Regulatory Compliance - A Burden or an Opportunity?

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ABSTRACT

All businesses must face the often, onerous task of complying with the many regulations. Should this compliance responsibility be considered a burden, or can it truly be turned into an opportunity for improving the functioning and cost effectiveness of business? All businesses stand to gain significant benefits if essential management system elements are in place. This paper will be informative presentation on integrated management of regulatory compliance with close attention to concepts that will enable businesses to improve the bottom line while ensuring regulatory compliance. A discussion of "System Elements Essential for Effective Management" will be discussed.

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Presented by:

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Be Reactive and Carry the Burden or Proactive and Benefit

Who needs it? Why should I be burdened by regulations when I am struggling to be profitable or effective? Who needs the added complications regulatory compliance brings when meeting my customer demands seems to be burden enough? Can I avoid the expensive OSHA fines, high worker compensation costs, loss of essential personnel due to injury, high fines or shutdown due to environmental incident? Business penalties can be ominous.

Recent US statistics include:

- 5,100 deaths and 3,800,000 injuries on-the-job,

- $30,000 to $40,000 cost for each disabling injury (includes indirect costs),

- $910,000 cost for each work related death,

- $250,000 in fines for the average EPA citation.

An OSHA Process Safety Management (PSM) standard covered process incident can easily result in fines of $500,000 or more.

All businesses and organizations face the often, onerous tasks of complying with the many regulations intended to protect people from injury or protect the environment from damage. Should this compliance responsibility be addressed as a burden, or can it truly be an opportunity for improving the functioning and cost-effectiveness of our business? The simple answer: *proactive management of regulatory compliance improves the bottom line!*

The same management systems, which improve compliance effectiveness, aid in profitability. All businesses stand to gain significant benefits if essential management system elements are in place. What are the benefits? If we consider the $500,000 fine for a PSM incident, the benefit for avoiding the fine, in a business that achieves 5% after tax profits, is equivalent to $10 million dollars in additional sales. Similarly, the profit from a reduction of 25 lost workday cases in a business is also equivalent to an increase in sales of $10 million. If the business' profit after taxes is less than 5%, the benefit is greater.

Many businesses and organizations have worked voluntarily and proactively to develop management systems for Total Quality Management (TQM). Meeting the requirements of ISO-9000, the International Standards Organization, quality system, helps businesses gain market recognition and new customers. Similarly, chemical related businesses have worked toward complying with the elements of the American Chemical Council, Responsible Care® codes of management practices.

All businesses <u>must</u> work to comply with applicable OSHA and EPA requirements. It is not an option! Efforts toward compliance with the requirements of safety and environmental regulations provide opportunities to improve existing management systems or to develop or refine necessary elements. Some regulations such as the OSHA PSM standard, the EPA Risk Management Program (EPA RMP), and the Food and Drug Administration (FDA) GMP requirements for manufacturing mandate documented management systems. All businesses and organizations will realize benefits by adopting the management systems required for compliance with these standards. By addressing compliance requirements proactively, using effective management systems, there will be substantial value added benefits. All aspects of the business will experience improvement.

Continuous Improvement Process - Integrating Systems

How can we accomplish meeting all the requirements of safety and environmental regulations; meet requirements such as OSHA PSM, EPA RMP, and FDA requirements for management systems; meet market driven requirements for total quality management systems, Responsible Care®, ISO-9000 and ISO 14000 and still remain effective and profitable? This complex question arises more and more frequently as we struggle to profitably satisfy the increased demands upon every aspect of our businesses. In managing safety and environmental responsibilities, the issues become most apparent when we are auditing or assessing a facility or business unit for program effectiveness.

Our experience tells us that "integrating management systems for continuous improvement" becomes a key mission concept and aids in the process for success. How can an organization begin to apply this concept? What are the common elements of an effective management system? With so many issues to face, how does one start? Which issues should be addressed first? Where is our business in this process? To answer these questions, an organization must have a clear understanding of the need for management systems and where they are in the process. The top management of the organization must be clearly and visibly behind the process.

First and foremost, management systems must be put in place or enhanced, if lacking. By necessity, the requirements for managing specific issues effectively, even diverse issues such as safely entering confined spaces, or quality assurance testing of raw materials, requires essential management system elements be addressed. Often, when carrying out auditing or compliance assessment activities, it can be observed that the elements necessary for management are not clearly defined. When evaluating for the cause of an incident, it is common to find that the incident can be traced to a failure to have recognized the need for formal management systems, or failure to address the need for a critical management system element. There are often opportunities for integrating systems. For example, a PSM incident may have been due to an inadequate system for managing change, yet there is a working FDA required management of change (MOC) system in-place at the site. The incident would have been less likely if there were one integrated system for MOC instead of having two separate systems. If the OSHA PSM required MOC system was integrated with the MOC system required for FDA, procedures would have been consistent and the training simplified. The avoidance of injuries to personnel, fines

for the incident, shut-down of the unit, and the dramatic costs for improving systems under the scrutiny of OSHA and EPA would have saved hundreds of thousands of dollars and the operations would have been smoother running.

System Elements - Essential for Effective Management

There are certain essential management system elements, which must be in place, in order to provide effective results. Establishing the essential system elements for management will ensure meeting organizational goals and objectives. The systems must be compatible with those developed to comply with the requirements of regulations such as OSHA PSM, EPA RMP and the FDA requirements for management systems. In addition, the established quality process systems such as ISO-9000, ISO-14000, and industry protocols such as Responsible Care® of the American Chemistry Council can be managed. In order to be effective in the long term, systems to manage all aspects of an organization would be integrated into one seamless process of continuous improvement.

Policy and Goals

Policies, goals, objectives and regulatory compliance requirements must be defined if people within or impacted by an organization are to meet them effectively. It is important that those impacted know the reasons behind the policies, goals and regulatory compliance requirements. The commitment and support of the organization's top management must be clearly stated in policy and goals. People within the organization, at all levels, must be aware of both the overall organization's objectives, in addition to any sub-group or function's objectives. Documenting and defining objectives will aid in establishing effective systems. Affected people must be aware of when to use a particular procedure, which strives to meet the driving policies, goals, and regulations.

Requirements

Requirements for meeting policies, goals, and regulations must be clearly defined and documented. The evolving methods arising from total quality management methods such as ISO-9000 are ideally suited to aid in defining requirements. Once requirements are defined and clearly understood, steps can be taken to develop procedures.

Procedures

The requirements for compliance with policies, goals, and regulations, which have been defined, can then be used for developing documented procedures, which will allow affected people to follow them or be guided by them. Documentation of those procedures is an essential step if affected people are to be trained. Procedures must be clean, concise, and understandable by those who are to follow them. All critical steps must be included.

Training

Training is likely the most critical element to ensure that, policies and goals, with their resulting procedures are understood. The required activities must be completed or carried out. Affected people must understand the "who, what, why, when, where, and how" of the required procedures. In addition, records of those who require, and those who received training, are essential controls. Once trained, the procedures must be used or followed to ensure effective management.

Application

Once affected people are trained in the objectives, goals, and the procedures developed to meet the requirements defined, they can strive to apply the training received. Only after application of the procedures developed, can an evaluation be made to determine whether the objectives defined have been met and those procedures are effective.

Auditing and Verification

It is essential to effective management, that there are systems, for auditing or verifying that procedures are meeting and satisfying the requirements. Some standards such as the OSHA PSM standard and the EPA Risk Management Program mandate auditing program and system effectiveness. Actual use of the procedures and compliance with policies, goals, and regulations must be audited or tested. In addition, there must be auditing or verification processes, which ensure the procedures are used whenever they are required.

System for Defining Responsibility and Accountability

To ensure that all requirements, goals, and objectives are met in a manner that provides regulatory compliance, responsibilities for key roles and activities must be defined. There must be a system of accountability if systems are to be effective and follow through is ensured. The definition of responsibility and accountability is essential for auditing and testing of systems. To avoid business liabilities in the prevention of an incident or system failure, having defined responsibilities and accountabilities is critical. Failure to define responsibilities and establish accountability can result is very costly human and financial penalties.

Management of Change (MOC)

Continuous improvement requires and allows for a positive evolutionary process. All aspects of the management system and its revisions, additions, or evolutions must be managed and documented, and people retrained. Changes in processes, controls, personnel and management must be addressed. The system must be kept evergreen.

System Documentation

If management systems are to be effective, all aspects of all system elements must be documented. Documentation is essential to allow those management systems to be audited. For optimum effectiveness, documentation must be complete and concise.

Integrating Management Systems for Continuous Improvement

Proactively take the steps toward continuous improvement. Do not wait for an incident or a regulatory compliance audit to provide the motivation. If your organization has TQM or ISO systems in place, use those systems as the framework for regulatory compliance. Conduct an audit of your safety, health, and environmental regulatory compliance. Use the findings of that audit to help define the priorities. All businesses will have some systems for management, which have led to their success. Define the opportunities for integrating and enhancing those systems into one seamless process for continuous improvement.

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Martin Siecke (Marty) has more than 35 years experience in Safety, Health, and Environmental Management. He served National Starch and Chemical, as its first Corporate Safety Manager after over 20 years in engineering and operations management. After retiring in 2000, Marty joined *PSRG*, a company providing safety, health, environmental, and energy management services to industries at home and abroad.

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Robert Weber (Bob) is the founder of PSRG, a company dedicated to providing the finest quality, most responsive, and highly cost-effective process safety management, risk management, loss prevention, and process plant reliability consulting and training services to the oil and gas, refining, petrochemical/chemical, food processing, pharmaceutical, and other industries worldwide.