RISK MANAGEMENT – BLENDING DOE, NRC, OSHA, AND EPA REQUIREMENTS INTO A WORKABLE APPROACH

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ABSTRACT

This paper addresses the various risk management requirements specified by the Department of Energy (DOE), the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA) and their impacts on work implementation. It presents a risk management approach that blends those requirements into a logical, step-wise process that ensures well understood and planned achievable, safe, and cost-effective projects relating to the operation, maintenance, modification, shut-down, and clean-up of nuclear facilities and sites. By following this approach, operators and contractors are able to improve safety, anticipate and mitigate potential problems, and maintain schedule while staying within budget. The approach addresses risk management planning and risk control during work execution.

INTRODUCTION

Risk management is a term whose definition is formed primarily by the perspective of the user of the term. Generally, government regulatory agencies primarily define risk management in terms of worker, public, and environmental safety and secondarily in terms of avoidance of budget or schedule overruns. Businesses on the other hand, take a broader (bottom line oriented) view of risk management as being the integration of all activities and functions that will ensure work is completed safely, within budget, on-schedule and to the technical specifications of the client.

Within the federal regulatory agencies, the primary focus of risk management varies both by agency and within agencies. In EPA, for example, risk management primarily relates to protecting the public and environment from current uncontrolled risks such as improperly disposed wastes and improperly treated effluents and emissions under either CERCLA or RCRA (1). It has a secondary meaning under the Clean Air Act that emphasizes chemical accident prevention through the development and implementation of a Risk Management Plan that incorporates engineered systems and operational processes to minimize accidental releases (2). OSHA, on the other hand, defines risk management strictly as worker safety and protection. The NRC incorporates risk management as part of the technical specifications with the intent of ensuring that nuclear facilities are built and operated to minimize the risks of worker exposure and uncontrolled releases.

Government implementing agencies, such as DOE, view risk management more as a two-fold process whereby the paramount objective is to complete a specific program or project, either construction-based or operations-based, safely and with minimal worker, public or environmental impacts. The second objective is completion within the baseline budget and schedule so as to meet either program or personal performance objectives or both.

RISK MANAGEMENT REQUIREMENTS

EPA

When the scope of a project or task involves the clean-up of contaminated facilities or sites, which is a major activity at most DOE sites, the essential elements for risk management are the nine evaluation criteria used by the EPA in their three step remedy selection process. These criteria include:

- **Threshold Criteria**
    - Overall protection of human health and the environment
    - Compliance with applicable or relevant and appropriate requirements (ARARS)
- **Primary Balancing Criteria**
    - Long term effectiveness and permanence
    - Reduction of toxicity, mobility, or volume through treatment
    - Short term effectiveness
    - Implementability
    - Cost
- **Modifying Criteria**
    - State acceptance
    - Community acceptance

The definition of the criteria and an explanation of the selection process is provided in several EPA documents (3) (4). Additionally, these same criteria will be used in determining the acceptability of waste management and disposal programs for both operational solid wastes and wastes generated during site restoration.

OSHA

OSHA risk management requirements are essentially addressed through Health and Safety Plans, which cover the equipment, systems, training, monitoring, and other processes required to ensure safe working environments and avoidance of accidents (5). Basically their risk management requirements specify that employers:

- Maintain conditions or adopt practices reasonably necessary and appropriate to protect workers on the job,
- Be familiar with and comply with standards applicable to their establishments, and
- Ensure that employees have and use personal protective equipment when required for safety and health.

NRC

The NRC approach to risk management is essentially contained in their technical specifications requirements for facilities producing or using nuclear materials (6). The NRC requires that each license application include technical specifications, derived from the safety analysis report, that cover the following:

- Safety limits, limiting safety systems, and limiting control settings
- Limiting conditions for operation
- Surveillance Requirements
- Design Features
- Administrative Controls
- Decommissioning
- Initial Notification, and
- Written Reports.

Essentially, the NRC uses a combination of structural, mechanical, and I&C systems with the appropriate education, training, experience, and quality checks to manage the risks of accidental exposures or releases.

DOE

Risk management in DOE is implemented through DOE Order (O) 413.3 (7) and DOE Manual (M) 413.3-1 (8) and includes, as a foundation, two basic elements:

- A strong Integrated Safety Management System and
- Comprehensive and thorough Environmental Safety, Health, and Quality Assurance Programs.

These elements, when fully and effectively implemented and maintained, will eliminate accidents, injuries, and unplanned exposures, which are also the most significant cost/schedule risks.

Chapter III of DOE O 413.3 states:

> "An essential part of project planning is to ensure that the risks associated with the project have been identified, analyzed, and determined to be either eliminated, mitigated, or manageable. Risk identification and analyses should be continued through the succeeding stages, including the Acquisition Plan and the Project Execution Plan. Each of the identified risks is monitored at future CD and review points to ensure that they have been satisfactorily addressed, eliminated, mitigated, or managed."

Chapter 14 of DOE M 413.3-1 provides extensive guidance on risk management during the four major program/project phases: planning, assessment (includes risk identification and analysis), handling (management during implementation), and monitoring. Corrective action as a concurrent activity during both the planning and monitoring phases should also be added as a fifth element. More specifically, Chapter 14 of DOE M 413.3-1 states managers should follow the guidelines below to ensure effective risk management:

- Assess project risks using a structured process, and develop strategies to manage risks throughout each acquisition phase.

- Identify early and intensively- managed design parameters that critically affect cost, capability, or readiness
- Use technology demonstrations/modeling/simulation and aggressive prototyping to reduce risks
- Use test and evaluation as a means of quantifying the results of the risk handling process
- Include industry and user participation in risk management
- Use developmental test and evaluation when appropriate
- Establish a series of "risk assessment reviews" to evaluate the effectiveness of risk handling against clearly defined success criteria
- Establish the means and format to communicate risk information and to train participants in risk management
- Prepare an assessment training package for members of the Integrated Project Team and others, as needed, and
- Acquire approval of accepted risks at the appropriate decision level.

RISK MANAGEMENT APPROACH

For the purposes of the approach described in this paper, we define risk management as *"A Comprehensive Planning and Implementation Program that integrates the technical, safety, quality, cost, schedule, and third party aspects of a project into a Risk Management Plan the achieves scope, schedule and budget objectives."*

Through application at various DOE sites, we have determined that the above criteria can be integrated and addressed through a four phase risk management approach that involves:

- Risk Evaluation – both quantitative and qualitative
- Risk Assessment – developing and employing a scoring algorithm
- Risk Mitigation – reducing or eliminating risk through mitigation, avoidance, or transfer
- Risk Monitoring & Reassessment – continuous evaluation of risk management throughout project implementation

The Risk Management approach presented in this paper integrates the requirements and guidance presented in DOE O 413.3 and DOE M 413.3-1 and the basic alternative analysis process from CERCLA.. Further, to be successful, this risk management approach must also be:

- Comprehensive – risk management must be applied to all activities and tasks
- Team-based – all members of project team must contribute
- Formal – the evaluation factors from CERCLA are used as the basis for alternative analysis related to risks and possible mitigation approaches
- Graded – the level of detail is developed only to the extent needed for competent/thorough analysis of effectiveness, implementability, schedule, and cost and to reduce performance uncertainties to acceptable levels.
- Monitored/Evaluated – as each task or project progresses, a continuing evaluation of the risks expected versus the actual risk is essential and immediate work adjustments are essential to keep the risk minimized.

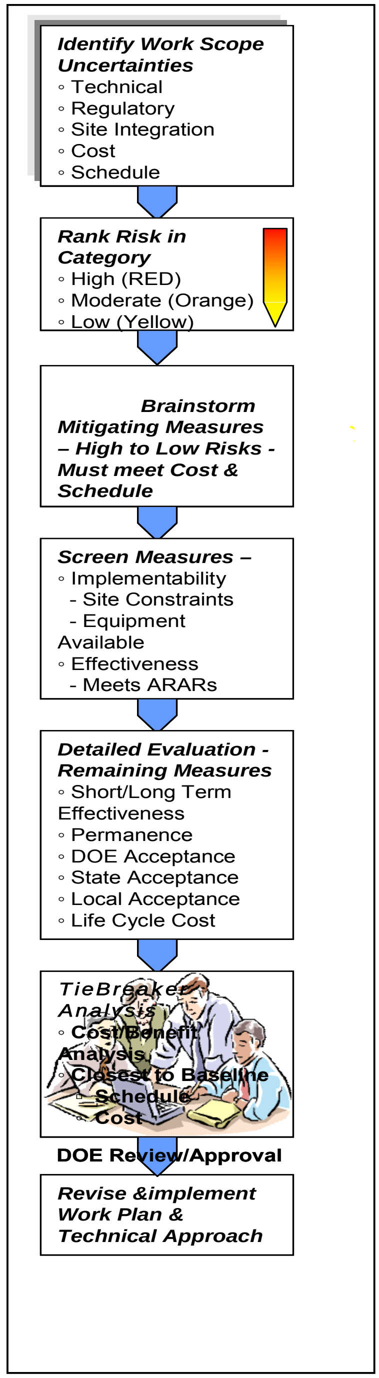

Fig. 1. The Logical Steps for Risk Management.

The overall approach to risk management, as presented in Figure 1, is centered on the development of a comprehensive Risk Management Plan that specifies a standard approach to risk planning, identification, assessment, mitigation, tracking of task and program risk elements, and applying lessons learned to future actions. It is essential that all the risk elements identified for any project or task be addressed, even if that is just formal documentation of the acceptance of that risk. The Risk Management Plan is a living document that evolves as the program becomes more defined, enabling the management team to continually narrow the focus on risk management issues.

Risk Evaluation

Risk evaluation involves both: **Quantitative** assessments for proven processes or a well-defined project objective and **Qualitative** assessments where technology or project uncertainties are more prevalent.

Whether we employ a qualitative or quantitative approach to risk assessment, the objective of risk evaluation is to define the probability of occurrence of a risk element and the consequence of the occurrence. The essential first step of risk evaluation is a thorough evaluation of all of the activities and elements of the Statement of Work (SOW) and the identification of any Work Scope Uncertainties. Work Scope Uncertainties (WSU) are those components of work planning and implementation used to develop the baseline or the basic work plan, budget and schedule, and thus, if different than assumed or planned, would cause changes in cost and schedule. The clearer and better defined the SOW is, the fewer WSUs and the lower the risk. Generally, though, we have found that SOWs for remediation, waste management, or D&D projects contain significant WSUs that must be risk evaluated and then mitigated. Similar WSUs are present in all nuclear facility modification or construction projects.

Through our experience in reviewing numerous SOWs for a wide diversity of projects, we have found that most of the WSUs can assigned to one of the following four categories:

1. Characterization,
2. Regulatory,
3. Technical, and
4. Execution.

The types of WSUs that can be found in each of the above categories for a typical environmental restoration project at a DOE site is presented in Table I.

Table I. Examples of Work Scope Uncertainties for a typical site restoration program showing Types of Risks and Factors Considered

- Characterization
  - Quantity, type, and composition of Solid Waste Management Units poorly defined
  - Quantity, composition, and classification of materials in Waste Management Areas not well defined
  - Extent of facility contamination not well defined
  - Extent of groundwater and/or soil contamination not well defined
- Regulatory (permits/standards)
  - Potential change in TCE cleanup standard
  - Delays in approval process for cleanup plans, treatment plans, etc.
  - Questions of acceptance of alternate proposals such as Monitored Natural Attenuation by regulators
- Technical (Process/Operations)
  - Construction methods not proven on local conditions
  - Estimated effectiveness of groundwater remediation (i.e. pump & treat) unproven at site
  - Optimistic estimate of availability of specialized equipment in required timeframe
- Execution
  - Change in the availability of off-site treatment/disposal facilities and any associated specialized transport systems could delay cleanup
  - WorkForce - loss of critical skills; strikes,
  - Restriction on space available for laydown yards, assembly yards, etc. may result in need to perform work off-site and drive up costs
  - Other site activities could cause delays (i.e. safety shutdowns, traffic impacts on project operations)
  - Forces of Nature
  - Sabotage/Terrorism
  - Funding – impacts of Continuing Resolution or reprogramming.

An example of the results of using this approach to identify WSUs was the conduct of a Probability Risk Assessment (PRA) as part of the development of the proposed cleanup plan for the Solar Pond Remediation Project at Rocky Flats in the mid 1990's. One of the first activities conducted was a thorough review of the SOW to identify the WSUs. For that project, the most significant WSUs included:

- Characterization – extent and volume of contaminated soil below the ponds was undefined. Also, the volume and contents of process sludge in the ponds was not fully defined.
- Regulatory – Implementation of any of the proposed cleanup alternatives would require a modification to the RCRA permit. The estimates of the time required to achieve this modification were found to be greatly underestimated.
- Technical – The plan for processing and containerizing the sludge for disposal was based upon an innovative processing system. A detailed review of the system design indicated WSUs with respect to uniformity of treatment and achievement of the Waste Acceptance Criteria (WAC) for the NTS.
- Execution – the largest WSU in this area was the future availability of the NTS for disposal of the wastes assuming they met the WAC.

This analysis, when complimented by the rigorous risk assessment inherent to a PRA, enabled the site to prepare and defend a realistic budget and schedule for the proposed cleanup alternative.

The risk evaluation should be performed by an Integrated Project Team (IPT) that includes all the key technical and operations specialists as well as ES&H personnel from the site or program office. It is also advisable to include several non-project personnel with experience with comparable SOWs on other projects or sites. Effectively, this approach integrates peer review into the evaluation process thereby saving time during the project planning stage.

The net result of the evaluation process is a summary list of WSUs for the entire SOW that are then assessed for the magnitude of risk for each WSU.

Risk Assessment

The risks identified in the first phase should be assessed using the risk management approach specified **in DOE M 413.3-1.** Risk assessment begins with a qualitative assessment of identified risk elements in order to categorize each risk as high, moderate, or low level. The definition of each level is subjective and should be made with consideration of the specific Work Scope and site. An example of risk level definitions that were developed for a major environmental restoration project are presented in Table II.

Table II. SUGGESTED RISK LEVEL DEFINITIONS:

- ***LOW –*** any activity that, if different from plan, causes a less than 5% overage in budget or less than 10% or three weeks extension of schedule, which ever is less. **NOTE: Any Schedule variance that cause missed milestones are either a Moderate or High Risk**
- ***MODERATE -*** anything that would cause costs to be from 5 to 10% over budget or schedules to slip by from 1-3 months plus any milestone misses that only result in loss of fee.
- ***HIGH -*** any cost growth over 10% or schedule slippage of more than 3 months and any risk elements that are beyond the control of CPC plus all milestone misses that result in Notices of Violations (NOVs), fines or penalties.

Once the levels are established, each risk is then scored. For elements in the high and moderate levels, a quantitative scoring of the risk is calculated on a pre-mitigated basis. If the scoring confirms the risk level, the IPT is tasked to develop a mitigation action plan for each risk.

Our suggested risk management approach involves five steps:

1. Rank the SOW activities from highest to lowest risk to workers, public, environment and possibility of Notices of Violations, fines or penalties.

2. Weight the SOW activities ranking. This is subjective and generally is based on the expected work effort (budget) and the complexity of the activity.
3. Determine the level of risk (Table II) for the WSUs for each SOW activity.
4. Assign a weight to each risk level. In the examples presented, High=5, Moderate=3, Low=1.
5. Calculate the total weighted risk for each WSU category and component by SOW

As an example of the application of the above approach, **we** evaluated the WSUs for the SOW for the recently solicited Paducah Environmental Restoration Support Contract and ranked the risks as shown in Table III. We chose this contract because its SOW includes almost all of the types of tasks and activities that would be expected for any environmental restoration project for DOE.

As an example of how the weighting and scores shown in Table III were derived, the evaluation of PCB Activities, SOW C.1.7, for the Paducah Environmental Restoration (ER) Contract per Step 1 above indicated that the relative ranking of that activity with respect to all the activities included in the Paducah was as the 7th highest risk with a weight of 7. A key assumption for that activity is that the TSCA incinerator will be available when/as needed. This assumption is categorized as an **External** WSU **Third Party Support** component, since the TSCA Incinerator is controlled by DOE-ORO. Review of available information by the subject matter experts on the Integrated Project Team indicates that it is very likely that the incinerator will NOT be available as and when needed, which will cause cost growth in excess of 10% and several months schedule slippage if not mitigated. Thus, per our definitions, this WSU is considered to be a **HIGH** Risk. and assigned a WSU weight of 35 (Rank=7 x Risk Level=5) .

TABLE III. Risk Associated with Each SOW Element – Paducah ER Support

Work Scope ► Uncertainty	**Characterization**		**Regulatory**			**Technical**							**Total**
SOW Element (Weighted in order of cost/schedule impacts of failure) ▼	Quantity	Content	Standards/Regs	RODs/Orders	Permits/Licenses	Process	Operations	Site Integration	Work Force	Unforeseen acts	Third Party Supt	Forces of Nature	
Source Control Weight 10	**H** 50	**M** 30	**L** 10	M 30	M 30	H 50	H 50	H 50	L 10	L 10	L 10	L 10	**330**
Plume Containment **Weight 10**	M 30	L 10	H 50	H 50	H 50	H 50	L 10	L 10	L 10	L 10	L 10	L 10	**290**
DMSAs **Weight 9**	H 45	H 45	L 9	L 9	M 27	L 9	M 27	M 27	L 9	L 9	H 45	M 27	**288**
Waste Disposition **Weight 9**	M 27	M 27	L 9	L 9	L 9	M 27	L 9	M 27	M 27	L 9	H 45	L 9	**225**
D&D of C-410/420 **Weight 9**	M 27	M 27	L 9	M 27	L 9	M 27	M 27	L 9	L 9	L 9	L 9	L 9	**198**
N-S Ditch Sec 3-5 **Weight 8**	M 24	M 24	L 8	L 8	L 8	L 8	L 8	L 8	L 8	M 24	L 8	M 24	**160**
PCBs Activities **Weight 7**	M 21	L 7	L 7	L 7	M 21	M 21	M 21	M 21	L 7	L 7	H 35	L 7	**180**
DUF6 Cylinder Mgt **Weight 6**	L 6	L 6	L 6	M 18	L 6	L 6	L 6	H 30	L 6	L 6	H 30	L 6	**150**
N-S Ditch Sec 1-2 **Weight 5**	M 15	M 15	L 5	L 5	L 5	L 5	L 5	L 5	L 5	L 5	L 5	M 15	**90**
Scrap Metal **Weight 5**	L 5	L 5	L 5	L 5	L 5	L 5	M 15	L 5	L 5	L 5	M 15	L 5	**80**
Inactive Facilities **Weight 5**	L 5	M 15	L 5	L 5	L 5	L 5	L 5	L 5	L 5	L 5	L 5	L 5	**70**
Sediment Controls **Weight 4**	L 4	L 4	L 4	M 12	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	**56**
S&M -C-340 Complex **Weight 4**	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	L 4	**48**
Grdwater Site Assesmnt **Weight 3**	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	**36**
Disposal Cell Planning **Weight 3**	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	L 3	**36**
Env. Monitoring & Surv **Weight 2**	L 2	L 2	L 2	L 2	L 2	L 2	L 2	L 2	L 2	L 2	L 2	L 2	**24**
Project Support **Weight 1**	L 1	L 1	L 1	M 3	L 1	L 1	L 1	M 3	L 1	L 1	L 1	L 1	**16**

Mitigation Approach

To develop the mitigation action plan, the IPT will consider as many alternatives as are reasonable and evaluate each alternative using the process shown in Figure 1. The output is a re-scoring of the risk element on a post-mitigation basis and the selection of the mitigation strategy that will provide the necessary risk reduction. Comparable to the definition of risk, the mitigation approach should be tailored for each project based upon size, complexity, location, and other site-specific considerations. A typical risk handling approach for each work scope uncertainty associated with environmental restoration work on a DOE site is described below:

- **Low Risks -** If risk is defined (whether qualitatively or quantitatively) as low, it is a common practice, with the concurrence of DOE, to choose to accept the risk. For cost & schedule purposes, low risk is defined as anything that would either cause a less than 5% overage in budget or either a less than 10% or three weeks extension of schedule, which ever is less.

- **Moderate or high level Risks** – The options are mitigate, avoid, or transfer the risk as discussed below. Moderate risks are defined as anything that would cause costs to be from 5 to 10% over budget or schedules to slip by from 1-3 months. High risks are defined as any cost growth over 10% or schedule slippage of more than 3 months and any risk elements that are beyond the control of the contractor.

  a. Mitigate – Revise technical approach to eliminate the risk. This could include revisions (one-time exceptions) to the regulatory requirements. Preferred mitigations would meet overall scope, budget and schedule objectives but could include a change in work sequence within the schedule.
  b. Avoid – Examples of avoidance is to negotiate a regulatory change that eliminates the risk element. For example, if a cleanup may create greater risk than leaving it in place, an avoidance strategy would be to petition the regulators for administrative/access controls instead of the removal.
  c. Transfer - In some cases, mitigation of a risk might be beyond our control. For example, the availability of the Oak Ridge TSCA incinerator may be essential for treatment and disposal of certain waste streams, but neither the specific DOE site nor the contractor have control over that incinerator. In these cases, a suggested approach is to transfer the risk to the source with the most control in mitigating the risk and develop an agreement that compensates DOE and the contractor for any cost growth or schedule delays caused by the controlling source.

When all of the risks have been linked with an appropriate mitigation strategy, the IPT summarizes them in the Risk Management Plan. The plan should also contain a summary of the alternate mitigation strategies that were considered and the major reasons they were not selected. This summary will be helpful during project implementation should new risks or significantly different risks be identified since they will expedite the assessment and mitigation process.

Risk Monitoring and Reassessment.

Thorough risk evaluation, assessment and mitigation, as documented in a Risk Management Plan, does not guarantee the smooth and risk-free completion of any project or task. It require a standard, proven system of project management and controls to ensure that identified risks remain mitigated or controlled as plans and that any newly detected risks are quickly identified and mitigated. Maintaining a close watch and control on risk during project execution requires a continuous assessment of the five principal facets of any project or task:

- Work Scope,
- Safety,
- Budget,
- Schedule,
- Quality.

The assessment of the activities associated with each of the above facets is most effectively accomplished through the application of the principles and practices of the DOE Integrated Management System (DOE M 411.1-1C) (9) By applying the ISMS based work administration process throughout the duration of a project, management is able to measure performance against work scope, cost, and schedule; identify areas of accelerated or lagging performance; evaluate the effectiveness of the Risk Management Plan and take management action to maintain cost and schedule. This process, which is depicted graphically in Figure 2, uses the standard management tools such as daily safety statistics, Earned Value analysis, Estimates to Complete and at Completion, Cost Performance Index, Schedule Performance Index, and quality audits to determine the status of the Actual Work Performed versus the Planned Work.

Activities → Elements ↓	Planning	Performing	Measuring	Adjusting	Continuin g	Close Out
Work Scope	◦ Technical Approach ◦ Sequence of Ops ◦ Risk Management	◦ Plan of Day	◦ % complete ◦ Quantities ◦ Activities	◦ Assess Variances ◦ Assess Risk ◦ Revise Plans	◦ New sequence of operations	◦ Owner Acceptance ◦ Operator trng ◦ Final Report
Safety	◦ ESH Requirements ◦ Hazards Controls ◦ ISMS Program	◦ Tailgate ◦ Monitoring ◦ Weekly Safety Meeting	◦ EMR ◦ OSHA reports ◦ Lost workdays	◦ Revised hazard controls ◦ Revised monitoring	◦ Revised HASP & job controls	◦ Shakedown tests – safety systems
Budget	◦ Labor ◦ Equipment ◦ Mtls & Supplies ◦ Other Costs	◦ Timesheets ◦ Accruals ◦ Commitmen ts	◦ CPI - Cost Performance Index ◦ EAC ◦ Earned Value	◦ ETC ◦ Internal reallocation ◦ Change Orders	◦ New budget breakdown by task/work remaining	◦ Final ACWP ◦ Final CPI
Schedule	◦ WBS ◦ Milestones ◦ Deliverables	◦ Reports ◦ Baseline Maintenance	◦ SPI - Schedule Performance Index	◦ Review Critical Path ◦ Revise Baselines ◦ Change Orders	◦ Revised CP schedule ◦ Increased LOE	◦ Final SPI
Quality	◦ Performance Measures ◦ Acceptance Criteria ◦ Incentives	◦ Inspections ◦ Sampling ◦ Audits	◦ Testing ◦ Specification Conformance	◦ Change suppliers ◦ Review/adjust technical specs. ◦ Increased audits l	◦ More rigorous testing & inspections	◦ Regulator acceptance ◦ Permits & licenses approval
Lessons Learned/Continuous Improvement						

Fig. 2. Risk Monitoring Process.

CONCLUSIONS

Risk is inherent in every activity we undertake. Risk mitigation is also a part of every activity: it generally is manifested in the terms of minimum standards and requirements for the workforce and supporting facilities and equipment, and plans, manuals and procedures that are designed to enable the worker to accomplish the task to the specifications of the client and with minimal risk to either personal or public safety and within the expected budget and schedule. Risk management is then the application of good project planning and management with an emphasis on the reality and probability of occurrence of all of the assumptions used to develop the project plan. By applying a disciplined risk management approach as described in this paper during both the planning and implementation stage, the management team can identify both internal and external risks, assess their potential impacts on project implementation, and develop controlling and/or mitigating measures that minimize the risks.

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