



OSWER Docket  
EPA Docket Center  
Mail Code 2822-1T  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Attention: Docket ID No. EPA-HQ-OEM- 2015-0725

RE: Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Proposed Rule and associated EPA ICR number 2537.01

Dear Sir/Madam:

The Vinyl Institute appreciates the opportunity to provide input to EPA to assist the agency in assessing the effectiveness of its chemical safety regulations – particularly its Risk Management Programs (RMP) -- and determining what steps (e.g., rulemaking, enforcement, outreach) the agency might take to improve chemical safety in the environment. The Vinyl Institute, founded in 1982, is a U.S. trade association representing the leading manufacturers of vinyl chloride monomer, PVC resin, vinyl additives and modifiers. The Vinyl Institute is dedicated to enhancing the growth and protecting the stature of the vinyl industry.

### **The Rush to Judgment**

On March 14, 2016, EPA issued the referenced proposed rule (NPRM),<sup>1</sup> which would amend 40 CFR Part 68, and invited public comment on the proposed rule and the associated Information Collection Request by May 13, 2016. However, EPA somewhat ambiguously indicated that comments on the associated Information Collection Request (ICR) being submitted to OMB for approval under the Paperwork Reduction Act should be filed by April 13, 2016 to ensure they were given full consideration. The NPRM (p. 13695, col. 3) states:

Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than April 13, 2016. The EPA will respond to any ICR-related comments in the final rule.

In contrast, p. 13638, col. 1 of the NPRM states:

Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of

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<sup>1</sup> Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Proposed Rule, 81 FR 13638 (March 14, 2016).



Management and Budget (OMB) receives a copy of your comments on or before April 13, 2016.

This unfortunate approach to the ICR is consistent with what we believe to be an inappropriate pre-judgment or rush to judgment for the entire initiative. We were greatly disappointed by EPA's decision not to extend the comment period in this proceeding as requested by many allied trade associations, and do not believe that decision was in the public interest. That action, in combination with the fact that the agency scheduled the public hearing in this proceeding only 15 days after issuing the NPRM, and submitted the NPRM to OMB for approval before the final report was issued by the SBREFA panel, reflects an inappropriate rush to judgment. The further suggestion that ICR comments need to be submitted by April 13 further reinforces that conclusion, especially when, with the exception of emergency response drills, virtually the entirely regulatory burden that would be imposed by the proposed rule falls into the category of the collection of information.

It is important to distinguish ICRs seeking an extension of approval of an existing rule and ICRs seeking approval for a new or significantly amended rule. In a situation like this one involving a new rule, with a potentially enormous information collection burden, it seems inconceivable that OMB would even consider approving the ICR before it approved the revised rule.

Given the circumstances, we determined it would be appropriate to raise these concerns sooner rather than later, provide EPA and OMB with input on some major areas of concern EPA ICR number 2537.01, and state that, for a variety of legal and public policy reasons, OMB should reject this ICR.

### **Overall Perspective**

We respectfully disagree with the premises and rationale for much of the proposed rule on legal and policy grounds. We do not believe the proposed requirements are reasonable and appropriate. We further conclude that EPA has dramatically underestimated the burden hours and costs for rule familiarization and each of the major components of the proposed rule: third party audits, root cause analysis, and the safer technology and alternatives analysis.

### **Third Party Audits**

We respectfully disagree with the premise and rationale for the proposed provision that would require third party audits following an accidental release or if required by an "implementing agency" (a term of unknown meaning, and will address the issues in our more detailed comments on this proposal. However, for purposes of discussion only, we will provide some preliminary thoughts on the potential impact of the requirement for a third party audit



following “an accidental release meeting the criteria in §68.42(a).” EPA failed to provide any explanation for the small number of facilities it estimated would be affected by this requirement.

The term “accidental release” is defined in Section 68.3 to mean “an unanticipated emission of a regulated substance or other extremely hazardous substance into the ambient air from a stationary source.” Section §68.42 appears to include “all accidental releases from covered processes that resulted in deaths, injuries, or significant property damage on site, or known offsite deaths, injuries, evacuations, sheltering in place, property damage, or environmental damage.” Under EPA’s approach, it appears that a third party audit would be required whenever there was an “accidental release” (regardless of the amount) that causes any “injury” (regardless of severity). That would lead to absurd results, which suggest that the term “accidental release” is being misinterpreted and that its scope needs to be narrowed or, in the alternative, equated with the term “catastrophic release.”

Consider the following examples.

A worker is standing within earshot of a relief valve or an audible alarm linked to the valve, there is a small, unanticipated emission of a covered chemical from the valve, the worker hears the release or the alarm, the worker is startled and bumps into a piece of equipment and incurs a bruise. Would a third party audit be required?

A worker is changing the packing on a valve on an anhydrous ammonia system and a small quantity of ammonia is released from the packing causing the worker (who should have been wearing a respirator) to experience nasal irritation. Would a third party audit be required?

A worker is checking or repairing some piping containing a covered chemical (e.g., ammonia > 20% and water mixture) and a small quantity of the mixture leaks out and causes some minor skin irritation to the worker. Would a third party audit be required?

A worker is driving a vehicle to respond to an unanticipated emission of a covered chemical and, on the way, incurs a minor injury in a traffic accident, or takes a short cut to the site by driving over and damaging some beds of plants. Would a third party audit be required?

Clearly, none of these events are catastrophic releases; nor do they provide any basis for concluding that a catastrophic release is more likely to occur at the site where one of these events occurred. EPA has not made any attempt to quantify the number of accidental releases that fall into this category. Under that set of definitions, it seems likely that a large portion of RMP sites would be subject to mandatory third party audits.



While unclear, the proposed rule seems to suggest that a triggering accidental release from one process would trigger a third-party audit obligation with respect to all RMP- covered processes at the same site, which may not be on the same audit schedule. For a site that has more than one covered process, it seems inappropriate and punitive for an accidental release from one process to automatically trigger a third party audit requirement for all covered processes.

As the agency has heard from many regulated entities, the people with the most expertise in process safety for a particular process are generally the people who design, operate and maintain that process, rather than outside consultants. If it was necessary to retain outside consultants to audit multiple processes, it could often require the site operator to retain multiple consultants. That would involve the negotiation of multiple contracts.

For third party audits, EPA's analysis "assumes that 10% of the overall burden hours are devoted to information collection." We would think 100% of the hours would be devoted to information collection, which means the burden would be 10 times EPA's estimates. The ICR asserts: "The burden for source staff to prepare for and support the auditor is covered in the existing ICR for Part 68." We respectfully disagree. An in-house audit team is already familiar with the process and the company, and has previously audited the process. It would be a relatively streamlined activity compared to a third party auditor that has to be initially educated on the process and then re-educated if called upon 3 or more years later to conduct another audit.

For an audit of a complex facility, EPA allocated 32 to 44 hours for site management time, 4 hours for an attorney's time, 0 to 56 hours for engineering staff time, and 0 hours for production staff time. Depending on the number and complexity of the processes, we believe the estimated management time of 32 to 44 hours, and the high end estimate of 56 hours of engineering staff time would approximate the minimum burden rather than an average burden. It is far more likely that an in-house attorney or outside counsel will require 10 to 40 hours to negotiate the consulting contract (depending on its complexity) and another 10 to 60 hours to review the developing work product (again depending on the complexity of the process). The production staff would have to be involved in an audit of the process and we estimate that burden would be at least 25 hours depending on the number and complexity of the processes.

Rather than proceeding on the basis of an informed risk assessment, an outside auditor would be more likely to take an overly conservative route based on a lack of knowledge of the process, and the overreaching and potentially chilling certification language contained in proposed Paragraph 68.80(c)(1)(v). This means site personnel will need to invest a significant amount of time (typically ranging from 3 to 30 hours, depending on the complexity of the process) on the "front end" to further educate the auditor to avoid having to spend additional time on the "back end" explaining why the proposed findings/conclusions are inappropriate and



should be changed, or documenting why the site rejected the auditor's findings or recommendations, and then explaining those points to an EPA enforcement official.

### **The Proposed STAA Requirement**

Again, as with the third party audit requirement, EPA "assumes that 10% of the overall hours are devoted to information collection" whereas we believe 100% of the hours involve information collection, which indicates that, if one accepts EPA's estimates, they should be multiplied by a factor of 10.

In our more detailed comments, we anticipate explaining why we respectfully disagree with the premise and rationale for the proposed STAA requirement. If the process risks are adequately addressed, there is no need for any process modifications. If there is no need for any process modifications, there is no need for an STAA analysis, which becomes nothing more than a huge and inappropriate expenditure of resources on an academic exercise. As a threshold matter, it does not appear that EPA has any sound basis for its information collection estimates, or that it has given adequate consideration to what it would be requiring. There is a huge concern that, once adopted, the STAA requirement would be interpreted in ways that were never contemplated.

For example, the proposed STAA requirement could be interpreted to mandate a comprehensive evaluation of every aspect of a process to determine whether there is any technically feasible process modification that would move that aspect of the process up to a higher level on the hierarchy of controls, under the erroneous presumption that it would improve the safety of the process. Once such a modification was identified as a possibility, the rule would then require a comprehensive economic analysis to determine whether the modification was economically feasible. The only way to make that determination would be to design and cost out the modifications. The preamble simplistically suggested that one example would be to substitute a non-regulated chemical for one of the regulated chemicals (e.g., substituting a non-ammonia refrigerant for anhydrous ammonia). That seems to suggest that the operator of an existing facility would have to go through the academic exercise of retaining an outside engineering firm to completely redesign a facility to utilize a substitute refrigerant (which would require a wholesale replacement of equipment) and then hire another outside firm to conduct an economic analysis to determine its economic feasibility (including terminating existing supply agreements, hiring or retraining personnel familiar with the new process, etc.). It would undertake that enormous burden involving hundreds of hours, knowing in advance that it would not be proceeding with the alternative refrigerant because it had adequately controlled the risk posed by the use of anhydrous ammonia, which is a widely recognized and accepted refrigerant, and the



adverse impacts of other options (e.g., financial waste, damage to the ozone layer) weigh against it.

The costs of engaging in the academic exercise of fully assessing the technical and economic feasibility of every process modification that could advance any aspect of the process up to a higher level in the hierarchy of controls would be enormous and a highly inappropriate use of scarce resources. We do not believe the agency has even scratched the surface in estimating the information collection costs of this proposal.

### **Root Cause Analysis**

Again, as with the third party audit requirement, EPA “assumes that 10% of the overall hours are devoted to information collection” whereas we believe 100% of the hours involve information collection, which indicates that, if one accepts EPA’s estimates, they should be multiplied by a factor of 10. EPA failed to provide any explanation for the small number of facilities it estimated would be affected by this requirement.

As explained by EPA (preamble pp. 13647, col. 3 and 13648, col. 1), the cause of an incident often can be described as an immediate cause, resulting from causal factors, which are a product of root causes:

Event	Immediate Cause	Causal Factors -- a major unplanned, unintended contributor to the incident (a negative occurrence or undesirable condition), that if eliminated would have either prevented the occurrence, or reduced its severity or frequency	Root Causes – According to EPA, “most root causes are associated with weaknesses, defects or breakdowns in management systems.”
Reactor rupture	Operator Error	Poor training, inappropriate procedures, or poor design of control systems	To be determined
Explosion	Equipment Failure	Improper maintenance, misuse of equipment (e.g., operating at too high a temperature), or use of incompatible materials	To be determined

Given the complexity of the covered processes, and the complexities and dynamics of human behavior, it is not credible to suggest that a root cause analysis can be properly conducted



by the responsible engineering and/or production staff in 1 to 5 hours, and that 10 to 50 hours would be more appropriate. The burden hours must reflect the time required to develop and document the necessary information and analysis. It cannot be limited in scope to the time spent hand writing, typing and/or editing the document. Furthermore, if EPA is correct in asserting that “most root causes are associated with weaknesses, defects or breakdowns in management systems,” it is likely that a root cause analysis could become a fairly complex, time-intensive and sensitive matter requiring the participation of management and legal counsel.

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VI appreciates the opportunity to submit these comments. Please contact me at if you have any questions.

Sincerely,  
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Vice President Regulatory & Technical Affairs

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