Roles for Third Parties in Improving Implementation of EPA’s and OSHA’s Regulations on the Management of Low-Probability, High-Consequence Process Safety Risks

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1) Introduction
A recent Wharton study on “Roles for Third Parties in Implementing USDA Food Safety and Inspection Service (FSIS)’s Food Safety Process Management Programs” (Wharton 3rd Party Food Safety paper) examined the roles that third parties played in implementing a variety of regulations dealing with a low-probability, high-consequence (LP-HC) process risks. The regulations that were examined are:

1. Annual financial reports on Public companies [SEC]
2. Mechanical press safeguarding [OSHA]
3. Process safety management [OSHA]
4. Process safety management [EPA]
5. Hazard analysis and critical control point (HACCP) [USDA]
6. Boiler and pressure vessel integrity [State Boiler & Pressure Vessel Agencies]

The objective of this examination was to determine whether the use of third party auditors could enhance the ability of USDA/FSIS to ensure that food processing facilities covered under its Hazard Analysis Critical Control Point (HACCP) regulation adhered to required safe food processing practices. The Wharton 3rd Party Food Safety paper concluded that enhanced use of third party audits by USDA/FSIS could lead to enhanced implementation of its HACCP regulation.

During the development of the Wharton 3rd Party Food Safety paper, it became apparent that OSHA’s and EPA’s implementation of their respective process safety regulations were significantly less effective than what USDA/FSIS had achieved with their present HACCP regulation. Wharton undertook this paper’s study of whether the use of third party audits might enhance OSHA’s and EPA’s ability to more effectively implement their respective process safety regulations.

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i This research has been supported by a grant from the USDA’s Economic Research Service (ERS) office http://www.ers.usda.gov/ and the Wharton Risk Management and Decision Processes Center.
This paper is also focused on a third party audit proposal whose objective is improving OSHA’s and EPA’s ability to implement their respective process safety regulations more effectively and it incorporates the ‘lessons learned’ from the six regulations studied in the cited Wharton study, and a seventh regulation:

7. Mine Safety and Health Administration’s (MSHA) regulation on coal mine health and safety

Before we examine the problems affecting the implementation of EPA’s RMP and OSHA’s PSM Regulations in the next section of this paper, it is of value to review the following observations made in the Wharton 3rd Party Food Safety paper:

- Achievement of the objectives of the first five of the six examined regulations was compromised by one or more significant deficiencies in the provisions and/or the implementation of these five regulations.
- Implementation of three of these six regulations, ‘Mechanical press safeguarding’, ‘Annual financial reports on public companies’ and ‘Boiler and pressure vessel integrity’, depended heavily on the use of third party auditors.
- By and large, only the various State Boiler and Pressure Vessel Regulations have all of the following attributes:
  - Reasonably successful in controlling their covered risks
  - Supported by fees imposed on facilities covered under the Regulations
  - Utilize third party auditors associated with Boiler & Pressure vessel insurance companies in executing their compliance audits

As noted, this paper’s major objective is development of an auditing proposal aimed at improving OSHA’s and EPA’s ability to implement their respective process safety regulations more effectively and it also address pertinent observations on major problems currently affecting the implementation of all of the seven previously listed regulations.

Before presenting its observations on the major problems currently affecting implementation of all of the previously listed regulations, the paper will briefly review the problems affecting the implementation of EPA’s RMP and OSHA’s PSM current Regulations.

II) Problems affecting the implementation of EPA’s RMP and OSHA’s PSM Regulations

The OSHA PSM regulation was promulgated in 1992 about three years before the EPA RMP regulation. Most of the provisions of EPA’s RMP’s major accident prevention regulation are similar to those in OSHA’s PSM regulation, and effective implementation of the two regulations is closely intertwined.

The OSHA PSM regulation is focused on the reducing the likelihood and impacts of process accidents on plant employees, contractors and property, whereas EPA’s RMP regulation is focused on reducing the likelihood and impact of process accidents on the public, off-site property and the environment.
Achieving ‘adequate’ implementation of either the OSHA PSM or the EPA RMP regulations is a challenging task since both regulations are management based. Management based regulations do not operationally detail the specific technical, and performance practices that must be in place in order for a covered process to be compliant with the regulation’s requirements.

The Wharton Risk Management and Decision Processes Center and EPA Region III held a series of roundtables from May 3, 1994 to March 24, 1995, at which a diverse group of participants explored the use of third party auditors as a tool for assisting RMP covered ammonia facilities’ implement the RMP regulation. Participants in these roundtables included Federal and State regulators, university faculty, representatives from the refrigeration industry, insurance and other industry segments. The major lessons learned in these roundtables in regard to the use of third party auditors as a tool for assisting facilities’ in their implementation of the RMP regulation were summarized in Er et al. (1998).7

Despite this Region III-Wharton initiative and similar efforts by Industry and government, both EPA’s RMP and OSHA’s PSM Regulations have been relatively ineffectively implemented and some EPA staff members anticipated that this would be the case. For example, in 2001, Belke, an employee of EPA’s Chemical Emergency Preparedness and Prevention office (CEPPO) which managed EPA’s implementation of the RMP regulation, presented a paper 8 that discussed EPA’s RMP implementation program, and noted:

“Considering the difficulty inherent in risk management program audits, and the small number of government inspectors available to do them, it is unlikely that EPA will ever be able to regularly perform comprehensive RMP audits on more than a small fraction of the total number of regulated facilities) (emphasis added). Recognizing these realities, EPA is considering the feasibility of a voluntary (emphasis added) program where qualified third parties (emphasis added) program would perform comprehensive RMP audits at facilities that volunteer to undergo such an audit.”

In December 2001, EPA proposed a regulation aimed at the addressing the resource problem noted in the cited Belke paper. This proposed regulation dealt with voluntary third party audits of covered facility RMP compliance programs. In 2003, this proposal was withdrawn by EPA for unstated reasons.

As the following series of ‘Observations’ shows, it soon became apparent that both the OSHA PSM and EPA RMP process safety regulations have been poorly implemented to date.

III) Observations on problems affecting EPA’s implementation of its RMP Regulation

In 2009, EPA’s Inspector General Office (IG) commented on EPA’s implementation of the RMP program and made the following observations:
1. “Over 65 percent of all active RMP facilities had not received an on-site inspection or audit since inception of the Risk Management Program in 1999.”

2. “EPA had not inspected or audited over half (296 of 493) of the high-risk facilities (emphasis added) identified by EPA’s Office of Emergency Management (OEM).

3. “Of the 296 uninspected high-risk facilities managed by EPA, 151 could each impact 100,000 people or more in a worst-case accident.”

IV) Observations on problems affecting OSHA’s implementation of its process safety Regulation

The following observations show that OSHA also did not adequately implement its PSM regulation:

1. The frequency of OSHA PSM compliance inspections decreased drastically over the 1994 - 2006 time period (Table 1).

<table>
<thead>
<tr>
<th>Time period of OSHA inspections</th>
<th>Number of PSM accident-related inspections</th>
<th>Number of PSM accident-related citations</th>
<th>Number of citations per accident inspected</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA 92-93</td>
<td>16</td>
<td>14</td>
<td>0.9</td>
</tr>
<tr>
<td>OSHA 94-98</td>
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<tr>
<td>OSHA 99-03</td>
<td>37</td>
<td>243</td>
<td>6.6</td>
</tr>
<tr>
<td>OSHA 04-06</td>
<td>9</td>
<td>249</td>
<td>27.7</td>
</tr>
</tbody>
</table>

* Data on PSM inspections between 1992 and 2006 was taken from Honghong Luo paper12.

2. A 2010 CPRii report13 on “Workers at Risk: Regulatory Dysfunction at OSHA” noted that:

“Today OSHA’s enforcement staff is stretched thin and the rulemaking staff struggle to produce health and safety standards that can withstand industry legal challenges. In short, OSHA is a picture of regulatory dysfunction.”

ii CPR, the Center for Progressive Reform, is an organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment that seeks to inform policy debates, critique anti-regulatory research, enhance public understanding of the issues, and open the regulatory process to public scrutiny. http://www.progressivereform.org/aboutCPR.cfm
3. The US Chemical Safety Board (CSB) commented on OSHA PSM inspections and noted that:
“OSHA conducted only one planned process safety management inspection of the Texas City refinery facility in the 1998–2005 time periods though this facility was one of the largest refineries in the USA.”

V) Observations on other Agencies’ problems in implementing regulations covering LP-HC risks.

As Er et al. (1998) and the following examples show, the resource and other problems that EPA and OSHA face in adequately implementing their process safety regulations is not unusual. It has been generally the case that most government agencies have similar problems that hinder them from adequately addressing LP-HC risks.

Some specific observations on these problems and obstacles in regard to regulations other than the OSHA PSM and EPA RMP regulations are:

• USDA’s Office of the Inspector General (OIG) issued a report on the efficacy of FSIS assessments of covered facility’s food safety in 2006 and concluded:
“Based on our audit results, we question whether FSIS has the systems in place, at this time, to provide reasonable assurance that risk can be timely or fully assessed, especially since FSIS lacks current, comprehensive assessments of establishments’ food safety systems.” (emphasis added)

• The 2009 Congressional Research Service (CRS) report on FSIS contained a similar finding:
“From time to time in the past, FSIS has had difficulty in sufficiently staffing (emphasis added) its service obligations to the meat and poultry industries. Usually a combination of factors causes these shortages, including new technologies that increase plant production speeds and volume and insufficient appropriated funds to hire additional inspectors.” (emphasis added)

• The Inspector general of the Department of Labor commented on the Mine Safety and Health Administration’s (MSHA) implementation of its coal mining health and safety regulations at a Congressional House Education and Labor committee hearing, and the chairman of this committee noted:
“The Inspector General’s alert raises very serious concerns that go to the heart of health and safety of mine workers. Prior to Assistant Secretary Main’s confirmation, MSHA obstructed a key safety enforcement tool that could have endangered the lives of mine workers,” said Miller, chairman of the House Education and Labor. “We will continue our rigorous oversight of mine safety, including introduction of significant reforms to our nation’s health and safety laws in the coming days. This memorandum also raises questions about whether MSHA districts have sufficient resources to enforce the law.” (emphasis added)
• The Securities and Exchange Commission (SEC), the USA agency ultimately responsible for the preparation of financial reports on public companies, experienced failures in ensuring the mandated independence of the financial auditors certified to prepare the SEC’s required annual Public company financial reports.

For example, Gillan and Martin\textsuperscript{19} made the following observation in regard to the ‘independence’ required of Andersen as a third party auditor following the Enron Scandals:\textsuperscript{iii} “Andersen served as both Enron’s internal and external auditor. Essentially, when Andersen performed its external audit it was reviewing its own work (\textit{emphasis added}). For example, Andersen advised Enron on the structure of many its SPEs, received consulting income for doing so, and audited those transactions. This leads to the third challenge to auditor independence – auditors accepting consulting engagements with audit clients have long been recognized as a potential source of conflict of interest problems.”

• On March 14, 1988, OSHA issued an amended Mechanical Power Press regulation permitting the use of Power Sensing Devices (PSDI).

The amended regulation contained an added paragraph (h) which required among other things that the safety of a PSDI mechanical power press must be validated by an approved OSHA-certified “validator” (third party auditor) (\textit{emphasis added}) before it is placed into operation and must also be recertified as “safe” annually.

This standard was never implemented because no applicants sought to become an approved OSHA-certified “validator” (third party auditor). Industry sources interviewed on why no applicants sought to become OSHA third party validators provided similar comments to OSHA. The major thrusts of these comments\textsuperscript{20} are as follows:

“The standard requires the third party auditor to validate that “no single failure will result in an injury.” Given that a mechanical power press has a single brake, a single clutch, and a single transmission, it is impossible to state that a single failure will not result in an injury. A catastrophic mechanical failure could, and occasionally has, resulted in injuries. The only machine guard that prevents operator injuries in this case is the automatic pullback device. Pullbacks, like the other non-PSD guards, do not protect non-operators who are sometimes the ones injured. Consequently, no third party (or original equipment manufacturer (OEM)) would be willing to make this validation that OSHA requires (\textit{emphasis added}).

Any organization that served as a third party would be taking on considerable potential liability, (\textit{emphasis added}) sharing with the OEM exposure if an injury occurred. Because injuries continue to occur and lawsuits against OEMs are not uncommon, most testing organizations do not want to take the risk.

\textsuperscript{iii} A large number of company accounting malpractices and frauds emerged in the 2000-2002 period. The scandal at the Enron Corporation was the most notorious of these cases which were collectively labeled by the press as the “Enron Scandals.”
Third-party testing organizations usually test to a specific test standard that covers a particular kind of item (e.g., hardhats, electrical wires). Paragraph (h) requires the testing of the press, the PSD, and the control system, plus the installation. Combined with liability concerns (emphasis added), this type of validation raises substantial concerns about the ability of organizations to do the validation.”

V) Observations on reasonably successful implementation of LP-HC process risk regulations.

The only one of the five LP-HC process risk regulations examined in the Wharton paper that appears to have been reasonably well implemented were the various state boiler and pressure vessel integrity regulations. The principle factors that appear to have contributed to the effective implementation of the boiler and pressure vessel integrity regulations were:

1. The quality and operational nature of the ASME Boiler and Pressure Vessel (‘Boiler’) code used by regulators to help define acceptable practices.
2. A relatively high frequency of regulatory agency inspections of covered Boiler facilities (annually).
3. Funding of compliance audits with fees imposed on regulated Boiler facilities to counter the tendency of governments to underfund enforcement of regulations dealing with LP-HC risks.
4. The bulk of the audits of covered facilities compliance with the Boiler and Pressure Vessel regulatory requirements were performed by third party auditors associated with insurance companies that covered losses associated with Boiler and Pressure Vessel accidents and such auditors were likely to have a self-interest or pre-disposition towards preventing such losses (emphasis added).

VI) Outline of a Proposal on the Use of Third Party Audits, Funded by Imposed Fees, to Strengthen EPA’s and OSHA’s Implementation of Their Process Safety Regulations.

The paper has previously presented observations on the resource and other problems faced by a wide variety of agencies in implementing regulations dealing with LP-HC risks. Based on these observations, this section proposes a strategy for improving EPA’s and OSHA’s implementation of their process safety regulations.

The proposed strategy calls for the use of third party audits funded by fees on facilities covered under the EPA RMP and the OSHA PSM regulations. It also incorporates measures aimed at addressing a variety of the other problems that the previously examined agencies faced in attempting to adequately implement their discussed LP-HC regulations.
**Objective of the Proposal**
The objective of this proposal is to improve covered facilities’ compliance with the requirements of the EPA RMP and the OSHA PSM regulations by providing each agency with the resources needed to adequately ascertain whether a covered facility has either:

a. Achieved reasonable compliance with the Agency’s process safety regulations  
   or:  
b. Undertaken reasonable steps to address Agency findings of noncompliance

**Required Qualifications for Third Party Auditors**
The following qualifications would be required of third party auditors:

1. Educational background, knowledge and experience equivalent to that which EPA and/or OSHA would require of its staff members if the staff member was detailed to execute the specified audit function.

2. Commitment to be available for at least a specified number of audit assignments each year.

3. Agreement to treat the results of audits performed for the Agencies as confidential information unless explicitly released of this obligation by OSHA or EPA in regard to a specific audit.

4. Ability to establish either:
   a. Their neutrality and independence.  
   or:  
b. Past conduct of a significant number of process safety audits for organizations that have a self interest in the prevention of process accidents, such as insurance companies that provide coverage to firms for process accident losses, labor unions whose members are engaged in operating processes covered under the OSHA PSM or EPA RMP regulations, and public interest organizations whose constituents might be adversely affected by a process accident.

**Responsibilities of Regulatory Agencies**
In accepting and acting on the findings of third party RMP or PSM auditor reports regulatory agencies will have the following responsibilities:

1. Verifying that the third party audit report addresses all pertinent EPA RMP and OSHA PSM regulatory requirements.

2. Judging whether the third party audit findings justify issuing non-compliance citations.

3. Integrating third party auditor’s findings into an Agency final audit report on the facility.
4. Conducting a Regulatory Agency re-inspection to evaluate the validity of a third party auditors’ “non compliance” finding, if:
   a. The third party audit findings appear to justify the Agency issuing a citation for a “serious violation”\textsuperscript{21}
   or
   b. The final audit report is disputed by the audited facility.

**Use, Frequency and Funding of Third Party Audits**

1. EPA and OSHA will conduct a third party audit of all covered facilities compliance with their Agencies’ process safety regulation at least once every two years\textsuperscript{iv}.

2. If either EPA or OSHA do not have the resources to execute the number of audits required to meet the targeted audit frequency, they shall request that Congress and/or the appropriate Presidential executive office either:
   a. Appropriate or allocate the funds required to hire the additional employees and cover the expense of conducting the required audits,
   or
   b. Authorize EPA and OSHA to fund third party audits with fees imposed on the inspected facilities.

**Notes and Comments on the Four Elements of the Third Party Proposal:**

The paper’s previous observations showed that there are a number of problems that hinder one or more of the seven examined agencies’ implementation of their process safety regulations. The author believes that the following three problems present the greatest challenges to the effective implementation of their process safety regulations by EPA, OSHA and the other reviewed seven agencies.

Problem 1: Underfunding of the Agencies responsible for implementing the Regulations.

Problem 2: Hidden conflict of interest problems that compromise the objectivity of supposedly independent third party auditor findings. (See reference 14 of this paper and the papers’ earlier observation on Andersen’s audit of Enron’s financial statements.)

Problem 3: Third party auditor concerns in regard to being sued if their findings on covered facilities lack of regulatory compliance were used directly for regulatory agency enforcement actions. (See this paper’s earlier observations on OSHA’s Mechanical Power Press regulation.)

\textsuperscript{iv} The author believes that EPA and OSHA should try to ensure that both Agencies’ compliance audits of a covered facility do not take place in the same year. This coordination of audit schedules should be a cost effective way of improving each Agencies’ implementation of their respective regulations since both Agencies process safety regulations share my common requirements.
Problem 1 is addressed in this paper’s third party audit proposal by requiring that the Congress either:

1. Appropriate the funds EPA and OSHA need to hire the staff needed to conduct compliance inspections at least every two years.

or

2. Authorize EPA and OSHA to impose fees on regulated facilities to cover the cost of such third party audits.

Problem 2 is addressed by this paper’s criteria for the selection of third party auditors which takes into account TITLE II—AUDITOR INDEPENDENCE of the Sarbanes Oxley Act.22

Problem 3 is addressed by this paper’s audit proposal requirement that EPA and OSHA shall Conduct a Regulatory Agency re-inspection to evaluate the validity of a third party auditors’ “non compliance” finding, if:

1. The third party audit findings appear to justify the Agency issuing a citation for a previously defined “serious violation.”

or

2. The final audit report is disputed by the audited facility.

VII) Closing Observations

Many regulatory agencies use third party auditors, funded by imposed fees, as a tool for implementing of a wide range of regulations. Examples of this practice are the:

1. State Boiler and Pressure Vessel Regulations
2. State automobile and truck vehicle inspection requirements
3. Various State Ground Water Discharge regulations such as the one in Colorado23
4. USA Security and Exchange Commission requirement that that a Certified Public Accountants (CPA) audit ‘public’ company financial statements
5. USDA’s National Organic Program24 which mandates that qualified Certifying Agents paid by the facility, verify covered facilities’ compliance with the regulations requirements.
6. EPA’s Underground Storage Tank Inspection Program25 which requires that a state-authorized third-party inspector, paid by the owner or operator of an underground storage tank (UST), perform on-site inspections.

Clearly, third party audits, funded by imposed fees have been implicitly or explicitly adopted as a tool for implementing regulations by most of the forty eight States and numerous Federal Government regulatory agencies.

Hopefully this paper’s discussions will help communities at risk from the consequences of process safety accidents convince Congress that it should either:

1. Provide the additional funding that EPA and OSHA require to hire the number of agency employees they need to adequately implement their process safety regulations.
2. Authorize EPA and OSHA to impose the inspection fees needed to execute the third party audits both agencies need to ensure adequate implementation of their process safety regulations.

The author believes that Congress should choose the second alternative, given its history of failing to consistently and adequately fund implementation of most regulations dealing with LP-HC risks.

However, it is clear that obtaining Congressional approval of the use of third party audits, funded by imposed inspection fees, as a major tool for implementing the OSHA and EPA process safety regulations will be a challenging task: It will require, at the minimum, appropriate lobbying by stakeholders directly at risk from process accidents such as:

- Plant communities affected by process safety accidents
- Process safety workers and their unions, and
- Companies that insure covered facilities against accident losses

References


2 Third-Party Inspection as an Alternative to Command and Control Regulation, Howard C. Kunreuther, Patrick J. McNulty, and Yong Kang, Risk Analysis, Vol. 22, No. 2, 2002 “The use of third-party inspections has had very beneficial effects on reducing the risks associated with different activities. Steam boiler accidents have been very rare ever since it was required that boilers be inspected.” http://opim.wharton.upenn.edu/risk/downloads/02-03-HK.pdf


5 “Management-Based Regulation: Using Private-Sector Management to Achieve Public Goals” Coglianese, C., and Lazer, D. http://web.hks.harvard.edu/publications/workingpapers/citation.aspx?PubId=677 “Yet missing from the traditional emphasis on technology-based and performance-based regulation has been much systematic attention to a third type of regulatory instrument that we call ‘management-based regulation.’ Management-based regulation does not specify the technologies to be used to achieve socially desirable behavior; nor does it require specific outputs in terms of social goals. Rather, a management-based approach requires firms to engage in their own planning and internal rulemaking efforts that are supposed to aim toward the achievement of specific public goals.”
6 “Operational”: i.e., meets the Deming definition “An operational definition is one that people can do business with.... It must be communicable, with the same meaning to vendor as to purchaser, same meaning yesterday and today...” Deming, W.E. (1982). Out of the Crisis, pp. 287-289. Cambridge, MA: MIT Center for Advanced Engineering Study.


17 Mine Safety and Health Administration, SUBCHAPTER O -- COAL MINE SAFETY AND HEALTH [Link](http://www.msha.gov/30cfr/0.0.HTM)


Regulatory Review of OSHA's Presence Sensing Device Initiation (PSDI) Standard:

a. CHAPTER 4: ANALYSIS OF WHY THE PSDI STANDARD WAS NOT IMPLEMENTED

b. Chapter 4, Section 4.1 Third-Party Validation, May 2004

"Introduction to OSHA", Citations and Penalties, Princeton University.
http://web.princeton.edu/sites/ehs/healthsafetyguide/F1.htm


"Overview of the Colorado State Domestic Ground Water Discharge Permit Program”
http://www.cdphe.state.co.us/wq/PermitsUnit/PERMITS/Domesticpermitsrats/GW_Permitting_Overview.pdf
This article notes that Colorado:
“also assesses fees for the development of preliminary effluent limitations (PELs) during the site application
process for new or modified domestic wastewater treatment plants.” Additional information on PELs and the fee
schedule is available for download at: www.cdphe.state.co.us/wq/PermitsUnit/PELBrochure.PDF

USDA’s PART 205—NATIONAL ORGANIC PROGRAM
(This regulation mandates the use of “Certifying Agents”, who are in essence USDA approved third party auditors
paid by the facility, to verify covered facilities’ compliance with the Regulations requirements on producing
products that meet USDA’s definition of “Organic”).
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=7:3.1.1.9.31&idno=7

EPA Brochure on Developing a Third-Party Underground Storage Tank Inspection Program: A Guide to Assist
States. See Page 1 which notes, “EPA defined a third-party inspection program in the inspection grant guidelines
as a state program in which a state-authorized third-party inspector is paid by the owner or operator of an
underground storage tank (UST) to perform an on-site inspection.”
http://www.epa.gov/oust/pubs/thirdpartyinspections.pdf