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September 1, 2009

Request for Regulatory Interpretation
U.S. Department of Labor
Occupational Safety & Health Administration
200 Constitution Avenue
Washington, D.C. 20210

Ms. Debby Dietrich
Director, U.S. EPA Office of Emergency Management
Ariel Rios Building (5104A)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Request for interpretation of PSM and RMP regulations

Ladies and Gentlemen:

The purpose of this letter is to request an interpretation of the PSM and RMP regulations as they apply to onsite vendors of chemicals and gases on a facility subject to PSM/RMP. My clients, a pharmaceutical company and three of their suppliers, have jointly drafted this letter to clarify their roles under these regulations. The letter is being submitted to EPA and OSHA at the same time, as both agencies have similar regulations that apply.

Current Situation

My direct client, a pharmaceutical manufacturer ("PHARMA"), has facilities in four states that are subject to PSM and RMP requirements. Several of these sites have at least one "on site vendor" ("VENDOR") who supplies chemicals or gases, which are subject to PSM/RMP, to the PSM regulated processes operated by PHARMA.

The following characterizes the relationships between the VENDOR and PHARMA:

1. The VENDOR owns, operates, and maintains their storage and chemical supply equipment located on the PHARMA site with no involvement of PHARMA. In most cases, the contract between the VENDOR and PHARMA prohibits PHARMA from doing any work or operating the VENDOR equipment.
2. The VENDOR equipment is always located in a separate physical location from PHARMA equipment (and often fenced). The connection between the two subsystems is by pipe with PHARMA usually taking "control" at the point where the pipe leaves the "property" occupied by the VENDOR.
3. The property occupied by VENDOR is sometimes officially leased and sometimes not. However, the VENDOR has physical control of the area where their equipment is located.

4. PHARMA owns, operates, and maintains their chemical distribution piping and production equipment. VENDOR has no involvement with that equipment.
5. The VENDOR and PHARMA have done a process hazard analysis on each of their respective subsystems and on the potential effects of any interaction between them, fully defining any issues where a malfunction in one system would affect the other. Any alarm and/or automated shutdown system that was identified as required by the process hazard analysis between the two systems has been installed, tested, and maintained to the satisfaction of both parties. The parties have agreed that when the time comes up for reviewing and renewing the process hazard analysis, it will again be a joint effort.
6. Both the VENDOR and PHARMA have shared all management of change information between them.
7. PHARMA has registered the system under RMP with EPA and has completed the required estimated release and offsite consequence analysis. The VENDOR reviewed the choice of release scenarios (some of them involved releases from VENDOR equipment) and the two parties agreed on the scenarios and results.
8. The VENDOR has given a copy of their PSM manual to PHARMA, usually holding back some details of operating procedures or maintenance procedures as a trade secret. In general, PHARMA has no direct visibility of the VENDOR implementation of their manual (employee training, employee participation, certification of operating procedures, implementation of mechanical integrity procedures, etc.).
9. PHARMA has not given the VENDOR any copy of their PSM manual, nor does the VENDOR have any visibility of the implementation by PHARMA of their PSM/RMP program.

Questions to be Resolved

PHARMA and VENDORs want to understand, from the point of view of both EPA and OSHA, the relationship and regulatory requirements that apply under RMP and PSM. PHARMA has a variety of contractual arrangements with VENDORs and is not sure that all roles and responsibilities defined under these contracts comply with the regulations. VENDORs also want to assure that they understand and fulfill their regulatory obligations.

EPA-Specific Questions

Currently, PHARMA has registered some RMP systems with VENDOR as operator and others that do not identify the role of VENDOR at all in that system's operation. There is effectively no difference in actual role of the two parties in operations of the system that exist, despite the different form and format of the registration.

A. What is the correct method(s) for registering a RMP-regulated system with two distinct parts, one subpart of which is owned and operated by a VENDOR and another subpart of which is owned and operated by PHARMA?
B. Does the method of registration of such a system shift the regulatory burden and obligation between VENDOR and PHARMA in any manner? If so, how?

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OSHA-Specific Questions

The question of the multi-employer work place policy and its applicability is unclear in this circumstance. Both PHARMA and VENDOR can see arguments where each of them is a controlling employer in their owned area with some obligations to the other party. Another alternative interpretation would have PHARMA be the overall controlling employer VENDOR being only potentially an exposing or creating employer.

C. Does the multi-employer workplace policy apply?
D. What are the respective potential roles of the PHARMA and VENDOR under this policy?
E. What obligations do the two parties have to share data and information under those roles, as it would apply to PSM information?

To the extent you can be specific about the various pieces of information that must be shared under PSM, it would be extremely helpful. For example, should each party provide the other information about various subcontractors they may use? Must they share compliance information more often than the every three year compliance audit? Must they share information on their completion of required mechanical integrity inspections or maintenance?

Questions to both regulators

There are several issues that appear in both the EPA and OSHA regulations and thus require interpretation by both regulatory agencies. Ideally, the interpretations from both agencies would match but PHARMA and VENDORs can see circumstances where they may not.

<u>Contractor Requirements</u>

It is unclear if the contractor regulations in the PSM/RMP regulations apply in the circumstance where each onsite party owns and operates part of the process:

F. Is VENDOR a "contractor" (as defined under PSM/RMP) to PHARMA or are they essentially an equal party subject to PSM/RMP requirements for the portion of the system that they own, operate, and maintain?

<u>Compliance Audit</u>

The parties agree that a compliance audit must be conducted on the whole system. We see the following alternatives as potentially being acceptable:

1. PHARMA and VENDOR conduct a joint audit on both systems, including the safety systems that interconnect them.
2. PHARMA and VENDOR each conduct an audit on their part of the system and they jointly review the safety systems that interconnect them.
3. Either PHARMA or VENDOR conduct an audit on the whole system, including the safety systems that interconnect them.

G. Are we correct in stating that these options are all valid?

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H. Is there any obligation to share audit results between the two parties, if option 2 is chosen? [We recognize this conclusion may be different between EPA and OSHA due to OSHA's multi-employer workplace policy, if it applies].

I. Is there any obligation to share compliance information or provide a compliance certification to the other party between audits, given that they are required only every three years?

Compliance Obligation

How would EPA and OSHA view the compliance obligations of each party, given the arrangements discussed above?

J. Would PHARMA, as the overall site owner, be responsible for compliance of the overall system; or
K. Would PHARMA and VENDOR be each responsible for compliance of their separate parts of the system and jointly responsible for the safety systems that interconnect them?

Any information or explanation that you could give on the relative roles and responsibilities would be appreciated, as the parties currently have widely varying contracts between them that have different assumptions about the compliance obligations of each party.

We recognize that the questions stated above are complex, but both PHARMA and VENDORs agree that they apply to many workplaces subject to PSM and RMP. Given that both EPA and OSHA regulate these issues, we would hope that the two agencies would coordinate their replies, if possible. If any parts of this letter are unclear or if decisions hinge on unstated data, please feel free to call me at 510-495-6060 so that I may provide additional information to help in the clarification. We appreciate your time and attention to this issue.

Sincerely,

Randy Roig, PhD
President
Specialty Technical Consultants, Inc.