Hazardous Materials Pharmacies – A Vital Component of a Robust P2 Program

S. McCarter
Dynamac Corporation
2719 Pulaski Highway, Edgewood, MD 21040
USA

ABSTRACT

Integrating pollution prevention (P2) into the Department of Energy Integrated Safety Management (ISM) – Environmental Management System (EMS) approach, required by DOE Order 450.1, leads to an enhanced ISM program at large and complex installations and facilities.

One of the building blocks to integrating P2 into a comprehensive environmental and safety program is the control and tracking of the amounts, types, and flow of hazardous materials used on a facility. Hazardous materials pharmacies (typically called HazMarts) provide a solid approach to resolving this issue through business practice changes that reduce use, avoid excess, and redistribute surplus. If understood from concept to implementation, the HazMart is a powerful tool for reducing pollution at the source, tracking inventory storage, controlling usage and flow, and summarizing data for reporting requirements. Pharmacy options can range from a strict, single control point for all hazardous materials to a virtual system, where the inventory is user controlled and reported over a common system.

Designing and implementing HazMarts on large, diverse installations or facilities present a unique set of issues. This is especially true of research and development (R&D) facilities where the chemical use requirements are extensive and often classified. There are often multiple sources of supply; a wide variety of chemical requirements; a mix of containers ranging from small ampules to large bulk storage tanks; and a wide range of tools used to track hazardous materials, ranging from simple purchase inventories to sophisticated tracking software. Computer systems are often not uniform in capacity, capability, or operating systems, making it difficult to use a server-based unified tracking system software.

Each of these issues has a solution or set of solutions tied to fundamental business practices. Each requires an understanding of the problem at hand, which, in turn, requires good communication among all potential users. A key attribute to a successful HazMart is that everybody must use the same program. That requirement often runs directly into the biggest issue of all… institutional resistance to change. To be successful, the program has to be both a top-down and bottom-up driven process. The installation or facility must set the policy and the requirement, but all of the players have to buy in and participate in building and implementing the program.

Dynamac's years of experience assessing hazardous materials programs, providing business case analyses, and recommending and implementing pharmacy approaches for federal agencies has provided us with key insights into the issues, problems, and the array of solutions available. This

paper presents the key steps required to implement a HazMart, explores the advantages and pitfalls associated with a HazMart, and presents some options for implementing a pharmacy or HazMart on complex installations and R&D facilities.

INTRODUCTION

Proper control and flow of hazardous materials (HM) is a key building block for integrating a Pollution Prevention (P2) program into a comprehensive environmental and safety program as required by DOE Order 450.1. The pharmacy approach for a Hazardous Materials Management Program (HMMP) provides the mechanism to control the purchase, distribution, and flow of HM, as well as a method to track key information for human and environmental safety. Use of a pharmacy or HazMart, as these are typically called, assists the facility or installation in reducing HM purchase, use and waste by implementing business practice changes and using a unified software to order, track, and report on HM chemical constituents, usage, distribution, and storage at the facility and user level. Controlling and limiting the use and storage of HM to that which is needed, enhances worker safety and reduces the potential for injury and liability.

Specifically a pharmacy or HazMart can be used to centralize the purchase and distribution of HM, identify recurrent needs, identify excess, and provide a mechanism for the redistribution of excess prior to shelf life expiration. Using a unified tracking software across the facility or installation provides a single method of tracking HM transactions from "cradle to grave", including: waste disposal transactions; report use trends and stockage levels to maximize P2 opportunities and anticipate logistical needs for HM; a centralized database for safety of use information (MSDS and chemical constituents and hazards); information to emergency responders by reporting storage at the facility, building and/or user level, along with emergency control measures; correlating HM usage with health and safety data to identify risks to or trends in health and safety where HM are used; tracking required HM training for personnel; and providing key data for required chemical reporting, both internally and externally (e.g., inventory and cost data and Tier II and Form R EPCRA reports).

Reducing the level of HM stored and used to that required by, but not in excess of the work at hand, will assist the facility or installation in enhancing personnel safety by minimizing the potential for chemical exposures. Using trained personnel to purchase, store, and distribute HM, as well as centralizing the storage location of primary HM stocks, further reduces the potential for exposure, spills, and accidents; improves compliance with OSHA and RCRA standards, and overall materials management. Better management leads to reductions in stocks on hand, shelf life expirations, waste disposal, safety and environmental liabilities, and overall operating cost.

Before a pharmacy approach can be implemented, it is important to understand the operations of the facility or installation, and the attendant issues that may present obstacles that need to be addressed and overcome prior to implementation. This is especially true on large and complex R&D facilities where unique chemical use and operational requirements may exist. To achieve the level of understanding required, a survey of the facility for current practices (including purchase, handling and storage), chemical use requirements at the user level, chemical recovery methods, waste collection and disposal methods, current HM procurement and handling time requirements, and program costs must be completed.

Once all of the factors are understood, a business case analysis for a HazMart should be completed and presented. The analysis provides workable options, the business practice changes that are required, a cost benefit analysis for each option, and a recommendation for implementation. Done properly, this provides the facility or installation with the information necessary to make an informed decision that best fits the management objectives and funding abilities.

Throughout the process, open and frank communication is an absolute key to success. Good communication ensures that all levels, from management to user, are properly informed about the process and progress. A free flow of information provides feedback on required data and operations, and often results in the identification of innovative ideas that enhance the program.

KEY STEPS TO IMPLEMENTING A HAZARDOUS MATERIALS PHARMACY

Prior to defining and implementing the pharmacy approach, an analysis of current operations (Current Status Assessment) to establish the baseline from which a business case analysis will be built should be completed. The basic building blocks required to design and implement an effective HazMart, include:

Current Status Assessment (CSA)

Assessing the current status of HM management, from initial procurement to final disposal of HM derived waste is key to understanding the facility or installation operations necessary to develop and present options for a HazMart approach. Without a current assessment of the existing program, no baseline can be established and proposals for business practice changes are pure conjecture.

There are **eight** key data points that must be included in any current status assessment; levels of HM use, procurement methods, distribution methods, storage methods, recovery methods, waste collection and disposal methods, time allocations for HM tasks (multilevel) and collective costs of the program. Typically these data are gathered by visiting at least one of each distinct operation on large, complex facilities or installations. It is generally not necessary to visit multiple locations with identical operations and operational requirements. Although visiting multiple sites may yield more accurate data, it is often not a cost-effective approach.

- ***Levels of Use:*** Documenting the levels of HM use at the user level establishes the baseline need at the lowest possible level, which can later be rolled up with all other user requirements into a standing inventory requirement for the facility or installation that will determine the central stock requirement for the HazMart (or HazMarts if a distributed pharmacy approach is used). It also provides a method of comparing current inventory (if available and accurate) with actual inventory needs. If the facility desires, a current inventory can be performed at the operational site; however, it must be understood that inventories at similar sites may vary.

- ***Procurement Methods:*** The methods by which HM are procured are important because they help the practitioner understand potential obstacles and efficiencies to HazMart

approach and implementation. One of the most common issues on large R&D facilities, for example, is diverse sources of funding for HM in which individual organizations or tenants on a facility or installation procure their own HM rather than going through a central facility/installation logistical center. This may be a function of the parent organization's funding resources, or it may simply be a matter of choice. Central procurement provides distinct advantages over operational level or distributed procurement. Specifically, purchases can benefit from economies of scale and can be controlled more effectively.

- ***Distribution methods:*** Similarly, distribution methods must be understood to establish a baseline and to determine potential efficiencies and economies. Central distribution often presents opportunities for better control of HM, faster delivery, and cost control. One of the most difficult things to control with virtual or distributed pharmacies is off-site purchase of HM that is not reported or tracked, whereas centralized procurement and distribution, along with a facility- or installation-wide prohibition on outside purchases minimizes excess and waste that might otherwise occur.

- ***Storage methods:*** Cataloguing and documenting storage methods leads to insights about space usage, handling and distribution efficiencies, storage costs, and compliance with regulatory and internal requirements. Understanding these methods down to the user level often leads to identifying opportunities for better storage methods than are currently used or reductions in storage requirements when coupled with other business practice changes. It also may provide indications of hidden hazards or potential for exposure, spills, and accidents.

- ***Recovery methods:*** The methods, if any, by which unused HM is recovered and redistributed or returned to the manufacturer prior to expiration are used to compare to potential business practice changes that may result in more efficient handling and cost savings. In addition, the potential for on-site recovery/recycling of used or expired shelf life HM can be explored.

- ***Waste collection and disposal methods:*** Understanding the collection and disposal methods employed for wastes generated from the use of HM is important to describing "cradle to grave" processes and provides a basis for comparison with potential efficiencies that can be created with a HazMart operation. It is also important to understanding if there is an expired shelf life issue on the facility/installation.

- ***Time allocations for HM tasks (multilevel):*** Time allocation for various HM/HW handling, storage, and distribution functions are carefully catalogued with assigned costs to provide a comparison with proposed functions within the HazMart options in the business case analysis. Typically, these are multilevel tasks, ranging from initial procurement requirements at the facility/installation or organization level down to the user level operations. The objective is to provide as clear and comprehensive a picture of the time and cost required throughout the process, exclusive of the actual costs of HM, HW disposal and storage space.

- ***Collective costs:*** For each of the aspects of the current assessment listed above, costs are either documented or estimated to provide a baseline against which the options for HazMart implementation and their efficiencies can be compared. A total of the costs is used to compare with the projected costs of the HazMart operation options and presented to the facility or installation in the business case analysis. The cost-benefit or economic analysis should present a clear cost comparison in either Net Present Value (NPV) or actual/estimated dollar amounts with a built-in cost escalation factor based on historic cost increases.

Prepare a Business Case Analysis

The Business Case Analysis (BCA) summarizes the current operations, presents options for implementing a HazMart and compares the costs of the options to current costs. These costs include those incurred by a facility/installation in procuring, handling, storing and distributing HM and disposing of wastes derived from the use of HM. In addition, the BCA specifies the technical approach each option provides and the efficiencies and economies gained. The latter data is often presented in both numeric and graphic formats, using easily understood spreadsheets and charts. As a general rule, the options are ranked based on cost reduction and efficiency of operation. Projected startup and maintenance costs (including tracking hardware and software costs) are quantified as a part of the overall cost of operation. The BCA offers a recommended approach with the reasons for the recommendation clearly stated. The final decision on the approach is made by the facility/installation. Once decided, an implementation plan is written and agreed to, a charter is drawn up and signed by a cognizant official, and implementation begun. There are several standard approaches to implementing HazMart operations. Each of these is flexible and can be customized to fit the needs of the facility/installation.

- ***Defining Hazardous Materials Management Program (HMMP) - HazMart Approaches.*** Under various HMMP approaches, the principal purpose of establishing a pharmacy or HazMart may range from changing the way materials are tracked to establishing a single point of procurement, receipt, issue and recovery and, where possible, residual reissue of hazardous materials. In Army installation implementations, various concepts of the HazMart have been employed, including the virtual pharmacy, multiple HazMarts, centralized HazMart, and variations of these three general approaches. Each of these approaches has its advantages and disadvantages, several of which are explored below. The software employed in each approach will be the same, but its capitalization and maintenance may vary, depending on the software chosen. Tracking software, while a vital part of the program that must be consistent among all users, is determined by the requirements and preferences of the facility or installation.

  Virtual pharmacies usually involve little, if any change in procurement, receipt and issue practices, focusing instead on the HM tracking system. Among the advantages accruing to this approach are low capital costs and relatively little change in maintenance costs. There is no requirement for additional facilities or facility modification, little change in personnel requirements, and essentially no change in procurement, receipt or issue business practices. Disadvantages may include continuing organizational and unit HM

management problems such as the stockpiling of HM, which leads to expired shelf life disposal costs, excessive time expenditures at the unit level for internal management of HM and HW, which adversely impacts mission-related activities, and continuing environmental reporting coordination problems.

Multiple or distributed HazMarts represent more centralized HM control and change the facility or installation business practices in the manner in which HM is procured, receipted and issued. Among the advantages to this approach: are better control of HM, which reduces opportunities for HM stockpiling; the potential to facilitate HW disposal procedures; reduction of personnel time expenditure for HM handling; and more direct environmental reporting. Among the disadvantages are capital expenditures for additional facilities or modification of existing facilities, increased costs for HMMP personnel, and adjustment to business practice changes.

The centralized HazMart represents the most intensive approach to HM control and the highest level of business practice changes for procurement, receipt, distribution and recovery. It involves strict HM control procedures, which can include a "tailgate" service for pick up and delivery of HM at the unit level, assisted stock rotation, consolidation or decanting of HM for free re-issue and HW handling services. Advantages to this approach include a major reduction in or elimination of HM stockpiling and associated disposal of expired shelf life material, more efficient and cost effective use of HM, reduction in health and safety risks associated with HM and HW handling at the organization/unit level, and maximum coordination of environmental reporting. Disadvantages include higher capital costs for facilities, increased HMMP personnel requirements, and adjustment to major changes in business practices.

Regardless of the r program selected, the HMMP will generally include the following components:

- The HMMP Team - a cross-functional group of managers and users;
- A HazMart - where hazardous materials are stocked, stored and distributed;
- An HM software tracking system - usually including bar coding capabilities, with terminals in the Pharmacy and supporting offices; and
- An HM authorization process - that provides a standardized procedure for requesting and authorizing HAZMAT through all sources of supply.

- ***Hazardous Materials Tracking Software.*** Although tracking software is integral to HazMart operations, the type of software used is discretionary and not mandatory. The key thing to remember is that the software is a tool for implementation of a pharmacy program, it is NOT the program. The program is about changing business practices that result in the reduction of use and waste, improved safety for workers and reduction of liability for the facility/installation.

HM tracking systems (software) typically perform functions that fall into the following categories:

- Material Authorization - tracking who can request or receive the material and for what purposes. Generally, this is specified in an Authorized Use List or AUL;
- Receipt and Storage -accounting for receipt of material, assigning unique codes or numbers to containers, tracking storage and typically using a barcode system;
- Transactional tracking -accounting for the transfer of materials from storage to individual, process or waste container. It includes transfers between users as well;
- Waste Generation -gathering waste information to comply with regulations and track costs;
- Waste Storage and Turn-In - tracking storage and movement of waste;
- Manifest and Shipping - tracking HW data and associated manifests;
- Employee Management - managing employee information as it relates to handling HM, including training and certification information/records;
- Reports - executing standardized and specialized reports using system data, which may be generated internally or using a software such as Crystal Reports®; and
- System - controlling access to system data [administrative and user accounts] and performing system maintenance.

A good BCA will define each of these aspects within the context of the options presented, along with projected costs of implementation and maintenance. Throughout the process, from the initial survey, through the final implementation, clear and open communication and liaison is critical.

Communication

Communication is essential to the success of any program, and this is particularly true of an HMMP/Pharmacy operation. It is absolutely necessary to involve key stakeholders from management to user levels, accumulate accurate and effective information, and identify and provide effective solutions to impediments and issues as they arise. Information must flow not only from management down, but from the user up to ensure that the HazMart developed and implemented will fully serve the needs of the facility and at the same time provide the user with the needed HM in a timely fashion. Since what is being developed is a management system, a good communication approach is to use established strategic planning or Environmental Management System approaches and procedures as the foundation. The Plan, Do, Monitor, Review, Improve model works as well for this system as it does for any other and it provides the added advantage of integrating the HMMP into both the ISM/EMS and facility/installation sustainability programs at the same time.

- ***Management support.*** Upper level management must be supportive of the HMMP/Pharmacy from concept to implementation if the program is to be successful. While it is not necessary for the director of a facility or installation to be directly involved in the process, it is important that he/she be briefed routinely on the progress and status of the program. The director must, through policy directives and actions show support throughout the process.

- ***Team building/Stakeholder Involvement.*** Team building and stakeholder involvement really begins in the initial stages of the survey; however, it becomes critically important

during the decision-making process for the direction the HMMP is to take and the final implementation phase. Having the proper team in place to steer the program is absolutely essential to the success of the program. This team, usually referred to as a Hazardous Materials Control Group (HMCG) is composed of key managers at the facility/installation and tenant levels, along with key players at the user level, usually those directly involved in the ordering and distribution of materials. Assembling a quality team chaired by a good facilitator helps to surface all of the potential issues and impediments to standing up a pharmacy program so that they may be fully explored and mitigated. In addition, the team helps disseminate information from management to the user at the most local level to keep all informed and to bring concerns back to the committee.

- ***Outreach.*** Throughout the process, the use of facility/installation publications, websites, and other media, as well as periodic briefings will help keep the management, users and other interested parties informed about the direction and progress of the program. As the program moves forward, it can be promoted through these media to help achieve a higher level of effectiveness and report on successes. A good outreach program informs the public of the sound environmental stewardship at a facility.

Barriers to HazMart Implementation on Complex Facilities/Installations

Large and complex facilities/installations present some interesting issues and barriers to implementing a pharmacy program. Most of the issues are related to organizational and funding considerations, rather than strictly logistical matters. In some cases, large installations with widely separated operational and administrative centers create logistical problems as well. These issues may range from institutional inertia to the need for secrecy at R&D facilities. Typical issues that present barriers to implementing a pharmacy, include:

- ***Multiple Funding Sources.*** Large and complex facilities/installations, particularly R&D facilities, often have multiple tenants with independent funding for their operations. They purchase their materials and fund their operations independent of the host. Tenants are often reluctant to relinquish control of their ordering and purchase lines or to suborn their operation to "outside" control. While often viewed as a "turf battle," there may be sound reasons for the tenant maintaining direct control of the ordering and distribution of HM. Solutions to this issue will vary with the complexity of tenant requirements. Some tenants may find that funding HM is less costly when purchased by central procurement, since economies of scale come into play. If the barriers to funding and purchase of HM at the tenant level cannot be overcome, the use of a virtual pharmacy to track HM on the facility/installation may prove the best option.

- ***Multiple Sources of Supply.*** Most facilities (and pharmacies) use multiple sources of supply for HM.. In most cases multiple sources are required simply because of the variety of products required; however, this is often magnified on large complex facilities by independent purchases made by tenants and users. It is not uncommon for an initial survey to identify up to a dozen independent suppliers or manufacturers for a single

product on these facilities. In fact, it is common to find multiple manufacturers for a single product at the user level. The largest issues here are cost, the requirement for multiple MSDS, and having all of the information reported correctly. Using a unified approach may not eliminate multiple sources of supply, but it can minimize them, make use of economies of scale, and organize the information accurately in a single repository.

- ***Classified Activities.*** Classified activities in R&D present a unique set of issues. The need to maintain secrecy regarding the types and amounts of HM used in a process may supercede all other requirements, including cost and reporting. Not only does this present barriers to the initial collection of data, but it also presents special issues in tracking and reporting. In such cases, it may still be possible, and perhaps preferable to have a central source for ordering and distribution with the proviso that work center information be kept proprietary or have an alternate designation that will mask its identity (e.g., an alpha-numeric or numeric designation in the tracking software). Taking this approach will ensure that the facility/installation meets its cost and reporting requirements, safety of use information is centrally available, and the location of the work center and the types and amounts of HM use are kept secret.

- ***Tenant/Organizational Territoriality -- Turf Battles.*** Tenant or organizational territoriality is, perhaps, one of the most common barriers to implementing a pharmacy approach on a complex facility or installation. Tenants and organizations have generally developed their own approaches to HM supply and control, albeit to varying degrees. They are often very reluctant to turn over control of that process to a central facility and will often argue that central control will impede their ability to obtain and distribute HM in a timely fashion. Arguments about availability of specialized chemicals required on an occasional basis may also arise, since many logistical programs are predicated on demand determination. For example, if the logistical system determined demand based on an annual cycle and a particular material may only be required once every two years, it will not appear on the logistical requirements. Underlying all of the arguments is often a concern about loss of jobs, since many tenants have funding for positions to handle their HM needs. Each of these concerns has solutions. Fully explaining the process and involving the key user personnel usually addresses questions regarding availability, supply and distribution. Special standing requirements or expedited ordering processes for seldom used materials, with instructions on requirements review ensures that special needs are met. The potential for job loss, while potentially good for the facility and organizational levels in terms of overall costs, presents a challenge. While a loss of jobs may occur, it may be possible to alter the work requirements of affected personnel to a more mission-related set of tasks depending on the organizational requirements. Regardless of the issue, open communication is a necessity.

- ***Institutional Inertia.*** This barrier is characterized by several hallmark responses, among them, "We've always done it this way, why change now?" and "If it ain't broke, don't fix it." The fact is, people are inherently suspicious of and resistant to change. Change means learning new things, adapting to new situations, and altering current practices. It upsets the status quo. Of all the barriers to implementing change, this presents the most difficult challenge. People will spend enormous amounts of energy coming up with

arguments against change, especially if they don't understand the process and if it is a top-down driven program. That is why it is critical to involve the multiple levels of a facility, from management to user, in the process, reinforcing that each of these levels has ownership in the overall program. If they help build it, the arguments against change become difficult to sustain.

CONCLUSION

This paper explores the drivers for a pharmacy program, chief among them protection of human and environmental health and safety; the process for implementing the program; and the barriers to implementing the program. This serves as an overview; the process is simple and straightforward. The survey, properly communicated and conducted, and the data assembly are also simple processes. Determining the options available and agreeing upon an approach, then actually implementing a pharmacy program present the greatest challenges in terms of involving the stakeholders, communicating the process and program, and implanting the program. It is here that understanding of the issues, planning, patience, skill, and knowledge come into play. Understanding facility/installation complexities and needs, listening to and incorporating ideas from all levels, and ensuring that all staff are properly and continually informed BEFORE the pharmacy is decided upon is key to success. One can guide this process and present options for consideration, but ultimately the management and users at the facility/organization must take ownership of the program to achieve success in worker safety, cost savings and avoidance, efficiency of operation, and tracking and reporting. When that happens, the facility/installation wins, the organization wins, and the worker wins.