



PNNL-XXXX

Integrated Issues and Risk Management

A Theoretical Framework

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1.0 Introduction

The contractor requirements document for DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, requires DOE/NNSA contractors to establish an assurance system that includes, among other things, “Rigorous, risk-informed, and credible self-assessment and feedback and improvement activities. Assessment programs must be risk-informed, formally described and documented, and appropriately cover potentially high consequence activities” and “Contains an issues management process that is capable of categorizing the significance of findings based on risk and priority and other appropriate factors...” However, the term “risk-informed” is not defined in this or any other DOE order, and no formal guidance on how to integrate the two concepts currently exists. The *Risk Management Guide for Defense Programs* released by NA-18, Office of Systems Engineering and Integration (SE&I), states it is “a framework and general guidance to program office personnel on the effective management of program risks and issues”, however it then defines issues as “events with 100% likelihood of affecting program objectives” and states “unless specified otherwise, the term “risk” will also serve to represent issues for the remainder of this plan,” severely limiting its ability to provide adequate guidance on this topic.

Outside of DOE scope, the U.S. Nuclear Regulatory Commission (U.S. NRC) imposes similar requirements. ASME NQA-1-2015 Requirement 16 states “Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified”.

The purpose of this document is to provide a best-in-class framework for an integrated risk and issues management process. This process would provide a robust feedback loop between risk management and issues management to:

- Enhance risk identification and characterization,
- use risk handling principles to improve corrective action planning,
- and ensure regulatory compliance.

2.0 Background

Defense Programs (DP), supporting the National Nuclear Security Administration (NNSA), are performed in compliance with DOE requirements, have two related needs that are currently managed separately:

- To have risks identified and appropriately managed
- To have issues resolved quickly and their recurrence prevented whenever possible

Historically, there are two tool sets to meet these needs, Risk Management driven by DOE O 413.3B Chg 6, *Program and Project Management for the Acquisition of Capital Assets* and its associated guide, and Issues Management driven by the Contractor Requirements Document (CRD) of DOE O 414.1D, *Quality Assurance* and associated DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*. Additionally, projects that fall under the U.S. Nuclear Regulatory Commission (NRC) jurisdiction must follow additional requirements including 10 CFR Part 21 and American Society of Mechanical Engineers (ASME) NQA-1 2015, *Quality Assurance Requirements for Nuclear Facility Applications*. It is important to note the NRC requirements do not supersede DOE requirements in relation to issue or risk management. The NRC requirements documents reference back to DOE O 414.1D, with only very narrow areas of scope in which they override DOE O 414.1D. This linkage is not completely clear in the associated project documentation.

Right now, DP is trying to manage issues using risk management tools without the benefit of integrated issues management practices. There is an opportunity to develop a framework to integrate these two tool sets to allow the program to manage events that might happen, and those that have happened, in a holistic fashion. This framework would improve DP's current risk management practices by enhancing its ability to identify future risks as well as help identify and prevent future issues.

3.0 Definitions

Assurance systems: "Assurance systems encompass all aspects of the processes and activities designed to identify deficiencies and opportunities for improvement, report deficiencies to the responsible managers, complete corrective actions, and share in lessons learned effectively across all aspects of operation." (DOE O 414.1D)

Corrective Action: "Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition." (DOE O 414.1D referencing ASME NQA-1-2008 with the NQA-1a-2009 addenda).

Risk: "Factor, element, constraint or course of action that introduces an uncertainty of outcome, either positively or negatively that could impact project objectives". (DOE O 413.3B, 62R-11).

Issue: "... a risk that has occurred or an unplanned question or decision that needs to be addressed by a process other than risk management (e.g., regulatory changes where the scope, schedule, or cost implications have not been analyzed)". (62R-11).

4.0 Integrated Risk and Issues Management Framework

It is important to note that while all realized risks are issues, not all issues are realized risks. This is because issues include events impacting the project that may be performance based, and performance-based issues are not risks by performance management reporting requirements. For DP, the specific performance management requirements are defined, based on the complexity of the projects, in DP Program Execution Instruction NA-10 Program Management tools and Processes document.

Figure 1 shows a visualization of the potential overlap between risks and issues, and their relationship to the availability of information and how much management can control of the

situation. The overlap between risks and issues means the tools used to mitigate and recover from risks can also be applied to recovering from an issue and preventing future occurrences of it. The recommended process for integrating these processes is detailed below.

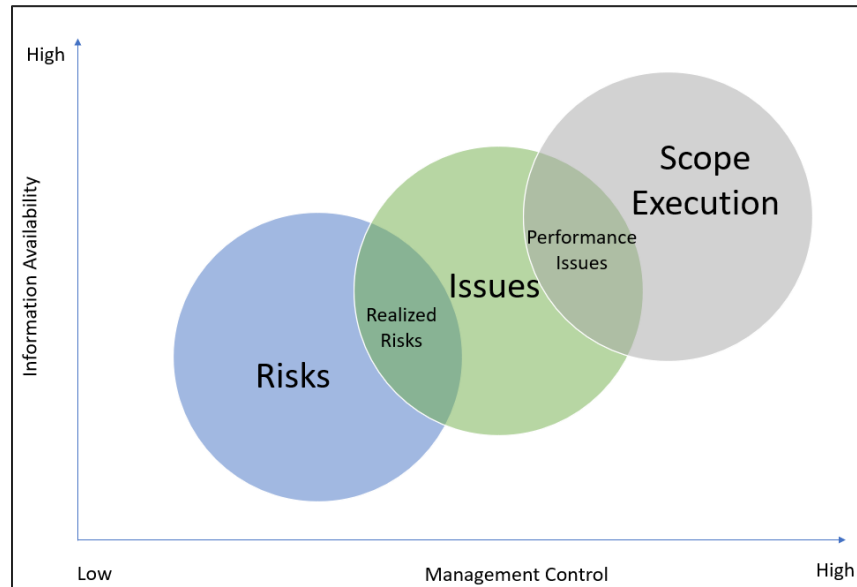


Figure 1. Risk and Issues Relationship Illustration

The key element to a successfully integrated risk and issues management system is communication. In many organizations, separate teams are responsible for Risk Management and for Issues Management (otherwise known as Corrective Action Management [CAM]). In order to ensure these teams gain the benefit of each other's knowledge, it is critical to develop a feedback loop that allows each group's expertise to support the other. See Figure 2 below for an example communication loop.

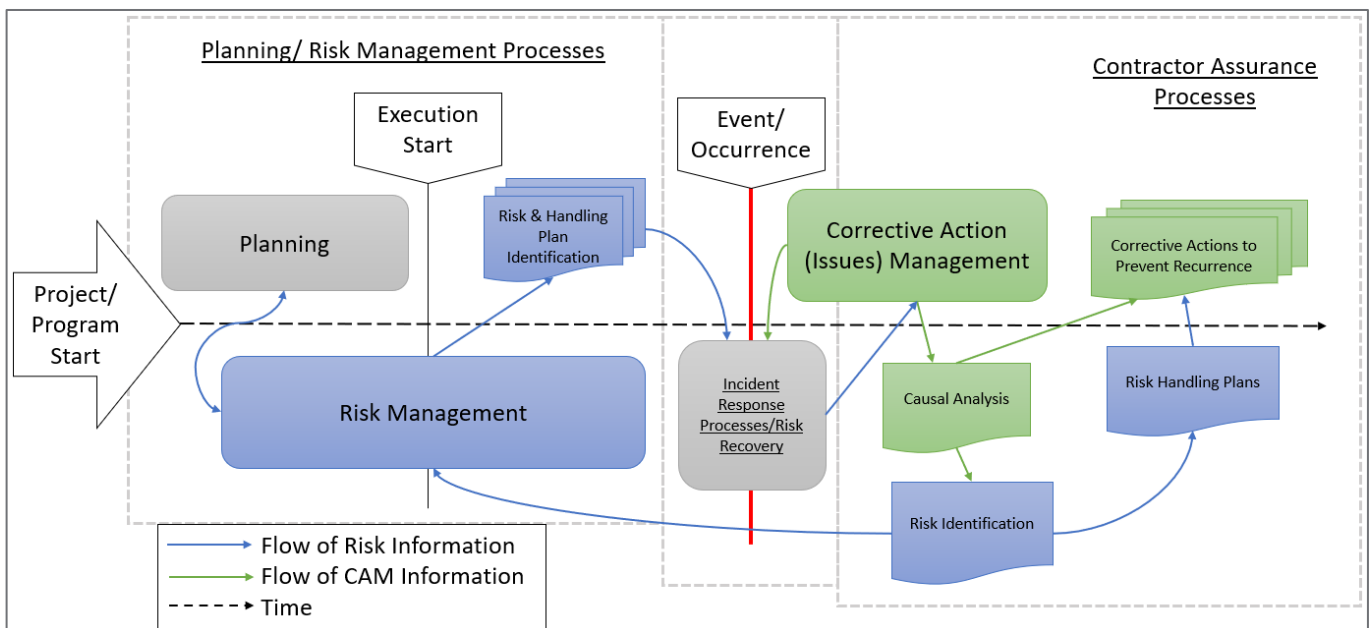


Figure 2. Risk and Issues Management Feedback Loop

At the project or program start, the first focus is on planning and predictive tools including Risk Management. During this phase, future issues are identified as potential risks and risk handling plans are developed to reduce either the likelihood or limit the potential consequences of a risk becoming an issue. At this time, recovery plans – the steps that are planned to be taken to recover from the risk if realized – can also be identified. Please note, some programs may not identify risk recovery plans in the risk register, but instead identify and manage them through incident response procedures when applicable.

Realized risks and issues occur during the execution phase of the project. Initial recovery from the realized risk or issue is performed following incident response procedures. It is at this point the event has historically been tracked and monitored either using Risk Management tools, if the event had been identified as a risk before it occurred, or using CAM processes, if the event had not been predicted. This method results in inconsistent recovery and handling actions, and gaps in knowledge both in the risk register and in corrective actions.

To improve on the historical approach, an integrated risk and issues management process would first determine whether the event was a realized risk (whether previously identified or not) or a non-risk driven issue. This evaluation should be performed jointly by subject matter experts from the CAM and Risk Management teams to best determine the appropriate handling/reporting of the event.

If the event is determined to be a realized risk, then the steps taken to recover, and the cost and schedule impacts realized should be documented in the risk register. Additionally, any risk handling actions that were performed prior to the risk being realized should be evaluated to determine if they were effective in reducing the likelihood or severity of the risk impacts realized. Evaluating the risk handling actions in this way allows the project or program team to determine if the actions taken were worth the time and investment, and therefore whether or not they should be repeated for similar risks in the future. This information should be shared with the CAM team to inform future corrective action development.

If the occurrence is determined to be a non-risk driven issue, then CAM processes should be followed, in alignment with the organization's graded approach. In this case, the event would not be captured in the risk register. For high severity issues, CAM principles require that a Causal Analysis be performed to determine either the apparent or root cause of the issue. During this process, risks may be identified that should be communicated back to the risk management team and captured in the risk register.

Once the apparent or root cause is determined, corrective actions or corrective actions to prevent recurrence (CAPRs) must be developed. Risk handling plans previously identified, or elicited at this point by the risk team, can enhance the likelihood of success for CAPRs to actually prevent the issue from occurring again in the future. Previous realized risks and the actions taken to prevent and recover from them should also be considered, to ensure the organization is not repeating actions that failed to be effective historically.

It is possible for an event to be both a realized risk and a severe enough issue to warrant causal analysis. In this case, the risk status would be updated to an issue in the risk register, and CAM processes would be followed to perform causal analyses and determine corrective actions. To reduce redundancy between the systems, the risk register should reference the issue identification number from the CAM system and only be updated if recovery plans/handling actions are updated as a result of the causal analysis process.

Finally, issues that had previously been encountered on a similar project should be reviewed and incorporated as appropriate in future risk elicitations to help the estimators develop a more accurate plan and forecast.

5.0 Other Risk Implications for Contractor Assurance Systems

Issues management is just one aspect of a Contractor Assurance System (CAS); however, risk management is related to all aspects of CAS. Energy Facility Contractors Group (EFCOG) best practices state that one attribute of an effective CAS is that it will be risk informed; “Risk management is a foundational element of CAS; it enables management to optimize performance. The CAS is risk informed and focused on outcomes.”

This statement is additionally supported by the National Nuclear Security Administration Technical Bulletin 2020 – Special Edition which identified “a need to overhaul oversight planning so that risk is better assessed and balanced with the needs of mission execution” as well as “a need to practice risk management rather than risk avoidance”.

Other aspects of CAS that can be improved through enhanced integration with risk management include:

Graded Approach – Risk management principles can support the development of the graded approach that is applied to issues management for any given organization. By identifying potential impact thresholds based on the organization’s risk tolerance, the graded approach can be adjusted to require the most stringent rigor on only those issues of highest potential risk, and have less formal approaches to handling issues of minimal risk.

Self-Assessment Programs – EFCOG Best Practice #124 states “An important tenet of contractor assurance is an effective self-assessment program. However, with limited resources one must use a graded approach to determine where to focus assessment efforts. Use of a risk-based/performance adjusted process ensures an effective and efficient assessment program”. Improving the integration of risk management in the assessment program supports prioritization of work so that assessments are performed on the highest risk work scope, and resources are not wasted on low-risk scope.

6.0 Current Issues and Risk Management in Defense Programs

As mentioned in the introduction to this paper, The *Risk Management Guide for Defense Programs* released by NA-18, Office of Systems Engineering and Integration (SE&I), defines an issue as a risk with a 100% probability of occurrence. While this makes tracking issues within the risk register simple, it does not adequately meet DOE O 226.1B, *Implementation of Department of Energy Oversight Policy* requirements for issues management because it does not require a causal analysis for significant issues, among other specific activities that should be performed. Each of the contractors performing DP scope will be performing corrective action management separately to meet DOE O 226.1B requirements, however there is no feedback loop between risk and issues management at this time.

As a result of this lack of communication between functional areas, the centralized risk register (CRR) for both the Tritium Modernization Project and the United States High Performance Research Reactor Conversion Program (USHPRR) document issues without any causal analysis, corrective action, or risk handling documentation. This practice, although compliant with *Risk Management Guide for Defense Programs*, Version 0.1, Second Release, March 2022, leaves the programs vulnerable to potential audit findings as a result of conflict with DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, requirements. Additionally, recovery actions for an issue that was caused by a performance issue cannot be funded with risk reserve dollars due to earned value management system guidelines. Capturing issues in the risk register may result in inadvertently spending risk reserve funds (where available and applicable) on performance-based issues, which would artificially improve the calculated performance of the program. It is recommended that issues be kept separate using a corrective action management system, and the risk register only contain risk information to avoid this problem.

7.0 References

10 CFR Part 21, *Reporting of Defects and Noncompliance*

AACE International Recommended Practice 62R-11, *Risk Assessment: Identification and Qualitative Analysis*.

ASME NQA-1-2015, *Quality Assurance Requirements for Nuclear Facility Applications*.

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DOE O 413.3B Chg 6, *Program and Project Management for the Acquisition of Capital Assets*.

EFCOG Best Practice #124: *Risk-based Assessment*. EFCOG.ORG

EFCOG Best Practice: *Contractor Assurance System Effectiveness Validation*. EFCOG.ORG.

Risk Management Guide for Defense Programs, Version 0.1, Second Release, March 2022.

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