

Chapter 2. Risk & Opportunity Analysis

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0) Introduction

This chapter is on risk and opportunity analysis (R&O), which is the greatest change in ISO's approach to ISO9001 for this new version. ISO9001 will no longer be one-size-fits-all. The clauses of the Standards while is still useful, will be implemented in reference to risk and opportunities facing an organization.

1) 4.1 Understanding the organization and its context (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine and analyse external and internal issues that are relevant to its purpose and its strategic direction. In particular it should examine those that can affect its ability to achieve the intended result(s) of its quality management system. The organization shall continue to monitor and review information about these external and internal issues.

3 NOTES are provided to clarify what are external and internal contexts. Issues can be both negative or positive and both shall be considered.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause.
- ISO is moving a little into strategic management for quality. Instead of prescribing a set of rules and requirements to be followed, it now allows some priorities to be based on risks and opportunities.
- The risks and opportunities (R&O) will be analysed from both external and internal aspects. Both positive and negative issues shall be captured for analysis.
- The analyses need to be monitored and reviewed. In other words, the analysis is not a one-time affair.

(Compliance Best Practice)

4.1 Understanding the organization and its context

1. For compliance with this clause, a full analysis is required on external and internal contexts of your organization.
2. There are guidelines given under NOTES of the Clause, on how to run the analyses. You are also permitted to use other methods, so long they serve the purpose and lead to accurate conclusions.
3. For external analysis, you can use the suggested method (based on PESTEL). There are 2 ways this is done. **Exhibit 2-1** (Type 1) is used in the traditional strategic sense, with both risks and opportunities seen as they stand, **Exhibit 2-2** (Type 2) shows another method, where opportunities are improvement opportunities rather than windfall. **See SN 2.5 and SN2.6.** I recommend Type 2, but you can make your decision.

4. For internal analysis, most organizations would use the processes (turtle diagrams) as bases of the analysis, which is very practical and recommended. **See Exhibit 2-4**
5. For internal analyses, you should look at only a few major risks, and not everything. See **Exhibit 2 - 5A & Exhibit 2-5B..**
6. After deciding on the potential risks, scoring should begin on each item. Scoring tables are provided. External analysis have both a risk table and an opportunity table. For internal analysis only the risk table is needed. The risk table is a 4X3 scoring table. See **Exhibit 2-6. Also see SN2.7 and SN2.10** for explanations.
7. After the scoring, the residual risk of each item is derived. See **Exhibit 2-1 & 2-3** for External scoring, and **Exhibit 2-4** for Internal. For actions, see Clause 6.1 below.
8. Review is required. I recommend an annual cycle as it is easy to remember. Retain the notes made during Review as evidence. See **Exhibit 2-9 and Exhibit 2-10** on how to document the reviews.

2) 6. Planning, 6.1 Actions to address risks and opportunities (ISO9001)

(Clause Description-Paraphrase)

After the analysis of external and internal context, interested parties and their needs and expectations, follow-up actions may be needed : (a) to ensure that the QMS can achieve its intended result(s); (b) enhance desirable effects; (c) prevent, or reduce, undesired effects; (d) achieve improvement.

(Highlights and Additional Caution)

- (Ref to old Standards). This is a totally new clause
- This clause flowing down naturally from both 4.1 and 4.2. From the analysis on 4.1 (risks and opportunities), and 4.2 (Interested parties and their needs and expectations), there will be a list of conclusions.
- Final action is we must mitigate against risks and capitalize on opportunities

(Compliance Best Practice)

6. Planning, 6.1 Actions to address risks and opportunities

1. We need to have a system to decide which R&O to adopt. This had been discussed to some extent in Clause 4.1 above. This section discusses a little further and address the question of 'opportunities'..
2. For the suggested system here, only a 'risk' table is used for scoring. See (**Exhibit 2-6**). There is no 'opportunity' table.
3. When a final score shows up as H or M+, it is a higher risks, and action shall be taken.
4. For scores of M and L, they are the lower risks, and actions are optional. However, if actions are taken, they are considered as improvement, or opportunities for improvement. **See SN-2.4, SN-2.5, and SN2.8** for more explanations.
5. How detail show we document the action plans? 3 types of action plans are commonly used: a) bullet points, b) simple action plan, and b) full project plan. Type a) bullet points, is understood by everyone, and therefore not shown here. The other 2 types are shown in **Exhibit 2-7 and Exhibit 2-8.**
6. For recording, action plans can be on the same document of the analyses, as shown in **Exhibit 2-11.** Action plans can also be on separate documents, or other documents

3) 6.1.2.1 Risk Analysis (IATF16949)

(Clause Description-Paraphrase)



The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. The organization shall retain documented information as evidence of the results of risk analysis.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- This clause is meant to capture risks rising not detected earlier. Some of the areas/events where risk are found at: Product recalls, product audits, field returns and repairs, complaints, scrap, and rework etc are events that risks can be found; and therefore must be prevented.
- Retain records on such risk studies

(Compliance Best Practice)

6.1.2.1 Risk Analysis

1. This is a second net to catch risks which may have escaped from the 'context analyses'. This is activated after each failure. Risks associated with the failure shall be analysed and actions taken. The failure list is given in the Clause Description.
2. As this secondary capturing of risks involves many departments, a procedure should (not shall) be prepared for use by all. See **Exhibit 2-12**
3. Once a risk is resolved, lessons learned can be updated to the FMEA, control plan and other lesser documents down the line to prevent recurrence.

4) SIs and FAQs

None for this Chapter

5. Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
4.1	CBP	SN2.1 Why do we analyse only a few major items for risk and opportunities? There may be risk missed out in the unchecked areas.
4.1	CBP	SN2.2 Why not we use the internal analysis method recommended?
4.1	CBP	SN2.3 What do we check for during review of risk and opportunities?
6.1	CBP	SN2.4 Does it make sense to use risk table to look for opportunities?
6.1	CBP	SN2.5 Any evidence that opportunities for improvement can be accepted as 'Opportunities'?
6.1	CBP	SN2.6. Is it better to have action plans placed on the same document together with analysis?
EXH	EXH 2-3	SN2.7 Why don't we use SWOT for external analysis?
EXH	EXH 2-1, 2 -2	SN2.8 For External analysis, there are 2 options to use. Which one is better?
EXH	EXH 2-5	SN2.9 Where do I find the major areas for risk and opportunities for internal analysis?
EXH	EXH 2-6	SN2.10 Your scoring table is not 3x3, or 5x5. It is 4X3 which is rather unusual. What is the rationale behind?



EXH	EXH 2-9	SN2.11 If R&O review ended with changes and revision of document, do I still have to keep the review notes?
EXH	EXH 2-12	SN2.12 The procedure shows we have to update so many document, after a risk is captured and resolved. Are we going a little overboard?
EXH	EXH 2-1	SN2.13. How do we file the project plans, especially if another department is the process owner?
6.1.2 b(1)	Clause	SN2.14. What does integrating and implementing the actions into is QMS processes?

SN2.1. Why do we analyse only a few major items for risk and opportunities? There may be risks missed out in the unchecked areas.

It is not the intent of the clause to catch every little fish in the pond. Your QMS which is based on the standard will cater for most of the risks; and you don't have to repeat everything here. This exercise is to focus on major potential risks which have significant impact. Analysing too many items is not only a waste of resources, but it also tend to obscure the critical risks.

SN2.2 For internal analysis, why not we use the method recommended?

The method given in the standard is to analyse internal context is rather academic . Automotive organizations have the turtle diagrams that can provide more tangible analysis and evaluation. We should use what gives us a better handle.

SN2.3 What do we check for, during a review of risk and opportunities?

When conducting a review, we should check on: a) adequacy of the list, b) continued suitability of the assumptions and scoring, and c) the action plans. Revise the document as necessary.

SN2.4 Does it make sense to use risk table to look for opportunities?

Yes. In the analysis of organization contexts, the items being analysed will end up either as H, M or L, which stands for high, medium and low. Only the H items are adopted in most situations. And they are just a handful of them, perhaps 5-10%. The other 90-95% of the items are just left to waste. But they represent opportunities for improvement. If adopted, they can make an organization better, more effective and more efficient. Lower risks are therefore opportunities.

SN2.5 Any evidence to support their theory, that opportunities for improvement can be accepted as 'Opportunities'?

We are all conditioned by the SWOT in thinking, and interpreting Opportunities as the opposite of Risks. But that is not the intent of ISO. It did not mention SWOT and did not suggest opportunities must be opposite of risks. Risks and opportunities can be on the same side of the coin. In my model, higher risk are 'risks', lower risks when acted on are 'opportunities'. The model is in no way, in conflict with ISO's definition. See ISO's definitions on opportunities below:

- IATF16949:2016 Clause 0.3.3 states: "Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract, develop new products and services, **reduce waste or improve productivity**" <author: the favourable situation can be anything, including a weakness, that leads to actions taken>
- ISO9001:2015. 6.1.2 NOTE2. Opportunities <author: opportunity can be anything, including a weakness, that leads to actions taken> can lead to the adoption of new practices, launching new products, opening new markets, addressing new markets, building partnerships, using new



technology and other desirable and viable possibilities to address organization's or its customer's needs.

Other ISO Management Systems are even clearer of ISO's bent towards my improvement argument:

- ISO45001:2018. Clause 3.22. OH&S opportunity: "circumstances or set of circumstances that can lead to **improvement of OH&S**..."
- ISO22000:2018. NOTE at 6.1.3. Opportunities can lead to the adoption of new practices (modification of products or processes) using new technology and other desirable and viable possibilities **to address the food safety of** the organization or its customers.

ISO14001: 2015. 3.2.11 risks and opportunities. Potential adverse effects (threats) and **potential beneficial effects** (opportunities)

One final point to note is for both ISO9001 and IATF16949, the core theme is quality, and not about investments or business strategies. Hence opportunities should refer to opportunities for improvement within the QMS context. The strategic tools of SWOT or PESTEL if used in the conventional method, is for investments and business strategies.

SN2.6. Is it better to have action plans placed on the same document together with analysis?

There is no right or wrong here, but a matter of personal preference. Personally, I prefer all information on the same page, so I don't have to look elsewhere for the information and data.

SN2.7 Why don't we use SWOT for external analysis?

ISO touches on the elements of SWOT but did not specifically mention the tool. Instead it suggests a method close to PESTEL for external analysis. For internal analysis, it also did not mention about SWOT but 4 angles to study risk and opportunities. Yes, you can use SWOT but you need to use it in a way to show risks and opportunities in sufficient depth, to allow actions to be formulated and implemented.

SN2.8 For external analysis, there are 2 options to use. Which one is better?

Both can be used, so it is a matter of personal preference. Type 1 is based on mainstream strategic approach, and may tangent you off to investment and business strategy mode. Type 2 stays on the subject of QMS risk and improvement, which is the core concern of ISO9001 and IATF16949. There are people who are not comfortable with Type 2, and they can go to Type 1.

SN2.9 For internal analysis, where do I find the major areas for risk and opportunities for internal analysis?

Major or primary risks and opportunities should be concentrating in the output and the KPI areas. Only sparingly can you find a major risk, here and there in the rest of the places. See **Exhibit 2-5A**. You can also start with the purpose of a process, and think of 3-5 major obstacles as the primary risks. See **Exhibit 2-5B**.

SN 2.10 Your scoring table is not 3x3, or 5x5. It is 4 X 3, which is rather weird. What is the rationale behind?

A 4x3 is better than a 3x3 table. The latter results in far too many M (medium risks) that requires further decisions on adoption, as 'M' is an optional area. Since it is an optional area, most people will opt for the easy way-no actions. No action means no benefits to the QMS and the organization. In this 4 X 3 method, there are M+ as well as M in the risks . M+ is higher risk and actions must be taken. M



is somewhat safe and actions remain optional. When actions taken on M, it is Opportunity (for Improvement). More action items is the result.

4x3 is better than a 5 X 5. A 5 X 5 tends to split things too fine and more time taken to complete the analysis. In this head-count world, time use should be guarded jealously.

SN2.11 If R&O review ends with changes and revision of document, do I still have to keep the review notes?

No, no need. The revised document is your evidence of review.

SN2.12 The procedure shows we have to update so many document, after a risk is captured and resolved. Are we going a little overboard?

That is the requirement of IATF. You need to monitor, review and update on risk management. There are many areas with R&O, starting with internal and external contexts, interest parties, and contingency plans. The procedure ropes them all in for the review. If you do them in good time, it will be not taxing and every minute spent here is worth it.

SN2.13. Why is a scenario used to analysing external environment?

An external analysis based on current situation is history by the time it is done. You will miss opportunities and be troubled by threats when they appear. I advocate people to look a little into the future when doing external analysis. 12 months planning is very reasonable. Standard strategic management would look into 5 years or more.

SN2.13. How do we file the project plan, especially if another department is the process owner?

This has to follow your organization's practices. But the suggested method below should not be in conflict with most organizations. Project papers should be kept by the respective process owners. QMR should be informed, or allowed to review with the process owner periodically as a monitoring activity. For audit purpose, a copy should be provided to the QMR. It will speed up the audit, as IATF auditors may accept this copy and move on, without calling in the process owner.

Tracking is still an issue though. It is good to have a dashboard view of all ongoing projects. Your analysis documents can be dashboard. Records the external files and folders here link you to the responsible department. **(Exhibit 2-11)**

SN2.14. What does integrating and implementing the actions into is QMS processes?

It means that actions should really link to the functional departments. They should not be done by the QMR for the purpose of completing the risk analysis, for audit purposes only. The corrective or improvement actions must be truly implemented in the relevant departments to derive the benefits.

6) Exhibits

Exhibit 2-1 External Analysis PESTEL (conventional)

External Factors	(Scenario) Expected Changes in 0-1 years & Impact	Risk				Opportunity			
		S	P	R	Action/ Project No	A	E	O	Project No
Legal	Minimum wage will be increased (Negative: will increase operating costs a lot since we have 1000 workers)	M+	H	H	R1. EXTP-01	NA			NA
Economic & market	Economy is picking up very well. (Positive: more sales expected, and we have excess capacity to handle)	NA	NA	NA	None	M	M	M	NA
Technological	No change (We are in precision injection moulding serving E&E and automotive sectors)	NA	NA	NA	None	NA	NA	NA	NA
Competition	News that a China competitor is setting a subsidiary in the country (Negative: not a direct competitor immediately but can be in the future)	M	M	M	R2. EXTP-02	NA	NA	NA	NA
Social	Not Applicable (Our industry is not directly affected by changes in consumer behaviour)	NA	NA	NA	None	NA	NA	NA	NA
Cultural	Not Applicable (Our industry is not directly affected by cultural issues)	NA	NA	NA	None	NA	NA	NA	NA

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
R1. EXT-01	Risk	<ul style="list-style-type: none"> Outsource some low value-added processes Adopt some automation 	Top Management	Refer to detail project	Top Management
R2. EXT-02	Risk	<ul style="list-style-type: none"> Carry an impact study on the China company's intended activities on our business 	Marketing HOD	Mar 2018	Marketing

Legend:

Risk: H (High, Must Take Action), M (Mid, Action Optional), L (Low, Action Not Required)

Opp: H (High, Should Adopt), M (Mid, Adoption Optional), L (Low, Adoption Not Required)

Remarks given in this section explain on the exhibit. Do not include them as part of the Exhibit

- This analysis is based on the suggested method given in ISO9001:2015 Clause 4.1. NOTE 2, and according to conventional method of PESTEL
- In projecting risk and opportunity, a scenario within the year is used.
- Action plans in this example are given just below the analysis so they can be seen together. Sometimes the plan needs to be in greater detail, and this has to be done outside of the form due to space constraint. And the last column "Action Plan Location" links you to where you can find the detail plans and records
- In this example, a simple scoring method is based on the score tables given

Exhibit 2-1 External Analysis PESTEL (conventional)

Exhibit 2-1 External Analysis PESTEL (conventional)- Page 2

Risk Ranking Table

Severity (S)		Risk Evaluation		
Category	Description	Probability		
Low Impact (L)	Impact to interested parties is low. The effect is minor, mainly as inconveniences	Low probability	Mid probability	High probability
Mid Impact (M)	Impact to interested parties is moderate. The effect can be moderate financial losses (can handle without much hardship)	L	L	M
Mid Plus Impact (M+)	Impact to interested parties is moderate but nearing High. The effect can be moderate to high financial losses (can handle with some hardship)	L	M	M+
High Impact (H)	Impact to interested parties is high. The effect can be heavy monetary losses causing jeopardy, injury or fatality, or seriously affecting the organization's reputation	M	M+	H
		M	H	H

Probability (P)		Action Guide		
Category	Description	Risk Level	Description	Corrective Actions
Low Probability (L)	Very remote probability to occur, or 0-25 %% chance to occur	H	High Risk	Remedial actions needed
Mid Probability (M)	Has not occurred before, but chance to occur is moderate e.g. 25-50%	M	Moderate Risk	Remedial actions are optional
High Probability (H)	Has occurred before, is occurring or >50% probability will occur	M +	Moderate Plus Risk	Remedial actions encouraged
% given above is rough estimates only. There is no requirement for exact data as evidences		L	Low Risk	Remedial actions

Opportunity Evaluation Table

A. Opportunity Evaluation				C. Attractiveness	
Attractiveness	Ease of Implementation			Category	Description
	Low (L) (Difficult)	Mid (M) (moderate)	High (H) (Easy)		
Low (L)	L	L	M	Low Attractiveness	Project requires lot of work for very little return. Or ROI >5 years.
Mid (M)	L	M	H	Mid Attractiveness	Moderate work relative to the acceptable returns. ROI is 2-5 years
High (H)	M	H	H	High Attractiveness	Return is very good relative to work load. ROI <2 years. Or the project has strategic importance to the Organization

B. Action Guide			D. Ease of Implementation	
Opportunity Level	Description	Actions	Category	Description
L	Low Opportunity	Generally not to consider	Low Ease (difficult)	Requires a lot of resources and may cause some disruption to the main business line
M	Moderate Opportunity	Can consider	Mid (Moderate)	Requires some additional resources and training required, but within the means and control of the Organization.
H	High Opportunity	Case should be adopted	High Ease (Easy)	Easy to implement, resources are largely in place and people able to implement without much training

Exhibit 2-2. External Analysis. (Risk and Improvement)

External Analysis. PESTEL Risk & Improvement

Ext Factors	(Scenario) Expected Changes in 0-1 years	Impact	S	P	Risk	Actions
Legal	Minimum wage will be increased	Will increase operating costs by a lot since we have 1000 workers	M+	H	H	EXT-01-19
Economic & market	Economy is picking up very well.	Pressure to retain employees with good offers around	M+	M	M+	EXT-02-19
Technological	No new technology required from customers	No new risk	NA	NA	NA	NA
Competition	News that a China competitor is setting a subsidiary in the country	Heard they are very competitive at costing. May force us to lose margin	M	M	M	EXT-03-19
Social	Not Applicable	Our industry is not directly affected by changes in consumer behaviour)	NA	NA	NA	NA
Cultural	Not Applicable	(Our industry is not directly affected by cultural issues)	NA	NA	NA	NA

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
EXT-01-19	Risk	<ul style="list-style-type: none"> Outsource some low value-added processes Adopt some automation 	Top Management	Refer to detail project	Top Management
EXT-02-19	Risk	<ul style="list-style-type: none"> Improve our industrial relationship 	HR/ HOD	Mar 2018	HR
EXT-03-19	OPP (OFI)	<ul style="list-style-type: none"> Understand more about the competitor 	Marketing HOD	Mar 2018	Marketing

Legend:

Risk: H & M+ (High, Must Take Action), M & L: (medium and Low-When actions taken on M&L, it is opportunity for improvement).

Remarks given here explain on the exhibit. Do not include them as part of the document

- This analysis is based on the suggested method given in ISO9001:2015 Clause 4.1. NOTE 2 , but focusing on risk and opportunity for improvement.
- For this type, only scoring table is used. H and M+ are considered high risks and actions shall be taken. M and L are lower risks, but when actions taken are considered as opportunity, opportunity for improvement

Exhibit 2-3. External Analysis - SWOT

SWOT Analysis (2018)

<p>Strength</p> <ul style="list-style-type: none"> ○ Unique taste ○ Quality Ingredients ○ Friendly Staff 	<p>Weakness</p> <ul style="list-style-type: none"> ○ Low profits ○ No business website ○ Competition has more offerings
<p>Opportunities</p> <ul style="list-style-type: none"> ○ Market boom ○ Could expand to add pastries ○ can implement loyalty program 	<p>Threats</p> <ul style="list-style-type: none"> ○ Gluten-free societal trends ○ Drought ○ Negative reviews

Remarks given here explain on the exhibit. Do not include them as part of the document

- Actually SWOT is both internal and external analyses. Strength and Weakness are internal, while opportunities and threats are external.
- Thus some overlap work exist in the internal & external analysis. The tool may be good for a pastry shop, but not for automotive plants.
- The information is what you see on the grid. There is no further analysis of the risk and opportunity. You need to have other documents to record your final conclusion and actions.

Exhibit 2-4. Internal Analysis-Process based

Internal Analysis 2019 (Process: Purchasing)

Table 1. Analysis

No	Major Risks/Deviations (What can go Wrong)	Impact	Current Controls	S	P	Risk Level	Additional Controls	Action Code
1	Not maintaining a good base of suppliers to support the operations	Cost and quality may not be well controlled	Procedure for selection and evaluation of suppliers (not well implemented)	M+	M	M+	<ul style="list-style-type: none"> Qualify for more suppliers Implement multisource purchasing 	RP-PUR-01
2	Purchasing incorrectly-type and quality	Affect quality and delivery	Procedure for purchasing and incoming inspection (gen no mistake)	H	L	M	Not Required	None
3	Supply not on time	Affect delivery	Monitoring system for incoming control and provide forecast to assist suppliers (Generally no problem)	H	L	M	Visit critical suppliers often to ensure they are controlling inventory well	None
4	No evaluation on suppliers	Supplier may not be performing at their best	Procedure for evaluation of suppliers available and implemented (Service and indirect type suppliers not evaluated)	M+	M	M+	Include service type of suppliers and indirect suppliers	RP-PUR-02

Table 2: Action Summary

Action Code	Risk/ Opportunity	Action	Due date	Doc Information Location	Effective?	Evidence
RP-PUR-01	Risk	Qualify for more suppliers and implement multisource purchase	Jun 2018	Purchasing		Purchasing
RP-PUR-02	Risk	Include service type of suppliers and indirect suppliers	Sep 2018	Purchasing		Purchasing
OP-PUR-01	OPP	Training Purchasing Personnel to negotiate price and also practice multi-sourcing, where applicable	30 Dec 2018	Purchasing		HR/ Purchasing

Remarks given in this section explain on the exhibit. Do not include them as part of the Exhibit

1. Internal analysis method here is based on 'process'. The analysis shown here is only 1 process- purchasing. Other processes shall be analysed the same way.
2. But it is important is to limit the analysis to only a few major items. Otherwise you are overloading without an equivalent payback.
3. Only a single scoring table is used for both risk and opportunity. The scoring table use is a 4 X 3 (not 3 X 3). I found that 3 X 3 ends up with too many M, which requires more thinking and decisions. Organizations normally take the easy way by choosing no action. While it is technically correct, it is not helpful.
4. 3 X 4 will end up with M & M+. Items ending as M+, like H are higher risks and actions shall be taken. That is for risk mitigation.
5. Unlike external analysis, there is no special column to analyse opportunity in internal analysis. For internal analysis, opportunity will be construed as "opportunity for improvement", which are risk ratings of M and L. See Supplementary Notes for more explanations.

Exhibit 2-5A. Critical Internal Risks Areas

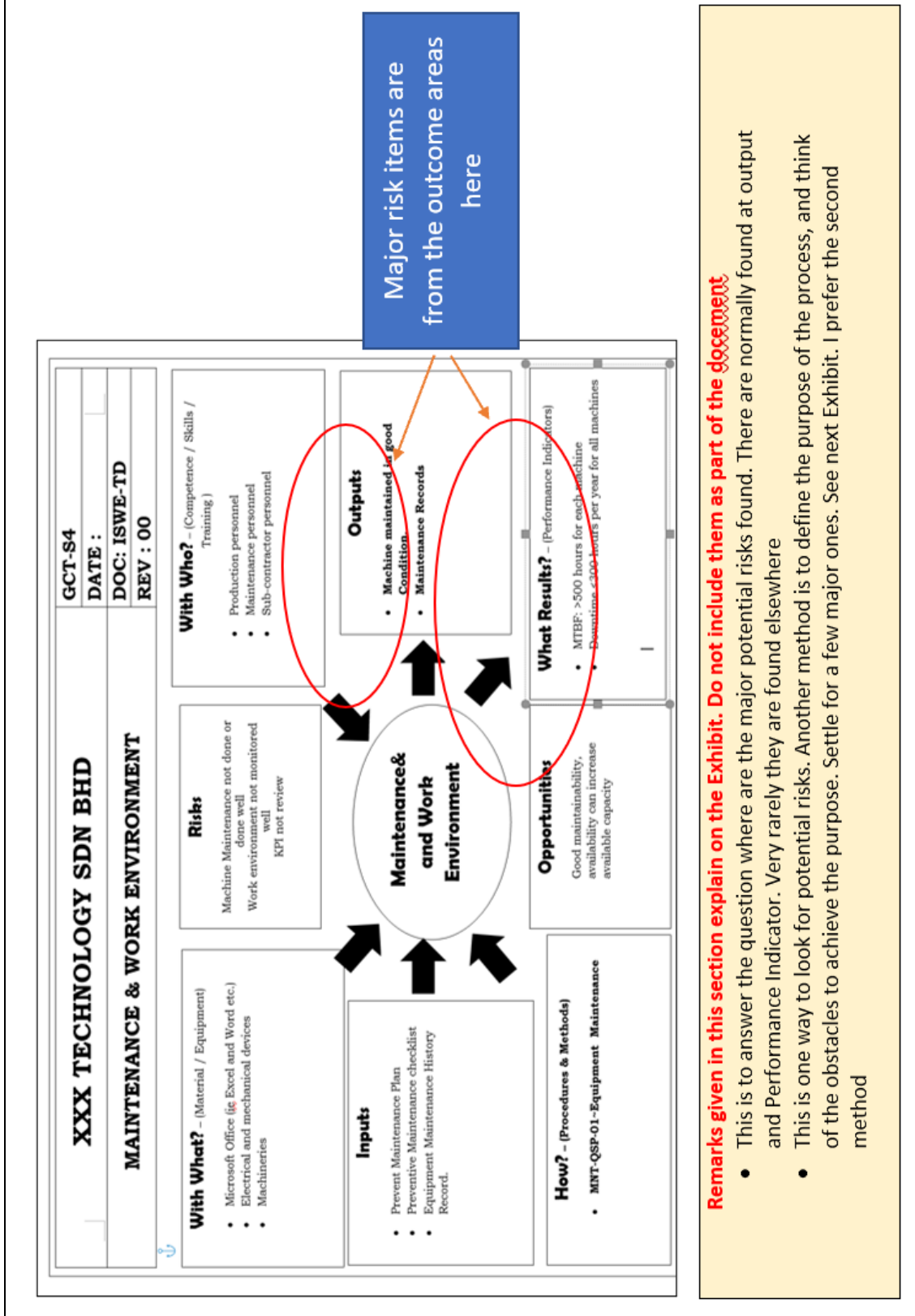


Exhibit 5B. Internal analysis (based on risk to purpose)
15. Storage & Receiving

Purpose of Process	Major Potential Risk
To control material receiving, identification, storage and preservation to ensure production can take place on time.	Identification, Traceability, FIFO and Storage not well carried out
Also ensure traceability of materials for problem solving	Inventory not well control
To control on material obsolescence to ensure product quality	Shelf-life not well control

16. QAQC

Purpose of Process	Major Potential Risk
To conduct quality checks and inspection to ensure conformity of products and processes as per quality plan	Not preparing Inspection Plan or Inspection Plan not tally with customer agreement or requirement
	Not performing IQA on incoming materials
Internal lab complies to IATF requirement	First piece not performed or late to authorize production
	In process QC not conducted according to quality Plan
	FQA not conducted according to quality Plan
	Internal lab does not fully comply to IATF requirement e.g competence, methods, equipment and environment

17. Delivery / FG Store

Purpose of Process	Major Potential Risk
To deliver products ontime and according to customer requirement, and premium freight under control	Delivery wrong parts or not on time
	Damage to product during transportation
	Not delivered as per customer instructions
	Premium freight exceeding allowable limits

18. Customer Feedback

Purpose of Process	Major Potential Risk
Customer feedback, including satisfaction, complain, scorecards and portal data are studied and understood. Any shortfall shall be responded with improvement actions	Customer complaints/claims not handled well
	Customer complaints takes too long to resolve

18. Customer Feedback

Purpose of Process	Major Potential Risk
Customer feedback, including satisfaction, complain, scorecards and portal data are studied and understood. Any shortfall shall be responded with improvement actions	Customer complaints/claims not handled well
	Customer complaints takes too long to resolve
	Customer scorecard not studied and responded to
	Customer portals not studied and responded to

19. NCP, CAPA

Purpose of Process	Major Potential Risk
Control Nonconforming output to prevent unintended use	Does not contain an NCP well to prevent intended use
Manage nonconformity to correct them and to prevent their recurrence	Does not conduct Root Cause Analysis well
Also learning lessons to prevent occurrence of nonconformity in similar or potential situations	Corrective action plans not effective
	Did not check on horizontal processes to prevent potential problems
	Suspect product not well control
	Scrapped product are not well control to prevent recycling or unintended use

20. Calibration

Purpose of Process	Major Potential Risk
Ensure measuring equipment is suitable for use, calibrated on time and result traceable to international standards or national equivalent. Independent labs shall be certified to ISO/IEC17025 or equivalent national standard	Calibration not done/ not done ontime
	Internal verification is not traceable to international standard
	Some calibration is not performed by labs with ISO/IEC17025

Remarks given here explain on the Exhibit. Do not include them as part of the document

- This is another way to look for R&O. They should relate to the purpose of a process, and we just think of the major obstacles to this purpose for your risks and opportunities
- There is always the temptation to list out everything. But the extra analysis is not necessary. Your QMS will take care of the minor obstacles, and so you do not need to repeat them here.
- What is seen above is only 2 out of 7 pages of the original document, due to space constraint

Exhibit 2-6. 4 X 3 Risk Table

Exhibit 2-6. The 4X3 Risk table

Severity (S)		Risk Evaluation			
Category	Description	Low probability	Mid probability	High probability	Probability
Low Impact (L)	Impact to interested parties is low. The effect is minor, mainly as inconveniences	L	L	M	High probability
Mid Impact (M)	Impact to interested parties is moderate. The effect can be moderate financial losses (can handle without much hardship)	L	M	M+	M
Mid Plus Impact (M+)	Impact to interested parties is moderate but nearing High. The effect can be moderate to high financial losses (can handle with some hardship)	L	M+	H	M+
High Impact (H)	Impact to interested parties is high. The effect can be heavy monetary losses causing jeopardy, injury or fatality, or seriously affecting the organization's reputation	M	H	H	H

Probability (P)		Action Guide		
Category	Description	Description	Corrective Actions	Risk Level
Low Probability (L)	Very remote probability to occur, or 0-25 % chance to occur	High Risk	Remedial actions needed	H
Mid Probability (M)	Has not occurred before, but chance to occur is moderate e.g. 25-50%	Moderate Risk	Remedial actions are optional	M
High Probability (H)	Has occurred before, is occurring or >50% probability will occur	Moderate Plus Risk	Remedial actions encouraged	M+
% given above is rough estimates only. There is no requirement for exact data as evidences		Low Risk	Remedial actions	L

Actions taken on red circle M+ items are mandatory for risk mitigation, just like for any H items

Actions taken on blue circle M items and Green L items are not mandatory. When actions are taken, they are for improvement (opportunities for improvement)

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This is Severity x Probability (S X P) risk table. It is a 4 x 3 rather than 3 X 3, or 5 X 5
- A 3X3 produces too many M, which is optional. Any most organizations would just ignore them because there are optional. Usually no actions will be taken
- A 5 X 5 is ok, but takes too much time to do
- A 4 X 3 is a happy compromise. 2 types of M will be produce, the normal M and M+. M+ needs to take action

Exhibit 2-7. Simple Action Plan

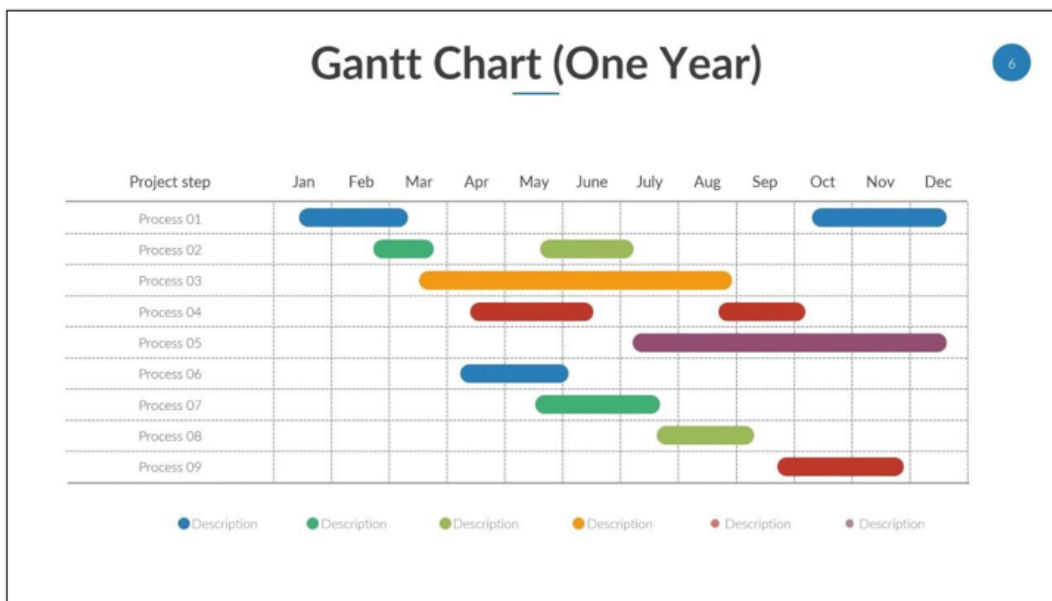
Project Title: To reduce the temperature at the mixing platform by installing air turbines Objective: <ul style="list-style-type: none"> To reduce discomfort and therefore work errors To reduce medical leave 	Doc No.	Year
	PDN-2/2019	2019
	Completion Date	Compiled by/Date
Project Team Members:	1 Apr 2019	
Project Leader: Mr M	Relevance/Integration	Approved by/Date
Team members: XXX, XXX	QMS/EMS	

Step	Program/Tasks	Person Responsible	Due Date	Completed on	Outcome	Status (Monthly)
1	Meeting to finalize decision	Proj Team 23	15 Jan 19	15 Jan 19	Proposed idea accepted	
2	Quotations for installing air turbines	Mr R, Purchasing	20 Jan 19			
3	Get approval from MD	Mr M, Proj Leader	25 Jan 19			
4	Project implementation, installation by supplier XXX	Mr S, Mtn	30 Jan 19			
5	Operate the system	Mr P, Production	20 Feb 19			
6	Review meeting, evaluating data and effectiveness	Project Team	20 Mar 19			

Remarks given in this section explain on the exhibit. Do not include them as part of the document

- This type of plan is by far the most popular method. It is easy to use and provides sufficient information on a single page.
- It shows the plan direction and work scope, due dates, responsibilities, and outcome.
- It can also be checked at any time on progress. The last column status is used to record updated status, which can be on pencil, until closed out

Exhibit 2-8. Project Plan with Gantt Chart



Remarks given here explain on the exhibit. Do not include them as part of the document

- When an action plan gets too complex, bullet points and simple action plans may not be suitable. A proper project plan is required. This can be internally prepared or by project contractors.
- A Project Plan shows a lot of details that are omitted in the simpler systems. A detail project plan can be a stack of document, or even a proper project paper. You often see: project title and project number, description of outcome, project budget, time frame, reporting requirements, stakeholders, qualifications etc. A Gantt Chart showing phases is also a common item in a Project Plan.



Exhibit 2-9. Review Evidence Type 1. Notes on the document

Internal Analysis 2019 (Process: Purchasing)

Reviewed on 17 May 2019
By XXX, XXX, XXX

Table 1. Analysis

No	Major Risks/Deviations (What can go Wrong)	Impact	Current Controls	S	P	Risk Level	Additional Controls	Action Code
1	Not maintaining a good base of suppliers to support the operations	Cost and quality may not be well controlled	Procedure for selection and evaluation of suppliers (not well implemented)	M+	M	M+	<ul style="list-style-type: none"> Qualify for more suppliers Implement multisource purchasing 	RP-PUR-01 OK
OK2	Purchasing incorrectly-type and quality	Affect quality and delivery	Procedure for purchasing and incoming inspection (gen no mistake)	H	L	M	Not Required	None OK
3	Supply not on time	Affect delivery	Monitoring system for incoming control and provide forecast to assist suppliers (Generally no problem)	H	L	M	Visit critical suppliers often to ensure they are controlling inventory well	None OK
4	No evaluation on suppliers	Supplier may not be performing at their best	Procedure for evaluation of suppliers available and implemented (Service and indirect type suppliers not evaluated)	M+	M	M+	Include service type of suppliers and indirect suppliers	RP-PUR-02 OK
5	(added 21 Jan 2019) Suppliers are not aware of statutory and regulatory requirements	Some customer requirement not fulfilled	Stated requirement on PO	M+	M	M+	Brief suppliers in person, rather than rely on document	RP-PUR-02 New

Table 2: Action Summary

Action Code	Risk/ Opportunity	Action	Due date	Doc Information Location	Effective?	Evidence
RP-PUR-01	Risk	Qualify for more suppliers and implement multisource purchase	Jun 2018	Purchasing	Yes	Purchasing OK
RP-PUR-02	Risk	Include service type of suppliers and indirect suppliers	Sep 2018	Purchasing	Yes	Purchasing OK
OP-PUR-01	OPP	Training Purchasing Personnel to negotiate price and also practice multi-sourcing, where applicable	30 Dec 2018	Purchasing	Yes	HR/ Purchasing OK
RP-PUR-03	Risk	Brief suppliers in person, rather than rely on document	2 May 2019	SQE/Purchasing		New

Remarks given in this section explain on the exhibit. Do not include them as part of the document

- This is an example of reviewing the risk analysis. Line by line, and point by point.
- Check for inadequacy as well as changing conditions and factors. In other words, you should check if the items are sufficient, and also the assumptions are still valid. You may need to add new items, delete items, re-score the risks etc.
- Hand written notes are as acceptable. For review with changes, document change shall follow and that itself is evidence of review.

Exhibit 2-10. Review Evidence Type 2. Recording on Doc change History

Document Change History			
Type of Doc Internal Analysis-Purchasing		Process Owner Purchasing	
Date	Document Title and No	Revision	Changes
1 Jul 18	Internal Analysis-Purchasing	00	Newly created
23 Feb 19		01	Added a new risk- customer statutory and regulatory requirement not followed by supplier.
Record review results on the Doc Change History			

Remarks given here explain on the exhibit. Do not include them as part of the document

- This is another type of recording analysis reviews.
- However, to use this, your organization should have a practice of using document change history for this type of document.
- In most organizations, I see document change history for quality manual, procedures, and forms, but not for technical and analytical document

Exhibit 2-11- Project Linkage Management

Exhibit 2-9. Project Linkage Management

**External Analysis
Template Technology**

External Factors	Scenario Expected Changes in 0-3 years & Impact	Risk		Opportunity			
		Risk Level	Action ?	Project No	Opport. Level	Action ?	Project No
Legal	Minimum wage will be increased (these changes are affecting costs a lot since we have 1000 workers)	H	Yes	R1. EXP-01	None	None	None
Economic & market	Economy is picking up very well. (Positive: more sales expected, and we have excess capacity to handle)	None	None	None	M	None	None
Technological	No change	None	None	None	None	None	None
Competition	News that a China competitor is setting a subsidiary in the country (Negative: not a direct competitor immediately but can be in the future)	M	None	R2. EXP-02	None	None	None
Social	Not Applicable (Our industry is not directly affected by changes in consumer behaviour)	None	None	None	None	None	None
Cultural	Not Applicable (Our industry is not directly affected by cultural issues)	None	None	None	None	None	None

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
R1. EXP-01	Risk	<ul style="list-style-type: none"> Outsource some low value-added process Adopt some automation 	Top Management	Refer to detail program	Top Management
R2. EXP-02	Risk	<ul style="list-style-type: none"> Carry an impact study on the China company's intended activities on our business 	Marketing HOD	Mar 2018	Marketing

Legend: Accessibility Investigate Focus

This is your dashboard. Use this area to track the locations of information and responsible persons to get updates

Exhibit 2-12. Risk analysis following a failure

Activity Flow	Description	PIC
<pre> graph TD 1[1 Failure occurs] --> 2[2 Containment] 2 --> 3[3 Problem Solving 10.2.3] 3 --> 4[4 Impact on Safety and Env] 4 --> 5[5 Update Risk & Opportunity Analyses] 5 --> 6[6 Update Interested Parties' Needs & Expectations, IPNE] 6 --> 7[7 Update Contingency Plan, if applicable] </pre>	<ol style="list-style-type: none"> 1. <u>Failure occurs</u> <ul style="list-style-type: none"> • Failure can occur in any part of the value-add chain, including after delivery to customer 2. <u>Containment</u> <ul style="list-style-type: none"> • Actions shall be taken immediate to contain the fallout of the failure • Containment shall include impact on safety and environment 3. <u>Problem Solving</u> <p style="margin-left: 20px;">Problem solving shall include :</p> <ul style="list-style-type: none"> - root cause analysis - corrective actions - horizontal application to similar or potential problems 4. <u>Impact on Safety and Env</u> <ul style="list-style-type: none"> • Analyse impact on safety and environment • Relevant action plans should be implemented 5. <u>Update Risk & Oppo Analyses</u> <ul style="list-style-type: none"> • Enter the incident into the risk and analysis, with score representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed 6. <u>Standardize IPNE</u> <ul style="list-style-type: none"> • Enter the incident into IPNE analysis, with scores representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed 7. <u>Standardize Contingency Plan</u> <ul style="list-style-type: none"> • Enter the incident into Contingency Plan, with scores representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed 	<p>Relevant Process Owner/ Contingency Team</p> <p>QMR to assist</p>

Remarks given in this section explain on the exhibit. Do not include them as part of the document

- This chart links up all the problem-solving steps and updating of related documentation
- Use this as a checklist after a failure to make sure none of the steps and risks are missed out