every 20 years – if mitigating that would require an overly expensive surge protection that isn't justified. The key with acceptance is **to document that you considered the risk and judged it acceptable**. Often, accepted risks are revisited periodically to ensure they remain acceptable as circumstances change. ISO 9001's continuous improvement approach encourages being aware of even accepted risks and watching for any signs they need re-evaluation.

In practice, risk handling is often documented in a plan or register. For each significant risk, you would record the chosen strategy (avoid/mitigate/transfer/accept) and the specific actions. For example:

- *Risk:* "Supplier may deliver substandard bolts that fail strength tests." *Decision:* **Mitigate** – Plan: Pre-qualify multiple suppliers; perform incoming quality testing on batches; specify in contract that supplier must certify materials.
- *Risk:* "New composite material may delaminate in service." *Decision:* **Mitigate** – Plan: Conduct additional fatigue testing on coupons; design a protective coating; if results are not satisfactory, be ready to switch material by design freeze date (avoidance fallback).
- *Risk:* "High winds during construction could destabilize crane operations." *Decision:* **Transfer** – Plan: Hire specialist lifting subcontractor that has wind-load insurance and expertise; ensure contract transfers weather delay risk to contractor.
- *Risk:* "Electronics enclosure may overheat on rare extreme hot days." *Decision:* **Accept** – Rationale: Worst-case, unit will shut down for safety and reboot when cooled; occurs <1% of time and does not damage unit. Monitored via thermal sensor in system; logs will be reviewed in annual maintenance.

As these examples illustrate, often **multiple strategies are combined**. Mitigation is usually the default, but if mitigation isn't fully effective, you might also transfer some risk (e.g., get insurance, or contract terms) and still end up accepting some residual risk.

The **ISO 9001 framework** expects that risk treatment actions are integrated into your processes. This means once you decide on a mitigation or other action, it should translate to concrete changes: update design requirements, change a test plan, adjust a procedure, inform the supplier, etc., and then follow through. Moreover, it's important to **verify the effectiveness of risk mitigations**. Continuing our examples:

- If you planned to mitigate material failure risk by using a higher safety factor, you might later verify (through analysis or testing) that the new design indeed lowers stress to acceptable levels.
- If you implemented a new inspection routine as a mitigation, you'd later check that those inspections are happening and catching issues.
- If you transferred risk via a warranty, you'd ensure the warranty agreement is in place and covers what you expect.

Lastly, **document the outcomes**. By the end of the selection process, you should be able to produce a summary (in a report or meeting minutes) of *why* a certain component or material was chosen, what risks were identified, and how they were addressed. This provides traceability and confidence in the design. It's also invaluable for future projects and continuous improvement: if something ever does go wrong, you have the record of what you foresaw and can learn if anything was missed. If everything goes right, those records become best-practice templates for future risk assessments.

5. Documentation and Traceability

Documentation is a theme we've touched on throughout the course, and it deserves its own brief focus. In the context of ISO 9001 and professional engineering, **"If it's not documented, it didn't happen."** While that statement is a bit tongue-in-cheek, it underscores the importance of keeping records of your risk-based decisions and analyses. Here's how to approach documentation in a practical, value-added way (not just paperwork for its own sake):

- **Risk Register or Log:** Maintain a simple risk register during your project or design selection process. This could be a spreadsheet or table noting each identified risk, its assessment (likelihood, severity, ranking), and what was decided (mitigation actions, etc.). It doesn't have to be formally called a "Risk Register," but the concept is to have a one-stop reference for all significant risks considered[13]. This helps during design reviews or if a question comes up later like "Did anyone think about X?" – you can show that it was considered and see what was done.
- **Design Review Minutes:** If you hold engineering design reviews or risk assessment meetings (which you should for significant decisions), record the minutes. Note down key discussion points about component choices and risks, and the recommendations or decisions made. These minutes serve as evidence that a multidisciplinary team applied their minds to the problem, fulfilling both ISO's expectation of involving *relevant stakeholders* and the professional standard of due diligence.
- **Technical Memos / Calculation Sheets:** When you perform analyses – say, a quick calculation of expected risk cost, or an FMEA table, or a decision matrix – include those in your project documentation. Even rough calculations can be cleaned up and put into an appendix for record-keeping. If you decided not to choose a particular material because, for example, your calculation showed its risk of failure would cost more in the long run, write that down. These documents don't need to be lengthy reports; even a one-page memo to the file, or a slide in a review deck, can suffice if it captures the rationale.
- **Specifications and Plans:** Incorporate risk-mitigation requirements directly into design documents. For instance, if you chose a material partly because of its quality requirements, ensure the project specifications explicitly state those quality requirements (chemical composition, heat treatment, compliance with a standard, etc.). If you decided to mitigate a risk by testing, make sure the test plan or QA plan includes those tests. This way the **traceability goes both ways**: from risk assessment to design documents and vice versa. An auditor or colleague can pick up the spec and see the careful considerations embedded in it, even without reading your separate risk register.
- **Continuous Improvement Feedback:** ISO 9001 encourages that you learn from projects. So after project completion or after the component has been in service for some time, note

[13] https://www.qmii.com/comprehensive-guide-to-risk-based-thinking-in-iso-90012015-transition/

any lessons. *Were there any surprises?* If a risk you thought was minor turned out to be major (or vice versa), that's vital information for next time. Many organizations update their design checklists or standards based on such feedback – essentially growing a knowledge base of risks and mitigations for future engineers to draw from.

One great aspect of good documentation is that it reinforces **defensible engineering judgment**. If ever a failure does occur and an investigation happens (or in the worst case, litigation), having documented that you followed a rigorous risk-based process can be a strong defense. It shows the engineer acted responsibly and systematically. It's not a guarantee against something going wrong – engineering always has uncertainties – but it demonstrates professionalism and adherence to quality management principles.

In summary, documentation in risk-based component and material selection isn't about creating bureaucracy; it's about **making your decision process transparent and reproducible**. ISO 9001 leaves flexibility in *how* you document (you won't find a requirement for a specific form or report format), but it does expect that the organization (and by extension its engineers) can show evidence of risk-based thinking and actions[14]. As a Professional Engineer, you should view this as part of your due diligence and a way to communicate your decisions to others (clients, team members, reviewers, auditors) clearly.

[14] https://www.qmii.com/comprehensive-guide-to-risk-based-thinking-in-iso-90012015-transition/

6. Multidisciplinary Examples: Applying Risk-Based Selection

Throughout the course, we've woven in scenarios from different branches of engineering. Here we consolidate a few brief **case examples by discipline** to illustrate how risk-based component and material selection plays out in practice. These examples demonstrate that while the fundamental process is similar (identify, analyze, mitigate, document), the specific context and technical details differ:

- **Electrical Engineering Example – Backup Generator Selection:** An industrial facility needs a backup power generator. Two fuel options are considered: diesel vs. natural gas. Key risks identified include fuel storage safety (diesel is flammable liquid on site; gas is supplied by pipeline – risk of supply cutoff), start-up reliability (diesel engines have risk of failing to start in cold weather; gas generators might have lower output in extreme cold), maintenance and fuel stability (diesel fuel can degrade over time; natural gas supply contracts might have interruptions). The engineering team uses a decision matrix with criteria weighted for reliability, safety, runtime cost, and environmental compliance. They find natural gas scores higher in reliability (no fuel refill needed) and environmental impact (cleaner emissions), but diesel scores higher in power output and familiarity (technicians are more experienced with diesels). They also perform a simple FMEA on the diesel option (one failure mode: fuel filter clogging – moderate risk mitigated by regular testing and fuel maintenance) and on the gas option (failure mode: gas supply pressure drop – low likelihood but severe if it happens, mitigated by installing a gas line pressure monitor and backup diesel bypass). In the end, they choose the **natural gas generator**, primarily to **avoid the fuel storage risk** (risk avoidance) and due to long-term sustainability goals, while **mitigating the supply risk** by securing a priority service contract with the gas utility (risk transfer via contract). All this is documented in a short report and the procurement specs include the monitoring system and service agreement as risk controls.
- **Mechanical Engineering Example – Pump Material in a Chemical Process:** A chemical processing system requires a pump to handle a corrosive fluid at elevated temperature. Options include a stainless-steel pump, a polymer-lined pump, or a high-performance alloy. The team identifies risks for each: stainless steel could corrode if the chemical concentration spikes (moderate risk, as the material is near its corrosion limits); the polymer-lined pump might suffer liner degradation or blistering (risk of leak, moderate likelihood if process upset occurs); the exotic alloy offers great corrosion resistance but has a supply chain risk (few suppliers, long lead time, very high cost – risk of schedule delay and budget overrun). An FMEA table is developed for the polymer-lined option since it had multiple potential failure modes (liner blistering, seal failure, etc., each with severity and occurrence ratings). Meanwhile, a quantitative cost-of-risk analysis is done for the exotic alloy: if a delay in procurement could idle the project for 1 week, costing $100k, and the probability of that delay is estimated at 20% (due to supplier variability), the expected risk cost is $20k – which is actually small compared to the price premium of the

alloy itself (which might be $200k extra). The decision matrix and risk analysis lead the team to select the **stainless-steel pump**, as it provides a good balance of performance and cost, and its corrosion risk can be **mitigated** by specifying a slightly higher grade (with added molybdenum for corrosion resistance) and adding a corrosion inhibitor to the fluid (reducing the likelihood of corrosion). The polymer liner was deemed too risky (uncommon for this application – the team wants to avoid being a "first adopter" due to uncertainty), and the exotic alloy's benefits did not justify its high cost and procurement risk. The team documents the decision, including the requirement for the corrosion inhibitor and periodic fluid testing (to ensure chemistry stays within safe limits) as part of the mitigation plan.

- **Civil Engineering Example – Bridge Deck Material:** A city must choose between traditional steel-reinforced concrete vs. newer fiber-reinforced polymer (FRP) panels for reconstructing a small pedestrian bridge. Key concerns: for concrete, risks include cracking/spalling over time (medium likelihood, mitigated by improved mix design and rebar coatings) and longer installation time (affecting traffic – to mitigate, they plan accelerated curing concrete). For FRP panels, risks include unknown long-term performance (new technology – could have hidden failure modes, high uncertainty), higher upfront cost, but much faster installation (less time with the bridge closed) and corrosion immunity. The team conducts a risk workshop with experts from a state DOT that has tried FRP on similar projects. They use an RBS to guide the discussion: categories include design risks (will it carry loads? thermal expansion differences?), construction risks (fit-up of panels, contractor experience), operation risks (slipperiness, UV degradation), and financial risks (life-cycle cost). Many risks for FRP are *uncertain* since there's limited data; each is qualitatively rated high/med/low. The risk matrix shows several high risks (if an FRP panel failed, impact would be high in terms of safety and public confidence; likelihood is hard to gauge, call it medium, giving high risk). For concrete, most risks are medium or low (well-understood material). **Result:** The engineers decide to stick with **reinforced concrete**, the tried-and-true option, thereby **avoiding the novel FRP risks** at this time. They incorporate several mitigations for concrete durability (good design practices from past lessons) to ensure a long service life. The decision is explained in a memo citing that while FRP has potential benefits, the uncertainty and high potential impact of failure made it an unsuitable choice for a public safety-critical structure under a risk-based evaluation.
- **Environmental Engineering Example – Contaminant Barrier Selection:** An environmental remediation project requires a barrier to prevent groundwater contamination from spreading. Options: a bentonite clay slurry wall vs. a geomembrane (plastic) wall. Risks: the clay wall could crack if not kept saturated (risk of pathway opening, moderate likelihood in drought conditions, high impact if it happens), whereas the geomembrane could tear at seams (low likelihood if installed well, but possible high impact leak if large tear). The clay is a natural material (more forgiving to install, self-healing to a degree, but requires long-term water level management), while the geomembrane is precise (needs

quality installation, but once in place requires less maintenance). The team does a partial FMEA focusing on installation failures: for the geomembrane, failure modes like "improper seam welding" (Severity high – leak, Occurrence low with certified crews, Detection moderate since leaks might not be obvious immediately) resulting in an RPN that flags careful contractor choice and maybe on-site seam inspection (mitigation). For the clay, a failure mode is "drying and shrinkage cracks" (Severity high, Occurrence medium in hot climate, Detection relatively easy via monitoring wells – still a high RPN, so mitigation is needed: e.g., adding a water recharge system to keep it wet). After weighing these, they choose the **geomembrane wall**, with a robust quality assurance plan (every seam 100% inspected and tested) to **mitigate installation risk**, and they secure insurance (transfer risk) for any unforeseen future leak remediation. This choice is documented in the design report, and the O&M (operations & maintenance) plan includes regular inspection of the barrier and surrounding monitoring wells to detect any issues early.

Each of these examples underscores how the **risk-based selection process is applied in different contexts**. The specifics vary, but the pattern is the same: identify what could go wrong, evaluate how bad it would be and how likely, take actions to reduce those risks, sometimes decide to not pursue a risky option at all, and always document what was done for future reference.

Step 1: Identify Risks

Brainstorm potential failures or issues with each component/material option. Use past experience, data, and team input to list out what could go wrong and what the consequences would be.

Step 2: Analyze & Prioritize

Estimate the likelihood and severity of each risk. Use qualitative scales (High/Med/Low) or simple scoring. Tools like risk matrices or FMEA help rank the risks and highlight which ones are critical.

Step 3: Decide and Mitigate

For each significant risk, decide on a handling strategy: avoid, mitigate, transfer, or accept. Implement mitigation measures or changes to reduce risk to acceptable levels. Revise your design or choice as needed.

Step 4: Document & Implement

Document the decision-making process – risk assessments, chosen actions, and rationale. Update design documents (specs, drawings, procedures) to reflect any risk controls (like design changes or testing requirements). Communicate the plan to all stakeholders.

Step 5: Monitor & Learn

During project execution or component operation, monitor for new risks or the effectiveness of mitigations. Afterward, review what went well or not – feed this knowledge back into future projects for continuous improvement.

(The above timeline summarizes the overall process of risk-based component/material selection, from initial risk identification through analysis, action, documentation, and later monitoring.)

7. Conclusion

Risk-based thinking, as encouraged by ISO 9001, leads to **better engineering outcomes** by ensuring that potential problems are addressed upfront in the design and selection of components and materials. By systematically identifying risks, evaluating their likelihood and impact, and taking appropriate actions (or making informed choices to avoid certain risks), engineers can significantly improve the quality, safety, and reliability of their projects. Moreover, coupling this process with good documentation practices means that decisions are transparent and can be reviewed or audited with confidence.

In practical terms, adopting a risk-based approach doesn't necessarily mean more paperwork or bureaucracy – it's often just a matter of **expanding the decision criteria**. Instead of choosing a material solely on lowest cost or highest strength, we add considerations like "What if it fails? How easy is it to get a replacement? Does it introduce any new hazards?" This broader view leads to more robust choices. Tools like FMEA, risk matrices, and decision matrices are there to assist, but even when used informally, the core mindset is what's important: **be proactive, think ahead, and be prepared for the unexpected**.

For Professional Engineers, this approach aligns with our ethical responsibility to hold paramount the safety, health, and welfare of the public. It helps avoid negligence by forcing us to ask "what could go wrong?" and address it. It also aligns with business goals: fewer failures and surprises mean more successful projects and satisfied clients.

Finally, integrating ISO 9001's risk-based thinking into engineering practice creates a culture of continuous improvement. Each project's lessons feed the next. Over time, organizations build up a repository of risk knowledge (like checklists of known risk factors, preferred materials with proven track records, etc.) and improve their standard designs. The risk-based approach becomes second nature – part of the "design DNA" of the team – which is exactly what the framers of ISO 9001 intended.

Thank you for engaging with this course. In the next section, you'll find a short **20-question quiz** to test your understanding of the key concepts covered. Remember, the goal is not just to pass a test, but to internalize these practices in your daily work as an engineer. **Proactive risk-based decision-making** will help you deliver designs of enduring quality and reliability.