Risk Assessment - A first primer

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Specialist Consulting Engineers for Plastics Processing, Plastics Building Products and PVC-U Windows.

COMPANY PROFILE

- Tangram Technology Ltd. was formed in 1996 as a technology based consultancy dealing with the needs of the plastics processing, plastics building products and PVC-U windows industries.
- Tangram provides high quality change management, technical writing, training, product design consultancy and field services for these diverse industries.
- Our client base consists of some of the largest plastics processing companies in the UK, window systems designers, window fabricators, specifiers, large contractors, hardware manufacturers and computer services companies. We carry out extensive work for the UK Government (DEFRA and DTI), the EC and the World Bank in a variety of fields.
- Tangram is technology based consultancy, not a management consultancy. We supply specialist technical knowledge needed by our client base.

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Introduction to risk assessment

Risk assessment is a process of logically assessing the risks involved in a process to determine the actions necessary to reduce or control the risks.

The process of risk assessment is carried out in many areas of industry such as:

- Design and development: To assess methods of reducing failure risks and the hazards associated with design features.
- Production processes: To assess and reduce the risks associated with process failure and subsequent product failure.
- Health and safety: To assess the risks to affected parties (staff, contractors and the general public) of various processes and activities.
- Environmental affects: To assess and minimise the risks associated with industrial processes and possible associated outputs.

Risk assessment can be carried out in a variety of ways but the method to be discussed here is based on the methods developed for FMEA or Failure Modes Effects Analysis. This is a rigorous technique developed for use in the automotive industry to assess both the design and development risks and the process risks. In the automotive industry the type of FMEA used has been strictly differentiated between Design and Process and the two tools are referred to as Design FMEA and Process FMEA. Despite this the basic technique is very similar and the fundamentals remain the same. The FMEA method is well documented for Design and Process and it is not intended to repeat this information. This document concentrates on the use of FMEA in Health and Safety (for HASAWA Risk Assessments) and in Environmental Management (for ISO 14000 and similar compliance).

The FMEA is a proven methodology for the reduction of risk in many areas and is widely used throughout industry.

Risk assessment through a formal FMEA type of procedure enables:

- Concentration on taking action to reduce major risks.
- Effective use of resources.
- Avoiding having to try to deal with all the risks (including the insignificant ones).

The process

Assessing risk using the FMEA method involves assessing three or more factors (for most applications the number of factors assessed is 3 but for environmental assessment it is more usual to assess 4 factors). The number of factors assessed is discussed in more detail in the examples for each application.

The individual assessment of each factor is then combined to provide an overall assessment of the risk or Risk Priority Number (RPN) to allow targeted actions and risk reduction.

Assessment of individual areas.

For a typical assessment the three factors to be assessed are:

Severity: What is the severity of the effect? A failure inevitably creates an effect and the severity of the effect is judged on a scale of 1 to 10. A rating of 1 indicates a low severity of effect should a failure occur and a rating of 10 indicates a very high severity of effect should a failure occur.

Probability: What is the probability of the failure occurring? A failure can be likely to unlikely and the probability of failure occurring is judged on a scale of 1 to 10. A rating of 1 indicates a low probability that a failure will occur and a rating of 10 indicates a very high probability that a failure will occur.

Detection: What is the likelihood that a failure will be detected before it becomes critical? A potential failure may be easily detected and avoided or very difficult to detect and avoid. A rating of 1 indicates a high probability of detection and avoidance before failure and a rating of 10 indicates a very low probability of detection and avoidance before failure.

Each factor is assessed individually to allow a considered judgement on the basis of the individual factors. The separation of the severity, probability and detection factors makes assessment of the overall risk easier and less judgemental than attempting to assign a single risk number. Another advantage is that the separation also provides an insight into areas that require improvement and preventative measures.

When assessing significance:

- Be consistent - Develop a consistent approach that allows each issue to be clearly treated in the same way.
- Be able to demonstrate and justify the methodology used - Use criteria that provide a rational basis for the rest of the assessment.
- Record the method and decisions in a systematic manner.

Creating the RPN

The overall Risk Priority Number (RPN) is simply the product of the ratings for the factors:

RPN = Severity Factor x Probability Factor x Detection Factor.

This gives a simple and single number to assess the overall risk associated with the design feature, process event, activity or environmental aspect.

Example:

Assume that a designer is producing a design FMEA for a braking system in a car. The process (for this single factor) would be as follows:

Severity Factor: Assessed as a value of 10, i.e. Brake failure is a severe effect and the severity would be high.

Probability Factor: Assessed as a value of 3, i.e. Brake failure is not likely to occur given the robust design of the braking system.

Detection Factor**:** Assessed as a value of 3, i.e. Braking system has detectors to indicate possible failure and wear.

The overall RPN for this factor would then be:

RPN = 10 x 3 x 3 = 90

Note: The absolute RPN is not in itself a meaningful number. It is only meaningful when compared to other RPN numbers to allow assessment of the risk and actions to be taken to reduce the risk.

The individual areas of concern are assessed (preferably by a team or group of people to allow discussion and to prevent personal bias) and RPNs assigned to the various factors.

The RPNs can then be prioritised (highest first) to have corrective action to reduce the RPN. The individual RPN factors provide strong guidance on the actions to take to reduce the RPN.

For the example above an obvious area for action would be the severity factor. Reducing the severity factor would greatly reduce the RPN. Actions to take might include:

- Fitting seat belts to the car.
- Fitting warnings to the car to prevent motion without seat belts being fitted and operational.
- Fitting air bags to the car.

Taking these actions could reduce the severity factor to 7 and reduce the overall RPN to 63. This is a considerable reduction in the RPN and would increase the chances of survival in the event of a failure of the brake system.

The essential point about an RPN is not the absolute number generated. It is the RPN of a given factor or feature relative to other factors and features.

Setting the RPN limits

A company or person must act to reduce the most significant risks and the RPN allows an easy method to prioritise the risks. One question that is always asked is 'What is the threshold for action?' This assumes that there is some magic RPN number above which action must be taken.

The setting of the RPN limits for action is an entirely judgemental decision. Each assessor will evaluate each factor differently but the end result of the judgement will be a set of RPNs that prioritise the criticality of each risk.

The reality is that the assessor or management sets the RPN threshold for action. The only critical factor is that the assessor or management must be prepared to justify their actions in the setting of the RPN threshold. This is made easier using an RPN than with many other broader judgemental methods. The logic of the RPN makes decisions on thresholds easier to make and justify.

Experience and RPN

Where there is experience of failures, risks or emissions then the actual historical records can be used to build the RPN factors and to justify the values used or set for RPN. When this is the case the standard methods such as Pareto Analysis can be used to identify the critical factors and then to take the relevant corrective or preventive action.

Assessment of the relative factors can be based on:

- Previous designs, products or events.
- Similar designs, products or events.
- Analogous designs, products or events.

The amount of previous information available is almost always underestimated and the initial work should always be to survey the existing warranty, claims or experience data to provide a well-reasoned judgement for the allocation of values to the individual factors. The use of historical data improves the decision-making and also makes subsequent justification of the allocated value easier should this be necessary.

Using the factors for improvement

The clarity of the decision-making in assessing the various RPN factors also allows clarity in assessing the benefits of improvements (both theoretical and practical). Any proposed improvement can be assessed in terms of the RPN factors and a quick assessment of the likelihood and magnitude of the improvement made. The RPN spreadsheets provided below for the assessment of risk include sections for the assessment of improvements where these are thought to be necessary.

The living document

A risk assessment is not a static document that is produced and then forgotten. The whole of the FMEA ethos is that the document is a 'living document', the initial focus will be on reducing the highest RPN factors in the document but this will simply mean that other (and lower RPN factors) will become top of the list. These 'top of the list' factors are then subject to analysis and improvement to lower the overall risk profile. This is part of the reason for avoiding an absolute RPN threshold. The tasks to work on are always those at the top of the list and reducing these will reduce the risk profile of the process or task.

A risk assessment should always be under continuous review but at the very minimum should have a specified review date. Risk assessments should be reviewed with any significant change in circumstances.

Applications

This document is not designed to cover the whole range of risk assessment; there are other far more adequate texts that cover this area. A search of the Internet will provide a range of material covering Design and Process FMEA. A simple example only will be given for the basic quality management applications.

This document is to act as a primer for the use of the FMEA methodology for improved risk assessment in the areas of Health and Safety and Environmental Management risk management.

Each application is only covered briefly with an example spreadsheet for further work. The spreadsheets are not protected and can be freely downloaded and modified as necessary. The examples are for guidance only and carry no guarantee in any form.

Quality improvement

Risk assessment of possible events is an essential in quality management. An assessment of the potential effect of process and design failures is necessary to implement the relevant controls to prevent failures.

ISO 9000: 200 explicitly requires preventive action for quality improvement (Clause 8.5.3) and risk assessment using the RPN method is an excellent method for defining preventive action to meet the requirements of this clause.

The process and design are investigated to assess potential areas where failure will impact on the product quality or safety and each potential risk is assigned a rating after considering the following:

- Severity (S) – 1 is low severity and 10 is high severity.
- Probability (P) – 1 is low probability and 10 is high probability.
- Current controls (C) - 1 is high current controls and 10 is low current controls.

For each risk, the individual factors are rated to produce a composite RPN (S x P x C) and a total risk assessment for the risk.

As with all risk assessements it is necessary to review and revise the risk assessments with the passage of time ('living document') to reflect new equipment, processes, substances and procedures.

Severity of event (S)	Ranking
Hazardous: without warning	**10**
Hazardous with warning	**9**
Very High	**8**
High	**7**
Moderate	**6**
Low	**5**
Very low	**4**
Minor	**3**
Very minor	**2**
None	**1**

Probability of event (P)	Ranking
Very High: event is almost inevitable	**10**
	9
High: Repeated events	**8**
	7
Moderate: Occasional events	**6**
	5
	4
Low: Relatively few events	**3**
	2
Remote: Event is unlikely	**1**

Current controls (C)	Ranking
Absolute uncertainty	**10**
Very remote	**9**
Remote	**8**
Very low	**7**
Low	**6**
Moderate	**5**
Moderately high	**4**
High	**3**
Very high	**2**
Almost certain	**1**

Area: Compiled By:

Item / Function	Potential Risk Event	Severity of event	S	Probability of Event	P	Current Controls	C	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	New S	New P	New C	New RPN
Survey inaccuracies	Survey is not carried out correctly	High due to possible inability to fit the product. Customer satisfaction will be affected.	8	Low due to signoff of survey after carried out.	2	Signoff of survey.	2	**32**	None at this time						
Profile storage: Profile not stored at correct temperature	Profile shrinks or expands due to temperature changes.	Small due to low expansion and contraction over possible temperature range	3	Low due to conditioning of profile for 24 hours before use.	1	Profile lengths checked after cutting and window sizes checked after completion	1	**3**	None at this time						**0**
Profile storage: Profile not stored at correct temperature.	Profile may not weld correctly.	High due to potential failure of weld.	8	Low due to conditioning of profile for 24 hours before use.	1	Weld strength checking carried out.	1	**8**	None at this time						**0**
Sawing	Incorrect lengths cut.	High due to possible inability to fit the product.	6	Low due to cut length checking after cutting.	2	Final inspection of completed product.	1	**12**	None at this time						**0**
Hardware storage	Incorrect hardware selected from stores.	High as customer satisfaction will be affected.	6	Low due to paperwork specifying hardware.	3	Final checking to paperwork.	1	**18**	None at this time						**0**
Gearing								**0**							**0**
Installation								**0**							**0**

Continue sheet completion to assess and rank the potential events and provide improvements or corrective actions to reduce the RPN.

Health and safety

Risk assessment is a vital tool in Health and Safety and risk assessments must be carried out to comply with HASAWA requirements.

Each potential risk is assigned a rating after considering the following:

- Severity (S) – 1 is low severity and 10 is high severity.
- Probability (P) – 1 is low probability and 10 is high probability.
- Current controls (C) - 1 is high current controls and 10 is low current controls.

For each risk, the individual factors are rated to produce a composite RPN (S x P x C) and a total risk assessment for the risk.

Risk assessment for Health and Safety is simply an assessment of what could cause harm to people and what precautions are being taken or can be taken to minimise the risk. The important decisions are what hazards are significant and what precautions have been taken to minimise the risk. The FMEA approach documents these decisions regarding evaluating the risks and assessing the current precautions. In assessing the risks the assessments and controls must be 'suitable and sufficient' this is not necessarily the same thing as perfect! It is suitable and sufficient if reasonable precautions are taken so that the remaining risk is low. The use of RPN can document these actions and the residual risk.

When evaluating Health and Safety risks do not forget to include the risks ot the general public, visitors to the site and contractors as well as trhe risks to employees in the site. All are covered under HASAWA.

As with all risk assessements it is necessary to review and revise the risk assessments with the passage of time ('living document') to reflect new equipment, processes, substances and procedures.

See the sample Health and Safety Spreadsheet below for some typical assessment values.

Severity of event (S)	Ranking
Hazardous: without warning	**10**
Hazardous with warning	**9**
Very High	**8**
High	**7**
Moderate	**6**
Low	**5**
Very low	**4**
Minor	**3**
Very minor	**2**
None	**1**

Probability of event (P)	Ranking
Very High:	**10**
	9
High: Repeated events	**8**
	7
Moderate:	**6**
	5
	4
Low: Relatively few events	**3**
	2
Remote: Event is unlikely	**1**

Current controls (C)	Ranking
Absolute uncertainty	**10**
Very remote	**9**
Remote	**8**
Very low	**7**
Low	**6**
Moderate	**5**
Moderately high	**4**
High	**3**
Very high	**2**
Almost certain	**1**

Area:
Note: Immediate action required for an RPN greater than 80

Compiled By:
Date:

Item / Function	Potential Risk Event	Severity of event	S	Probabilty of Event	P	Current Controls	C	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	New S	New P	New C	New RPN
Accessible powered clamps (all types of machinery)	Trapped fingers and hands	Potential lost limb or extremities	8	Low probability	2	Restricted stroke (6 mm or less), two-hand control, guarding of the clamps and low pressure approach to within 6 mm of the workpiece. Clamp retracts if an obstruction is detected during descent. Approach pressure on the clamp is not adjustable by the user.	2	**32**	None						**0**
Workpiece movement	Cuts and lost limbs	Potential lost limb or extremities	8	Low probability	3	Clamping provided and blade/cutter interlocked with the clamping mechanism, so that blade/cutter cannot be presented to the workpiece until it is clamped.	2	**48**	None						**0**
Contact with the blades of the following types of saw: pivoting single- and double-head mitre, cut-off/pull-up, cross-cut/ draw, bead and snip	Large cuts and possible loss of limb	Severe	7	Low probability	3	Moveable guarding encloses the saw blade only in cutting position.	6	**126**	Fixed guarding provided to enclose the saw blade in both its cutting and retracted position.	Works Manager Immediate	Complete	7	1	3	**21**
Contact with mitre saw blades where blade movement is lateral	Contact with blades and loss of limbs	Potential loss of limbs	9	Low probability	1	Interlocked guards fitted to prevent access to the blades in cutting *and* retracted positions.	3	**27**	None						**0**
Contact with knives and cutters at cabinet enclosed corner cleaning machines transom grooving machines		Potential cuts	9	Lack of effective guarding gives high probability	7	Minimial guarding	7	**441**	Fixed or distance guards at the front of the machine to prevent access to the knives and cutters.	Works Manager Immediate	Complete	10	2	2	**40**
Large automated equipment (eg cutting and welding centres)		Potential loss of life from contact with machine	10	Lack of guarding gives high probability	6	Limited	9	**540**	Fixed guarding. Person-sensing devices, limited movement devices deployed within the perimeter fencing for access with the machine under power.	Works Manager Immediate	Complete	10	1	2	**20**

Continue sheet completion to assess and rank the potential events and provide improvements or corrective actions to reduce the RPN.

Environmental risk assessment

Assessing the significance of environmental aspects is a key requirement of ISO 14001.

Section 4.3.1 of ISO 14001 requires identification of significant aspects (those that have a significant impact on the environment) using a formal procedure. ISO 14001 does not specify a set method for assessing the significance of environmental aspects. However, the procedure used to assess significance should be recorded in a systematic manner for future reference.

Environmental aspects that are judged to be significant are the ones that will be managed by the Environmental Management System. As part of the preparation for ISO 14001 an 'Initial Review' is recommended to reveal which activities are covered by legislation and/or have a high cost. These will be areas where improvement activities will have a high beneficial environmental impact and significantly reduce costs.

Each potential impact is assigned a rating to after considering the following:

- Hazardous properties (H) - 1 is not hazardous and 10 is very hazardous.
- Size (S) - 1 is small and 10 is large.
- Frequency or likelihood of occurrence (F) - 1 is low frequency or likelihood and 10 is high frequency or likelihood.
- Presence of sensitive environmental receptors, e.g. people, a watercourse and/or site of special scientific interest (R) - 1 is little presence of sensitive environmental receptors and 10 is high presence of sensitive environmental receptors.
- Presence or absence of environmental controls, e.g. techniques designed to control or prevent the environmental impact (C) - 1 is high presence of environmental controls and 10 is low presence of environmental controls.

For each impact, the individual factors are rated to produce a composite RPN (H x S x F x R x C) and a total risk assessment for the impact.

See the sample Environmental Spreadsheet below for some typical assessment values.

The sample spreadsheet contains no information on the recalculation of the RPN. This is to be carried out as a separate exercise.

Hazardous properties (H)	Ranking
Major hazard	**10**
Extremely high hazard	**9**
Very high hazard	**8**
High hazard	**7**
Moderate hazard	**6**
Low hazard	**5**
Very low hazard	**4**
Minor hazard	**3**
Very minor hazard	**2**
Non hazardous	**1**

Size of event (S)	Ranking
Very large	**10**
Large	**9**
Very high	**8**
High	**7**
Moderate	**6**
Low	**5**
Minor	**4**
Very minor	**3**
Small	**2**
Very small	**1**

Frequency of event (F)	Ranking
Repetitive	**10**
Extremely high	**9**
Very high	**8**
High	**7**
Moderate	**6**
Low	**5**
Very low	**4**
Minor	**3**
Very minor	**2**
None	**1**

Environmental controls (C)	Ranking
Absolute uncertainty	10
Very remote	9
Remote	8
Very low	7
Low	6
Moderate	5
Moderately high	4
High	3
Very high	2
Almost certain	1

Environmental receptors (R)	Ranking
Major environmental receptors	10
Extremely high environmental receptors	9
Very high environmental receptors	8
High environmental receptors	7
Moderate environmental receptors	6
Low environmental receptors	5
Very low environmental receptors	4
Minor environmental receptors	3
Very minor environmental receptors	2
No environmental receptors	1

Area:

Note: Immediate action required for an RPN greater than 2000

Risk event	Hazardous properities	H	Size of event	S	Frequency of event	F	Environmental receptors	R	Environmental Controls	C	RPN	Recommended Action(s)	Responsibility & Target Completion Date
Leak from sludge tank	High	7	Small until sensors sound	4	Low	5	Moderate in adjoining river	6	Sensors	5	**4200**	Improve sensors. Provide bund for overflow. Re-calculate RPN after completion.	Works Manager Immediate
Leak from refrigeration system	High	7	Small until system empty	3	Very minor	2	Few in vicinity	3	none	10	**1260**		
General waste disposal	Low	2	Moderate	3	Repetitive	10	Few in landfill area	3	None	10	**1800**		
Petrol usage in vehicles	Emissions	6	Minor	4	Repetitive	10	Dependent on area	5	Catalytic convertors fitted to all vehicles and lead free , ULS petrol used in all vehicles	3	**3600**	Evaluate diesel options. Evaluate LPG options. Re-calculate RPN after completion.	Transport Manager 6 months from date of issue.

Continue sheet completion to assess and rank the potential events and provide improvements or corrective actions to reduce the RPN.
Actions to be taken for the risk events with the highest RPN values