STRUCTURED RISK ANALYSIS

just making sense!

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WHAT IS RISK?

Risk is an *action*, event, or situation that carries the potential for *loss, harm, or danger*, or that may *reduce* the ability to achieve an objective.

Risk may also refer to the probability of negative, undesirable, or uncertain outcomes, or to an asset's vulnerability to a threat.

Winning the lottery, for example, is better described as an opportunity than as a risk.

A risk scenario describes the sequence of events from a hazard to resulting harm or damage. The hazard is present first; a root cause then acts as a trigger, followed by a failure then the Exposure occurs when the target encounters the hazard, after which harm or damage follows.

In summary: Hazard → Root cause → Failure → Exposure → Harm or damage.

This sequence describes the scenario; it does not establish a causal order.

Failure can be a real event or the Possibility to happen or Non-existent at all, this depends on the type evidence used in the analysis and the type of hazard.

RISK Key Takeaways

Risk is opportunity-linked, not just hazard-linked — it includes anything that can erode the ability to reach a goal, not only physical loss or damage.

Two complementary lenses — risk is both a **qualitative condition** (an action or situation with downside potential) and a **quantitative measure** (the probability of an adverse outcome).

Asset-and-threat framing — risk explicitly ties **vulnerabilities** to **threats;** this is a cybersecurity aspect. It will not be part of this document.

WHAT IS FAILURE?

Failure is the inability of a component, system, or process to perform its intended function under specified conditions.

Risk refers to the possibility of an adverse event, whereas failure is an actual event that occurs when the associated risk materializes, whether or not that risk was recognized beforehand. Understanding this relationship is essential to effective risk management: it connects potential adverse outcomes to specific failures that can be analyzed and addressed.

In engineering, the loss or reduction of an intended function is considered a functional failure.

During natural disasters, failures can contribute to harm to people and damage to assets. Examples include a seawall of insufficient height, missing or delayed warnings, a generator located in a basement, and the absence of evacuation planning.

Importance of Risk-Taking

Risk-taking and failure are often treated inconsistently some organizations encourage risk-taking to foster innovation while penalizing the failures that may result. Yet pursuing ambitious ventures can involve setbacks that provide valuable lessons and contribute to lasting growth and achievement.

Taking risks supports personal and professional growth by encouraging development and accomplishment.

Embracing challenges can foster creativity and create new opportunities, while lessons learned from setbacks can strengthen future success.

Failure can be a steppingstone to success when it provides valuable lessons. Risk-taking precedes the possibility of failure; the aim is to pursue opportunities, not failure itself. This distinction is reflected in the term "risk-taker," rather than "failure-taker."

Conclusion

Risk and failure are interconnected concepts central to the pursuit of success. Understanding their relationship helps individuals and organizations respond to uncertainty, learn from setbacks, improve decision-making, and foster innovation.

Accordingly, Risk Analysis, Failure Mode and Effects Analysis, and HAZOP should be treated as complementary approaches within a unified study. Rather than debating whether hazard, risk, or failure comes first or is most important, the focus should be on their interrelationships and how these promote continuous improvement.

WHAT IS RISK ANALYSIS?

The concept Risk Analysis refers to the assessment process that identify, prioritize, analyze and mitigate current and future adverse actions or events that may negatively impact customers, organizations, and the environment.

It is a systematic method to mitigate Risks by trying to correct, detect or eliminate their root causes, rather than simply treating the symptoms and highlighting the importance of prevention and detection.

RISK ANALYSIS BUSINESS GOALS

Risk Analysis is one of the tools to change the business, “reactive” old way strategy to wait for a failure and then start looking for a solution to a “proactive” new way approach to learn what can go wrong and start solving it before it happens, becoming more profitable, reliable, and safe.

The long-term purpose of Risk Analysis must be the creation and protection of value. It improves performance, encourages innovation and supports the achievement of objectives.

WHAT IS RISK EFFECT AND IMPACT?

Effect is reserved for the description of what the risk or failure produces — **Impact** is the magnitude of that effect. The two are separate fields and are not interchangeable.

Effect is a deviation from the expected result from its execution while **Impact** is the rating; therefore, **Impact** is large or small, ranging from **Catastrophic** or **Hazardous** down to **Minor** or **Negligible**.

> **In other words, Impact is the measure of a negative result on customers, organizations, and the environment.**

WHAT IS RISK CAUSE?

A Risk Cause is the reason that can trigger an action leading to a potentially risky situation.

The Root Cause is the underlying or fundamental trigger of the risk or failure. Therefore, it is what has to be addressed for an effective solution.

WHAT IS FAILURE MODE?

A Failure Mode is the way a system, component, or process loses its ability to perform its intended function.

It describes in detail how failure occurs, its impact, causes, incidence and, and methods of prevention and detection.

WHAT IS A RISK STATEMENT?

The Risk Statement is One sentence, five parts, always in this order: If the failure, exposing the target to the hazard, it will result in the harm or damage, because of the root cause, with this incidence or likelihood.

1. **Failure — What goes wrong?**
2. **Exposure — Who or what gets hit, and by what?**
3. **Harm or Damage — What happens to them?**
4. **Root cause — The fundamental Trigger to go wrong?**
5. **Incidence or Likelihood — (Branch A) How often: counted, implies past or (Branch B) Expert estimation, prediction, implies future**

Example: If the spindle seal leaks, exposing the bearing to coolant, it will result in a seized bearing and an unplanned rebuild, because seal lip wear is not caught between service intervals, with incidence 4.

The sentence carries the words; the priority scores, RPN+ and RE+, stand beside it.

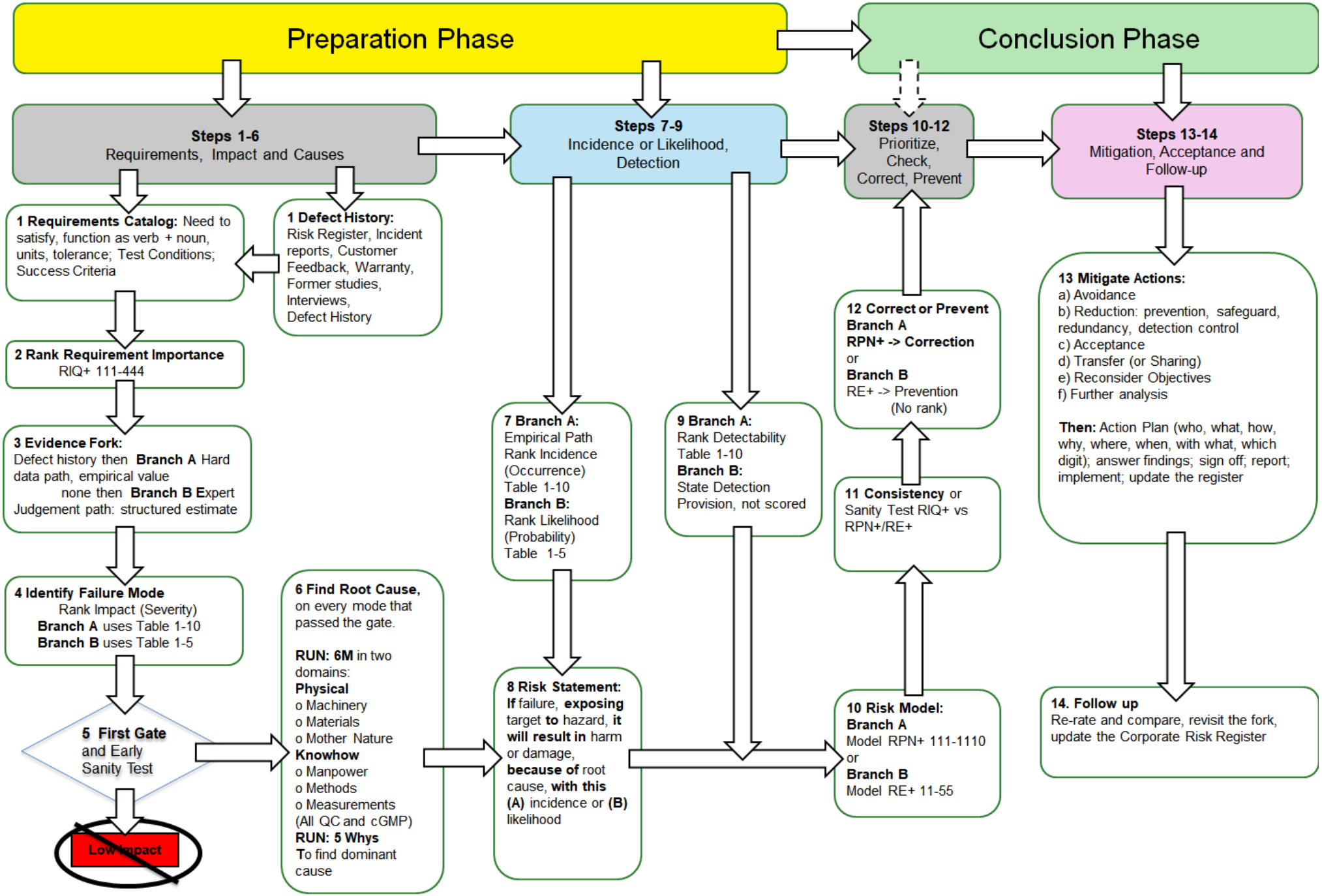
RISK CONCEPTS

1. Risk
2. Risk is opportunity-linked, not just hazard-linked
3. Risk is both a qualitative condition and a quantitative measure
4. Failure (Inability) or Loss of Function (Reduction)
5. Impact (Severity or Consequence; Measurement of the Effect)
6. Causes and Root Cause
7. Incidence (Occurrence, Frequency) or Likelihood (Probability)
8. Failure Mode, and introduction of Prevention and Detection
9. Risk Statement

STRUCTURED RISK ANALYSIS

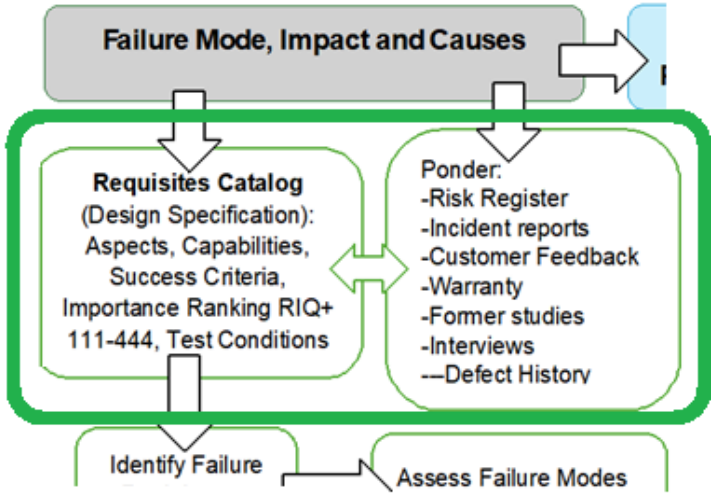
Structured Risk Analysis (SRA) Process Workflow illustrates the logical order, laid out by a risk statement of the steps required in a Risk Analysis based on process-oriented methodology that creates a logical flow of 14 interactive steps just like the 7 in design. New information or a change in circumstances will induce a step revisit or a more radical branch change.

STRUCTURED RISK ANALYSIS WORKFLOW



Identify Failure Mode, Impact and Causes

Failure modes may be identified through multiple information sources, including stakeholder interviews, incident reports, customer feedback, warranty claims, structured brainstorming sessions, and related operational data.



One of the most critical inputs is the set of capabilities documented in the Requirements Catalog. This information is frequently underutilized, despite its significant value in improving analysis effectiveness and efficiency, as it may capture a substantial portion of the key system functions that are susceptible to failure and therefore warrant evaluation. SRA rescues it. Also, the Requirement's Importance is a qualifier for its future reference. The MoSCoW method of 4 buckets: Must, Should, Could, and Won't, has being hardly criticized, SRA offers the refined ©Requirement Importance Quantified (RIQ+).

The Functions Catalog contain qualitative functions that may represent a risk and if they are important, they must be included in this process.

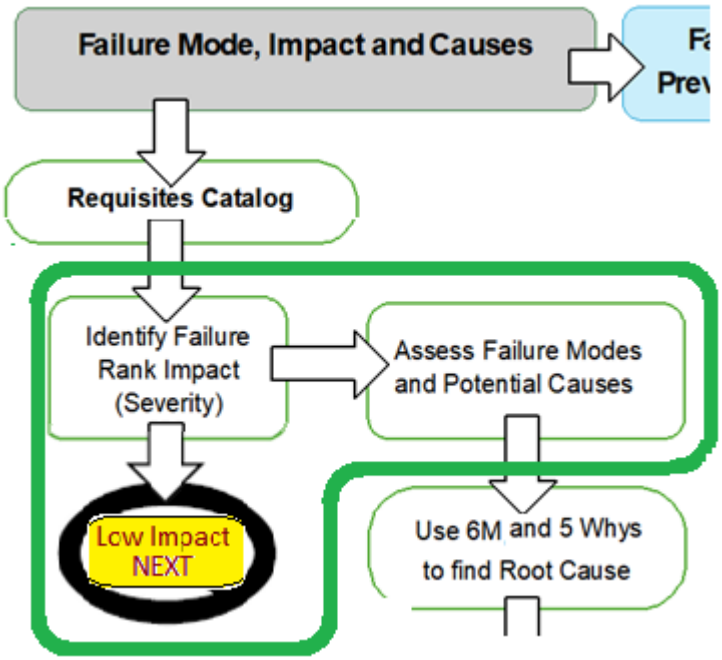
Failure Mode Effect Analysis assesses nature and magnitude of each one. Use Official Impact Table. See next slide.

i)Use Impact (Severity) Ranking 1 to 10 when **there is access to a history of actual failures**

ii)Use Impact simplified Ranking 1 to 5 for potential failures when **there is not a history of actual failures**, typically in the concept design phase

iii)Gather the corrective actions taken to understand completely the effect

iv)Management must establish procedure when Low Impact disables the rest of the analysis.



OFFICIAL FAILURE MODE "IMPACT" TABLE		
Impact	**Impact Criteria**	**Ranking**
Hazardous without warning	Very high severe ranking when a potential failure mode affects safe vehicle/device operation and/or involves noncompliance with government regulation without warning	**10**
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle/device operation and/or involves noncompliance with government regulation with warning	**9**
Very High	Vehicle/Device inoperable (loss of primary function)	**8**
High	Vehicle/Device operable but with a reduced level of performance	**7**
Moderate	Vehicle/Device operable but Comfort/Convenience Items inoperable. Customer dissatisfied	**6**
Low	Vehicle/Device operable but Comfort/Convenience Items operable but with a reduced level of performance. Customers are somewhat dissatisfied	**5**
Very Low	Fit and finish/Squeak and rattle item does not conform. Defect noticed by most customers (>= 75%)	**4**
Minor	Fit and finish/Squeak and rattle item does not conform. Defect noticed by customers (>= 50%)	**3**
Very Minor	Fit and finish/Squeak and rattle item does not conform. Defect noticed by discriminating customers (>= 25%)	**2**
None	No discernible defect	**1**

if there is not a simplified way for grading the **Potential** Risks Impact Number (Imp) is the following:

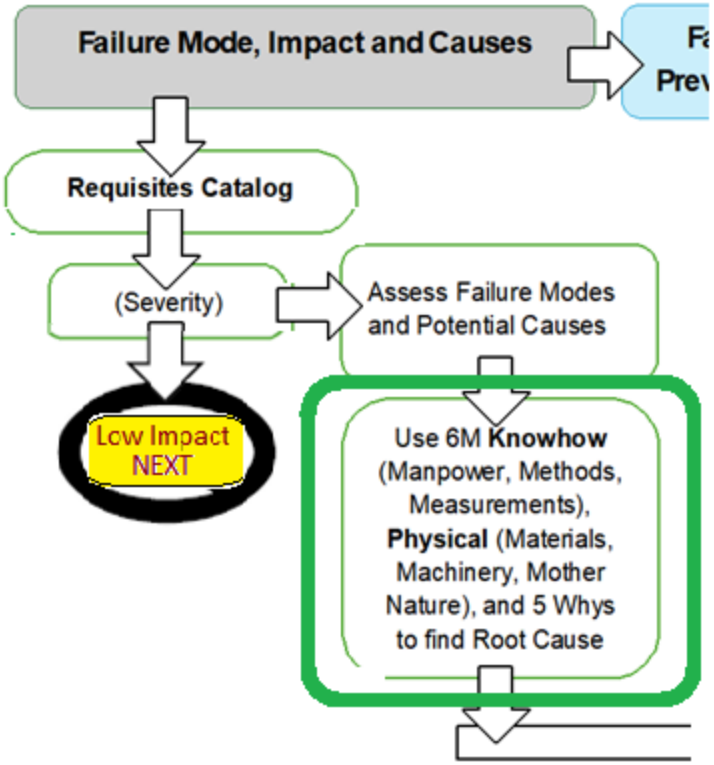
OFFICIAL SIMPLIFIED FAILURE MODE "IMPACT" TABLE		
Impact	**Impact Criteria**	**Ranking**
Catastrophic	Very severe consequences. Regulatory and Safety factors cannot be overlooked. An overall design change may create major defects	**5**
Major	Loss in the primary function of the item	**4**
Moderate	Reduction in the primary function of the item	**3**
Minor	Loss or reduction in the secondary function of the item	**2**
Negligible	Annoyance that does not affect function	**1**

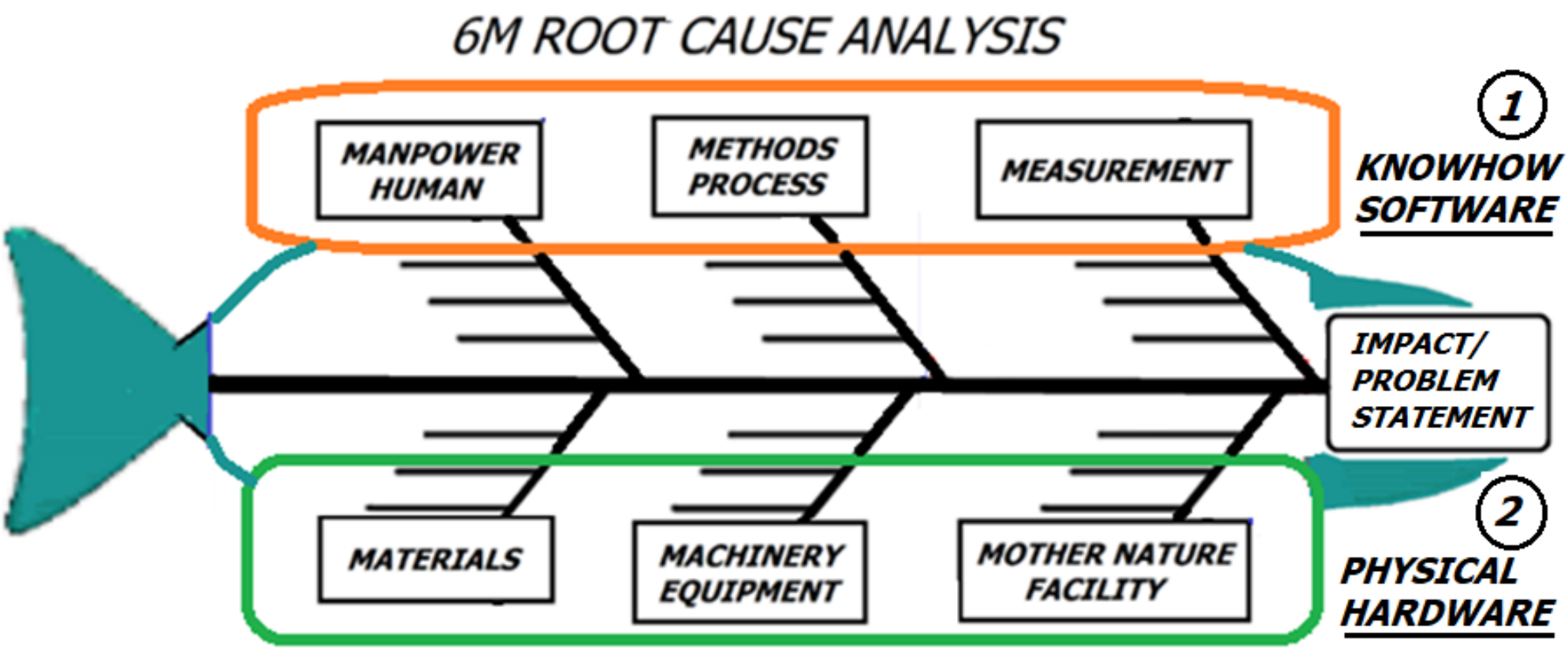
Find Root Causes. What actions will cause a function not to be delivered or a system to fail

I. Root Cause Analysis or 6M Analysis or Fishbone Analysis. Use it when a problem is complex, cross-functional, or has multiple contributing factors (e.g., Systemic yield drop across an entire facility). SRA 2 Domains are: **Knowhow**: Manpower, Methods, Measurements, and **Physical**: Materials, Machinery, Mother Nature/Environment. How these aspects influence each Failure Mode.

II. 5 Whys Analysis. Use it when a problem is linear and simple (e.g., A caused B). With the gathered information perform this analysis to find the Root Cause triggering each Failure Mode.

III. Complement 6M with 5 Whys for best results.





Kaoru Ishikawa proposed the 6Ms analysis of six possible categories that you might evaluate and assess in the hope that, by addressing one or more of them, you will be able to improve your process. From them, SRA gathers the two (2) basic sources

1. Knowhow or Software Domain, three top spines:
   A. Manpower
   B. Methods
   C. Measurements
2. Physical or Hardware Domain, three bottom spines:
   A. Materials
   B. Machinery
   C. Mother Nature/ Environment

Knowhow or Organizational causes

A. Manpower: Identifies issues related to human resources, training, and personnel management engaged in delivering a product or service and everything that relates to them that may contribute to defects or inefficiencies: Human, Stakeholder, Leadership, Staff, Subject Matter Experts, Operator, Team, PPE, Clerk, Customer. Manpower causes: Human error, lack of skills and knowledge to perform a task, attitude, job qualification. Employees do something incorrectly or don't execute something that was needed. This is the easiest class to blame, typically it leads to an underlaying factor in another "M" class.

B. Methods: The process sequences and requirements needed to produce an output or deliver a service, in general will be the Organization. Including Documentation, Flow Diagrams, P&IDs, Times and Flow Charts, Communication, Process Conditions Data, Bill of Materials, Labels, SOPs, Funding, Detailed Instructions, Training, Qualification, Design, Specification, Requirements, Drawings, Programs, Audits, Maintenance, Change Control. Faulty procedure, process, or policy in place; insufficient system or process that gives incorrect or incomplete instructions, training materials, making wrong decisions, or mishandling staff and property.

C. Measurements: Within SRA, It represent a distinct source associated with Quality Assurance and cGMP activities, integrating the other five categories. This approach eliminates unnecessary confusion with the analysis and gathering of these causes. This category includes the collection and management of records, tables, key performance indicators (KPIs), reports, inspection results, and other quantitative or qualitative data obtained from process inputs, transformation activities, and process outputs. It also encompasses the devices and procedures used to capture, analyze, qualify, and report data, including samples, automated and manual logs, testing results, scatter diagrams, and graphical or textual information. Measurement systems including condition and qualification of instruments, gauges, physical devices, test methods, records, as well as the Inspectors or Lab technicians.

Knowhow or Organizational Causes Examples

Examples of Causes Per Spine

Manpower or Human Factors	Methods, Process	Measurement or Inspection
Absence or Deficiency of Handling	Outdated or Lack of Clarity in SOPs	Faulty Record keeping
High employee turnover	Absence or Deficiency of SOP identity	Inconsistent quality checks
Negligence, Attitude, Lack of Skills	Absence or Deficiency of Handling	Absence of Proper Instrumentation
Absence or Deficiency of Training	Absence or Deficiency of Specification	Absence of Specification or Preparation
Aptitude	Absence of Planning	Absence of Calibration
Absence or Deficiency of Supervision	Sequence Step Error	Defective Go/No-Go Gages
Absence or Deficiency of Management	Bad Communication	Faulty Contracted Procedure
Health or Safety Issues	Disconnected Data Silos	Instrument or Condition ID
Operators do not understand instructions	Absence or Deficiency SOP Validation	Inspectors do not understand instructions
Operators do not understand the specification	Absence or Deficiency of Document Change Control	Inspectors do not understand the Specification

PHYSICAL CAUSES

Physical causes: May arise due to problems with any physical component of a system, such as:

1. **Materials**: The materials, consumables, or assemblies that you need to produce the output or deliver the service. Materials that can be Direct or indirect. The Direct ones are raw materials, components, packaging or assemblies that will be part of the final product or service. Indirect Materials, also known as Vitals, are not part of the final product, but they are necessary in its production or execution: Lubricants, Cleaners, Solvents, Gloves, Garbage, Disposables and Rejects. Particularly, the Labels Class that you need to put together, showing: Identification and Condition. Logistics to make, store, and deliver. Keep in mind a Purity quality term that will be hurt by Contamination: Crankshaft failures because of machining debris or Infected Medical Device
2. **Machinery**: Machines (Hand replacement) and tools are all physical elements you need to use to produce an output or deliver a service. Process use of Machines, Equipment, Robots, Effectors, Nozzles, Tools, Dies, Material Handling and Storage, Piping, Conveyors, Support Systems and Vehicles
3. **Mother Nature**: Environmental and Working conditions both controllable or random that you have, both internal and external to the process. Like Facility. Site, Floor Plan. Utilities, Piping, Ducting, Conveyors, Elevators and Transportation Paths, Storage Space. Noise, Weather, Illumination, Dust Control, Electrostatic Charge, Market, Geopolitical

PHYSICAL CAUSES EXAMPLES

Examples of Causes Per Spine

Material	Machinery, Devices, Tools	Mother Nature, Facility
Absence or Deficiency of Election	Absence or Deficiency of Specification	Extreme temperature changes
Absence or Deficiency of Application	Absence or Deficiency of Design	Climate – Weather - Moisture – Dryness
Absence or Deficiency of Handling	Absence or Deficiency of Construction	Poor Illumination
Absence or Deficiency of Receiving	Absence or Deficiency of Facility Equipment	Location
Absence or Deficiency of Supply	Aged machinery/tools	Public Services
Absence or Deficiency of Proper Storage	Absence or Deficiency of Maintenance	Government
Chemical Composition Defect	Equipment or Condition ID error	External Agents
Heat Treatment Defect	Absence or Deficiency of Jigs & Fixtures	Demarcation – ID areas
Surface Protection Defect	Absence or Deficiency of Storage Equipment	Social
Material or Condition ID	Absence or Deficiency of Material Handling Equipment	Housekeeping Deficiency

Root Cause Five (5) Whys Analysis

The 5 whys is a simple technique that helps you dig deeper into the root causes of a problem by asking "why" repeatedly until you reach a satisfactory answer. The idea is to find the causality train that most problems have as multiple layers of causes, and by asking "why" five times, you can peel off those layers and reveal the underlying cause. Combining this analysis with 6M can unveil a train of causality to find the problem root case.

For Example, if your problem is that your customers are dissatisfied with your product, you can ask:

1. Why are the customers dissatisfied? Because the product is defective.
2. Why is the product defective? Because the material quality control process is ineffective
3. Why is the quality control process ineffective? Because the standards are unclear
4. Why are the standards unclear? Because the design and production standards are poor
5. Why are design and production standards being poor? Because there is a lack of engineering standards and engineering management

This way, the root cause was identified as the lack of engineering standards and a lack of engineering management, rather than just the product defect.

Failure Mode Incidents, Prevention and Detectability of each Failure Mode

a) Rank Incidents (Occurrence) or Likelihood (Probability).

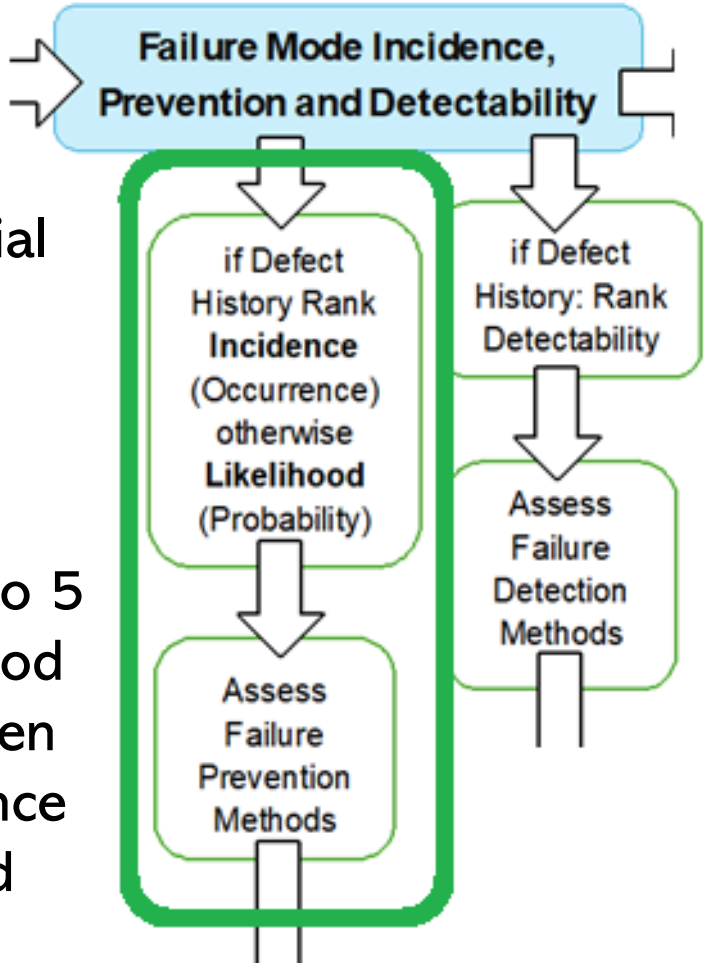
b) Dive in Failure History or lack thereof. Use Official Incidents/Likelihood Tables

   a) If there is access to history of actual failures Rank Incidents (Occurrence) from 1 to 10

   b) If there is not a history of actual failures use Likelihood (Probability) simplified Ranking 1 to 5

   c) It is possible to use the table relating Likelihood to Incidents, although, it can be confusing when there is fork pointing to actual defects incidence

c) The Prevention control (method) goal is to avoid the effects of failure. With the information just gathered the Prevention measures can begin to appear, they are to remove the causes of failures rather than corrective actions.



Simplified Likelyhood Table when there is not Incidence History

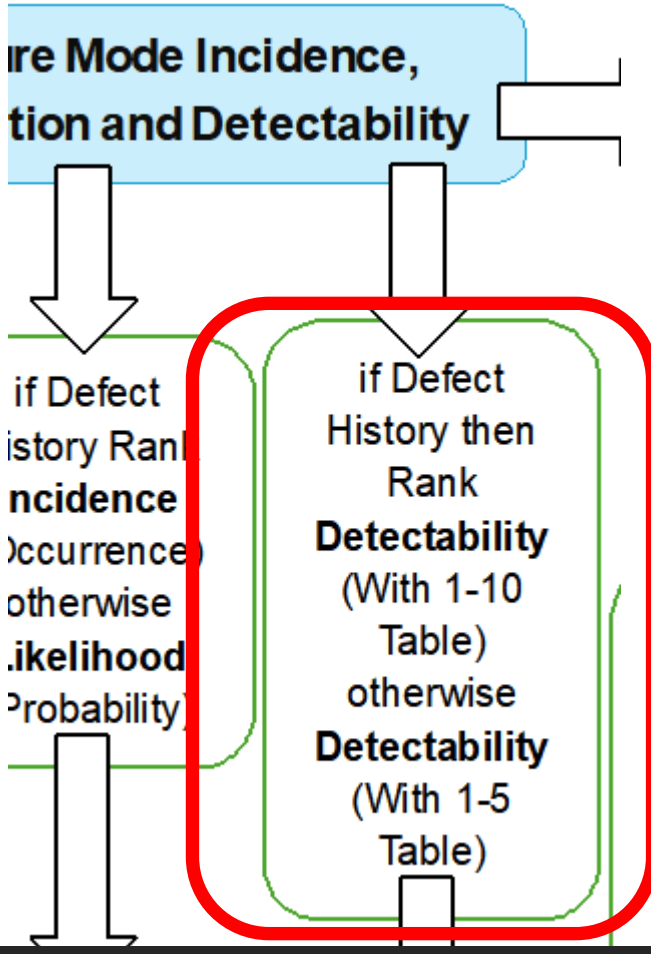
Description	Rare	Unlikely	Possible	Likely	Almost Certain
Ranking	**1**	**2**	**3**	**4**	**5**

OFFICIAL FAILURE MODE "INCIDENTS/LIKELIHOOD" TABLE		
Likelihood of Failure	**Incidents Criteria**	**Ranking**
Very High. New design/technology/application with no history.	>= 100 per 1000 pieces >= 1 in 10	**10**
High. Failure is inevitable with new design/technology/application or change in duty cycle/operating conditions.	>= 50 per 1000 pieces >= 1 in 20	**9**
High. Failure is likely with new design/technology/application or change in duty cycle/operating conditions.	>= 20 per 1000 pieces >= 1 in 50	**8**
High. Failure is uncertain with new design/technology/application or change in duty cycle/operating conditions.	>= 10 per 1000 pieces >= 1 in 100	**7**
Moderate. Frequent failures associated with similar designs or in design simulations and testing.	>= 2 per 1000 pieces >= 1 in 500	**6**
Moderate. Occasional failures are associated with similar designs or in design simulations and testing.	>= 0.5 per 1000 pieces >= 1 in 2000	**5**
Very Low. Isolated failures associated with similar designs or in design simulations and testing.	>= 0.1 per 1000 pieces >= 1 in 10000	**4**
Minor. Only Isolated failures associated with similar designs or in design simulations and testing.	>= 0.01 per 1000 pieces >= 1 in 100000	**3**
Very Minor. No observable failures associated with similar designs or in design simulations and testing.	>= 0.001 per 1000 pieces >= 1 in 1000000	**2**
Very low. Failure is eliminated through preventative control	Failure eliminated	**1**

Assess Detection Methods

1) Fetch Detection Methods. “How likely will the current system detect the failure mode, if it occurs or best detect its cause. If not, what we need to implement to detect it.
2) Early failure detection is critical for minimizing downtime and ensuring system reliability.
3) If history of defects is available, assign Detectability Rating. Use the Official” Detection Difficulty” Table. Detection ranks on a 1 to 10 scale, 10 means worst detection capability. See next slide.
4) If there is not History of defects classical FMEA disregards Detectability. SRA recommends to establish a Detection Provision to prove acknowledgment.
5) Recommend how to use detectability by adding sensors, squealer metal tabs or measuring systems in the design

Risk Detection is an important thought for the design procedure. Think Risk and how you perceive risk. Can you tell the cause before it happens, or do you need to wait until it happens? or there is an opportunity to add a sensor device and/or alarm that can fill the gap?



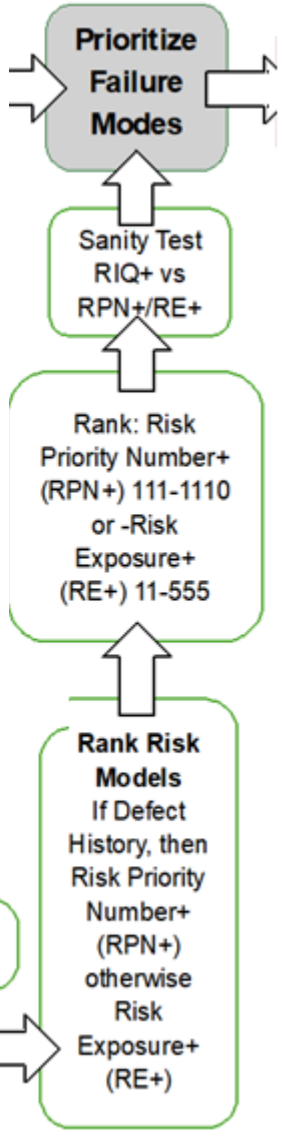
The Detection Provision

Branch B failure mode checks one presence, not size,:

- **Sensor or monitor:** For Cause or Failure
- **Test or inspection: To** catch it
- **Scheduled check:** Preventive Maintenance
- **Self-revealing design:** Shows up early
- **Warning to the user:** Announces itself before harms
- **None possible:** no practical way to see it
- **Write-in:** any other means, described it manually

Detectability Criteria: Mechanical	Criteria: Controller	Description	Ranking
No current design control. Cannot defect or is not analyzed.	Cannot detect	Failure Absolute Uncertainty	**10**
Design analysis/detection controls have a weak detection capability. Virtual Analysis (e.g. CAE, FEA, etc.) is not correlated to expected/actual operating conditions.	N/A	Difficult to Detect	**9**
Product verification/validation after design freeze and prior to launch with pass/fail testing (Sub-system or system testing with acceptance criteria e.g. Ride and handling, shipping evaluation, etc.)	N/A	Post Design Freeze and Prior to Launch	**8**
Product verification/validation after design freeze and prior to launch with actual failure testing (Sub-system or System testing until failure occurs, testing of systems interaction, etc.)	N/A	Post Design Freeze and Prior to Launch	**7**
Product verification/validation after design freeze and prior to launch with degradation testing (Sub-system or system testing (Sub-system or system testing after durability test e.g. Function check)	Test and validate in HIL, not possible in SIL.	Post Design Freeze Design analysis/detection and Prior to Launch	**6**
Product verification (reliability testing, development or validation tests) prior to design freeze using pass/fail testing.	N/A	Prior Design Freeze	**5**
Product validation (reliability testing, development or validation tests) prior to design freeze using test to failure (e.g. until leaks, yields, cracks, etc.)	Test and validate in SIL	Prior Design Freeze	**4**
Prod uct validation (reliability testing, development or validation tests) prior to design freeze using degradation testing (e.g. data trends, before/after values, etc.)	N/A	Prior Design Freeze	**3**
Design analysis/detection controls ha strong detection capability. Virtual Analysis (e.g. CAE, FEA, ect.0 is highly correlated with actual and/or expected operating conditions prior to design freeze.	Test and Validate in MIL – Design Flaw of functionality. Directly impacts model results	Virtual Analysis Correlated	**2**
Failure is fully prevented. Through design solution (e.g. Proven design standard/best practices or common material, working design reference.)	N/A	Detection is not applicable.	**1**

a) Create Risk Model from each Failure Mode. See details next slide.
   a) If there is an actual Incidence History Model Risk Priority Number RPN+: place Impact, iNcidents, and Detectability
   b) If there is not an actual Incidence History Model Risk Exposure Index RE+: Place Impact and Likelihood
   c) New or updated information can modify the models
b) Prioritize Risks. Focus on the largest Risk Priority Number (RPN+) or Risk Exposure (RE+) to sort the Failure Modes. Secure funding top to down.
c) The consistency test: RIQ+ against RPN+ and RE+. The same judgement is made twice, at two levels, by people looking at different things. Where the two disagree, one of them is wrong — and that is worth knowing before the register is signed.
d) Start writing the Risk Analysis Report including all the findings



Create Risk Model: RPN+ or RE+

If there is an actual history of defects estimate the **Risk Priority Number+ (RPN+)** for each Failure Mode: Range 111 - 1110

Risk Priority Number+ = 100 x Impact (Severity) + 10 x Incidents (Occurrence) + 1 x Detection

If there is not an actual history of defects use the simplified **Risk Exposure+ (RE+)** for each Failure Mode: Range 11 - 55

Risk Exposure+ = 10 x Impact + 1 x Likelihood (Probability)

Use the following Official Risk Exposure Table:

Impact or Severity ↓		Risk Exposure +				
Catastrophic	5	51	52	53	54	55
Major	4	41	42	43	44	45
Moderate	3	31	32	33	34	35
Minor	2	21	22	23	24	25
Negligible	1	11	12	13	14	15
Likelihood or Probability →		1	2	3	4	5
		Rare	Unlikely	Possible	Likely	Almost Certain

RPN+ and RE+ are free for anyone to use. No patent has been sought, and none will be.

Where the method is implemented, described or taught, please attribute it as:

© **RPN+ and RE+, from Structured Risk Analysis by Jorge A. Parra.**

They provide clear, tie-free risk rankings with distinct scores that prioritize impact.

Conclusion Phase:

Risk Mitigation or Acceptance

a) Assess Mitigation or Acceptance to 80% of selected Failure Modes with high RPN+ or RE+ and RIQ+

   i. Avoidance: Change plan or strategy
   ii. Reduction: Lower Likelihood and/or Severity
   iii. Acceptance: Passive or Active
      - Add Warning Sensor
      - Redundancy: Backup(s) creation
      - Monitor: Active surveillance
   iv. Transfer (Sharing): Outsource or Insurance
   v. No solution yet: Reconsider Objectives
   vi. No solution yet: Further analysis

b) Development of Action Plan: Who, what, how…

c) Finish the Risk Analysis Report with your Recommendation

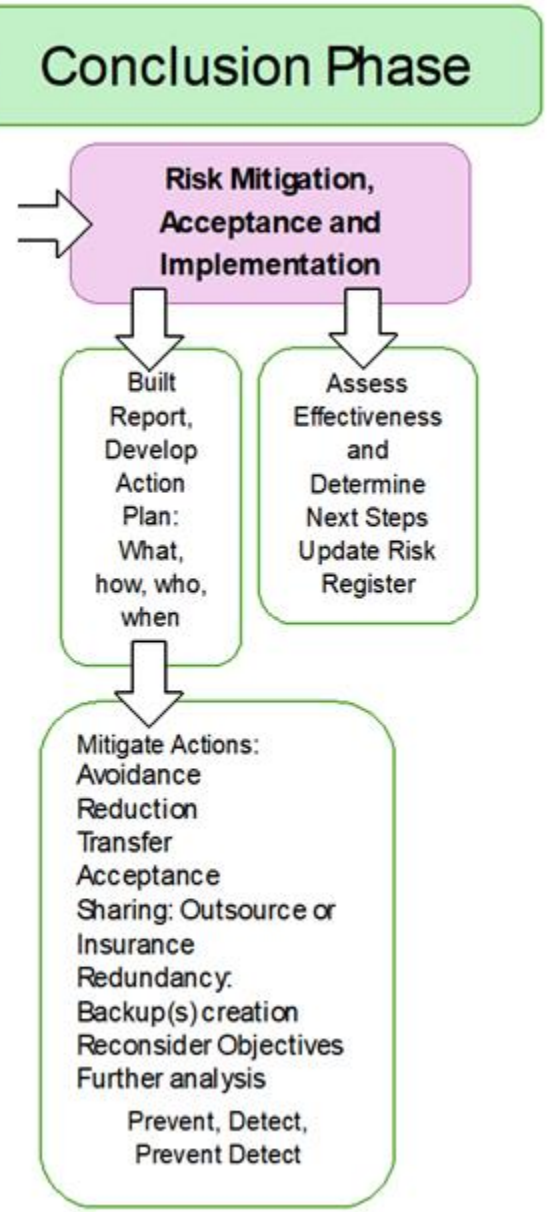
d) Implement Solutions

e) Update Corporate Risk Register Database

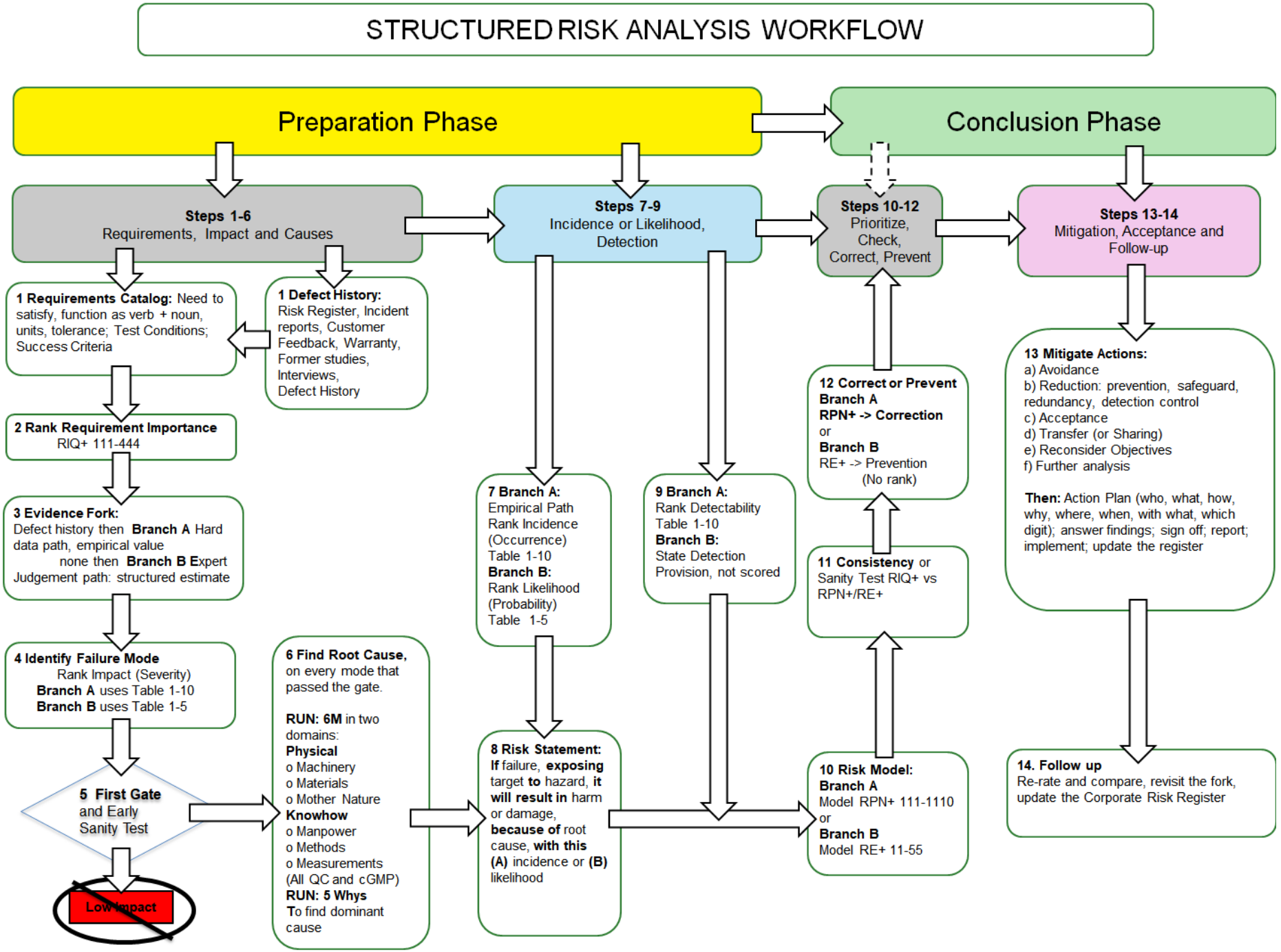
f) Follow Up; It did work or we need to start again

g) Monitor Effectiveness

h) Plan Next Steps



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Hello friends,

Throughout almost half a century of daily design work, I relied mostly on what I learned in my Basic Design course: the seven interactive principles of the Philosophy of Design. I used to joke about Lean, Agile, and even Six Sigma, Kaizen, and Total Quality because they were built on the same principles, promoted by a new breed of expensive evangelists whose slogans and catchy terminology, resulted in tiny adjustments, adding only marginal value to the product, they could not help me; and the seven remained hidden. I was fortunate to have received training in Logistics, Production Planning and Control, and Project Management, which prepared me to tackle the largest projects that came my way. But still, I felt there was something missing to design better.

Over the years, I recognized several scattered dots that needed to be connected: Value Engineering, FAST diagrams, Function Description, Design Requirements, Risk Analysis, Quality Control, Testing and Validation. Unfortunately, I was unable to apply them as effectively as I wished to create value, while my main responsibility was my family, time was not on my side.

One day, I suddenly found myself with time to spare. I chose to study Risk Analysis, only to discover that its evangelists struggled with their most basic task: prioritizing risks RPN and RE.

Later, when I learned the importance of the Catalog of Requisites in Risk Analysis, it was a revelation: this was exactly what I had always needed to start a design in Value Engineering. Requisites had been everywhere all along, yet my managers and I routinely skipped that formal step because we could not escape the urgency factor, it was always there. It was painful. That inspired me to create a resource that could help everyone. So, I began developing tools to describe functions and define requirements, and I ultimately built them into a Risk Analysis tool designed for engineers.

Ironically, this technology I set out to "simplify" gave me the tool to tackle the other hidden pain point in risk management: prioritize requirements by importance. The MoSCoW method sorts into four buckets—Must, Should, Could, and Won't, and that's it. It is worth knowing what it does not do.

It has been hard for me to believe that risk management has remained so complex, opaque, almost intimidating and controversial since 1950 that it seems you need an evangelist just to make it accessible.

Today my objective is to democratize STRUCTURED RISK ANALYSIS as a design tool paired with Philosophy of Design. Hopefully one day with Value Engineering to create successful innovations, pain free.

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