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MOC BEST PRACTICES

Contents

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Perspectives

Last time we took a detailed look at all the data contained in and referenced by MOC's. The volume of contained and related data is large.

When the PSM regulations were promulgated in 1992, and plant owners began the process of complying with these regulations, the focus was on compliance with the safety aspects of the regulations. That was appropriate to the times.

But, the world has moved on from 1992. Today, most information is created electronically (could you even find a typewriter at your plant?), and stored electronically. If you go to a conference focusing on electronic document management (oops, it's called ECM now), you will hear concerns about records management and email management from at least half of the speakers. (See page 9 for a full list of abbreviations).

What happened? Records management used to be a relatively benign, low profile, service function in most companies. While a good records manager requires fairly advanced education (many have master's degrees in Library Science), records managers were usually treated with friendly paternalism similar to the way secretaries or file clerks are viewed.

Several high-profile lawsuits (see Ref. 3 below) and multi-million dollar judgments have shocked executives into paying much more attention to records management issues. Ten years ago, most executive would have had a hard time identifying their corporate records manager. Today, most executives are on a first-name basis with the corporate records manager.

This brings us to the obvious question, "Well, if records management is so important, how does that impact MOC's?" Regrettably, OSHA doesn't give any clear-cut answers to that question, so it's necessary to do some critical thinking about this question. Read on....

In the Next Issue

The reason for dealing with records management right now, is that many of our readers are involved in MOC improvement projects. It's best to plan the records management aspects of MOC's, right up front, rather than retrofitting later on.

Speaking of MOC improvement projects, in the next issue we'll take a look at the steps involved in an MOC improvement project.

Disclaimer

This newsletter discusses certain perspectives on records management that are relevant to MOC's. Many records management requirements, and especially retention periods, are determined by laws and regulations. The author is not an attorney and has not been admitted to practice law in any state or province. Gateway Consulting Group, Inc. is not a law firm, nor does it offer any legal advice. All statements in this newsletter are for informational and discussion purposes. The reader should validate any conclusions drawn from this information with competent legal counsel.

This disclaimer applies to each section and subsection of this report, even though the disclaimer is only stated once.

MOC Data Content

An MOC has and requires a great deal of data, shown diagrammatically in Figure 1. In the January Newsletter (Volume 2, Number 1) , explanations were provided for the following:

- ER Diagram Notation
- Data Owned by the MOC Business Process, and,
- Data Owned by Other Applications

This allowed the reader to interpret the diagram. However, there are many implications of the diagram that were not fully explained in Ref. 1, which will be explained herein..
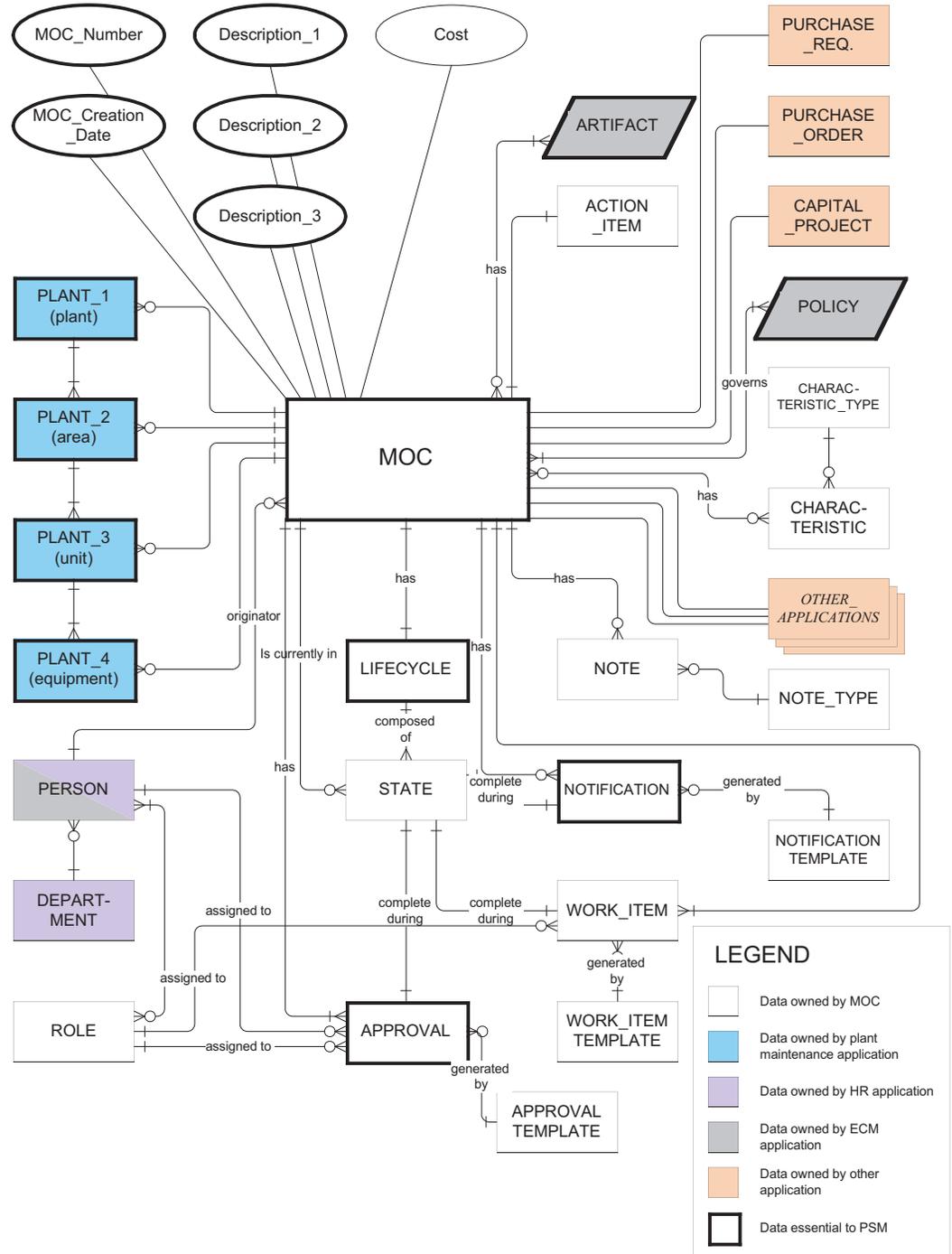
Figure 1. MOC data model.

Ref. 1.   Hoff, R., MOC Best Practices Newsletter Volume 2, Number 1: MOC Data Content,
           Gateway Consulting Group, Inc., www.gatewaygroup.com, January 2008.
Ref. 2.   Flynn, N., and Kahn, R., E-Mail Rules, AMACOM, New York (2003), p.66.

Records Management Aspects

There are sometimes lively discussions about what constitutes a business record and what doesn't. Some use the following definition:

Business record: Evidence of business-related activities, events, and transactions with ongoing business, legal, compliance, operational, or historical value.

This raises some immediate questions…

1. Are MOC's business records? Yes.

2. Are electronic MOC's also business records? Yes. The definition doesn't specifically include or exclude electronic information from being a business record, and courts and governments have unequivocally stated that information stored electronically can be considered a business record. Recently, multi-million dollar fines have been levied for improperly managing electronic records and email[3].

3. Do MOC's have a records retention period? Yes.

4. What is the retention period for MOC's? That depends. The question of retention period is a legal question, because records retention is governed by many laws and regulations. Again, the reader is advised to consult with competent legal counsel.

5. Can records be changed? No. Records are immutable. New records may be created from existing records, as in the case of new revisions, but once an information item is a record, it must be managed in such a way as to prevent deliberate or inadvertent changes.

MOC Forms

We have not found a clear statement on retention period for MOC's in the PSM regulations[4] or any other publically available information from OSHA [5,6,7]. So, the retention period must be inferred from other evidence.

The regulations specify that procedures must be in place for MOC; paragraph (l)(1) states, "The employer shall establish and implement written procedures to manage changes (except for 'replacements in kind') to process chemicals, technology, equipment, and procedures; and, changes to facilities that affect a covered process."

Not surprisingly, OSHA has the right to, and does, audit compliance with the PSM regulations. According to OSHA's own enforcement procedures, as stated in paragraph k(3), "Verification of the employer's and the contract employers' effective implementation of the [PSM] program can be made through review of written programs and <u>records of activity</u>, …" [emphasis mine].

Interestingly, although the PSM regulation identifies many documents by name: e.g. P&ID, electrical one-line, MSDS, the regulation does not specifically require an "MOC form". Appendix C, paragraph 11[5] does however suggest that an MOC form is a good idea, "Employers may wish to develop a form or clearance sheet to facilitate the processing of changes through the management of change procedures." Furthermore, without an MOC form to collect all the MOC elements together (process safety information changes, notifications, training, procedure updates, hazards analysis, approvals, etc.), it becomes exceedingly complex to track the progress and completeness of MOC's and provide adequate evidence of compliance to auditors.

Ref. 3   See, for example, Zubulake v. UBS Warburg, 217 F.R.D. 309 (S.D.N.Y. 2003).

Ref. 4   29CFR1910.119 Process Safety Management of Highly Hazardous Chemicals, Occupational Health and Safety Administration, July 2007 edition.

Ref. 5   29CFR1910.119-Appendix C Compliance Guidelines and Recommendations for Process Safety Management (Nonmandatory), Occupational Health and Safety Administration, July 2007 edition.

Ref. 6   OSHA Directive CPL 02-02-045 – Process Safety Management of Highly Hazardous Chemicals –Compliance Guidelines and Enforcement Procedures, Occupational Health and Safety Administration, Sep 13, 1994.

Ref. 7   Clarification on the documentation of inspections and tests required under the mechanical integrity provisions, Clarification letter from John B. Miles, Jr., Director, Directorate of Compliance Programs, OSHA, to Sylvester W. Fretwell, Director of Safety, Lever Brothers Company, Sep-16-1996.

MOC Forms (continued)

To summarize:

- The PSM regulations state that procedures must be in place for MOC.

- OSHA does audit MOC compliance, and expects to see records that the MOC procedures are being followed.

- The regulations don't specify that an "MOC form" is needed. However, use of an MOC form is recommended by OSHA, and, it would be very complex to provide evidence during an audit that MOC procedures are being followed, without the use of an MOC form.

Common industry practice is to use an MOC form for managing MOC's. These may be paper or electronic, and they may have different names, however, they tend to serve the same function. MOC forms serve to link all the elements of a given change together.

The fact that OSHA doesn't mandate something called an MOC form, partially explains why there is no stated retention period for MOC forms.

A New Look at Process Safety Information "PSI"

Section (d) of the PSM regulation, describes process safety information, or "PSI" for short. According to the regulation, PSI includes:

1. Information pertaining to the hazards of the highly hazardous chemicals in the process, often contained in Material Safety Data Sheets,

2. Information pertaining to the technology of the process, including block flow diagrams, operational limits, etc.

3. Information pertaining to the equipment in the process, including P&ID's, relief systems, design basis, etc.

Section (l)(4) of the PSM regulation, which details the MOC requirements, specifically mentions PSI: "If a change covered by this paragraph results in a change in the process safety information required by paragraph (d) of this section, such information shall be updated accordingly.

And, paragraph (l)(2)(v) of the PSM regulation requires that, "Authorization requirements for the proposed change", be properly considered.

What are the implications of this for a given document, like an engineering drawing? In order for a drawing to be useful in a plant, and to be officially recognized as a record, it must have at least 3 elements:

1. A graphic, showing the relevant aspect of the process,

2. Approval, by at least one authorized person,

3. An effectivity date, which usually occurs at startup, just after the pre-startup safety review,

Some would apply the label "released for operations" to a drawing that satisfied all of these requirements. But, it's the "released for operations" drawings that are useful for operations, that are required by OSHA and that constitute an official company record. Intermediate drafts, preliminary versions, etc., have lesser legal standing; only the released drawings have the ability to satisfy regulatory requirements; only the released drawings are considered authoritative.

How is the released status usually indicated on a drawing? Generally, it isn't. A drawing may have a signature block, which indicates acceptance by a competent engineering authority, but the release information (approval to release to operations, and effectivity date) is normally information that's on the MOC form!

So, one could make a strong argument that drawings are not authoritative unless they have an associated MOC, which releases them for operations. Drawings are only one example of PSI, so this logic would apply to all PSI. And that means that the retention period of MOC's is at least as long as any of the PSI documents that the MOC's release to operations.

A New Look at Process Safety Information "PSI" (continued)

Again, to summarize:

- Process safety information is required by the PSM regulations.

- In order for any PSI document to become authoritative, it must be released to operations and given an effectivity date.

- The release to operations and effectivity date information is often not written on the PSI document(s); it's written on the MOC form.

- Since the MOC's give other PSI documents their authoritative standing, the MOC's have to be retained at least as long as the PSI documents.

Retention Periods for MOC's

The Compliance Guidelines and Enforcement Procedures[6] deals with retention of PSI; in Appendix B (d) this reference states, "In order to demonstrate compliance with this paragraph, and to meet the purpose of the standard, the process safety information is to be kept for the lifetime of the process, and updated whenever changes other than 'replacement in kind' are made."

This notion of "lifetime of the process" is pervasive in the PSM regulations and other writings. Another example is in paragraph (e)(7) of the PSM regulation, " Employers shall retain process hazards analyses and updates or revalidations for each process covered by this section, as well as the documented resolution of recommendations described in paragraph (e)(5) of this section for the life of the process."

One could imagine that this is the time period beginning with the very first pre startup safety review and ending with the decommissioning and dismantling of the unit. This period is likely decades in length.

Using the logic of the previous section, if the PSI must be retained for decades, then the MOC's must also be retained for decades.

Impact of PHA Revalidation

Some sites do not accept the logic presented in the previous sections. In fact, the counterargument to the foregoing presentation goes something like this:

- The useful life of an MOC is until all the changes implied by the MOC are incorporated into the periodic update and revalidation of the process hazards analysis for the affected unit.

- Process hazards analyses are updated no less frequently than once every five years, due to the PSM regulation requirements,

- So, the retention period for MOC's is of the order of 5 years.

However, this "until the next PHA update" position has 3 flaws:

1. It requires that the approval and effective dates must be recorded on each item of PSI. As previously discussed, PSI documents don't typically contain their own release information.

2. The transcription of changes from a collection of MOC's into an updated PHA may introduce errors into the updated PHA.

3. In the case of a future incident, the change approvers would be a useful resource during an investigation. If the records of who approved which change are purged, then, it becomes problematic identifying these individuals.

OSHA has provided some insights on this issue as well, in a clarification letter dealing with mechanical integrity . The requestor poses the following question: "…how long must inspection records be kept? Is only the most recent inspection record, supplemented by a history of prior inspections and finding sufficient?"

The OSHA response is, "In order to demonstrate compliance with paragraph 1910.119(j), and to meet the purpose of ongoing mechanical integrity, the documentation required under paragraph 1910.119(j)(4)(iv) must be kept for the <u>lifetime of the process</u>."

Impact of PHA Revalidation (continued)

In other words, every inspection record must be kept for the lifetime of the process. While more recent inspections may render old inspections obsolete from an operations perspective, they do not render old inspections obsolete from a records management perspective.

This author does not accept the "until the next PHA update" position on the retention period for MOC's. This author believes that tying the MOC retention is the "life time of the process" is more appropriate and more defensible.

Practical Implications of Managing MOC's For Decades

Many companies choose to implement their PSM compliance program, and the MOC program in particular, using a paper-based system of forms, folders, and supporting documents in hardcopy form. Paper-based business processes can be made to satisfy all regulatory requirements for MOC's, have been used for hundreds of years, and are well-understood by most people.

Records management for paper-based business processes are well established and well understood at most companies.

Paper records, however, suffer from loss (i.e. records disappear from the archives, with no way of determining where they are), and degradation (i.e. they may be damaged by moisture, and mildew), particularly when the records must be managed for decades. Paper-based processes have efficiency shortcomings as well.

MOC's can be processed with substantially shorter cycle times, with substantially lower error rates, and with substantially better compliance with many regulations (e.g., PSM, records management) in an electronic system. The author is very active in the field of Electronic Document Management, often called Enterprise Content Management nowadays.

There are several concerns associated with long term management of records, such as MOC's, in an electronic system. Clearly, the following must be maintained over long time periods:

1. MOC data, including the MOC attributes and records of electronic signatures,

2. Supporting documentation,

3. Links to other systems.

MOC Data

The data "owned" by the MOC is unshaded in Figure 1. A properly implemented electronic system to handle MOC's would maintain all of this data according to demonstrable records management standards. Although OSHA does not currently have its own electronic records standard, such standards exist in other fields, such as defense[8] and life sciences[9,10]. Normally, it's possible to comply with these records management standards, since leading commercial-off-the-shelf enterprise content management applications normally provide support for these standards. Such an enterprise content management system, which might be used to manage MOC's, would reasonably be seen as embodying current standard practice for the management of electronic records.

Although leading ECM products support electronic records management, the reader is cautioned that this capability must be properly configured. This is analogous to a DCS system: although they can all improve plant operations, they must be configured to perform this task.

Not all electronic MOC implementations are composed of an MOC application built on a framework provided by an ECM vendor. Often electronic MOC's are implemented as single, "stand alone" applications from software vendors. The number of stand-alone solutions is much larger than the number of MOC applications on an ECM framework, and their support for records management varies considerably. The reader, if contemplating the implementation of a stand alone electronic MOC application, should include records management capabilities as part of the evaluation criteria.

Ref. 8.   DOD 5015.2-STD Design Criteria Standard for Electronic Records Management Software Applications, Department of Defense, June 2002.

Ref. 9.   ISO 13485:2003 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, International Standards Organization, 2003.

Ref. 10.   21CFR11 Electronic Records; Electronic Signatures, Food and Drug Administration, July 2007 edition.

MOC Data (continued)

Experience has shown that even the most current technologies ultimately succumb to obsolescence. The factors that contribute to obsolescence of ECM technologies include the following:

- hardware coming to the end of its supported life; spare parts no longer available from the hardware vendor,

- operating systems no longer supported by the vendor

- database versions no longer supported by the vendor

- ECM or eMOC applications no longer supported by the vendor

- Vendor bankruptcy, in any of the aforementioned components

- Mergers and acquisitions among technology firms, causing the discontinuation of certain product lines.

The longevity of a particular technology is difficult to predict, but 10 years would be a reasonable value for planning purposes. This implies that, at the time of this writing, 2008, technology investments from 1998 would be reaching the end of life. This appears to be borne out by current events—many ECM implementations from the mid- to late-1990's are currently being updated.

When one purchases a new car, the old car is often traded in and forgotten about. Such simplicity doesn't exist with computer systems since the data must be migrated from the old system to the new. It will be necessary to migrate MOC forms, electronic signatures and records management attributes (in addition to the artifacts, described below). That implies that there must be a validated mechanism to export such data from the "old" system, and allow it to be imported into the new system.

The point of this discussion is to sensitize readers to the need for considering these records management requirements, specifically the data export requirements, when an electronic MOC system is implemented. It will be too late to start thinking about this, 10 years from now, when the software vendor may no longer be available.

There is no intent to discourage readers from pursuing electronic MOC systems. In fact electronic MOC systems can be easily justified in a business case, with payback periods ranging from 6 to 24 months (based on other work by the author). The intent of this discussion is to emphasize the importance of proper and thoughtful planning and implementation.

Supporting Documentation

An MOC has a great deal of supporting documentation, including all the process safety information that is updated as part of the MOC process, procedures, training materials, etc. The various forms, reports, folders, files, etc. are grouped together under the heading of "Artifact". Artifacts are represented in Figure 1 by a parallelogram symbol.

Every electronic file is created in some format, usually predetermined by the creator of the authoring software. For example, files created in the AutoCad® program are usually in a format called .DWG, files created in Microsoft Word® are usually in a format called .DOC, and so on. These formats are termed "native" formats, and files stored in these formats are called "native files". The benefits of storing information in native files are well understood, since one usually needs the native files in order to make changes to the data.

Native formats have an inherent problem from a records management perspective: they don't have longevity. For instance, if one had a drawing created in version 1.0 of AutoCad, the current version of AutoCad may not be able to properly read the file. Similarly, the current Microsoft Word® program may not be able to read .doc files created in Word version 1.0.

Since the software business is still competitive and file formats (which used to change almost annually) still change every several years, there's a very good chance that today's native files may not be readable at some time in the future.

The standard approach to dealing with this native file format obsolescence problem is to store each file in a second, alternate format. The current favorite is the Adobe® Portable Document Format, usually called .PDF files. Rendering all documents in .PDF, in addition to keeping the native files, provides an additional benefit; the native files can be secured and are only available to a very limited set of document authors, while the .PDF files are made available for general distribution[11].

Links to Other Systems

Figure 1 clearly shows data that is important, or perhaps even necessary to the efficient functioning of MOC's, but stored in other applications. For instance, the blue-shaded boxes indicate data that may exist in a plant maintenance application, but is needed for MOC's. For example, the maintenance application may have a list of units and areas, and represent which units belong to which areas. It's not necessary to maintain this information in the MOC application—it's only necessary to link to the unit from the MOC. Users would perceive this as being similar to the way that hyperlinks work on web pages, although there are various mechanisms of how this linking is done between MOC's and other data sources. There are several benefits of linking, including:

- There's only one copy of the data, the "master" copy,

- When changes occur, the "master" data only needs to be updated once, which is more efficient than doing it multiple times,

- Updating the data in only one location avoids duplicates of the data becoming unsynchronized.

The same benefits apply to the lilac shaded boxes, showing data that may exist in an HR application, and the orange-shaded boxes showing data that may exist in an ERP application.

While the benefits of linking, outlined in the previous list, appear compelling and are indeed useful, there are certain problems from a records management perspective.

- The "other" applications are applications just like MOC. They will have their own lifecycles; they will be installed, modified and ultimately replaced. If an "other" application is replaced, then it's almost guaranteed that the links will break between the MOC's and the other application.

- An important aspect of records is that they are a "point in time" representation of something. If the MOC is linked to another application, and the data in the other application keeps changing, even if only due to routine updates, then there is no proper record of the MOC.

These are very, very significant issues. Nonetheless, it's reasonable to want to obtain the benefits of linking to other applications, but without suffering the shortcomings. There are two main approaches to achieving this:

1. Copy the data.
2. Use a fully-integrated application.

Copy the Data

The main benefit of the links was that the data existed elsewhere, and was updated elsewhere, with no effort on the part of the MOC user. One possibility is to link to the "other" application, while the MOC is being worked on, and once the MOC is closed, the necessary data is (automatically) copied from the other application and saved in the MOC form. Usually, the necessary data is minimal, like a unit number, an area identifier, a person's full name and employee ID, a purchase order number, a work order number, etc. This copying constitutes a small volume of data, so it ought not create performance problems. The copied data, now in the MOC application, would be managed just like any other MOC data.

Use a Fully-Integrated Application

The aforementioned problems arise because the complete data for an MOC is spread over multiple applications and data sources. If all the MOC data were in one application (i.e. Figure 1 would have no shaded boxes), then these integration problems disappear.

Ref. 11. There are some subtleties associated with .PDF files as well, from a records management perspective, and these may be addressed in a future newsletter.
Ref. 12. Two main approaches, with many variations on how they're implemented.

Use A Fully Integrated Application (continued)

An application that manages "all" the data shown in Figure 1 would be a very large application, since it has plant data, purchasing, financial, human resources, and of course MOC data. Such a large, integrated application, with MOC capabilities does not currently exist. And, given the current software landscape, creation of such a solution is limited to ERP vendors (e.g. Oracle®, SAP®) or vendors of large plant maintenance management systems.

Most electronic MOC systems, using current technology, will involve copying data from other systems, to some extent.

Closing Remarks

This paper has reviewed important issues regarding the management of MOC's as records. Key observations include:

1. OSHA does not have explicit records retention periods for MOC's, but the discussion presented herein suggests that MOC's may have to be retained for the lifetime of the process.

2. Electronic MOC systems provide business benefits and are a viable repository for MOC information, for very long time periods.

3. If any MOC "folder" contains electronic documents, then it's important to select appropriate file formats that can be read, say 10, 20 or even 50 years in the future.

4. The time to plan for technological obsolescence of electronic systems, which store MOC's, is before the systems are even implemented. It is vital to plan, demonstrate and test the capability of exporting MOC's, supporting documentation and electronic signatures from an electronic MOC system before the system is implemented.

5. A fully-integrated system, storing MOC's, all supporting documentation and all related information, does not currently exist. This kind of solution would only be possible from an ERP or large maintenance management software vendor.

Abbreviations

DCS   Distributed Control System
ER   Entity-Relationship
ERP   Enterprise Resource Planning
MOC   Management of Change
MSDS Material Safety Data Sheet
OSHA (U.S.) Occupational Safety and Health Administration
P&ID   Piping and Instrumentation Diagram
PHA   Process Hazards Analysis
PSI   Process Safety Information
PSM   Process Safety Management
SAP®   SAP is a vendor of ERP software

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