SANDIA REPORT
SAND2008-6074
Unlimited Release
Printed September 2008

Quality Framework Proposal for Component Material Evaluation (CME) Projects

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Quality Framework Proposal for Component Material Evaluation (CME) Projects

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Abstract

This report proposes the first stage of a Quality Framework approach that can be used to evaluate and document Component Material Evaluation (CME) projects. The first stage of the Quality Framework defines two tools that will be used to evaluate a CME project. The first tool is used to decompose a CME project into its essential elements. These elements can then be evaluated for inherent quality by looking at the subelements that impact their level of quality maturity or rigor. Quality Readiness Levels (QRLs) are used to evaluate project elements for inherent quality. The Framework provides guidance for the Principal Investigator (PI) and stakeholders for CME project prerequisites that help to ensure the proper level of confidence in the deliverable given its intended use. The Framework also provides a roadmap that defined when and how the Framework tools should be applied. Use of these tools allow the Principal Investigator (PI) and stakeholders to understand what elements the project will use to execute the project, the inherent quality of the elements, which of those are critical to the project and why, and the risks associated to the project's elements.

ACKNOWLEDGMENTS

Special thanks to the following who contributed their time, expertise and guidance to the approach proposed in this report:

Marcey Abate
Katie Drevenak
Ramon Pacheco
Melody Teixeira

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1. INTRODUCTION

Habit Two from Stephen Covey's book, *Seven Habits for Highly Effective People* states "Begin with the end in mind." This report proposes the first stage of a Quality Framework approach that can be used to evaluate and document Component Material Evaluation (CME) projects. This approach combined with basic project planning principles, should be considered when determining the intended and end use for a CME project deliverable. The deliverable might be a qualified process to transition from a pilot activity to ongoing surveillance. Other possibilities are data/information deliverables that will be used to determine design margin or fill a gap in the technical basis. Another example of intended use is a data/information deliverable is for safety or reliability assessments. Intended use will determine the level of inherent quality desired in the project elements because the inherent quality drives the risk to the project deliverable.

The first stage of the Quality Framework defines two tools that will be used to evaluate a CME project. The first tool is used to decompose a CME project into its essential elements. These elements can then be evaluated for inherent quality by looking at the subelements that impact their level of quality maturity or rigor. Quality Readiness Levels (QRLs) are used to evaluate project elements for inherent quality.

The Framework provides guidance for the Principal Investigator (PI) and stakeholders for CME project prerequisites that help to ensure the proper level of confidence in the deliverable given its intended use. The Framework also provides a roadmap that defines when and how the Framework tools should be applied. Use of these tools allow the Principal Investigator (PI) and stakeholders to understand what elements the project will use to execute the project, the inherent quality of the elements, which of those are critical to the project and why, and the risks associated to the project's elements.

Types of CME Activities: CME project activities are executed for four reasons:

1. component-level performance testing,
2. materials evaluation of the components,
3. predictive evaluation,
4. development of diagnostics and tools for component and materials.

Each of the four technical CME activities can be used to fulfill different needs that include filling technical gaps, determining design margin, developing necessary processes to transition from a pilot CME project to ongoing surveillance and information for stockpile evaluation. The different technical reasons and needs that each type of CME project addresses drive different approaches.

The CME products or deliverables from these four activities can be information, a process, a diagnostic tool, or a predictive model. The intended use for these deliverables impact how the CME projects are planned and conducted.

The Quality Framework provides guidance to evaluate each project and provide information back to stakeholders about rigor of the elements that comprise the project. Stakeholders are users of the CME project deliverable (e.g. Technical Basis Realization Team (TBRT), Systems Engineering, Reliability Assessment, Stockpile Evaluation Engineering, and Independent Surveillance Assessment (ISA) and Integrated Stockpile Evaluation (ISE) staff). Quality rigor provided by project evaluation is important because it is a starting point or a prerequisite for negotiations between the PI and the stakeholders for the following items before the project has started:

1. Intended use for the deliverable that includes documentation about the deliverable and rationale for why it is needed. Intended use will drive the level of rigor the project needs to provide a deliverable that the stakeholders can use with confidence.
2. Risks to the deliverable if the rigor or inherent quality is poor in critical areas of the project,
3. An action plan for the project if an anomaly occurs.

A primary goal of the Quality Framework is to provide a standard approach for evaluating the four types of CME activities. Providing a standard checklist of potential project elements, subelements and guidance for how to evaluate their level of existing or inherent quality will help provide consistency in how projects are executed. Use of tools in the Quality Framework will provide information back to stakeholders to assist them in making decisions prior to project execution regarding how the deliverable should be used.

Another goal of the Framework is to develop an approach that allows flexibility to the CME project based on stakeholder decisions about the three prerequisite items listed above: intended use of deliverable, project risks and action plans. A flexible process allows the project and project elements to be tailored in terms of where rigor is applied; thereby aligning with expectations for how the deliverable will be used. That is, the expectations for how the deliverable will be used will drive where and how rigor is applied to the project, and the rigor will drive the risks.

Once the PI establishes what project elements are required for the project, the Quality Framework will provide guidance to evaluate the inherent quality or rigor associated with those existing project elements. Understanding the project element inherent quality is key to understanding where risk to a project exists. Together with a prior knowledge of how the deliverable will be used, understanding of the project risks will assist the PI and stakeholders to make decisions to address the risk driven by quality or rigor. Because this is guidance, ultimately, the stakeholders will have the final decision on how the project should be executed, and responsibility for making recommendations about how the resulting deliverable will be used, and what level of rigor and/or risk mitigation to apply.

Finally, if desired, this Quality Framework will assist a CME project and all its critical elements, to attain a state of maturity where it can be transitioned and documented via the B-documents into a core surveillance activity. The methods, processes, technology, etc. that are parts of the CME project can be improved and matured through understanding the inherent quality, risks and risk mitigation strategies. The information acquired from CME projects managed using the Quality Framework tools can then be used with higher confidence to make statements about the safety or reliability of the weapon.

1.1. Acronyms

ACRR	Annular Core Research Reactor
ADC	Authorized Derivative Classifier
CD	Compatibility Document
CME	Component Material Evaluation
DoD	Department of Defense
ES&H	Environment, Safety and Health
ESC	Enhanced Surveillance Campaign
EUO	Engineering Use Only
GTS	Gas Transfer System
ISA	Independent Surveillance Assessment
ISE	Integrated Stockpile Evaluation
LEP	Life Extension Program
MC	Major Component
MQ	Mark Quality
MRL	Manufacturing Readiness Level
NNSA	National Nuclear Security Administration
NW	Nuclear Weapon
NWC	Nuclear Weapon Complex
PI	Principal Investigator
PPI	Process Prove-In
PRT	Product Realization Team
PS	Product Specification
PT	Product Tester
QMU	Quantification of Margins and Uncertainties
QRL	Quality Readiness (Risk) Level
SFI	Significant Finding Investigation
S&H	Shipping and Handling
SNL	Sandia National Laboratories
STS	Stockpile to Target Sequence
SXR	Special Exception Release
TBP	Technical Business Practice
TBRT	Technical Basis Realization Team
TF&G	Tools, Fixtures and Gages
TRL	Technology Readiness Level
UR	Unsatisfactory Report
WSL	Weapon System Lead
WR	War Reserve

2. PROJECT ELEMENTS

The Quality Framework approach requires that the PI identify project elements for the project. In the context of this report, a project element is anything required to execute the project. These project elements can be grouped into "basic" categories that should, as a minimum, be evaluated to help identify strengths or weaknesses in the project. Strengths and weaknesses in the project elements will impact the CME project's ability to deliver a product that is suitable for its application or intended use. Project elements can be hardware, processes, testers, trained operators, facilities, analytical software and data.

Grouping the basic project elements simplifies a high level approach for evaluating the inherent quality of project elements needed to execute a CME project. This approach should be used when there are schedule or budget constraints that would preclude a more in-depth approach. Generally, when the basic elements are not evaluated in-depth, the project risk increases and the deliverable (information, a process, a diagnostic tool, or a model) should be evaluated carefully to determine how it should be used. The basic project element grouping also provides some structure for how to think about the project elements and their relationships, and how and where rigor might be applied to achieve the greatest impact on project success. A high level approach for using the Quality Framework will be discussed in detail in Sections 2.3 and 2.4. A more in-depth approach will be discussed in Section 3.

Additionally, there are several other basic project elements that could be considered essential to the CME project success. Examples of these other basic project elements are budget, schedule, customers, production agencies, facilities or suppliers of product, material equipment, etc. This Quality Framework will address only the technical elements or "whats" that affect the CME project deliverable. Project elements like budget and schedule, while important, will not be discussed in this guidance because it is assumed that these will have already been addressed by stakeholders. However, it is important to recognize that additional negotiations around budget and schedule must take place if the PI and stakeholders require that inherent quality of a project element must be improved to improve confidence in the deliverable for its intended use.

2.1. Basic Project Elements and Inherent Quality

2.1.1. Basic Project Elements

The five basic project elements identified for the Quality Framework and depicted in Figure 1 are:

1. People,
2. Processes,
3. Hardware or materials,
4. Data acquisition,
5. A "miscellaneous" basic project element to capture items that do not associate easily into the other four basic elements.

For the most part, these basic elements are the "whats" that are needed to successfully execute the project and provide a useful product or deliverable.

In reality, people affect nearly all the other basic elements because they design, manufacture and evaluate the hardware. People design and manufacture data acquisition equipment and they affect the data acquisition and analysis. People design the processes used to manufacture and test hardware. For purposes of the Quality Framework, people are considered their own basic project element. The fact that people influence the other basic project elements is illustrated in Figure 1 by the solid arrows to and from each of the other basic elements. Where human influence might be questionable between basic project elements, dashed arrows appear.

One or several project needs may fall into one basic project element. For example, to perform some project activity, (testing for instance), several people might be required. One person might be responsible for preparing test material or hardware for a test (cleaning, disassembly, drying). Another might perform the test or tester set-up by connecting cables, calibrating data acquisition devices, or positioning hardware. Another might conduct the actual test and someone else might do data analysis and reporting. For each activity that each person performs, there might be one or more written processes that must be followed. Several pieces of data acquisition equipment may be used to obtain data or develop and refine a process for diagnostic testing. Several pieces of test hardware or different versions of a component might be used to obtain data, develop processes, or train people.

2.1.2. Inherent Quality and "Fitness for Use"

A defining characteristic of a basic project element is its inherent quality. A common definition of the adjective *inherent* is "built-in: existing as an essential constituent or characteristic". When the adjective inherent is used to describe quality, it infers that the quality is built in. When discussing the inherent quality of a project element, we are referring to its "built-in quality".

The inherent quality of a project element "is what it is" for the most part, meaning that in most cases of a project element, there is no way to instantaneously improve or upgrade the built-in quality. For instance, the test hardware used in a CME project has a pedigree that can not usually be improved. It is what it is. When the hardware was manufactured, materials, processes, people, data acquisition and other project elements were used to build the part, test it, install it into the next assembly, or store it. The inherent quality or as-built quality of the hardware is the culmination of the inherent quality of all of the project elements (processes, people, data acquisition, materials, etc.) that were used to create the hardware.

When identifying project elements that are necessary to execute a project, the PI should consider whether their inherent quality makes them acceptable or "fit for use" given the intended use of the project deliverable. Evaluating inherent quality by using a QRL tool will allow the PI to determine if the current state of the project element makes it fit to use. If the intended use of the deliverable drives a need for upgrades to the project elements to make them fit for use, the stakeholders need to be aware of what the upgrades are, and their cost and schedule impacts.

A PI can negotiate improvements to inherent quality in different ways. Upgrades to a hardware/material project element (and QRL) might be use of WR pedigree hardware or material for testing rather than development. People can be trained to understand requirements and technology, or to perform processes, operate equipment, or do data analysis and interpretation. If there are not enough qualified people, back-ups can be trained so work can continue even when unforeseen absences of primary people occur. Processes that define sample preparation, testing set-up, or data analysis can be documented to provide consistency each time they are performed and allow them to be characterized by analyzing their inputs and outputs.

2.2. Project Subelements and Inherent Quality

2.2.1. Project Subelements

Project subelements are associated with each of the basic project elements. The associations of subelements to their basic project elements are also depicted in Figure 1. These subelements are not the "whats" that are the basic project elements necessary for executing the project: instead, they can be thought of as the "whats" that change or impact the inherent quality of the basic project elements in some way. As with the basic project elements, the examples of subelements shown in Figure 1 are not all inclusive and should be changed to meet the needs of each unique CME project.

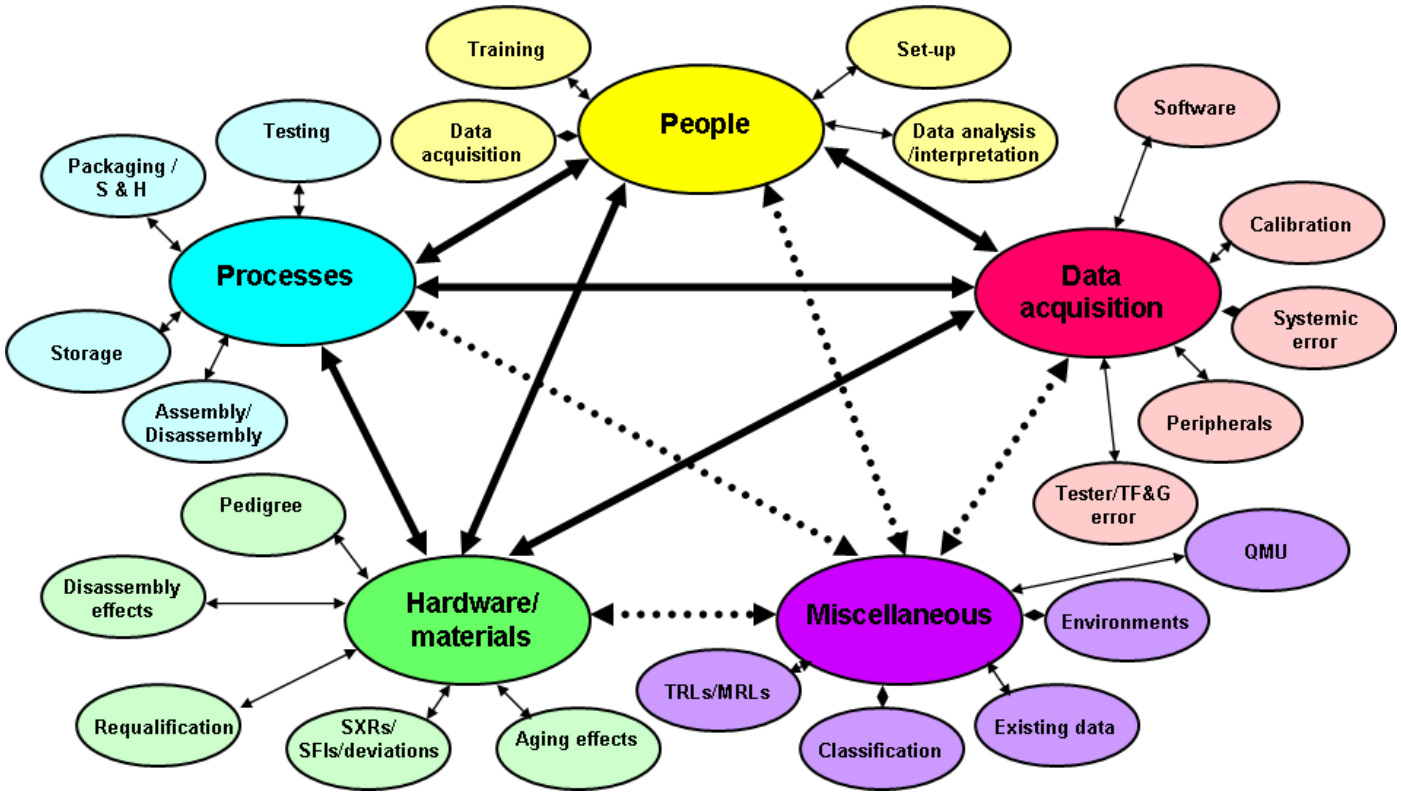

Figure 1 - Project Elements and Subelements

The grouping of subelements to basic elements shown in Figure 1 should not be considered prescriptive because in reality, the subelements themselves can be biased by any of a number of "outside" influences that would cause them to have one or more affinities to basic project elements. As an example, in Figure 1, the basic project element "Processes" has a "Storage" subelement. A process for storing a component, material or hardware might dictate under what environmental conditions it should be stored (dry nitrogen, ambient temperature). However, a Storage subelement can also be associated with an environment that may not be controllable, as in a stockpile-to-target sequence (STS) weapon depot storage setting. Because the STS environment in this instance is not under control or perhaps not entirely influenced by human intervention, the Storage subelement could have affinities for both the Storage and Miscellaneous basic elements (Storage Environments). Subelements for each unique CME project should be associated with the basic project element that addresses their impact on basic elements.

The Quality Framework is intended to be flexible for each unique CME project, in that if a particular subelement impacts more than one basic project element, then the PI should associate and evaluate it with respect to those basic elements. Figure 1 illustrates examples of project subelements, but it does not attempt to list or associate them all. It is the responsibility of the PI to recognize the critical project elements and their subelements that have the potential to impact project success and confidence in the project deliverable.

Appendix A contains a comprehensive list of the basic project elements with suggested groupings for the project subelements. This list and groupings can be used by the PI to ensure that all project elements that could affect the project are considered in terms of their impact to the project and the intended use of the deliverable. The list of subelements is by no means complete and there may be other subelements that could be included in the list. Ultimately, the uniqueness and purpose of each CME project will define its subelements.

2.2.2. Project Subelements and Inherent Quality

As stated earlier, the subelements can be thought of as the "whats" that affect the basic project elements, or that change or impact them in some way. When identifying CME project elements that will be used for the project, the PI should consider how inherent quality of those elements will impact the deliverable. Stated a little differently, when identifying project elements, the PI should consider how the subelements impact inherent quality of the project element and how those impacts might change the confidence and fitness for use for intended use of the deliverable.

Of the five project elements described in Section 2.1.1, nuclear weapon hardware has special significance because the PI and the CME stakeholders must negotiate quality and rigor levels. Whenever Mark Quality (MQ) hardware is part of or the principal subject of a CME project, the associated QRL of all the project elements must be the highest attainable, unless all parties agree to accept some stated reduction in quality or rigor. MQ hardware, whether it has been in the stockpile or in bonded stores, represents weapon hardware of the highest quality, and therefore drives all other project elements (people, processes, test equipment and materials, data acquisition systems, etc.) to the highest levels of quality and rigor.

Consider this comparison of inherent quality for different pedigrees of hardware. MQ hardware or war reserve (WR) hardware are considered to have been built with the same high level of inherent quality. Long term storage in controlled environments (bonded stores) for MQ hardware may also impact that hardware, albeit differently. Depending on the objectives of the project, one pedigree of hardware may be a more appropriate choice than the other. The PI and stakeholders need to know prior to the project start what the deliverable is and how it will be used. This information will assist them to make decisions about the pedigree of hardware that should be used to give them confidence in the information they will receive from the project, and conversely, the severity or level of concern should an anomaly be encountered. If the result of the test or evaluation could reasonably result in an anomalous result of finding, non-MQ hardware should be considered.

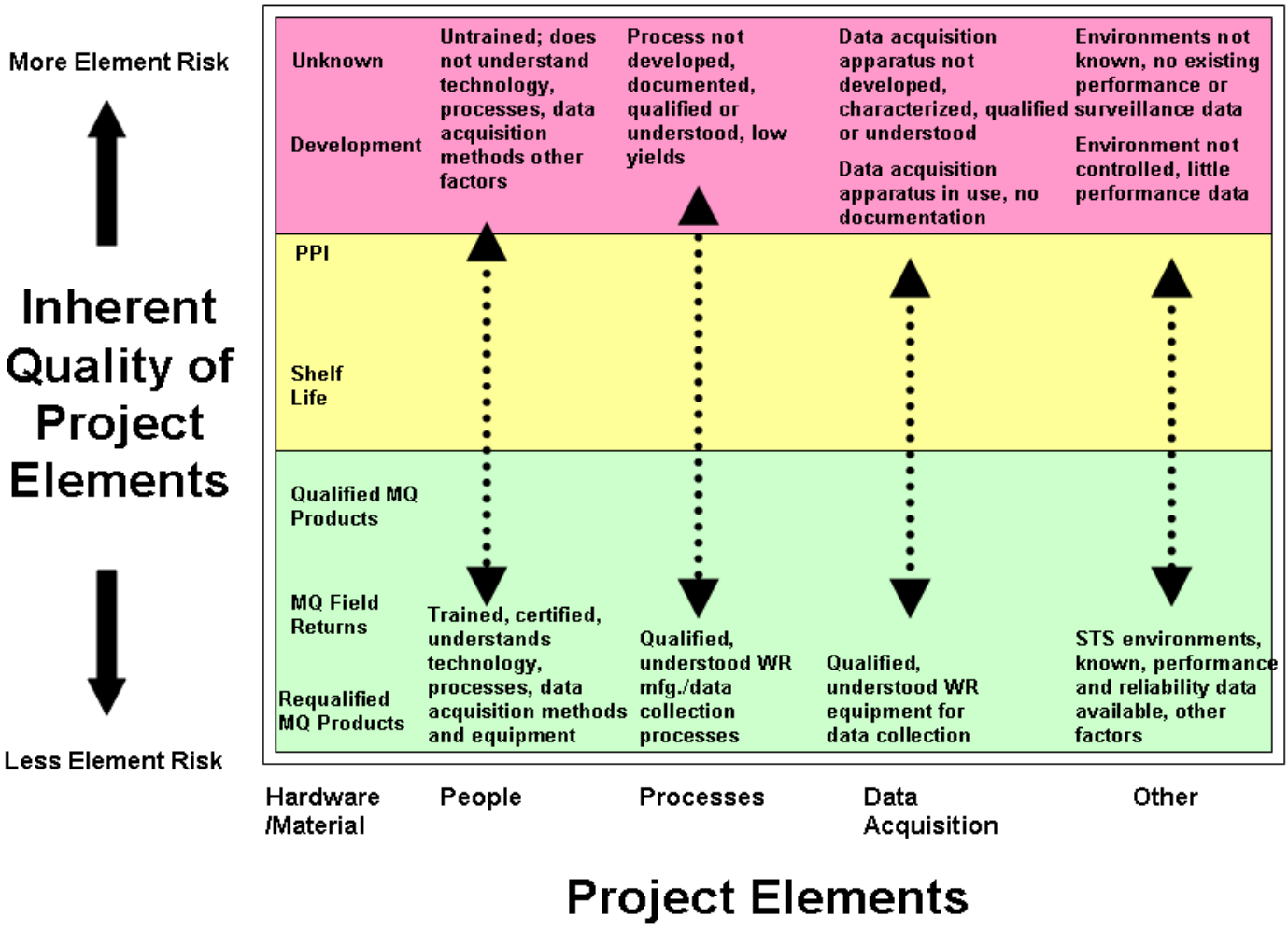

Figure 2 - Examples of Qualitative Project Element Evaluation

If the deliverable of the project is a comparison of performance or aging of bonded stores hardware to field return hardware, then the inherent quality for either pedigree could be considered to be equivalent and high. This deliverable might also be deemed appropriate by the PI and stakeholders for reliability assessments (with consideration to other project elements and subelements).

Figure 2 illustrates the comparison where requalified MQ field returns have the highest inherent quality for information whose intended use is for reliability assessment because the field returns have been exposed to stockpile environments. The X axis shows the five basic project elements. The Y axis is a qualitative description of subelements and risk. Figure 2 also illustrates how inherent quality for the other basic project elements might be defined for a project and how risk to the project deliverable increases as inherent quality decreases. Thus, the information obtained from MQ field returns (pending known defects) is likely the most representative of a stockpile output or response, and has the lowest risk to users because this hardware has high inherent quality and is considered fit for reliability assessment.

In contrast, development hardware has low inherent quality because it might not have released drawings, certified material, characterized manufacturing processes, trained personnel to manufacture or test it, qualified testers to test it, or other evidence that it met design requirements. Development hardware does not represent what is in the stockpile. Because inherent quality is low, use of development pedigree hardware produces a low inherent quality deliverable that may carry increased risk depending on its intended use. For a PI whose deliverable is information about a weapon system for reliability assessments, the better choice for obtaining that information is the MQ hardware that has been exposed to stockpile environments rather than development hardware.

2.3. Identifying Basic Project Elements and Subelements

When PIs propose a CME project, consideration should be given to what basic project elements are required to execute the project and deliver a product. The level of effort and depth of identifying project elements or subelements should be negotiated by the PI with stakeholders, and based on intended use of the deliverable. Together, the PI and stakeholders may choose to detail critical project elements only to the five basic project elements or go into more detail with subelements that impact the project elements.

One goal of the Quality Framework is to provide a means for identifying all the elements that are critical in some way to the CME project. Critical project elements will be different depending on the goal of the project. Most projects will have at least one entry from each of the five basic groups. Table 1 is an example of how entries from each basic group could be identified for an actuator. After entries in each of the basic groups have been identified, a preliminary evaluation of the subelements that could impact the original inherent quality of the entries is also identified. In some cases there are entries under the basic project element that are not impacted by a subelement.

Table 1 - Example of Basic and Subelement Identification for an Actuator

Basic Project Element	Subelement	Comment
People		
Test technologist (Dept. 25xx) - actuator functional test	One person deep – need a back-up	One person deep – need a trained back-up – primary is retiring
TBD - staff to disassemble actuator and obtain powder sample	Trained staff to disassemble actuator and obtain powder sample	Need to find out who can do this
Technologist (Dept. 18xx) - prepare powder sample for chemical composition testing and test		Trained staff available to prepare powder sample for chemical composition testing and testing
Chemist (Dept. 18xx)		Powder sample data analysis
Processes		
Functional test per PS		WR process is current for requirements, baseline testing
Disassembly	No written process	Will provide verbal instructions to extract powder
Sample preparation and test	General instructions for test equipment available	Need to review to determine if processes/procedures are adequate
Hardware/Materials		
Actuator	Actuators have not been in GTS	Hardware is MQ from bonded stores
Actuator	Sample size might not be adequate for reliability - 15 functional samples, 3 material samples	Need to determine acceptable quantity for testing for reliability
Powder from disassembled actuator	Disassembly of MQ actuator	Verbal instructions to extract powder, unsure of how process will affect powder
Powder from bonded stores	Powder is from materials stores and not an actuator, different lot, different supplier	Chemical composition per SS is the same as material in test actuators
Data Acquisition		
Functional test configuration (boom box)	Test configuration does not represent WR configuration	Free volume is different
Functional tester	Tester is a copy of PT, but is not qualified	Cost and schedule to qualify tester vs. using as is
Chemical analysis equipment		Check on calibration and operating procedures of powder analysis equipment
Miscellaneous		
Unresolved SFI	Performance data may be classified	Open SFI in process on earlier suffix, possibly due to powder aging.
Functional data	Performance data may be classified	Actuator performance may impact reliability of GTS, weapon – consult Authorized Derivative Classifier (ADC)
Qualification data		Original actuator qualification data available for comparison

Table 1 provides a high-level, but qualitative evaluation of the different basic elements and entries in each of them, along with the subelements and impacts. In this example, intended use of the information produced by the project has not been negotiated by the stakeholders and PI. In Table 1, under Processes, functional testing of the actuator is performed according to a current, released Product Specification (PS) used for acceptance of MQ product. Process steps, equipment parameters, and product requirements will not likely be changed because a copy of the Product Tester (PT) will be used, so there will probably be no impacts to the deliverable due to the processes used in this example.

Table 1 illustrates several instances where a basic project element entry and its original inherent quality are impacted by a subelement under the Subelement column. Under Processes, a mechanical disassembly operation to remove powder from an actuator will be performed. The process will be performed according to verbal instructions and it is not known if that process will affect the powder, so a MQ powder used in a MQ actuator will be impacted by the disassembly process, reducing its original inherent quality.

Another example of an impacted basic element is listed under Hardware/Material. Here, the PI proposes using actuators from bonded stores that have not seen weapon depot environments and for this reason these may not reflect the condition of actuators in the stockpile. When functional tests are performed on actuators that have been in "protected" environments, their performance could be different because the original inherent quality may have degraded from proximity to a gas transfer system (GTS).

Depending on intended use of the deliverable, negotiations with the stakeholders need to occur. If plans are to establish a baseline for actuator performance, then use of pristine bonded stores test samples is appropriate. If plans are to compare performance of stockpile units to baseline data that has already been established, then use of stockpile actuators is the appropriate choice.

2.4. Application of the Quality Framework

2.4.1. High Level Approach – Basic Project Elements and Subelements

Habit Two from Stephen Covey's book, *Seven Habits for Highly Effective People* states "Begin with the end in mind." This same approach combined with basic project planning principles should be considered when determining the intended and end use for a CME project deliverable. The deliverable might be a qualified process to transition from a pilot activity to ongoing surveillance. Other possibilities are data/information deliverables that will be used to determine design margin or fill a gap in the technical basis. Another example of intended use is a data/information deliverable is for safety or reliability assessments. Intended use will determine the level of inherent quality desired in the project elements because the inherent quality drives the risk to the project deliverable.

It is important that project elements that create risk or decrease confidence in the deliverable for its intended use are identified, understood and agreed upon by stakeholders just as it is important that the intended use of the deliverable is identified, understood and agreed upon by stakeholders. Put another way, deliverables acquired using project elements with low inherent quality are also of low inherent quality and these drive risk to stakeholders that want to use the deliverable.

The evaluation of basic project elements and the subelements that impact them shown in Table 1 can be used to communicate to stakeholders at a high level, what is needed to execute the project and deliver a product for some intended purpose. The subelements that impact project elements in some way and that determine risk to the project deliverable are also identified in Table 1. Table 1 can be used as a first-line communication to begin negotiations between the PI and stakeholders. The information in Table 1 also provides a qualitative "snapshot" of the inherent quality of the project elements proposed by the PI to the stakeholders.

Given the purpose of the CME project, the risks created by using project elements that have been negatively impacted by subelements can be entirely appropriate. Understanding how and why project subelements can impact the inherent quality of the basic elements is important to both PI and stakeholders when determining appropriate use for the project deliverable. In some cases proposing the project with existing, but perhaps impacted project elements as a starting point is appropriate to begin negotiations with stakeholders for funding and for determining intended use of the deliverable. This evaluation should be a high level qualitative analysis to inform the stakeholders about inherent quality that may impact confidence in the CME project deliverable.

The expectation is that when the PI and stakeholders recognize the status of inherent quality, even at a high level, they can choose one of the following four options. One, they can decide to preserve the intended use for the deliverable and preserve or improve the inherent quality of the basic project elements to maintain or improve confidence in the deliverable. A decision like this might be made by stakeholders if plans were to use the deliverable to make a statement about weapon reliability or safety. A specific example of this decision would be to use a WR field return rather than PPI hardware for the project. Another example of this first option is to document a CME process used for testing, sample preparation or some other activity, and put it under configuration control in a B-series document. This documentation for requirements (process steps, test parameters, etc.) might be particularly desirable if the process will be transitioned from a CME pilot project to ongoing surveillance.

A second option is for the PI and stakeholders to leave deficient inherent quality of the basic elements as is and downgrade the intended use of the deliverable. The decision to downgrade intended use should be based on what basic project element is affected. The second option can be illustrated by using a data/information deliverable that was obtained using PPI hardware because no WR hardware was available, to fill gaps in the technical basis rather than for reliability or safety assessment.

A third option might be downgrading inherent quality based on the end use of the deliverable. To illustrate this option, consider a project that was going to use MQ test hardware to determine

how a chemical disassembly process might change the original condition of the hardware. The PI and stakeholders might decide that PPI or development test hardware serves the purpose equally well and saves the project time and money because NNSA permission to use the MQ hardware is not required.

The last option might be a decision by the PI and stakeholders to leave both intended use of the deliverable and deficient inherent quality as is and accept the risk. Again, understanding the intended use of the deliverable, the status of inherent project element quality and how it will impact the deliverable is key to understanding the risk to the stakeholders.

The four different options above demonstrate that there is flexibility for the PI and stakeholders to negotiate the level of inherent quality and the intended use of the deliverable. The negotiations should be based on the desired confidence in the deliverable. Depending on the specific activity the CME project supports, attention to the requirements of QC-1 should be a consideration, especially when weapon activities that could impact nuclear safety or reliability assessments are concerned. The introduction to QC-1 states "The requirements specified in this document are not applicable to all aspects of research but must be applied to weapon development, engineering, production, surveillance, and dismantlement."

A required step of the high-level approach is to document the critical project elements and subelements, the qualitative assessment and any recommendations for changes to project elements based on intended use of the deliverable. Recommendations for use of the deliverable commensurate with the inherent quality might also be included if inherent quality can not be improved. This documentation of the CME project should be presented to the stakeholders.

In the example from Table 1 and in reality, there are several basic project elements (several people or processes) and each could have several entries with different subelements that impact inherent quality. The method demonstrated in Table 1 for identifying inherent quality provides only a qualitative feel for the project status. Section 3 describes method to evaluate the inherent quality of project elements.

3. GRADED APPROACH AND QUALITY READINESS LEVEL (QRL)

3.1. Project Element QRLs – Background

A means to provide flexibility is to use a graded approach when evaluating the elements of a project or activity or when comparing one project or activity and to another similar project or activity. The use of graded approaches is not new. Currently, graded approaches are used in the NWC to evaluate transportation activities or the readiness of technologies for use in weapons-related programs. Some of these approaches are documented and referenced in this report.

The Quality Framework also makes use of a graded approach, the Quality Readiness (or Rigor) Level (QRL) to assess the project elements of the CME projects. The method of applying a graded approach to assess project element QRLs is similar to that used to assess Technology Readiness Levels (TRLs). TRLs were first developed by NASA in the 1980s to provide information to management to make decisions about technology risk management, technology funding, and transition of technology from development into a system or subsystem. The original definitions included seven levels, later expanded to nine levels. Current definitions address levels of readiness or maturity on a scale from one to nine with one being the most immature and nine being the most mature.

Using TRLs helps management make decisions about development and transition of technology. The advantages of using TRLs are that they provide a common understanding of technology status, aid in risk management, and can be used to help make decisions about transitioning technology from a research and development setting to a production setting, and the funding that will be required to perform the transition. A summary and comparison of the TRLs used by the DoD, NASA and SNL can be found in Appendix B and several references are listed in Section 7.

Because the Quality Framework is a graded approach, the goals for using QRLs are similar to those for using TRLs. For instance, TRLs, Manufacturing Readiness Levels (MRLs) and QRLs are all evaluation and reporting tools and a means to promote communication, but there are also some differences. Rather than the nine levels used by TRL and MRL definitions, the QRL definition has five levels with QRL-1 designating the lowest level of inherent quality up to a QRL-5 that designates the highest level. Another major difference is the over-arching idea of inherent quality. While TRLs and MRLs deal specifically with readiness in technology and manufacturing, it is clear that the inherent quality and the fitness for use concepts apply to these areas as well as the five basic elements addressed by this Framework during a CME project.

Inherent quality always exists at some level in the project element at some specific point in time, and the goal is to evaluate it quantitatively using a QRL. Similarly, with the MRL and TRL levels, the goal is to evaluate existing maturity of the technology or manufacturing activity quantitatively, but with a different goal in mind. With TRLs and MRLs, the goal from an NW point of view is to develop a roadmap to mature the technology or manufacturing activity from concept to a state where it is reliable enough for use in a nuclear weapon. The roadmap defines the means or activities necessary to move to the next TRL or MRL, along with associated levels of inherent quality until the appropriate level of confidence is reached for nuclear weapons.

3.2. CME Projects and QRLs

As mentioned before, CME project activities can fall into the four activities that include component performance testing, materials evaluation, predictive evaluation of components and their materials, and development of diagnostic tools for both component and materials. These goals and the intended use for the deliverable should determine the inherent quality of the project elements.

Each project elements needed to execute the CME project can be evaluated for inherent quality and assigned a QRL. Based on the QRL, the PI must evaluate the cost-to-benefit ratio of improving the QRL by increasing the QRL to level necessary to support intended use. In some cases where the QRL of a project element is high, the risk associated to that element is low and nothing needs to be done to improve the QRL to improve confidence in the results. If the PI and stakeholders believe that low QRLs for basic project elements drive risks that are too high for the deliverable, they can negotiate some means to improve the QRL and improve confidence.

A quick example of QRL-1 for the basic project element of hardware or materials using the subelement pedigree that impacts its inherent quality is development hardware that has no or incomplete quality evidence for requirements, drawings, material, process control, or handing and storage. The opposite end of the spectrum would be WR (MQ) hardware that has been in the stockpile (field return). QRL-2 through QRL-4 levels between these two extremes. Appendix C describes all five levels of the other four basic project elements (processes, people, data acquisition, and miscellaneous).

Note that these descriptors address some, but not all, of the potential subelements that might impact a project element. The descriptors are meant to assist the user in evaluating the inherent quality of project elements so that some measure of risk can be reported to the stakeholders.

3.3. Project Element QRLs

3.3.1. Evaluating Project Element QRLs – Example

A QRL evaluation of basic project elements and the subelements that impact them provides a snapshot of the inherent quality. Some information from Table 1 will be used to demonstrate using the QRL for evaluating each of the basic project elements and subelements that impact the inherent quality. Refer to Table 2 for a discussion on QRL evaluation. These discussions assume that the CME project deliverable will become part of a data pool for actuator performance for reliability engineering and systems engineering. Because reliability assessment is the intended use for this data, the primary stakeholder is reliability engineering, so their priorities and perspectives are important to negotiate changes to project elements or the deliverable. QRL descriptors for the five basic project elements are in Appendix C.

The first entry under the "People" project element identifies a test technologist to execute an actuator testing activity. Because the PI is aware that the primary person doing the job is considered knowledgeable of the technology and requirements, and has been performing actuator testing to documented processes, this person is assigned QRL-4. The PI is aware that this person is retirement-eligible and there are no back-ups with this level of skill and knowledge. If another person is identified to perform testing, they would have to become familiar with technology, requirements, processes, equipment, etc., requiring time and money. Due to the uncertainty of the situation, the PI has averaged out the evaluation to QRL-2.

The next entry under the People identifies a resource needed to disassemble an actuator and obtain a powder sample for material testing. The PI is unaware of an experienced person who does this type of work, so until a resource is identified to conduct this work without impacting powder composition, this project element is QRL-2. Of course, when the resource is identified, depending on experience, training, and knowledge of such a process, the QRL may change.

Under the "Processes" basic element, the PI has decided that actuator functional testing will be performed according to the PS used at the production agency with no changes to any of the process steps or parameters. Because a qualified, proven process for this specific actuator will be used, the PI has evaluated a QRL-5 for the functional test process. As for the actuator disassembly process, the PI does not know if a written process for disassembly exists or if it has been done before. The PI and other SMEs do not have a good understanding of what the disassembly process might do to the powder, so the PI has assigned a QRL-1 for the disassembly process.

Subelements that affect the actuators under "Hardware/Materials" are use of non-field return actuators for testing and sample size. The subelement impacting the QRL is that the test hardware has not been exposed to STS environments, nor has it been exposed to potential material degradation caused by proximity to a gas transfer system (GTS). Test actuators will come from bonded stores and will have been kept at optimal conditions and as such, do not represent what is in the stockpile in terms of potential aging, or environmental degradation. These actuators might provide information about changes since their initial acceptance into bonded stores, but they might not provide information about the status or actuators in the stockpile.

The PI also provides additional information in Table 2 about the actuator and the fact that there is an open SFI on an earlier suffix. For this evaluation, because the test actuators are from bonded stores, they could produce data to help resolve the SFI. The fact that there is an open SFI on this actuator decreases the QRL because the cause of the SFI is as yet unknown, but could be due to exposure to degrading environments in field returns or an unrelated cause: a design flaw for instance. Due to the number of unknowns about these actuators, discussions and negotiations need to take place to determine if they are really fit for use. The PI assigns a QRL-3 to initiate this negotiation.

The second Hardware/Materials entry is actuators. Because the PI expects to provide data for reliability assessment, there is a concern that the sample size may be inadequate to give the confidence in the test data. At this point, the PI can consider whether to negotiate a different sample size or not to use the data for reliability assessment. Prior to submitting a proposal, the PI might want to work with a reliability engineer to determine a suitable sample size. Other options are to renegotiate intended use of the data, increase the sample size, or ask the stakeholder to accept the existing QRL and its risk. Because negotiations and decisions about the proposal need to take place, this project element entry is a QRL-3.

There are three entries in the "Data Acquisition" project element. The first entry concerns the boom box fixture geometry. The PI notes that this geometry does not represent the geometry of the weapon, but that it is the same configuration used in the PS in the WR acceptance process. Because the PI suspects that the geometry might have some impact on actuator performance, the boom box fixture is evaluated QRL-4 even though it is the same fixture used for actuator acceptance. If the PI wanted to upgrade this QRL, cost and schedule to manufacture and qualify a new fixture could be negotiated with the stakeholders, or the stakeholders may decide that using this fixture to obtain data about actuator performance is low risk to this deliverable and that it is fit for use. A numerical assessment of the risk for this boom box is not reported in Table 2, but because the fixture has been used to accept MQ actuators with no issues, the PI deems that the project element and its subelement are low risk. Risk assessment is discussed in more detail in Section 4.2.

The second entry under Data Acquisition describes functional testing of the actuator using an exact copy of a PT tester with an expired qualification engineering release (QER) and the tester is evaluated as QRL-4. The third entry describes the use of chemical analysis equipment to examine powder composition. The equipment is evaluated at QRL-3 because the PI has decided that more information about the equipment is required. This information is mostly centered on calibration schedules and written equipment operating procedures, but resolution, measurement error or other parameters specific to analysis of this particular powder might also be considered. The PI notes that after the analysis equipment has been evaluated more thoroughly, the QRL will be reevaluated.

The single Miscellaneous element entry notes that there are other actuator data available. Original lot qualification data and some surveillance data on the same lot as CME test actuators are available to compare performance over time. Data/information from past acceptances, evaluations, resolved SFIs, TSIs and sources can be used to help the PI evaluate inherent quality of other elements. This information could help determine how the project element is evaluated, how inherent quality might be improved, and what the risk is to the deliverable. Other miscellaneous considerations documented in Appendix A are time in the stockpile, environmental conditions over time, and known aging concerns.

Table 2 - Example of QRL Project Element and Subelement Evaluation

Basic Project Element	Subelement	QRL	Rationale/Comments
People			
Test technologist (Dept. 25xx) - actuator functional test	One person deep – need a back-up	2	QRL-2: Primary is QRL-4, but could retire at any time. Because there is no trained replacement with technical and practical knowledge, rating is QRL-1. Average of the two is QRL-4 until replacement is found and trained.
TBD - staff to disassemble actuator to get powder sample	Trained staff to disassemble actuator to get powder sample	2	QRL-2: SNL has technical capability, but need to find resource and train to disassemble actuator and obtain uncontaminated powder sample.
Processes			
Functional test per PS		5	QRL-5: WR process is current for requirements, baseline testing
Disassembly	No written process	1	QRL-1: undocumented process
Hardware/Materials			
Actuator	Actuators have not been in GTS	3	QRL-3: MQ actuator is not field return, open SFI in process, possibly due to powder aging.
Actuator	Sample size might not be adequate for reliability - 15 functional samples, 3 material samples	3	QRL-3: For intended use of data (reliability), sample size is probably inadequate – consult with reliability engineering or change intended use of actuator data.
Data Acquisition			
Functional test configuration (boom box)	Test configuration does not represent WR configuration	4	QRL-4: Test volume and geometry is used for product acceptance even though it does not represent WR geometry
Functional tester	Tester is a copy of PT, but is not qualified	4	QRL-4: Tester is not qualified, but has pedigree to qualify
Chemical analysis equipment		3	QRL-3: Will revisit QRL after verifying calibration and operating procedures for analysis equipment
Miscellaneous			
Qualification data		5	Original actuator qualification and ongoing surveillance data available for comparison and baselining – need to determine if tester changes/upgrades could cause data offsets when data is compared.

Because most of the project elements in this example have high QRLs, the PI can be reasonably confident that these elements will support the intended use (reliability assessment). However, there are project elements that drive a need for negotiations with stakeholders. The deliverable is a combination of performance testing and material testing data/information. While the functional testing project elements have mostly high QRLs, the material testing project elements do not. The PI might want to renegotiate intended use of the two data sets for different purposes or eliminate the powder testing altogether. The functional test data could still be used for safety or reliability assessment, but the powder analysis is questionable for this same purpose. The evaluation of project QRLs should be presented to stakeholders prior to the project start so that resources are not expended on a project that will not deliver a usable product.

If the PI and stakeholders decide that using project elements with low QRLs does not support intended use for the deliverable, they can upgrade project elements. People can be trained to use a piece of equipment or to understand the technology or product requirements. A data acquisition system can be dedicated, calibrated and characterized to determine measurement error. Software that models some characteristic or response can be documented or validated. PPI hardware can be exchanged for MQ hardware that has been exposed to stockpile environments.

This discussion around Table 2 demonstrates how basic project elements are impacted by subelements and how project element might be improved. There is an aspect of the project elements and interrelationships between them that is not discussed in depth in this report. In this example the people performing actuator disassembly and testing, the process used to perform disassembly, the tester and test fixture all affect each other and the deliverable. These relationships are demonstrated by the arrows to and from each of the basic project elements to one another shown in Figure 1.

The Quality Framework does not address these interrelationships as a whole, but breaks the project up into elements and subelements to make their evaluation simpler. It makes sense to break a major project element into many small pieces to describe how specific activities, materials, equipment, or people impact the deliverable. The element should be broken down as many times as necessary to obtain the desired discrimination for the project element and evaluation of its QRL.

3.3.2. Evaluating Project QRL – Example

The stakeholders may want a high-level project summary to report QRLs for the project at the basic element level to assist with prioritizing proposed projects. Table 3 shows how the PI might report a project-level evaluation. Table 3 uses Table 2 as the basis for determining project QRLs.

The QRL entries for each of the basic elements are averaged. Then the overall project QRL is obtained by averaging the entries for the five basic project elements (16.7 divided by 5 equals 3.34). The more detailed the QRL information provided for all basic project elements (as shown in Table 2), the higher the resolution for the project QRL. The detailed version of the evaluation shown in Table 2 provides back-up information if needed to explain the summary in more depth. The Comments column provides explanation or rationale for the QRL Summary column.

Table 3 - Example of Project QRL Evaluation

Basic Project Element	Subelement Summary	QRL Summary	Comments
People			
	Trained and available	2	Two entries under basic project element. Both entries evaluated at QRL-2 for an average of QRL-2 for project.
Processes			
	No documented process	3	Two entries under basic project element. One entry evaluated at QRL-5 for functional test process. Material evaluated at QRL-1 for an average of QRL-3 for project.
Hardware/Materials			
	Sample and sample size representative of WR	3	Two entries under basic project element. Both entries evaluated at QRL-3 for test hardware for an average of QRL-3 for project.
Data Acquisition			
	Test configuration, tester qualification, calibration and operation	3.7	Two entries under basic project element. Two entries (tester and test fixture) evaluated at QRL-4. One entry for chemical analysis equipment evaluated at QRL-3. Average of three entries is ~3.7 or about QRL-4:
Miscellaneous			
	Qualification data available	5	One entry under basic project element evaluated at QRL-5 to average QRL-5 for project.
Project QRL		**3.3**	

3.3.3. Flow Diagram for Quality Framework Tool

Figure 3 depicts a high level flow diagram that outlines use of the existing Quality Framework tools to identify project elements and evaluate their QRLs. The diagram also depicts responsibility for the tasks and the flow of information between the stakeholders and PI. Sections relevant to each of the activities in the diagram are also listed. At this time, the Framework addresses only activities on the right, shaded side of the diagram.

Decisions, activities and roles and responsibilities listed on the left side of the diagram will need to be developed to complete a framework that addresses concerns about how inherent quality of CME project elements support a project deliverable. Some of these are addressed in other existing processes used by the stakeholders and the PI to identify and prioritize data needs.

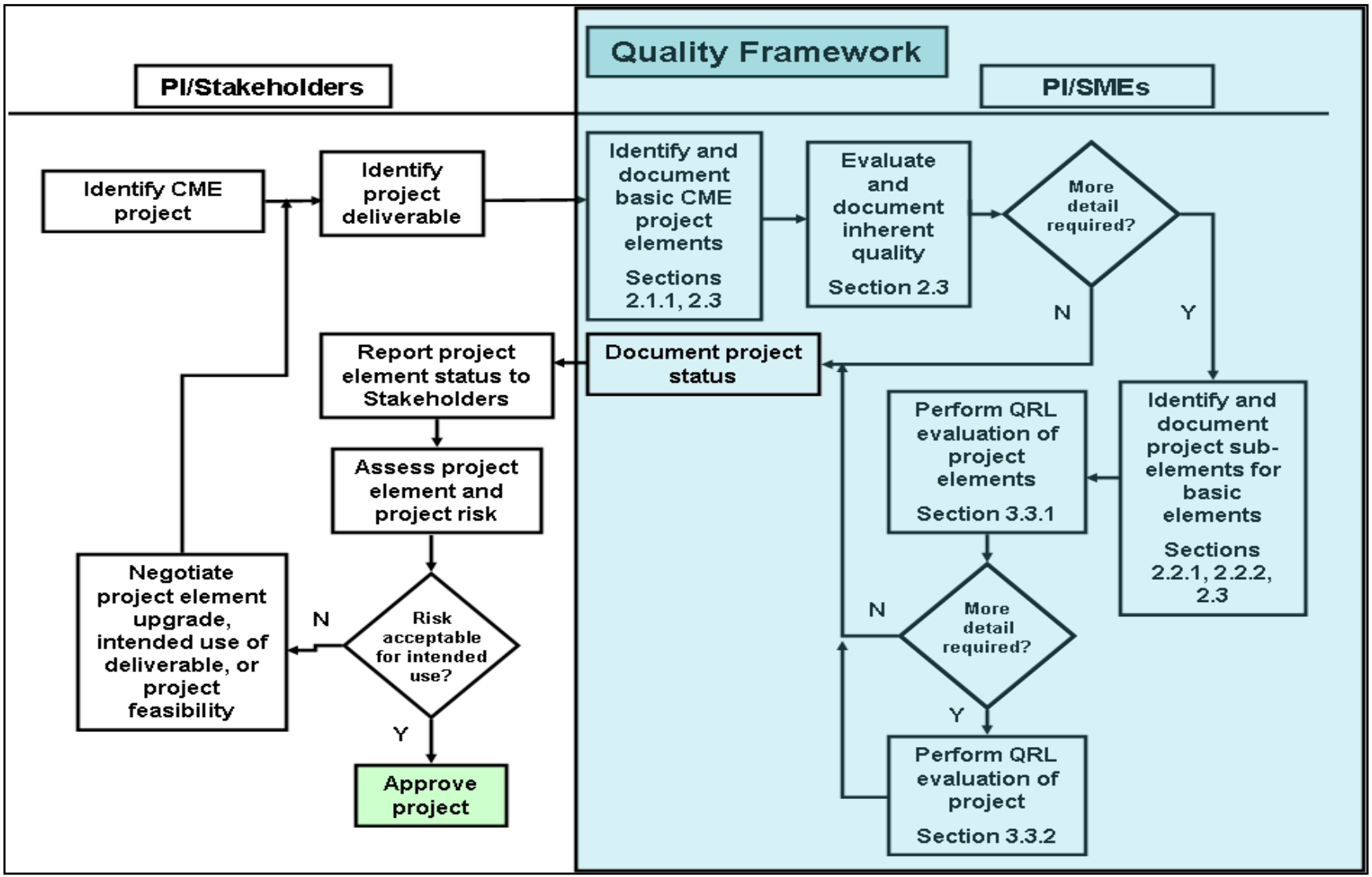

Figure 3 - Flow Diagram for Quality Framework Application

4. RISK ASSESSMENT AND MANAGEMENT

Corporate Process Requirement CPR001.3.13, "Risk Management", applies to all members of the workforce at Sandia National Laboratories (SNL), in that risk identification and control are activities integral to working safely, securely, and mindfully, and to delivering quality products and services to SNL's customers. This preference for risk management as a best practice is evidenced by inclusion in TBP-PRP that requires a Product Realization Team (PRT) to plan for risk as part of their project planning. Use of risk assessment and management provide a more proactive rather than reactive means to deal with unanticipated events during program execution.

The stakeholders that fund CME projects are also interested in risk that is driven by the inherent quality of project elements. Project elements with a low QRL will drive increased risk to a stakeholder depending on the intended use of the deliverable. If the stakeholders intend to use the deliverable to assess the stockpile, then inherent quality in all project elements becomes more important. The PI and stakeholders may be willing to negotiate to accept low QRLs for certain project elements if they agree that the risk is acceptable for the intended use of a deliverable.

4.1. Risk

There are many definitions of the term "risk" that vary according to a specific application and situational context. For purposes of the Quality Framework, risk can be defined as an existing or future event, action, situation or condition that might prevent the project from achieving a goal, an objective or milestone, or an approved work scope.

Risks have two components: the probability that the event, action, or condition will occur, and the severity of consequences (or impact) if that event, action, or condition does occur. These two components are defined as follows:
Probability (or likelihood) – the chance, likelihood or probability that some undesired event will occur
Impact (or consequence) – the results, impact or consequences of the undesired event
Risk can also be expressed numerically as the product of probability and impact (R = P * I).

There may be some confusion about the meanings of the terms "risk" and "uncertainty". To clarify, uncertainty might be described as an event where a pair of die is thrown and the outcome is of no consequence. Uncertainty reflects the likelihood of various possible events, but it does not reflect the consequences of those events. Risk is different from uncertainty in that it includes both the uncertainty that events will occur and the quantitative impact (or consequence) that can be assigned to the events.

A more concrete example to demonstrate the difference between uncertainty and risk is a lottery example. The outcome of the lottery is uncertain each time the numbers are pulled. If you did not purchase lottery tickets, when the event occurs, it is of no consequence because you have no stake in the outcome. In this case, there is only uncertainty around the outcome and no consequence to you. Risk on the other hand has the second component of consequence. If you bought a winning ticket, the outcome will be of (positive) consequence to you. Depending on how many of the numbers match, the degree of positive outcome will vary.

Additionally, problems or issues are often incorrectly described as risks. A problem is not a risk because risks have less than 100% likelihood of occurring, whereas if there is a problem, it has already occurred and has had impact or consequence. In other words, if a problem has occurred, it has a 100% chance of occurrence.

4.2. Risk Assessment and Management

4.2.1. Risk Assessment

Risk categories are the program areas where risk can occur. In a production setting, examples of risk categories involve cost, schedule and product performance. Under the cost category, drivers for cost risk include product yields, technology used in the product, reliability requirements that drive test quantities. Schedule risks can also be driven by low product yields, but other drivers like equipment down time, priority for limited resources and facilities issues can also drive schedule risk. Other examples of risk categories are related to human resources, technology used in a product or shipping and handling.

Risk assessment approach has been used to determine where risks to project success exist, what the severity might be, and to plan mitigation strategies to deal with them should they occur. Risk assessment and management has been used in the NWC and by the W76-1 and W80-3 Life Extension Programs (LEPs). The LEPs managed project risks by identifying risks to cost, schedule and performance and actively tracking and managing those that were moderate to high.

When used in the context of the Quality Framework on a CME project, risks to the project exist in the project elements because of impact of the subelements. The risk in each of the project elements will contribute to some degree of loss of confidence in the CME deliverable. Understanding where the QRLs are low and where they drive risks are to what degree, will help the PI to plan for a successful outcome for the project. To expedite a risk assessment process, the PI and stakeholders should only consider and document those elements that will impact confidence in the deliverable (data, process, model, diagnostic tool).

4.2.2. Risk Management

Risk management is defined as a disciplined approach for identifying, analyzing, prioritizing, mitigating, and tracking potential conditions that may impede the progress or success of a project (from corporate definition). It is through risk management that risk is assessed and systematically managed to reduce project risk to an acceptable level. Risk management also considered good business practice because it provides a forum for improved communications between the PI and stakeholders by demonstrating adequate planning to meet requirements and CME project objectives. It also provides a means to communicate where project elements, especially critical elements, might introduce or increase risk to the project deliverables.

4.2.3. Summary

Not every project element or subelement will introduce risk to a project. It is important for PIs to recognize and communicate the potential impacts to CME project deliverables from using project elements with low QRLs that drive high risk to the deliverable and the stakeholders. While some effort is required on the part of the PI to identify and document the QRLs, there are payoffs for doing so. One payoff is that there is awareness by both the PI and the stakeholders of the potential for the project not to meet expectations.

The stakeholders (TBRTs, Systems, reliability or safety engineering, use control or other authoritative entities) should evaluate the risks based on inherent quality of using deliverables with the existing level of inherent quality present in the project elements. The stakeholders will rely on information about the inherent quality of project elements to decide the appropriateness of the deliverable for its intended use.

If the risk is too high and will affect the confidence in the project deliverables or limit their intended use, the PI and stakeholders can negotiate upgrading the project elements that bring risk to the project to lower risk and increase confidence. Upgrading project elements to improve QRL, if desired or warranted by intended use of the deliverable can be planned for and communicated in terms of cost and/or schedule impacts. Future expansion of the Quality Framework should include formal risk assessment and management for the CME projects. Examples of a risk matrix to assess risk, and templates used to report individual risks and several project risks are detailed in Appendix D.

5. FUTURE PLANS

The development and documentation of a proposed approach for the Quality Framework was the major goal of 2008. The plan for the current fiscal year is to implement the high-level qualitative approach for the CME projects discussed in Section 2.4 to gather information about the project elements.

For FY2009, there are plans to create an interactive software application that implements a question-and-answer session for the PIs. The application will query the PI about project elements and the subelements impacting them. The application will query the PI for project element QRLs and request rationale about the QRL level. The goal is to provide a summary of the project elements required to execute the project and their status or QRL back to the stakeholders. The stakeholders can review the different projects and assess the risks versus desired results versus the intended use of the deliverable prior to deciding which projects to fund. Expansion of the Quality Framework might include a means to perform formal risk assessment and management for the CME project prior to beginning the project and during execution of the project. Risk assessment and management will help make clear what actions will be taken should other than "expected" results occur during project execution.

During the development of this Framework, contributors to this report have asked questions about how the evaluation of project elements would deal specifically with weighting project elements based on their criticality or impact to the project deliverable. This approach has not been explored in depth but could be part of the interactive application and weighting could be based on inputs from the PI about the project elements and subelements. At some point, the application may be matured to a level where QRLs are rolled up to the project level and a recommendation for intended use of the deliverable is part of the report back to stakeholders.

Finally, suggestions have been made to extend the Quality Framework to other activities such as SFI investigations or activities that require some knowledge of the inherent quality and intended use of the deliverable. This suggestion will need to be explored, but it should include practices outlined in TBP 801.

6. LESSONS-LEARNED AND CONCLUSIONS

At the time of this report, there were concerns about how CME projects are executed and how the project deliverable is used. The proposal for a Quality Framework is an attempt to address these concerns. There are several lessons that can be learned by using the Quality Framework approach. One lesson is to approach planning a CME project with a common understanding by the PI and stakeholders on the intended and end use for the CME project deliverable. The elements of the project should support a deliverable that is appropriate for its intended use. The PI and stakeholders should ensure that the project element QRLs are as high as possible to ensure that the deliverable can be used with confidence. When the PI and stakeholders recognize that the intended use of the deliverable is not consistent with the project element QRLs, steps should be taken to adjust the QRLs or renegotiate intended use.

The Quality Framework provides a systematic, consistent and defendable guidance to the PI for identifying project elements and evaluating inherent quality so that projects are evaluated consistently and with rigor. There is also guidance for a high level approach to provide qualitative information about the project elements and subelements, but a more in-depth quantitative approach for evaluating inherent quality is also described.

Another goal of the Framework is improved documentation and communication between the PI and stakeholders regarding the project goals and deliverables, project elements, inherent quality, areas of project element weakness and recommended improvements to the project elements. Because inherent quality drives risk, it is important that these drivers be identified, understood, documented and agreed upon by stakeholders. Documenting risks and handling strategies will make clear what actions will be taken should other than “expected” results occur.

In conclusion, the Quality Framework at this stage essentially contains best practices for effective project planning. Application of the Quality Framework to CME projects will provide expected benefits that include:

- A better up-front understanding and agreement between the PI and stakeholders of how the deliverable will be used,
- A consistent, understood and defendable, but flexible approach to guide the project so that the inherent quality of the deliverable is in line with the intended use of the deliverable,
- A better understanding of what project elements are required to execute the project,
- A better understanding of the inherent quality that those project elements possess,
- A better understanding of where inherent quality can be improved to increase confidence in the deliverable produced by the project and the cost and schedule time required to make these improvements,
- Documentation and communication of inherent quality, risks, decisions, rationale and purpose of the project,
- Guidance on how anomalies and other events that impact the “expected results” or deliverable should be addressed.

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APPENDIX A: BASIC PROJECT ELEMENT AND SUBELEMENT CHECKLIST

A suggested listing of basic project elements and groupings of subelements under them:
People: Affect most everything

- Adequate training, certification or knowledge for data acquisition
- Adequate training, certification or knowledge for tester set-up, tool or fixture set-up, analysis equipment set-up, set-up of data acquisition devices
- Adequate training, certification or knowledge for storage, handling, transport, or processing of hardware or material samples
- Adequate training, certification or knowledge for data analysis or interpretation
- Knowledge of design requirements (form, fit, function), why requirements exist, how requirements were met or not adequately demonstrated
- Knowledge of hardware or materials history, tribal knowledge, existing knowledge gaps
- Availability of adequate numbers of trained and knowledgeable people to perform the work.
- Knowledge of risks related to data acquisition, sample, tester, tool or fixture set-up, storage, packaging and handling, data analysis, hardware or materials used in the project

Data acquisition: Any tool, tester, fixture, gage or other device used to gather data for the project

- Test equipment hardware (electrical, material, etc.)
- Test equipment software (how does tester exercise hardware or material, when does it acquire test or response data, material sample data)
- Systematic error (differences in data acquisition system response when it is combined with the hardware or material being tested, e.g. a part tested in a war reserve (WR)-like configuration and volume versus a boom box that does not emulate the WR configuration)
- Software for acquiring data (sampling rate, rounding, probing trigger pressure)
- Software for analyzing data (data summary or reporting, statistical analysis)
- Calibration schedules for data acquisition equipment (testers, hand tools, gages, fixtures)
- Calibration methods
- Resolution or adequacy of data acquisition device (testers, hand tools, gages, fixtures, is data acquisition device adequate for purpose?)
- Measurement error (testers, hand tools, gages, fixtures or operator)
- Effects of errors when peripherals are attached (long test cables versus WR cables)
- Measurement methods (automated, operator dependent)
- Test environments or conditions (test space – abnormal, normal, hostile, over test, margin)
- Testing or degradation effects on hardware or material due to cumulative effects of environments – x-ray, temperature cycling, repeated testing (one-shot versus multiple shots)
- Analytical software (aside from modeling or tester)
- Modeling tools (model manipulates, projects or simulates test data into a result or response)
- Models – validated versus invalidated (is model outputting expected results or proven results)
- Data type (variables data, pass-fail data)
- Facilities – test or facility adequate to collect data Annular Core Research Reactor (ACRR, aerial test facilities)

Processes: Defined, characterized, repeatable, qualified or one-time, undocumented, uncharacterized, unqualified

- Manufacturing processes and use of manufacturing equipment (cleaning, pressing, curing, machining, mixing, assembly, etc.) and operation of manufacturing equipment (ultrasonic cleaners, blasting equipment, ovens, machine tools) used for test material or hardware
- Test preparation processes – tester set-up, set-up of other data acquisition devices, part or material sample preparation (part removal)
- Maturity and understanding of process used to remove samples or parts from a subassembly (understanding of potential for damage materials or hardware or materials such that the data might not be believable)
- Calibration process for data acquisition devices (testers, hand tools, gages, fixtures)
- Test processes – use of data acquisition devices or environmental controls to gather data in the appropriate environments (voltage at temperature, function during fratricide environment)
- Test material or hardware acceptance process criteria, design requirements (adequate, understood, relevant)
- Measurement process (automated, hand tools, gages, measurement methods, devices)
- Models – validated for application or not - (use of model, data types, expected results, appropriate application of model)
- Packaging, handling, shipping, storage processes for test material or for project activities

Hardware and materials:

- Pedigree (Mark Quality, Process Prove-In (PPI), development, unknown, similar) of material or hardware that will be used in project
- Test quantities available (more samples may better represent responses to test conditions)
- Known issues – reliability, unresolved Significant Finding Investigations (SFIs) and Tester Significant Investigations (TSIs), material aging, failure modes, anomalies, material hardware degradation of hardware due to proximity to radioisotopes)
- Known issues – manufacturing process (deficient or uncharacterized that may have altered materials or hardware in an undesirable manner, e.g. oven cure)
- Known issues – degradation of materials (deficient or uncharacterized that may have altered materials or hardware in an undesirable manner, e.g. oven cure, repeated exposure to x-rays)
- Degradation due to overtesting or too many test cycles
- Pre-processing of hardware or material prior to testing (did pre-process (e.g. cleaning) damage or change hardware or materials such that the data might not be believable?)
- Disassembly effects (impact on hardware or materials of chemical depotting, mechanical disassembly)
- Suffix rolls or Major Component (MC) upgrades (understanding of why they occurred and what they were supposed to fix)
- Hardware or material shelf-life and storage
- Packaging, handling, shipping and transport (known and understood)
- Design definition (complete, incomplete, nonexistent for hardware or materials)

Miscellaneous: Subelements that don't fit neatly into other basic categories

- Classification (hardware, data, reliability, test apparatus, technology)
- Environmental, Safety and Health (ES&H) concerns with test material, hardware, equipment, facility, etc.
- Existing data (reliability, qualification, requalification)
- Data from related or similar hardware or materials, similar processes, similar data acquisition devices
- Environments (uncontrolled Stockpile-to-Target (STS) environments)
- Project element Technology Readiness Levels (TRLs), Manufacturing Readiness Levels (MRLs) and Quality Rigor Levels (QRLs), and their implementation
- Risk assessments on project elements
- Other risks (cost, schedule)
- Significant Finding Investigation (SFI)-related issues or other anomalies
- Non-SFI issues (e. g. Unsatisfactory Reports (URs))

APPENDIX B: TRL DEFINITIONS (DOD, NASA, SNL)

TRL	Descriptor	DoD	NASA	SNL
1	Basic principals observed and reported	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Example might include paper studies of a technology's basic properties.	This is the lowest "level" of technology maturation. At this level, scientific research begins to be translated into applied research and development.	This is the first level of technology readiness and includes fundamental scientific research. At this level, basic scientific principles are being studied analytically and/or experimentally. Examples might include paper studies of a technology's basic properties.
2	Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be invented. The application is speculative and there is no proof or detailed analysis to support the assumption. Examples are still limited to paper studies.	Once basic physical principles are observed, then at the next level of maturation, practical applications of those characteristics can be 'invented' for identified. At this level, the application is still speculative: there is not experimental proof or detailed analysis to support the conjecture.	Practical applications are beginning to be invented or identified. Applications are still speculative and there is no proof or detailed analysis to support assumptions. Examples might include applied research in a field of potential interest.
3	Analytical and experimental critical function and/or characteristic proof of concept. Concepts demonstrated analytically or experimentally.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	At this step in the maturation process, active research and development (R&D) is initiated. This must include both analytical studies to set the technology into an appropriate context and laboratory-based studies to physically validate that the analytical predictions are correct. These studies and experiments should constitute "proof-of-concept" validation of the applications/concepts formulated at TRL 2.	Active research and development is initiated. This includes analytical and laboratory-based studies to physically validate analytical predictions of key elements of the technology. These studies and experiments should constitute "proof-of-concept" validation of the applications/concepts formulated at TRL 2. Examples include the study of separate elements of the technology that are not yet integrated or representative.
4	Component and/or breadboard validation in laboratory environment. Key elements demonstrated in laboratory environment.	Basic technological components are integrated to establish that the pieces will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of 'ad hoc' hardware in a laboratory.	Following successful "proof-of-concept" work, basic technological elements must be integrated to establish that the "pieces" will work together to achieve concept-enabling levels of performance for a component and/or breadboard. This validation must be devised to support the concept that was formulated earlier, and should also be consistent with the requirements of potential system applications. The validation is relatively "low-fidelity" compared to the eventual system: it could be composed of ad hoc discrete components in a laboratory.	The key elements must be integrated to establish that the pieces will work together. The validation should be consistent with the requirements of potential applications but is relatively low-fidelity when compared to a final product. Examples include integration of ad-hoc hardware or software in the laboratory such as breadboards, low fidelity development components, and rapid prototypes.
5	Component and/or breadboard validation in relevant environment. Key elements demonstrated in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so that the technology can be tested in a simulated environment. Examples include 'high fidelity' laboratory integration of components.	At this level, the fidelity of the component and/or breadboard being tested has to increase significantly. The basic technological elements must be integrated with reasonably realistic supporting elements so that the total applications (component-level, sub-system level, or system-level) can be tested in a 'simulated' or somewhat realistic environment.	Fidelity of the key elements increases significantly. Key elements are integrated with realistic supporting elements so that the technology can be tested and demonstrated in simulated or actual environments.
6	System/subsystem model or prototype demonstration in a relevant environment (ground or space). Representative of the deliverable demonstrated in relevant environment.	Representative model or prototype system, which is well beyond the breadboard tested for TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory environment or in simulated operational environment.	A major step in the level of fidelity of the technology demonstration follows the completion of TRL 5. At TRL 6, a representative model or prototype system or system - which would go well beyond ad hoc, 'patch-cord' or discrete component level breadboarding - would be tested in a relevant environment. At this level, if the only 'relevant environment' is the environment of space, then the model/prototype must be demonstrated in space.	Represents a major step in a technology's demonstrated readiness. Examples include testing a prototype or representative of a deliverable in a high fidelity laboratory environment or in a simulated operational environment.
7	System prototype demonstration in an operational (space) environment. Final development version of the deliverable demonstrated in operational environment.	Prototype near or at planned operational system. Represents a major step up from TRL 6, requiring the demonstration of an actual system prototype in an operational environment, such as in an aircraft, vehicle or space. Examples include testing the prototype in a test bed aircraft.	TRL 7 is a significant step beyond TRL 6, requiring an actual system prototype demonstration in a space environment. The prototype should be near or at the scale of the planned operational system and the demonstration must take place in space.	Development version of the deliverable is near or at the planned operational system. This represents a significant step beyond TRL 6 and requires the demonstration of an actual development version of the deliverable in the operational environment. Examples include integration and demonstration within the next assembly, and advanced concept technology demonstrations of integrated systems such as flight testing.
8	Actual system completed and "flight qualified" through test and demonstration (ground or space). Actual deliverable qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	In almost all cases, this level is the end of true 'system development' for most technology elements. This might include integration of new technology into an existing system.	The technology has been proven to work in its final form under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the actual deliverable in its intended application to validate that it meets design specifications.
9	Actual system "flight proven" through successful mission operations. Operational use of actual deliverable	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. In almost all cases, this is the end of the last "bug fixing" aspects of true system development. Examples include using the system under operational mission conditions.	In almost all cases, the end of last 'bug fixing' aspects of true 'system development'. This might include integration of new technology into an existing system. This TRL does not include planned product improvement of ongoing or reusable systems.	Application of the technology in its final form and under mission conditions such as those encountered in operational test and evaluation. In almost all cases, this is the end of the last bug fixing aspects of true system development. Examples include using the deliverable under operational mission conditions. This TRL does not include ongoing or planned product improvement of reusable systems.

APPENDIX C: QRL DESCRIPTORS – QRL-1

	People	Processes	Materials/Hardware	Data Acquisition	Miscellaneous
	Requirements knowledge	Manufacturing, assembly, test	Pedigree	Requirements and process knowledge	Requirements knowledge
	Technology experience	Acceptance	Disassembly or pre-processing effects	Software	Classification
	Set-up (sample, tester, hardware)	Disassembly, pre-process or test preparation	Requalification data (comparison for performance trends)	Calibration (methods and schedule)	ES&H
	Data acquisition, analysis or interpretation	Testing, data acquisition	Known aging effects that impact deliverable	Systematic error	Exposure to STS environments
	Back-up staffing levels (availability)	Software	Known deviations, SFIs, SXRs that impact deliverable	Data acquisition device error	Existing data (qualification, requalification, SFI)
	Other potential for human error (ES&H, classification)	Storage, packaging, shipping or handling		Set-up error	Technology or Manufacturing Readiness Levels (TRL, MRL)
	Other	Other	Other	Other	Other
QRL-1 (As-built (inherent) project element quality unknown - fill tech basis gaps)	Inexperienced with product requirements, technology, sample and tester preparation, testing and data acquisition methods, storage, data analysis and interpretation, and storage, handling and packaging requirements. No training available for any of previous items. No documented training on processing or data acquisition equipment. No operation manuals for processing or data acquisition equipment. All other aspects associated with other project elements (process, hardware, data acquisition, etc.) are prone or vulnerable to effects from human error. Other factors may be illness, retirement or unavailability of experienced staff.	No requirements, documentation, processes or configuration control for material acceptance, manufacturing and assembly, data acquisition and/or analysis, material sample or hardware preparation (pre-processing, mechanical/chemical disassembly), test set-up activities. Inconsistencies exist in all activities due to lack of processes. No software processes and algorithms. Product yields or results unknown or inconsistent. No storage, packaging, shipping and handling requirements or processes. All activities performed without documented requirements or processes in a R&D environment.	Test material requirements, history, documentation, composition is unknown. No material specifications or drawings for hardware, i.e. incomplete or unknown requirements. Material or hardware is development or prototype quality does not meet all known or existing form, fit or functional requirements. No record of training, processing, assembly, material certificates, test records, acceptance. No record of how material or hardware was stored, handled or processed, or shipped. Material or hardware supplier not known or qualified. All or most material or hardware-related activities performed in a R&D environment.	CME data acquisition devices consist of open set-up or a collection of devices. Acquisition devices are not dedicated and can be disassembled and deployed for other uses. No calibration schedule or methods to check device against calibrated standard exists. Software for device is uncontrolled and undocumented. Measurement error due to data acquisition device is unknown or unquantified. Systematic error due to device and material or hardware combination is unknown or unquantified. Error or effects from peripherals to main data acquisition device are unknown or unquantified (e.g. cables or other	Requirements are undefined. Deliverable (process, data, model) may be classified with no established classification guidance or controls. ES&H concerns (materials, hardware, processes, equipment) are unknown or uncontrolled. Environments may be uncontrolled with an unknown impact or degradation to materials, hardware, or equipment. Data from previous activities (other experimentation, material processing, assembly, testing) is not available. Technology or Manufacturing Readiness Levels (TRLs/MRLs) are 1 or 2. New, unproven technology used for a new application. All activities performed in a R&D environment.

APPENDIX C (CONTINUED): QRL DESCRIPTORS – QRL-2

	People	Processes	Materials/Hardware	Data Acquisition	Miscellaneous
	Requirements knowledge	Manufacturing, assembly, test	Pedigree	Requirements and process knowledge	Requirements knowledge
	Technology experience	Acceptance	Disassembly or pre-processing effects	Software	Classification
	Set-up (sample, tester, hardware)	Disassembly, pre-process or test preparation	Requalification data (comparison for performance trends)	Calibration (methods and schedule)	ES&H
	Data acquisition, analysis or interpretation	Testing, data acquisition	Known aging effects that impact deliverable	Systematic error	Exposure to STS environments
	Back-up staffing levels (availability)	Software	Known deviations, SFIs, SXRs that impact deliverable	Data acquisition device error	Existing data (qualification, requalification, SFI)
	Other potential for human error (ES&H, classification)	Storage, packaging, shipping or handling		Set-up error	Technology or Manufacturing Readiness Levels (TRL, MRL)
	Other	Other	Other	Other	Other
QRL-2 (Key inherent quality elements identified for relevant development applications)	Minimal experience and knowledge in areas of requirements and technology, sample and tester preparation, testing and data acquisition methods, storage, data analysis and interpretation, and storage, handling and packaging requirements. Some training available for many of previous items to draft, documented processes. Draft operation manuals with product parameters for processing equipment or data acquisition equipment are available for training. Due to draft status of processes, other project elements (process, hardware, data acquisition, etc.) may still be vulnerable to effects from human error. Other factors: no trained back-up staff.	Processes are rough draft, written during execution with many TBDs and no configuration control for acceptance, manufacturing and assembly, data acquisition and/or analysis information, material sample or hardware preparation (pre-processing, mechanical/chemical disassembly), test set-up activities. Rough drafts with TBDs for software and algorithms, storage, packaging, shipping and handling information. Inconsistencies for activities and process outputs exist due to missing or incomplete process information. Processes performed in a R&D environment.	Test material or hardware is development or prototype quality. Test material or hardware may not meet form, fit or functional requirements. Some information (incomplete) for material specifications or hardware drawings exist, i.e. incomplete or unknown requirements. Incomplete record of training, processing, assembly, material certificates, test records, acceptance. Incomplete record of how material or hardware was stored, handled or processed, or shipped. Material or hardware supplier not known or qualified. All or most material or hardware-related activities performed in a R&D environment.	CME data acquisition devices consist of open set-up or a collection of devices that may or may not be dedicated to one application. Device drawing definition is available but not under configuration control. Calibration schedule and/or methods to check device against calibrated standard are being developed. Device software is documented but may be uncontrolled. Measurement error due to data acquisition device is being investigated. Error due to device and material or hardware combination is being investigated. Error or effects from peripherals to main data acquisition device is being investigated (e.g. cables or other monitoring devices).	Requirements are being defined for product application. Deliverables (process, data, model) may be classified, but there is no established classification guidance. Environments may be uncontrolled, but impacts or degradation to materials, hardware, processes or equipment are being investigated and documented. Data from some previous activities (other experimentation, material processing, assembly, testing) is available. TRL and MRL is 3 through 5. New technology successfully has been used for a similar product application in an operational situation. All activities performed in a R&D environment.

APPENDIX C (CONTINUED): QRL DESCRIPTORS – QRL-3

	People	Processes	Materials/Hardware	Data Acquisition	Miscellaneous
	Requirements knowledge	Manufacturing, assembly, test	Pedigree	Requirements and process knowledge	Requirements knowledge
	Technology experience	Acceptance	Disassembly or pre-processing effects	Software	Classification
	Set-up (sample, tester, hardware)	Disassembly, pre-process or test preparation	Requalification data (comparison for performance trends)	Calibration (methods and schedule)	ES&H
	Data acquisition, analysis or interpretation	Testing, data acquisition	Known aging effects that impact deliverable	Systematic error	Exposure to STS environments
	Back-up staffing levels (availability)	Software	Known deviations, SFIs, SXRs that impact deliverable	Data acquisition device error	Existing data (qualification, requalification, SFI)
	Other potential for human error (ES&H, classification)	Storage, packaging, shipping or handling		Set-up error	Technology or Manufacturing Readiness Levels (TRL, MRL)
	Other	Other	Other	Other	Other
QRL-3 (Key inherent quality elements identified - potential transition applications)	Moderate experience, knowledge and skill in areas of requirements, technology, sample and tester preparation, testing, data acquisition and analysis methods, storage, handling and packaging activities. Trained to good material and hardware process drafts having few TBDs. Trained to good draft equipment operation manuals having most processing or data acquisition parameters defined with few TBDs. Recognizes lack of knowledge and/or skill and requests guidance prior to pursuing deliverable-related activities. Training and documentation along with product knowledge preclude introduction of much human error. Other factors: minimal trained back-up staff.	Maturity of documentation is consistent with Process Prove-In (PPI) status. Most requirements are defined so good draft documented processes with few TBDs exist for all critical product activities (material or hardware manufacturing, tester and equipment operation, software, sample preparation, pre-processing of hardware or samples, data analysis, storage, handling or packaging). Processes and other documentation are under configuration control. Processes are not qualified and have not been exercised significantly. Yields or results of executing processes are not always consistent or understood.	Material and hardware is WR with known deviations that affect form, fit or function, altered WR, or PPI. Drawings or material specifications exist and are under configuration control. Material or hardware meets most form, fit and function requirements, but not known how consistently (reliability, yields). Material preparation or hardware assembly processes are documented, but process inputs and outputs may not be understood. Processing, assembly, certifications and test records are available and under configuration control. Material or hardware storage, handling, transport and shipping records are available. Supplier is qualified.	Data acquisition device is not QERed. Data acquisition device is dedicated to this product. Calibration schedule and methods for data acquisition devices are established or being established and maintained. Software for device (sampling rate, collection, analysis, algorithms) is documented and under configuration control. Measurement and systemic errors, or error to peripherals (e.g. cables or other monitoring devices) are documented, but may not be completely understood or quantified.	Requirements are mostly defined for deliverables. Classified deliverables (process, data, model) are protected with released classification guidance. ES&H concerns with materials, hardware, processes or equipment have been identified and controls are in place. Environments and their impacts (degradation) to materials, hardware, or equipment are understood, but may not be controlled. Development data (form, fit, function) is available. TRL is 6 or 7. MRL is 7. New technology or new application for old technology in a laboratory or production facility using process controls for prove-in with some testing in operational environments.

APPENDIX C (CONTINUED): QRL DESCRIPTORS – QRL-4

	People	Processes	Materials/Hardware	Data Acquisition	Miscellaneous
	Requirements knowledge	Manufacturing, assembly, test	Pedigree	Requirements and process knowledge	Requirements knowledge
	Technology experience	Acceptance	Disassembly or pre-processing effects	Software	Classification
	Set-up (sample, tester, hardware)	Disassembly, pre-process or test preparation	Requalification data (comparison for performance trends)	Calibration (methods and schedule)	ES&H
	Data acquisition, analysis or interpretation	Testing, data acquisition	Known aging effects that impact deliverable	Systematic error	Exposure to STS environments
	Back-up staffing levels (availability)	Software	Known deviations, SFIs, SXRs that impact deliverable	Data acquisition device error	Existing data (qualification, requalification, SFI)
	Other potential for human error (ES&H, classification)	Storage, packaging, shipping or handling		Set-up error	Technology or Manufacturing Readiness Levels (TRL, MRL)
	Other	Other	Other	Other	Other
QRL 4 (High rigor in project elements - potential stockpile assessment, SES transition)	Experience, knowledge and skill in areas of requirements, technology, sample and tester preparation, testing and data acquisition and analysis methods, storage, handling and packaging activities, equivalent to QE status. Trained to released material and hardware processes. Trained to released operation manuals having all process and data acquisition parameters defined. Operates only in areas where trained and skilled in processes and operations, or in field of expertise. Documentation, training, experience and knowledge of deliverable preclude most human error. Other factors: adequate number of trained back-up staff.	Processes are mature enough that qualification-like activities are feasible for CME material sample or hardware preparation (e.g. mechanical or chemical disassembly) processes, test set-up, data acquisition, software, analysis and algorithms, acceptance, storage, packaging, shipping and handling. Product and CME processes have been exercised significantly. Product and manufacturing and assembly processes are being characterized and have good yields. Training for all above is available. Project elements are repeatable, and reliable and not subject to effects from human error. (e.g. QE production).	Material or hardware is non-altered WR with known deviations that do not affect form, fit or function, or mark quality (MQ) with no QER. Specifications for materials or drawings for hardware are complete and available. Material or hardware was procured from a qualified supplier. Records of processing, assembly, material certificates, test records, training records, all lot records and traceability are complete and available. Records for storage, handling or processing, or shipping are complete and available. MQ material or hardware has been tested with no deviations to form, fit or function, has not been in the stockpile, or been requalified.	Data acquisition device is ready to QER or has a conditional QER that should not affect data, data collection or analysis related to the CME deliverable. Data acquisition device is dedicated. Calibration schedule and methods to check device against calibrated standard are established. Software for device (sampling rate, collection, analysis, algorithms) is configuration controlled and documented. Measurement error is known and quantified. Systematic error due to device and material or hardware combination is known or quantified. Error or effects from peripherals (e.g. cables or other monitoring devices) to main data acquisition device are known or quantified.	Requirements are defined for deliverables. Deliverables (process, data, model) are not classified or handling of classified deliverables is established. ES&H concerns for materials, hardware, processes or equipment hazards are understood and controlled. STS or other environments have been documented if not controlled, and any potential degradation to materials, hardware, or equipment is understood, if not controlled. Existing data from other activities (requalification, surveillance) is not available. Technology or Manufacturing Readiness Levels are 8 or 9. Well understood, existing technology used in a conventional application. .

APPENDIX C (CONTINUED): QRL DESCRIPTORS – QRL-5

	People	Processes	Materials/Hardware	Data Acquisition	Miscellaneous
	Requirements knowledge	Manufacturing, assembly, test	Pedigree	Requirements and process knowledge	Requirements knowledge
	Technology experience	Acceptance	Disassembly or pre-processing effects	Software	Classification
	Set-up (sample, tester, hardware)	Disassembly, pre-process or test preparation	Requalification data (comparison for performance trends)	Calibration (methods and schedule)	ES&H
	Data acquisition, analysis or interpretation	Testing, data acquisition	Known aging effects that impact deliverable	Systematic error	Exposure to STS environments
	Back-up staffing levels (availability)	Software	Known deviations, SFIs, SXRs that impact deliverable	Data acquisition device error	Existing data (qualification, requalification, SFI)
	Other potential for human error (ES&H, classification)	Storage, packaging, shipping or handling		Set-up error	Technology or Manufacturing Readiness Levels (TRL, MRL)
	Other	Other	Other	Other	Other
QRL-5 (Full rigor in CME project elements - stockpile assessment, SES transition)	Experienced, qualified and certified to technology, sample and tester preparation, testing and data acquisition methods, storage, handling and packaging requirements. Operation manuals for processing or data acquisition equipment, material specifications are documented and available. Operates only in areas where trained, certified and skilled in processes and operations, or in field of expertise. Training available for all previous items. All aspects associated with other project elements are repeatable, and reliable and not subject to effects from human error. Other factors: adequate number of trained production back-up staff.	Product manufacturing, assembly and acceptance processes are QERed, under configuration control, and characterized with high yields. CME material sample or hardware preparation (e.g. mechanical or chemical disassembly) processes are documented, characterized and have high yields. CME test set-up and data acquisition device processes are documented and characterized. Software, analysis processes and algorithms are documented and characterized. Storage, packaging, shipping and handling processes are documented and characterized.	Material or hardware is QERed, non-altered WR with no deviations. Specifications for materials or drawings for hardware are complete and available. Material or hardware was procured from a qualified supplier. Records of processing, assembly, material certificates, test records, training records, all lot records and traceability are complete and available. Material or hardware has been tested with no known deviations to form, fit or function. Records for material or hardware storage, handling or processing, or shipping are complete and available. Material or hardware has been in the stockpile, has been exposed to some STS environments and has been requalified.	CME data acquisition device is QERed. Data acquisition device is dedicated to the product being tested. Calibration schedule and methods to check device against calibrated standard are established. Software for device (sampling rate, collection, analysis, algorithms) is documented and under configuration control. Measurement error is known or quantified. Systematic error due to device and material or hardware combination is known or quantified. Error or effects from peripherals (e.g. cables or other monitoring devices) to main data acquisition device are known or quantified. Some of previous errors listed above may be controlled.	Deliverables (process, data, model) are not classified or handling of classified project elements and deliverables is well established. ES&H concerns for materials, hardware, processes or equipment hazards are understood and controlled. STS or other environments have been documented if not controlled, and any potential degradation to materials, hardware, or equipment is understood and controlled. Existing data from other activities (qualification, surveillance) is available. TRL and MRL are 9. Well understood, existing technology used in a conventional application in a controlled production environment.

APPENDIX D: RISK ASSESSMENT AND MANAGEMENT METHODOLOGY

Figure D-1 shows an example of a risk matrix commonly used at Sandia National Laboratories for assessing risk. Risk is measured by its two components: probability on the Y axis and impact on the X axis. The X and Y axes both have values of 1 – 5 with the higher numbers indicating either higher probability or impact as shown in the diagram. The numbers inside the squares are the product of the probability and the impact that provide a quantitative assessment. The red-yellow-green signifies the qualitative assessment of risk. Green signifies that the risk is low because although probability can range from low to high, the impact is moderate at worst with a product at worst case of 5. Moderate risks have probabilities that can also range from low to high, but the impact is moderately high to high and the products can range from a 4 to a 12. High risks have both probabilities and impacts that range from moderate to high and whose products range from 15 to 25.

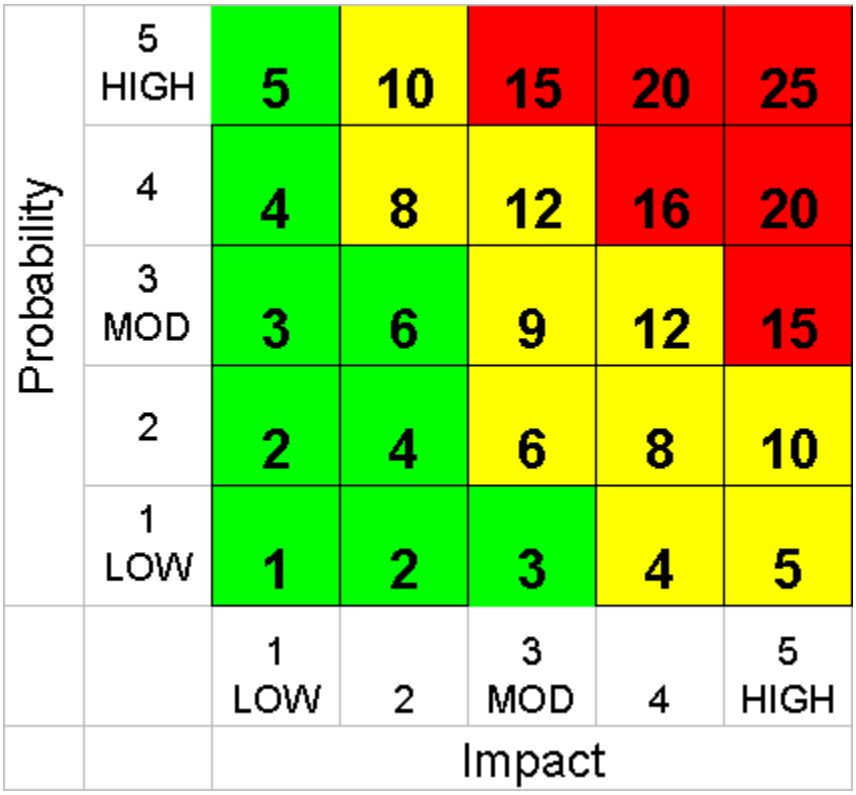

Figure D-1 - Risk Assessment Matrix

The PI or subject matter experts should determine the level of effort to apply to assess risks in project elements. Two different approaches to assess risk are described in Section 5. A high level approach can be used to provide information to stakeholders about the project risks while being conscious of project constraints (cost and schedule). This approach would provide more value where the deliverable does not require a high level of confidence, for instance when the project is of an exploratory nature.

The second approach uses an in-depth assessment and is more suited to projects whose deliverables will provide processes to transition from Enhanced Surveillance Campaign (ESC) or Component Material Evaluation (CME) projects to ongoing surveillance. The in-depth approach should also be used when a high level of confidence in the data is required. This approach will likely require more resources (funding and time). Both approaches can be used as a vehicle to determine where risks are and recommend strategies to mitigate them.

Because the goal and/or deliverables of CME projects are to deliver a process, information, or diagnostic or predictive means to evaluate components in the stockpile, risk management should be included as a project activity to ensure that the project is successful. Figure D-2 shows an example PowerPoint slide of a documented risk with the statement, handling strategies, triggers, status and contingency that was used to document a testing project subelement for an SNL product.

Formal risk management has several components. After the risk has been identified and assessed, other information about the risk can be documented. The risk should be formally documented in a risk statement that takes the form IF (the risk event occurs), THEN (the consequence or impact). The risk statement should be detailed so that it is clear what is at stake and why, when the risk is anticipated to become a problem or an issue or when handling strategies need to be implemented, status of handling strategies and any contingency actions.

Different handling strategies for the risk can be identified as a means of dealing with the risk. Handling strategies can be categorized as mitigation, avoidance, transfer or acceptance. Handling strategies can usually be planned to occur in parallel or in series and they should be initiated in advance, if possible, to prevent the risk's occurrence.

Mitigations are meant to decrease the risk such that its probability or impacts are decreased. An example of mitigation if product yields are low is to build extra lots to ensure the deliverable quantities are maintained, recognizing that cost will probably increase. An example of avoidance is changing a design from a new, unproven technology to a qualified, characterized and known technology, allowing the project to avoid the risk from a new technology that may not meet design requirements when it is tested. Transferring risk means moving the risk to a lower or higher level. An example of transfer is postponing environmental qualification testing of a stronglink coil from the coil level to the stronglink assembly level. The stronglink level then must deal with the risk of a coil failure and any increase in cost or schedule should failure occur.

Accepting the risk is usually the last handling strategy chosen because it indicates that there are constraints (time, budget, technology, or other resources or project elements) that will not allow the other three handling strategies to be planned or initiated. When risk is accepted, it is important that the PI and stakeholders recognize that if the risk event should occur, that there will likely be no way to improve or change the deliverable.

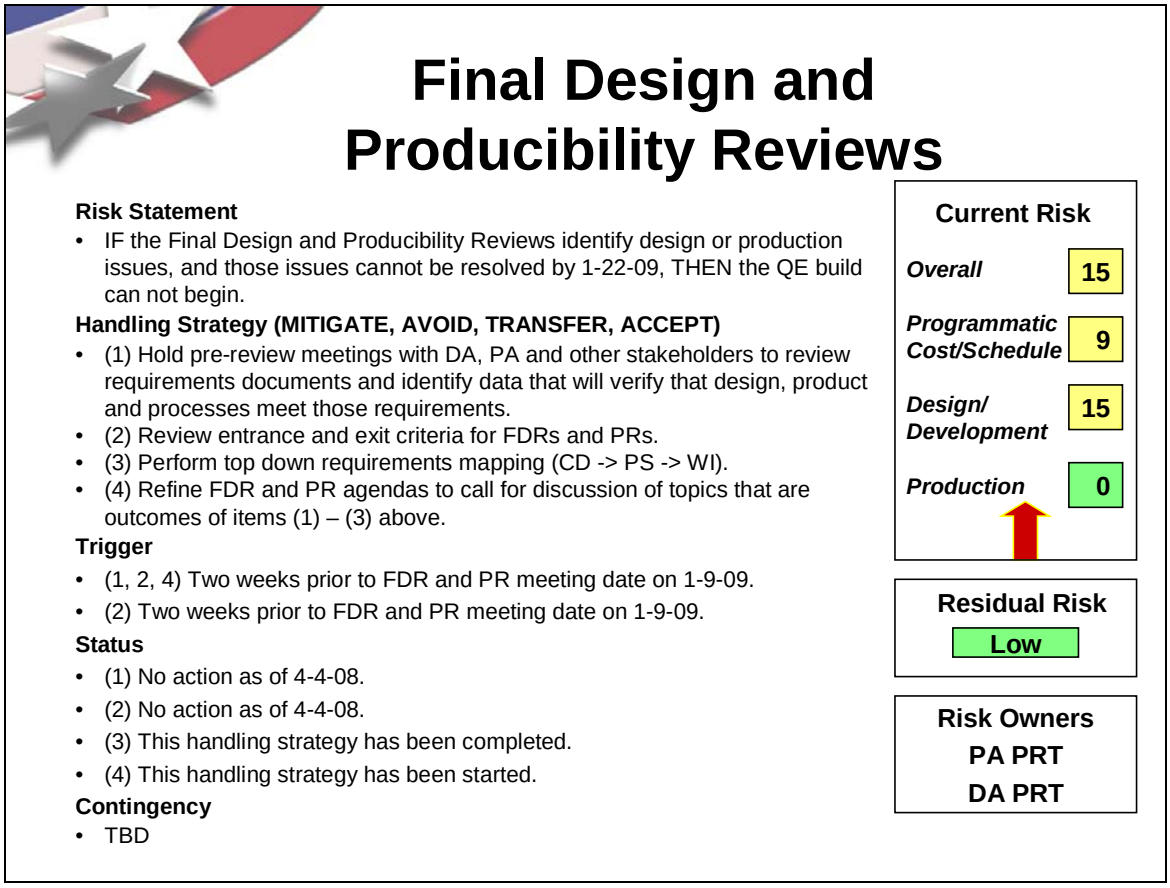

Figure D-2 - Example Individual Risk Assessment

Triggers are events that will initiate a handling strategy. Examples of triggers can be dates, availability of performance data, and completion of training or facility readiness. Obviously, if acceptance is the handling strategy, then triggers are not required. Documenting triggers is a means for the PI to achieve consensus from the project team and stakeholders beforehand about the action that will be taken. Often, a wait-and-see approach causes a project to fall behind because a decision has not been made to change course (initiate handling strategy) when an important milestone or deliverable has not been met. Identifying a trigger removes the difficulty of making a decision because the decision has already been made prior to reaching the trigger.

The status of the risk and any handling strategies that have been initiated should be tracked, updated and documented periodically to maintain awareness and communication between the PI and stakeholders.

A summary of the risks in different risk categories is also shown. The summary of risks for this example includes risks associated with design, development and production. The overarching programmatic risk (including cost and schedule) is also shown. The numbers assigned to the three categories is derived from application of the risk assessment matrix shown in Figure D-1 to project elements in this example. The combination of risks from the three categories is rolled up and presented as a summary risk to the project or program. The highest risk of the three categories is the risk reported in the rollup. The arrow in this box (pointing up in this case) indicates that this risk is increasing (probability or impact) since the last time it was evaluated.

Residual risk remains after some or all handling strategies have been successfully completed. For example, if yields of some product are low and the impact is not meeting deliverable quantities to the next assembly, a mitigation handling strategy might be to build an extra lot. Once the extra lot is delivered, the residual risk (not enough deliverables to next assembly) is low because quantities are on hand to satisfy needs at the next assembly. The last item on Figure D-2 is documentation of the risk owners who have responsibility to track and report risk status and implement handling strategies.

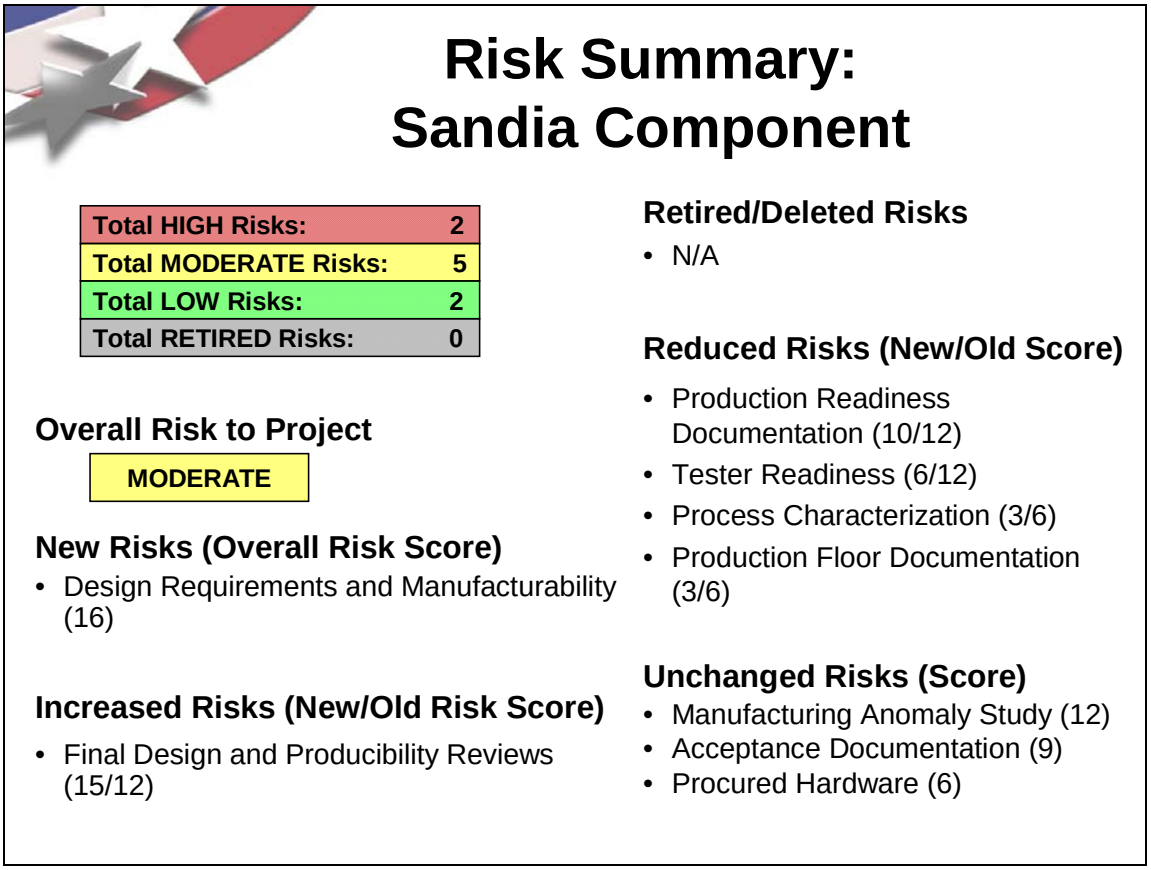

Figure D-3 - Project Risk Summary

Because there can be several risks associated with a project, the PI and stakeholders may want to track and report all risks in a project risk summary. An example of a project risk summary is shown in Figure D-3. The summary usually has all risks listed along with their titles and their ranking. Status of all risks is listed for new and old risks. Status can be increasing, retired or deleted, reduced (decreasing) or unchanged. Old risks that have been retired because of handling strategies or other factors (overcome by events) are listed along with new risks that have been identified.

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