ABSTRACT

A typical risk assessment or audit used in industry today will look at a single organization’s risk in an isolated business system dimension, such as the management system, product, or process deployed at a specific company. Risk must be found in both material and information flows and quantified in order to enable effective management decisions. Value Stream Risk Assessment™ (VSRA™) is a tool to identify, quantify, prioritize, and intelligently mitigate risk wherever it resides in a Value Stream. VSRA™ has been developed to complement Lean and Six Sigma techniques and enhances the quality audit process to provide more value to the organization.

INTRODUCTION

The world is a system of systems; interrelated dependencies that make up the whole. A typical risk assessment used in industry today will look at a single organization’s risk in an isolated business system dimension such as the management system, product, or process deployed at one specific company. Since businesses and system dimensions are interrelated, the risk for all parts is not simply the sum of the risk of each organization’s or dimension’s individual risk. Rather, risk can be found and increased at the intersections.

A new method for assessing risk through a complete system is required to understand the entire picture of vulnerability and apply resources to address such risk in the most efficient manner. Risk must be found in both material and information flows and quantified in order to enable effective management decisions. VSRA™ is a method to identify, quantify, prioritize, and intelligently mitigate risk wherever it resides in a Value Stream.

VSRA™ has been developed to complement Lean and Six Sigma techniques and enhances the quality audit process to provide more value to the organization. By definition, the Value Stream consists of the material and information flows from the moment the customer places an order to the time the product is received by the customer. Material and information risks reside in the Value Stream. It is the job of management to reduce the potential for risk.

Once you have established a baseline of your current risk you can begin measurable improvements.

DEFINE THE ASSESSMENT

START AT THE BEGINNING

The first step in undertaking a risk assessment is to identify the scope of the assessment. This is the most important task and is not a simple one. You must identify the bounds of the project which may be single or multiple organizations, single or multiple product lines or families, include suppliers or subcontractors, or be a single area or cell. This is a strategic decision and depends highly on a specific organization’s level of commitment, development and available resources. A more advanced organization with mature processes can often be more ambitious in increasing the scope of the assessment, and vice versa. All types of organizations must deal with risk in their processes. The immediate limits of assessment scope lie with resources to accomplish the assessment. If resources are scarce than the scope should be limited accordingly, but the saving comes at a cost of not identifying potentially serious risk items, so the alternates must be weighed carefully.

An excellent method to framing an assessment is by using the Value Stream. A Value Stream consists of the entire set of activities from the moment the customer calls until the instance final delivery of product is made; no matter where the activity is taking place or by whom. The terms, customer and delivery as mentioned above, can take on various meanings such as an internal process customer and delivery or final customer and delivery. Womack & Jones (1996) have defined Lean manufacturing techniques and theory that can be helpful to assist you in conducting a VSRA™. Many organizations are familiar with the Value Stream as defined above due to ongoing Lean initiatives. Value Stream and Value Stream Mapping training modules are readily available and have been established to be
effective tools for identifying the interaction of material and information flows over entire value streams. For this reason, VSRA™ capitalizes on the existing tool of Value Stream Mapping to lay the framework for a VSRA™ assessment. Value Stream Maps are used within Lean to identify opportunities to remove waste, so why not use this same format to identify the scope of a risk assessment and to identify areas of material and information flow risk.

ASSEMBLE THE TEAM

A VSRA™ starts by assembling a team. The team consists of value stream stakeholders. Each stakeholder should have a fundamental knowledge of Value Stream mapping, product and compliance audits, technical data and processes, and Lean to varying degrees of expertise. Typically a team will consist of three to six individuals. The team should be constructed in a similar fashion to an Integrated Product/Process Team, or IPT. The IPT structure is fairly standardized throughout industry, and a significant amount of information on IPT formation can be readily found. The objective is to ensure that you have a team that is capable of making decisions regarding process or product modifications that will not negatively affect up or down stream processes or products. The breakdown of typical VSRA™ team positions are as follows:

- Leader
- Information Flow Specialist
- Material Flow Specialist
- Functional & Process Owner(s)/Stakeholder(s)

Team member duties

Team members may cover more than one of the above listed team roles as long as a conflict of interest does not arise. These members may also fill multiple roles from an IPT or process/product lifecycle as well. Once the team is assembled, they should construct a team charter, or statement of purpose. This charter should include the following elements:

- Team Sponsor
- Team Members & Roles
- Team Objective
- Start & Finish Date
- Value Stream Map
- Value Stream Assessment Map

The Team Sponsor is the responsible manager that the team will report to. The Sponsor must also enable the team to break any barriers that they encounter during the assessment and ensure that the team has access to appropriate data, personnel and resources to successfully conduct the assessment.

The Team Members will be those previously described in this article, or a variation of such. The Leaders role is to lead and participate in the team activities and take full responsibility for the both the means and the ends of the assessment to ensure success. The Leader will set the agenda and norms of the team.

The Information Flow Specialist(s) should have an in-depth understanding of how data supports the system or process. They should also understand the data inputs/outputs and the operating systems that enable the data to reach the point of use. They should also be capable of verifying the integrity of the information flow, and verify if the system is functioning as it should. This will often require assistance from resources outside the team that the information flow specialist will need and be able to call upon as required.

The Material Flow Specialist(s) should be knowledgeable on product or process flows, in much the same way as the information specialist. Material flows consist of the activities associated with the physical product that the customer has requested, or the material that is consumed in the production of the end product. The material and information flow specialists should be the primary experts when defining the Value Stream map.

The team should also have the appropriate representation from functional and process areas involved. Functional areas might include quality, design, engineering, regulatory, purchasing, manufacturing, or service areas. Process owners might include those with process or product specific responsibility such as product manager, cell leader, manufacturing process engineers, product quality engineers, etc.

THE VALUE STREAM MAP

Once the team is assembled they will begin by creating or reviewing the value stream map. If a value stream Map does not exist, the team may need to be augmented to accomplish this task. As indicated by Rother & Shook (2003), the mapping should not take longer than one day to accomplish depending on the scope of the assessment. This may sound daunting, but that’s only because it is. Typically physical product flow is easier to grasp and map, while information flow can be more abstract and hidden. Information flow should be more prevalent on the map as compared to material flow.

The key to effective and actual value stream mapping is to witness material and information flows first hand and in real time. Avoid the tendency to make assumptions of what is or may be happening as you construct your value stream map. Go to the actual place and witness the actual transaction. Document the process in the as-
is state and not how it should have been accomplished with a minor revision. When you encounter such a situation just make a notation about the improvement opportunity to ensure it is not lost, and move on. While witnessing the process one should document the material and information flows, and share the knowledge with the rest of the team when they re-assemble. Teams set a standard interval, every hour or so, to return to a designated area to document the value stream processes and agree that all the steps are documented accurately. The value stream does not have to be perfect but should be accurate and legible enough to allow a newcomer to quickly understand the value stream. The value stream created or used for the assessment should be kept with the assessment documentation to ensure traceability of the event finding.

DEFINE THE ASSESSMENT SCOPE

The complete value stream, with its large amounts of material and information flows can be difficult to assess within the timeframe of a single event. Armed with the complete value stream map, the team can then decide the scope for this particular risk assessment. A strategy of engagement can be established by using the value stream map and the knowledge of the team members to highlight the paths and interactions of material and information flows that will be assessed.

Any number of issues can arise to limit the scope of the assessment including resource availability, limited time, or processes not running during the assessment, etc. It is not essential to have process experts involved with every aspect of the assessment since often a fresh set of eyes can bring a new perspective. It is important to keep the map of the assessment for use in planning future risk assessments. This way the number of areas assessed can be maximized, which in turn will help to minimize risk due to lack of attention. The organization should create a standard work procedure to cover the required documentation and assessment process.

CONDUCT THE ASSESSMENT

GATHER THE MATERIALS

With your team assembled, charter complete and value stream and value stream risk assessment map completed, do not immediately begin conducting the assessment. Make certain that all the documentation that you may require is available for the team’s use, preferably in a central location if it is only available in hardcopy. All the documentation that is required should be documented on the value stream map at this point. The documents may include system manual, process specifications, work instructions, regulatory data, product technical data, drawings, maintenance manuals, etc.

These documents can and should be heavily interrelated with the material flows.

VIEW THE ACTUAL PROCESS AND PLACE

The team should conduct the assessment as a group whenever possible, but more than likely a significant portion of the assessment will be done in smaller groups and breakouts. Allow the actual product flow to dictate the starting point of the assessment and again observe the process in action, if possible. As described by Dreikorn, “…system variation comes from aligning the policies and procedures of an organization by functional owner and not by process” (2004, p. 52). Many value streams will not follow a time ordered series of events but this should not impede progress, continue as logically as possible.

Stay on Track

Oftentimes while conducting an assessment it will lead the assessor in an unexpected direction. This is acceptable, but make sure you are always aware of what your initial assessment objective is. A seasoned auditor can be of great help with this aspect of an assessment. Over time a sense of where to go next and how far to go will be developed by the team members. For example, while assessing a machining operation you are looking at a work instruction that controls the operation. The instruction is not correct, which leads you to look at the procedure for work instruction modification which in turn is required by the quality manual and the quality manual is a requirement of the customer purchase order and regulation. It’s easy to see how an assessment can get derailed if you are not attentive to your objective. This simple example also demonstrates the importance of VSRA™ for the assessment of integrated systems and processes.

ASSESSMENT & DOCUMENTATION

It is helpful for further data analysis and grouping if the team identifies the type of process that the observations come from. The types can be varied and should be specific to the industry being assessed. Some example types can be inspection, drawing, test, specification, machining, weld, etc. Categories that describe the type can also be helpful in further refining of the data, such as, the type of welding or area of the quality manual or blueprint that was indicated.

Risk observations should be documented as the process is witnessed. Risk observations should be those items that cause, or have potential to cause, an unwanted outcome to the system, product or process. This is an important aspect of the VSRA™ assessment in contrast
to traditional audit and assessment models which are concerned with identifying noncompliance and nonconformance, and not risk. Risk, and the potential to cause risk, is different from a noncompliance or nonconformance. You may encounter an item during your assessment that must be brought to the attention of the responsible party immediately. These items should be quickly reported and handled accordingly. You may also wish to issue daily reports to stakeholders to ensure that they are aware of the items you have identified and the items are handled appropriately.

**QUANTIFY & PRIORITIZE THE RISK**

After conducting the assessment you will have a listing of all the potential risk items in the value stream. This is useful but the chances of a short list are slim. So the next step is to identify the items with the highest risk level. At this point VSRA™ can assist in creating the rank order list using a method that follows the Failure Modes & Effects Analysis (FMEA) process.

**RISK PRIORITY NUMBER**

With each opportunity for potential risk identified, you can then calculate a Risk Priority Number (RPN) for each potential risk item. The RPN is calculated after identifying the potential failure mode of the risk items and then by multiplying the assigned value of each of three rankings in severity of the potential outcome (SEV), the likelihood of the outcome occurring (OCC), and the probability of detection (DET). SEV, OCC and DET are each based on a predetermined scale of 1-10, with 1 being the best outcome and 10 being the worst. RPN can range from 1 to 1000. The team will rate each of the items. When the ratings are complete the team can create a rank ordered listing of all the items by RPN. This will highlight the most significant single issues that the team should consider addressing.

**DATA ANALYSIS**

**Sorting & Grouping**

The next analysis will entail sorting the data by the type of risk that was identified while conducting the assessment. By doing this, it will become apparent that there is a specific type of risk that has a large number of occurrences on the assessment. While there may not be a single large RPN for a specific risk item identified, the sum of the small items may indicate an underlying system deficiency that the team should address. A sort of the data by all types should be conducted and analyzed by the team. This is where the category information field becomes valuable. If there was a quality manual issue for instance, the category might indicate that most of the risk resides specifically in the contract review portion and not the entire quality manual.

These analyses’ will enable more effective decision making and use of resources to implement corrective action.

**Heart of the Problem**

After sorting and grouping, the team can identify what is causing the highest impact to the risk item in the assessment. This can be done in the same way for single risk items or groups of categories. Identify the cause of the high RPN, is SEV, OCC, or DET having the most impact to the high RPN. This will be accomplished quickly because this is a milestone of the assessment that the team will have been eager to reach. The team should document the suggested or potential solutions for each risk item or group of items identified during the assessment.

**Select Solutions**

After the potential solutions have been established, they can be evaluated to ensure that the desired outcome would be achieved if the corrective action were implemented. The easiest way to gage effectiveness is to rate the solution with respect to SEV, OCC, DET supposing it was effectively implemented. If a solution is effective then the RPN of the original risk item would be reduced. This will act as a check and balance before selection of a solution and can also be used to check the effectiveness of the solution after it has been implemented and closed.

**TAKE ACTION & CHECK**

The assessment has been defined, conducted, and the risk has been quantified and prioritized, now is the time to take action and ensure it’s effective. Identify the solutions that will be implemented. The solution should also identify an implementation date and potential responsible person. The date should be as aggressive as possible within reason to ensure quick action. It should also be appropriate to the impact of the risk item. At this point the team should get the commitment of the sponsor and managers that will be responsible for implementing the solutions.

**TEAM STATUS REPORT & ACTION ASSIGNMENT**

Getting commitment can be accomplished in most organizations with a team report out. The full team should present the entire assessment to the sponsor and stakeholders. Many organizations may already have an employee whose title is Value Stream Manager. The Value Stream Manager should be fully engaged with the VSRA™ team if not leading or participating in the assessment from the start. The objective of the
meeting is to review each element including the team charter, value stream map, value stream assessment map, VSRA™, data analysis, and proposed action items (including proposed dates and names). Then allow time for discussion and finalization of action items and owners, this action can be completed in a separate meeting. As a minimum, the team Leader should be an integral part of the process for assigning final action items.

ENSURE IMPLEMENTATION

The Leader is responsible to ensure that all the risk items the team documented are clear and concise throughout the assessment process. If this is managed throughout the event, the transition from the team to the person responsible for action closure will be smooth. The action owner will be able to completely understand the risk item, impact, solution, and due date.

Follow up on Action Status

The team will set a date for the assessment of implementation. This will be dependant on the timeframe assigned for the actions, but should be within a week to a month of the report out. Significant changes may occur in the value stream quickly. If this meeting is allowed to go longer than a month the assessment may no longer reflect the true value stream. All of the original team members and stakeholders should be present for the status meeting. Team members will often be assigned action items since they are typically working closely with the value stream. Some actions may fall to areas that are not directly linked with the value stream that was assessed. These actions will take strong project management skills to ensure closure. Make sure the process for closing the loop on actions is clear and agreed to by all parties involved in action items.

PERFECTION

Now that risk assessment has been completed and proposed actions closed out, it’s time to sit back, relax and kick your feet up…absolutely not. As this VSRA™ was closed, another team is already changing the process. A typical value stream map is only effective for 3 to 6 months, and the same must be true of a VSRA™ which is closely related to the value stream itself. As discussed in the Define the Assessment Scope section earlier, the assessment may have excluded some areas, or may not have included a process or a supplier’s process, or perhaps the solutions selected did not address every potential risk item initially found, etc. Any of these variables will increase your potential for risk and surprise you when you least expect. The consequences could be catastrophic!

Now that you have finished the assessment you have anywhere from 3 to 5 team members that have knowledge of the process, it’s time to put them to work as a team leader on the next event. Success is the absence of risk, and I am not aware of an organization that has simplified their processes and value stream to the point where risk is absent. Continue to improve and remove risk from your value stream.

CONCLUSION

Managing value stream risk is not a simple task. It requires a process based, customer focused, data driven solution to ensure sustainability and provide management with the information required to make intelligent decisions. Lean manufacturing has introduced the concept of the value stream for the purpose of the elimination of waste and FMEA has been used to quantify failure modes and effects. The two concepts applied together in a new structured process called VSRA™ can help yield significant identification and reduction of risk in the value stream by measuring, prioritizing, and intelligently mitigating risk wherever it resides in the value stream. Traditional risk and audit tools are not sufficient to identify the risk in an entire value stream. This process assesses the organizational performance and behavior in such a manner in which it recognizes organizational challenges prior to system noncompliance or product nonconformance.

REFERENCES


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