Maintenance Management and Regulatory Requirements

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Maintenance Management and Regulatory Compliance Strategies is designed to create an awareness of how a maintenance management function for a company can contribute or detract from a company's compliance with regulatory requirements. The paper is not designed to provide a complete listing of every possible regulatory requirement and how maintenance managers can impact these requirements. The paper is designed to give an overview of each of the four major compliance programs. It is also going to provide a cross-section of regulations for each component of a maintenance strategy and how it may impact it, including some little-known regulations of which most companies will find themselves in violation.

The four major areas the paper addresses are:

1. OSHA
2. EPA
3. FDA
4. ISO-9000

OSHA

OSHA deals with the health and safety of workers in the workplace. Many OSHA regulations are written directly for individuals in maintenance-related departments within a company.

What is OSHA?
OSHA is a U.S. government office (www.OSHA.gov) with the following mission statement:

The mission of the Occupational Safety and Health Administration (OSHA) is to save lives, prevent injuries and protect the health of America's workers. To accomplish this, federal and state governments must work in partnership with the more than 100 million working men and women and their six and a half million employers who are covered by the Occupational Safety and Health Act of 1970.

OSHA Services
OSHA and its state partners have approximately 2100 inspectors, plus complaint discrimination investigators, engineers, physicians, educators, standards writers, and other technical and support personnel spread over more than 200 offices throughout the country. This staff establishes protective standards, enforces these standards, and reaches out to employers and employees through technical assistance and consultation programs.

OSHA's Domain
Nearly every working man and woman in the nation comes under OSHA's jurisdiction (with some exceptions such as miners, transportation workers, many public employees, and the self-employed). Other users and recipients of OSHA services include occupational safety and health professionals, the academic com-

munity, lawyers, journalists, and personnel of other government entities. *

*The above material is derived from documentation posted on the OSHA website.

Note: While the OSHA standards (29 CFR) encompass regulations from part 70 – 71, part 1900 through 2400, the OSHA section of this book will focus on part 1910, where the majority of the general requirements are contained.

EPA

The mission of the U.S. Environmental Protection Agency is to protect human health and to safeguard the natural environment-- air, water, and land—upon which life depends (www.epa.gov)

EPA's purpose is to ensure that:

- All Americans are protected from significant risks to human health and the environment where they live, learn, and work.
- National efforts to reduce environmental risk are based on the best available scientific information.
- Federal laws protecting human health and the environment are enforced fairly and effectively.
- Environmental protection is an integral consideration in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade, and these factors are similarly considered in establishing envi ronmental policy.
- All parts of society--communities, individuals, business, state and local governments, tribal governments--have access to accurate information sufficient to participate effectively in managing human health and environmental risks.
- Environmental protection contributes to making our communities and ecosystems diverse, sustainable, and economically productive.
- The United States plays a leadership role in working with other nations to protect the global environment.

EPA deals with pollutants that may be released during a plant's operation. There are many regulatory requirements for maintenance related to record keeping and service of environmentally sensitive equipment.

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FDA

The Food and Drug Administration (www.fda.org) touches the lives of virtually every American every day for it is FDA's job to examine the following:

- Food
- Cosmetics
- Medicines
- Medical devices
- Radiation-emitting products
- Feed and drugs for pets and farm animals

First and foremost, FDA is a public health agency, charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws.

A primary mission of the Food and Drug Administration is to conduct comprehensive regulatory coverage of all aspects of production and distribution of drugs and drug products to assure that such products meet the 501(a)(2)(B) requirements of the Act. FDA has developed two basic strategies:

1. Evaluating through factory inspections, including the collection and analysis of associated samples, the conditions and practices under which drugs and drug products are manufactured, packed, tested, and held, and

2. Monitoring the quality of drugs and drug products through surveillance activities such as sampling and analyzing products in distribution.

This compliance program is designed to provide guidance for implementing the first strategy. Products from production and distribution facilities covered under this program are consistently of acceptable quality if the firm is operating in a state of control. The Drug Product Surveillance Program (CP 7356.008) provides guidance for the latter strategy.

The inspectional guidance in this program is structured to provide for efficient use of resources devoted to routine surveillance coverage, recognizing that in-depth coverage of all systems and all processes is not feasible for all firms on a biennial basis. It also provides for follow-up compliance coverage as needed.

FDA also ensures that all of these products are labeled truthfully with the information that people need to use them properly.

FDA investigators and inspectors visit more than 15,000 facilities a year, seeing that products are made safely and labeled truthfully. As part of their inspections, they collect about 80,000 domestic and imported product samples for examination by FDA scientists or for label checks.

If a company is found violating any of the laws that FDA enforces, FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product from the market. A recall is generally the fastest and most effective way to protect the public from an unsafe product.

When a company can't or won't correct a public health problem with one of its products voluntarily, FDA has legal sanctions it can bring to bear. The agency can go to court to force a company to stop selling a product and to have items already produced seized and destroyed. When warranted, criminal penalties--including prison sentences-- are sought against manufacturers and distributors.

Assessing risks-- and, for drugs and medical devices, weighing risks against benefits-- is at the core of FDA's public health protection duties. By ensuring that products and producers meet certain standards, FDA protects consumers and enables them to know what they're buying. For example, the agency requires that drugs--both prescription and over-the-counter--be proven safe and effective.

In deciding whether to approve new drugs, FDA does not do the research, but rather examines the results of studies done by the manufacturer. The agency must determine that the new drug produces the benefits it's supposed to provide without causing side effects that would outweigh those benefits.

FDA deals with equipment that is used to preclude produce food beverage and pharmaceutical products. There are many regulations that focus on the equipment used in manufacturing processes.

ISO-9000

In 1987, The International Standards Organization first published the standards on quality assurance, known as the ISO-9000 standards. There are three main models for the standards:

1. ISO-9001 – This standard is for companies whose conformity to specified requirements is met throughout the whole cycle from product design to product service. This is the most complete and stringent of the standards.
2. ISO-9002 – This standard is for companies that want to demonstrate their conformity to standards in production and installation.
3. ISO-9003 – This standard is for companies that need to demonstrate their capabilities in the inspection and testing, where the product is specifically for those requirements.

ISO-9000 regulations deal with quality and how equipment can impact quality. Many calibration and inspection items are required for maintenance. This book will highlight areas in which maintenance compliance is required to produce a quality product and meet the quality standards. Once again, the book is not so all-inclusive as to contain all the regulations. However, a good cross-section of regulations will be examined so that individuals can help assure their company's compliance.

The regulatory agencies described here are the most commonly encountered in companies in the United States. While some international companies are not bound by the regulatory agencies indigenous to the United States, they will typically have corresponding regulations in their particular country.

It is hoped that by understanding the standards in the context of maintenance (asset) management, compliance with these regulations will be easier to achieve and maintain.

Maintenance Management

Functional Maintenance Best Practices and Regulatory Compliance

In today's business environment, terms like best practices, benchmarking, and world class continuously bombard us. However, what are best practices? What are common functional best practices for maintenance or asset management that you can use to benchmark other companies in order to achieve best practices within your own organization? How do you know if you have achieved world-class status?

Best Practices Provide Competitive Advantage

A definition of best practices might begin with "the practices that enable a company to achieve a competitive advantage over its competitors in a specific business process." If that definition is adapted to the maintenance process, it would read: "The maintenance practices that enable a company to achieve a competitive advantage over its competitors in the maintenance process."

What are the functional best practices in maintenance management?

1. Preventive Maintenance
2. Inventory and Procurement
3. Work Flow and Controls
4. Computerized Maintenance Management System Usage
5. Technical and Interpersonal Skills
6. Operational Involvement
7. Predictive Maintenance
8. Reliability Centered Maintenance
9. Total Productive Maintenance
10. Financial Optimization
11. Continuous Improvement

Note – Figure One is taken from *Developing Performance Indicators for Managing Maintenance* Wireman, Terry. Industrial Press: New York City, New York. September 1998. ISBN 0831130806.

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1. Preventive Maintenance

The preventive maintenance (PM) program is the key to any attempt to improve the maintenance process. This program reduces the amount of reactive maintenance to a level that allows the other practices in the maintenance process to be effective. However, most companies in the United States have problems keeping the PM program focused. In fact, surveys have shown that only 20 percent of U.S. companies think their PM programs are effective.

Most companies need to focus on the basics of maintenance if they are to achieve any type of best-in-class status. Effective PM activities would enable a company to achieve a ratio of 80 percent proactive maintenance to 20 percent (or less) reactive maintenance. Once the ratios are at this level, other practices in the maintenance process become more effective.

When it comes to the issue of regulatory compliance, the preventive maintenance program is the single most essential function. The vast majority of regulations, whether for OSHA, EPA, FDA, or ISO, require maintaining assets in prime condition. In addition, the documentation necessary to achieve and maintain compliance is mainly a function of the preventive maintenance program.

2. Inventory and Procurement

The inventory and procurement programs must focus on providing the right parts at the right time. The goal is to have enough spare parts without having too many spare parts. However, the interdependency between the practices becomes apparent: No inventory and procurement process can cost-effectively service a reactive maintenance process. However, with the majority of maintenance work planned several weeks in advance, the practices within the inventory and procurement process can be optimized.

What level of performance is typical in companies today? Many companies see service levels below 90 percent, which means stock outs run greater than 10 percent of requests made. This level of service leaves customers (maintenance personnel) fending for themselves, stockpiling personal stores and circumventing the standard procurement channels to obtain their materials. They do not do this for personal reasons, but rather they want to provide service to their customers (operations or facilities). It is really a mechanism.

To prevent this situation, companies must institute the type of stores controls that will allow the service levels to reach 95 to 97 percent with 100 percent data accuracy. When this level of stores and procurement performance is achieved, you can then start the next step toward improvement.

These controls are imperative if all spare parts are to be tracked and controlled. Most regulatory programs require the tracking of spare parts and other materials that may have an impact on the integrity of the equipment or asset. In some cases, such as rebuildable spares, the tracking of the component is crucial to insure equipment/asset integrity. Such tracking requires tracing information not only about a location, but also about each individual component. Seemingly small details like this require extensive documentation and record keeping on the part of a maintenance organization.

3. Work Flows and Controls

This practice involves documenting and tracking the maintenance work that is performed. A work order

system is used to initiate, track, and record all maintenance activities. The work may start as a request that needs approval. Once approved, the work is planned, then scheduled, performed, and finally recorded. Unless the discipline is in place and enforced to follow this process, data is lost, and true analysis can never be performed.

The solution requires comprehensive use of the work order system to record all maintenance activities. Unless the work is tracked from request through completion, the data is fragmented and useless. If all of the maintenance activities are tracked through the work order system, then effective planning and scheduling can start.

Planning and scheduling requires someone to perform the following activities:

- Review the work submitted
- Approve the work
- Plan the work activities
- Schedule the work activities
- Record the completed work activities

Unless a disciplined process is followed for these steps, productivity decreases and reduced equipment downtime never occurs. Such results leave the perception that maintenance planning is a clerical function, making it vulnerable to the first cuts when any type of reduction in overhead costs is examined. At least 80 percent of all maintenance work should be planned on a weekly basis. In addition, the schedule compliance should be at least 90 percent on a weekly basis.

As respects the regulatory requirements, the work order function is crucial to recording all work that may have an impact on the equipment/assets. This documentation will include the date and time the work was performed and the detail of how the work was performed down to identifying the particular maintenance technician who performed the work and the skill level of the technician. These records may be kept manually, but in most cases are stored electronically in the computerized maintenance management system.

4. Computerized Maintenance Management Systems Usage

In most companies, the maintenance function utilizes sufficient data to require the computerization of the data flow. This facilitates the collection, processing, and analysis of the data. The usage of the Computerized Maintenance Management System (CMMS) has become popular in most countries around the world. CMMS software manages the functions discussed previously, and provides support for some of the best practices that will be mentioned in subsequent material.

CMMS has been used for almost a decade in some countries with very mixed results. A recent survey in the United States showed the majority of companies using less than 50 percent of their CMMS capabilities. This means the data collected by these companies is highly suspect and probably highly inaccurate. One requirement for a company to be effective in CMMS usage is complete usage of its system and complete accuracy of the data collected.

The lack of complete usage of a CMMS is a critical factor in record keeping compliance. The lack of complete and/or accurate record keeping requires that companies maintain a separate regulatory record keep-

ing system. In lieu of the separate system, many companies will fail a check of their documentation by a regulatory agency. It is only by dedicating sufficient resources to the CMMS utilization that companies will have sufficient electronic documentation for compliance record keeping.

It should be noted that electronic data collection and reporting systems are acceptable to the regulatory agencies. This eliminates the need to have redundant paper systems in addition to electronic systems. In one of the responses to questions about electronic record keeping, OSHA responded:

> 29 CFR 1910.179(j)(2)(iii) and 1910.179(j)(2)(iv) requires "monthly inspection with a certification record which includes the date of inspection, the signature of the person who performed the inspection and . . ." If the employer's use of the electronic system that identifies the person who performed the inspection, in lieu of the signature, is an acknowledgment that the person delegated responsibility for the inspection is certifying that it is true and complete to the best of that person's knowledge, then it would meet the intent of the record keeping requirements in 1910.179. In addition, an electronic system monthly inspection record, which does not include the person's signature, as required in 1910.179, would be considered a de minimis violation. De minimis violations are violations of standards which have no direct or immediate relationship to safety and health and will not be included in citations."

As will be shown in the chapter on Computerized Maintenance Management Systems, electronic work order systems are accepted by the regulatory agencies.

5. Technical and Interpersonal Training

This function of maintenance insures that the technicians working on the equipment have the technical skills that are required to understand and maintain the equipment. Additionally, those involved in the maintenance functions must have the interpersonal skills to be able to communicate with other departments in the company. They must also be able to work in a team or natural work group environment. Without these skills, there is little possibility of maintaining the current status of the equipment. Without these skills, the probability of ever making any improvement in the equipment is inconceivable.

While there are exceptions, the majority of companies today lack the technical skills within their organizations to maintain their equipment. In fact, studies have shown that almost 1/3 of the adult population in the United States is functionally illiterate or just marginally better. When these figures are coupled with the lack of apprenticeship programs available to technicians, the specter of a workforce where the technology of the equipment has exceeded the skills of the technicians that operate or maintain it has become a reality. These issues pose difficulties for companies trying to comply with regulatory agencies.

6. Operational Involvement

The operations or production departments must take ownership of their equipment to the extent that they are willing to support the maintenance department's efforts. Operational involvement, which varies from company to company, includes some of the following activities:

- Inspecting equipment prior to start up
- Filling out work requests for maintenance

- Completing work orders for maintenance
- Recording breakdown or malfunction data for equipment
- Performing some basic equipment service, such as lubrication
- Performing routine adjustments on equipment
- Executing maintenance activities (supported by central maintenance)

The extent to which operations is involved in maintenance activities may depend on the complexity of the equipment, the skills of the operators, or even union agreements. The goal should always be to free up some maintenance resources to concentrate on more advanced maintenance techniques.

The impact that operations' involvement has on the regulatory compliance programs varies depending on the activities carried out by the operations personnel. Where the operations personnel are heavily involved, additional training will be required for them to become proficient at regulatory record keeping. Additional technical training will also be required for most of the personnel to carry out the work in a safe and compliant manner. This training will prevent violation of lock out tag out regulations.

Extensive coverage of various training requirements for regulatory compliance is given in the chapter on Training and Skills Development.

7. Predictive Maintenance

Once the maintenance resources have been freed up because the operations department has become involved, these resources should be refocused on the predictive technologies that apply to their assets. For example, rotating equipment is a natural fit for vibration analysis, electrical equipment for thermography, and so on.

The focus is to investigate and purchase technology that solves or mitigates chronic equipment problems that exist, not to purchase all of the technology available. The predictive maintenance (PDM) inspections should be planned and scheduled utilizing the same techniques that are used to schedule the preventive tasks. All data should be recorded in or interfaced to the CMMS.

The predictive tools can do much to insure regulatory compliance. Instead of watching for visible signs of impending failure or replacing certain components on a scheduled basis, companies can now replace equipment components based on their actual condition. This eliminates the unnecessary expense of premature component replacement and yet still insures regulatory compliance as respects the component condition. Predictive maintenance can be a valuable tool for process safety management.

8. Reliability Centered Maintenance

Reliability Centered Maintenance (RCM) techniques are now applied to the preventive and predictive efforts to optimize the programs. If a particular asset is environmentally sensitive, safety related, or extremely critical to the operation, then the appropriate PM/PDM techniques are selected and implemented.

If an asset is going to restrict or impact the production or operational capacity of the company, then one level of PM/PDM activities is applied with a cost ceiling in mind. If the asset will be allowed to fail and the cost will be the expense of replacing or rebuilding the asset, then another level of PM/PDM activities is

specified. There is always the possibility that it is more economical to allow some assets to run to failure and this option is considered in RCM.

The RCM tools require data to be effective. For this reason, the RCM process compliance is to be minimized without compromising the integrity of the program. Using RCM techniques for equipment in the design phase through to the actual operational phase will help to insure the equipment is designed the decommissioning phase of its life cycle. Most of the regulations related to design criteria will be covered in this section.

9. Total Productive Maintenance

Total Productive Maintenance (TPM) is an operational philosophy whereby all workers in the company understand that their job performance impacts the capacity of the equipment in some way. For example, operations may understand the true capacity of the equipment and not run it beyond design specifications, which could create unnecessary breakdowns. Another example is the purchasing department that always buys the spare parts to the correct specifications—not trying to save a small amount and creating breakdowns because the parts did not last as long as they should.

TPM is like Total Quality Management. The only difference is that companies focus on their assets, not their products. TPM can handle all of the tools and techniques used to implement, sustain, and improve the total quality effort.

TPM is enhanced when implemented as a part of regulatory compliance. With all employees focused on the condition of the company assets, regulatory compliance becomes routine. The level of effort to maintain regulatory compliance is minimized, due to the fact that many of the TPM activities are synergistic. This focus allows complete compliance at minimum cost. There is no separate chapter on Total Productive Maintenance, since the regulatory requirements related to TPM are covered in other chapters.

10. Financial Optimization

This statistical technique combines all of the relevant data about an asset, such as downtime cost, maintenance cost, lost efficiency cost, and quality costs. It then balances that data against financially optimized decisions, such as when to take the equipment offline for maintenance, whether to repair or replace an asset, how many critical spare parts to carry, and what the maximum-minimum levels on routine spare parts should be.

Financial optimization requires accurate data, since making these types of decisions incorrectly could have a devastating effect on a company's competitive position. When a company reaches a level of sophistication where this technique can be used, it is approaching best-in-class status.

From a regulatory compliance standpoint, cost versus compliance is not a consideration. However, if the maintenance/asset management techniques employed to this point are properly focused, overall cost to the company will be minimized.

11. Continuous Improvement

Continuous improvement is best epitomized by the expression, “best is the enemy of better.” Continuous improvement in asset care is an ongoing evaluation program. This includes constantly looking for the little things that can make a company more competitive.

Benchmarking is one of the key tools for continuous improvement. Of the several types of benchmarking practices, one of the most successful is process benchmarking, which examines specific processes in maintenance, compares the processes to companies that have mastered those processes, and maps changes to improve the specific process.

The key to benchmarking is self-evaluation. A company must know its current status before it tries to benchmark against other companies. Without this knowledge, it is impossible to obtain an accurate comparison of the benchmarked process.

Benchmarking is a very useful tool when it comes to regulatory compliance. Understanding how other companies achieve compliance can help companies modify their approach to achieve a higher level of compliance or reduce the current cost of compliance. Studying other companies’ approaches, implementing improvements, and monitoring the improvements can achieve increased compliance levels.

Conclusion:

A well-designed, properly managed maintenance management system will help to insure regulatory compliance for most companies. However, companies that neglect “Best Practices” in the maintenance management discipline will, most likely, eventually incur some type of regulatory violation.

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