



JUN 1 2007

Dr. Michael Humora  
General Manager, TTC  
Hovione LLC  
40 Lake Drive  
East Windsor, New Jersey 08520

Dear Dr. Humora:

I am pleased to inform you that the Occupational Safety and Health Administration (OSHA) has approved your application for Star participation in our Voluntary Protection Programs (VPP). Please accept my hearty congratulations on this noteworthy achievement. You have joined an elite group of facilities that provide exemplary safety and health protection. Enclosed is a copy of the VPP Onsite Evaluation Report recommending approval of Hovione LLC, East Windsor, New Jersey.

Designation as a VPP Star participant is testament to sustained excellence in all areas of your safety and health management system. In recognition of this excellence and your cooperative partnership with the Agency, we will be removing your site from OSHA's scheduled inspection list. VPP participation, of course, does not diminish the rights and responsibilities extended to you and your employees by the Occupational Safety and Health Act of 1970. Employee complaints, fatalities, catastrophes, or significant chemical leaks/spills at your facility will continue to result in normal OSHA enforcement proceedings.

Each year by February 15<sup>th</sup>, please submit to OSHA your most recent safety and health management system evaluation and the following site-specific information for your facility and each applicable contractor:

- Injury and illness numbers and rates
- Total hours worked
- Average annual employment
- Any success stories that you would like to share

Send this information to the attention of your VPP Manager or Coordinator via:

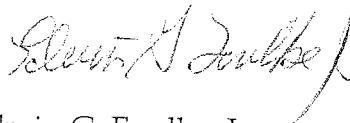
Patricia K. Clark  
Regional Administrator  
U.S. Department of Labor - OSHA  
201 Varick Street, Room 670  
New York, NY 10014

Your VPP Manager or Coordinator will receive the certificate and flag honoring your achievement within one month. Please make contact to arrange for their presentation.

VPP participants have shown a generous willingness to advance the cause of safety and health in their industries and communities. I hope you will consider sharing your expertise and experience by mentoring other companies. I also urge you to support your employees' participation in the VPP Special Government Employee (SGE) Program. SGEs have become a critical element in OSHA's efforts to increase worker protection by expanding VPP.

On behalf of OSHA, I extend my thanks to you and your employees for your commitment, hard work, and dedication to the principles embodied in VPP. I look forward to hearing about your continuing safety and health efforts and success.

Sincerely,



Edwin G. Foulke, Jr.

Enclosure

# VPP SITE REPORT

Recommending  
**Star Approval**

For

**Hovione LLC**  
**East Windsor, New Jersey**

Evaluation Date  
**December 19 – 20, 2006**

Report Date  
**December 20, 2006**

## Evaluation Team

Phil Mannheim, Team Leader  
Mike Yarnell, Backup Team Leader  
Kristine Logue, Industrial Hygienist  
Martin Davis, Safety Specialist

## **I. Purpose and Scope of Review**

An on-site review was conducted at Hovione LLC, 40 Lake Drive, East Windsor, NJ 08520 from December 19 - 20, 2006 to determine the site's eligibility for participation in the Occupational Safety and Health Administration's (OSHA's) Voluntary Protection Programs (VPP). The OSHA VPP Review Team consisted of: Phil Mannheim, Team Leader; Michael Yarnell, Back-up Team Leader; Kristine Logue, Industrial Hygienist and Martin Davis, Safety Specialist.

## **II. Methods of Data Collection**

The information for this report was obtained from the site's VPP Application; documentation reviewed onsite, interviews with employees, annual evaluations, previous evaluation reports if available and site walk-throughs of the facility.

## **III. Employees at the Worksite**

At the time of the evaluation there were 46 employees working on site. There was one contract employee onsite, the EHS Officer. Employees at the site are not represented by a collective bargaining agent. Formal interviews were conducted with 16 site employees. Informal interviews were conducted with 13 site employees.

## **IV. The Worksite**

The site is properly classified under the Standard Industrial Classification System (SIC) code 8731 and North American Industrial Classification System (NAICS) code 541710 for Scientific Research and Development Services. Hovione LLC conducts research and development of new drug products identified for therapeutic applications by its clients. Work typically entails development of alternative chemical synthesis and evaluation of raw materials. The company may proceed to small scale processes to verify a viable production path and confirm scalability of the process. Active pharmaceutical ingredients may be used by their clients in Stage 1 trials for drug development or commercial use. Housekeeping at the facility was considered by the OSHA VPP Review Team to be above average when compared to sites in similar industries.

## **V. Worksite Hazards**

Safety hazards at the facility include, but are not limited to explosion and fire, slippery floors, falls from elevations and lacerations from broken glass. Industrial hygiene hazards include, but are not limited to chemical exposure, ergonomic hazards and exposure to finished pharmaceutical products. The site does not use chemicals considered to be highly hazardous and in sufficient quantity to place the site under the Process Safety Management Standard.

## **VI. Injury and Illness Rates**

The three-year Total Case Incidence Rate (TCIR) and Days Away/Restricted/Transferred Case Incidence Rate (DART) for the period 2003-2005 are 1.2 and 0.0 respectively. The site

TCIR is 31 percent below and the DART is 100 percent below the 2005 BLS national industry average for NAICS 5417.

## **VII. OSHA Activity**

There has been OSHA inspection activity at this site within the past three years, but there have been neither Willful or Repeated violations nor fatalities. The site maintains an excellent relationship with their local OSHA Area and Regional offices.

## **VIII. Elements of the VPP Review/Program Changes**

The OSHA VPP Review team has examined each of the required elements of the site's safety and health management system and, in accordance with their application, found them to be consistent with the high quality expected of VPP participants. All VPP requirements are met and all OSHA standards are appropriately covered. For specifics on the individual site program elements consult the VPP Site Worksheet.

## **IX. Areas of Excellence**

All elements of the site's safety and health program met the high quality expected of VPP participants. In addition, the team considered the following examples of excellence in the programs reviewed:

- The labeling of piping in the Pilot and Kilo area were exceptionally clear with content and flow direction indicated.

## **X. Recommendation for Participation**

The OSHA VPP Review Team recommends Hovione, LLC be approved for participation in the OSHA VPP Star Program.

## Recordkeeping

A review of the OSHA 300 logs was made. The following are the total incidence and lost workday case rates since 2003:

Year	Hours	Total # of Cases	TCIR	Number of Cases Involving Days Away From Work, Restricted Activity or Job Transfer	DART Rate
2003	45100	0	0.0	0	0.0
2004	50112	1	4.0	0	0.0
2005	76509	0	0.0	0	0.0
<b>Total</b>	171721	1		0	
<b>Three-Year Rate (2003-2005)</b>			1.2		0.0
<b>BLS National Average for 2005 (NAICS 5417)</b>			1.7		0.8
<b>% Below/Above NAICS rates</b>			31		100
2006	79029	0	0.0	0	0.0

For the period 2003-2005, the site's:

- Total Case Incidence Rate (TCIR) is 1.2 (31% below the 2005 BLS industry averages for NAICS 5417).
- The Days Away from Work, Restricted Activity or Job Transfer (DART) case incidence rate is 0.0 (100% below the 2004 BLS industry averages for NAICS 5417).

The information on the OSHA 300 logs supports the information provided in the application, and the company's first report of injury forms support the data in the logs. The EHS Officer is responsible for the entries to the OSHA 300 log and verified the accuracy of the records. The EHS Officer understands the record-keeping requirements. Based upon interviews conducted with management and employees, the logs accurately reflect the injury and illness experience at this plant.

There were no temporary employees at the worksite at the time of the team's visit. Injuries or illnesses experienced by temporary employees under the direct supervision of Hovione LLC are recorded on the worksite's OSHA 300 log.

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				
<b>A. Written Safety &amp; Health Management System</b>				
A1. Are all the elements (such as Management Leadership and Employee Involvement, Worksite Analysis, Hazard Prevention and Control, and Safety and Health Training) and sub-elements of a basic safety and health management system part of a signed, written document? (For Federal Agencies, include 29 CFR 1960.) If not, please explain.	Y	X	X	X
•				
A2. Have all VPP elements and sub-elements been in place at least 1 year? If not, please identify those elements that have not been in place for at least 1 year.	Y	X	X	X
•				
A3. Is the written safety and health management system at least minimally effective to address the scope and complexity of the hazards at the site? (Smaller, less complex sites require a less complex system.) If not, please explain. MR⊙.	Y	X	X	X
•				
A4. Have any VPP documentation requirements been waived (as per FRN page 656, paragraph F5a4)? If so, please explain.	N			
•				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				
<b>B. Management Commitment &amp; Leadership</b>				
B1. Does management overall demonstrate at least minimally effective, visible leadership with respect to the safety and health program (considering FRN items F5 A-H)? Provide examples. MR⊙.	Y	X	X	
• Safety and health goals are established by Corporate				
• Achievement of goal is audited by EHS Officer				
• Top management attendance at safety committee meetings				
• Management is visible and accessible in all work areas				
B2. How has the site communicated established policies and results-oriented goals and objectives for worker safety to employees?		X	X	X
• Safety Committee				
• Periodic departmental meetings				
B3. Do employees understand the goals and objectives for the safety and health program?	Y	X	X	X
•				
B4. Are the safety and health program goals and objectives meaningful and attainable? Provide examples supporting the meaningfulness and attainability (or lack-there-of if answer is no) of the goal(s). (Attainability can either be unrealistic/realistic goals or poor/good implementation to achieve them.) (See: <u>CSP</u> Chapter 3 II C1a)	Y	X		X

<ul style="list-style-type: none"> <li>Controlling injuries and illnesses to the lowest possible level</li> <li>Maintenance of PPE</li> <li>To establish and maintain preventative maintenance records to facilitate more effective operations</li> <li>Prior to each use equipment is pressure tested</li> </ul>				
B5. <i>How does the site measure its progress towards the safety and health program goals and objectives? Provide examples.</i>		X	X	X
<ul style="list-style-type: none"> <li>Review and investigate near misses and implement changes/improvements as needed</li> </ul>				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				
<b>C. Planning</b>				
C1. <i>How does the site integrate planning for safety and health with its overall management planning process (for example, budget development, resource allocation, or training)?</i>		X		X
<ul style="list-style-type: none"> <li>Safety and Health is included in annual performance ratings</li> <li>Expenditures on safety related items are given priority</li> <li>Each area of the facility has responsibility to meet safety and health goals</li> <li>Safety and health is integral to all facility operations</li> </ul>				
C2. <i>Is safety and health effectively integrated into the site's overall management planning process? If not, please explain.</i>	Y	X		
<ul style="list-style-type: none"> <li></li> </ul>				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				
<b>D. Authority and Line Accountability</b>				
D1. <i>Does top management accept ultimate responsibility for safety and health in the organization? (Top management acknowledges ultimate responsibility even if some safety and health functions are delegated to others.) If not, please explain. MR⊙.</i>	Y	X	X	
<ul style="list-style-type: none"> <li></li> </ul>				
D2. <i>How is the assignment of authority and responsibility documented and communicated (for example, organization charts, job descriptions)?</i>		X	X	X
<ul style="list-style-type: none"> <li>Management has generated a staffing chart and has posted safety responsibility policy for the management staff</li> <li>Management has the responsibility to report hazardous conditions and assure that they are corrected in a timely manner</li> </ul>				
D3. <i>Do the individuals assigned responsibility for safety and health have the authority to ensure that hazards are corrected or necessary changes to the safety and health management system are made? If not, please explain. MR⊙.</i>	Y	X	X	X
<ul style="list-style-type: none"> <li></li> </ul>				
D4. <i>How are managers, supervisors, and employees held accountable for meeting their</i>		X		X

responsibilities for workplace safety and health? (Annual performance evaluations for managers and supervisors are required.)				
<ul style="list-style-type: none"> <li>Annual performance evaluations for managers include elements and goals for safety and health</li> </ul>				
D5. Are adequate resources (equipment, budget, or experts) dedicated to ensuring workplace safety and health? Provide examples. MR⊙.	Y	X	X	X
<ul style="list-style-type: none"> <li>Budget for a EHS consultant</li> <li>Medical surveillance, audiometric testing and respirator fitness evaluation is provided by an outside contractor</li> </ul>				
D6. Is access to experts (for example, Certified Industrial Hygienists, Certified Safety Professionals, Occupational Nurses, or Engineers), reasonably available to the site, based upon the nature, conditions, complexity, and hazards of the site? If so, under what arrangements and how often are they used?	Y	X		X
<ul style="list-style-type: none"> <li>Company contracts with SafeBridge East consultants for industrial hygiene expertise</li> <li>Company contracts with US HealthWorks and Interstate Mobile Care of New Jersey</li> </ul>				

	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				

<b>E. Contract Workers</b>				
E1. Does the site utilize contractors? Please explain.	Y	X		X
<ul style="list-style-type: none"> <li>The EHS Officer is a contract employee</li> <li>Contractors are used for various preventative maintenance tasks and system repair</li> </ul>				
E2. Were there contractors onsite at the time of the evaluation?	Y			
<ul style="list-style-type: none"> <li>The EHS Officer was onsite during the evaluation</li> </ul>				
E3. When selecting onsite contractors, how does the site evaluate the contractor's safety and health programs and performance (including rates)? (See: TED CSP Chapter 3 IV 3-19)		X		X
<ul style="list-style-type: none"> <li>Contractors must meet certain training and performance specifications</li> </ul>				
E4. Are contractors and subcontractors at the site to maintain effective safety and health programs and to comply with all applicable OSHA and company safety and health rules and regulations? If so, please provide examples.	Y		X	
<ul style="list-style-type: none"> <li>The EHS Officer was onsite during the evaluation</li> </ul>				
E5. Does the site's contractor program cover the prompt correction and control of hazards in the event that the contractor fails to correct or control such hazards? Provide examples. MR⊙.	Y	X		X
<ul style="list-style-type: none"> <li>Contractor activities are monitored by a management representative</li> <li>All contractors must undergo a site orientation and safety review prior to beginning work</li> </ul>				
E6. How does the site document and communicate oversight, co-ordination, and enforcement of safety and health expectations to contractors?		X		X
<ul style="list-style-type: none"> <li>All contractors must undergo a site orientation and safety review prior to beginning work</li> <li>Hotwork permit system is in effect for contractors</li> </ul>				
E7. Have the contract provisions specifying penalties for safety and health issues been enforced, when appropriate? If not, please explain.	Y	X		X
<ul style="list-style-type: none"> <li></li> </ul>				
E8. How does the site monitor the quality of the safety and health protection of its contract employees?		X		X
<ul style="list-style-type: none"> <li>Onsite oversight of the contractors by a project supervisor</li> </ul>				
E9. If the contractors' injury and illness rates are above the average for their industries,	Y	X		X

<p>does the site have procedures that ensure all employees are provided effective protection on the worksite? If not, please explain.</p> <ul style="list-style-type: none"> <li></li> </ul>				
<p>E10. Do contract provisions for contractors require the periodic review and analysis of injury and illness data? Provide examples.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X		X
<p>E11. Based on your answers to the above items, is the contract oversight minimally effective for the nature of the site? (Inadequate oversight is indicated by significant hazards created by the contractor, employees exposed to hazards, or a lack of host audits.) If not, please explain. MR⊙.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X		X

	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>Section I: Management Leadership &amp; Employee Involvement</b>				
<b>F. Employee Involvement</b>				
<p>F1. How were employees selected to be interviewed by the VPP team?</p> <ul style="list-style-type: none"> <li>Employees were randomly selected from a site employee roster by the Team Leader</li> </ul>				
<p>F2. How many employees were interviewed formally? How many were interviewed informally?</p> <ul style="list-style-type: none"> <li>16 formal and 12 informal interviews</li> </ul>				
<p>F3. Do employees support the site's participation in the VPP Process? MR⊙.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X	X	X
<p>F4. Do employees feel free to participate in the safety and health management system without fear of discrimination or reprisal? If so, please explain. MR⊙.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X	X	X
<p>F5. Please describe at least three ways in which employees are meaningfully involved in the problem identification and resolution, or evaluation of the safety and health program (beyond hazard reporting). (See: FRN Chapter 3 Paragraph II.C.1.b).</p> <ul style="list-style-type: none"> <li>Safety Committee participation</li> <li>Participation on emergency response teams</li> <li>Peer to peer program</li> <li>Safety hazard reporting (near miss) and safety suggestion program</li> <li>Employees at all levels are involved in risk assessment, PPE selection and the HAZOP process</li> </ul>		X	X	X
<p>F6. Are employees knowledgeable about the site's safety and health management system? If not, please explain.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X	X	X
<p>F7. Are employees knowledgeable about the VPP program? If not, please explain.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X		
<p>F8. Are the employees knowledgeable about OSHA their rights and responsibilities? If not, please explain.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X		
<p>F9. Do employees have access to results of self-inspection, accident investigation, appropriate medical records, and personal sampling data upon request? If not, please explain.</p> <ul style="list-style-type: none"> <li></li> </ul>	Y	X		X

## Section I: Management Leadership & Employee Involvement

**Merit Goals:** (Include cross reference to section, subsection, and question, e.g., 1.B2)

1.

**90-Day Items:** (Delete this section for final transmittal to National Office)

1.

**Best Practices:**

1.

**Comments including Recommendations** (optional)

1. The facility should more publicly promote their participation in the VPP to heighten and maintain employee awareness

**Documents Referenced, Programs Reviewed** (optional):

1.

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>A. Baseline Hazard Analysis</b>				
A1. Has the site been at least minimally effective at identifying and documenting the common safety and health hazards associated with the site (such as those found in OSHA regulations, building standards, etc., and for which existing controls are well known)? If not, please explain. MR⊙.	Y	X	X	X
<ul style="list-style-type: none"> <li>At times the hazards of the products could not be fully understood based on the fact that the product is in the development stage, therefore a prescribed high level of protection and awareness is used based on raw materials and on a worst-case scenario.</li> </ul>				
A2. What methods are used in the baseline hazard analysis to identify health hazards? (Please include examples of instances when initial screening and full-shift sampling were used. See FRN page 45657, F5.B.2.b )		X		X
<ul style="list-style-type: none"> <li>The site has JHAs, sampling plans, respirator cartridge change out schedule</li> </ul>				
A3. Does the site have a documented sampling strategy used to identify health hazards and assess employees' exposure (including duration, route, and frequency of exposure), and the number of exposed employees? If not, please explain.	Y	X		
<ul style="list-style-type: none"> <li>It is difficult to schedule sampling because products are continually changing based on the needs of their clients and there are no existing occupational exposure limits.</li> <li>Past sampling was valid</li> </ul>				
A4. Do sampling, testing, and analysis follow nationally recognized procedures? If not, please explain.	Y	X		X
<ul style="list-style-type: none"> <li></li> </ul>				
A5. Does the site compare sampling results to the minimum exposure limits or are more restrictive exposure limits (PELs, TLVs, etc.) used? Please explain.	Y	X		X

<ul style="list-style-type: none"> <li>All analysis reports reference the exposure level and the OSHA PEL and action levels</li> </ul>				
A6. Does the baseline hazard analysis adequately identify hazards (including health) that need further analysis? If not, please explain.	Y	X		X
<ul style="list-style-type: none"> <li></li> </ul>				
A7. Do industrial hygiene sampling data, such as initial screening or full shift sampling data, indicate that records are being kept in logical order and include all sampling information (for example, sampling time, date, employee, job title, concentrated measures, and calculations)? If not, please explain the deficiencies and how they are being addressed.	Y	X		X
<ul style="list-style-type: none"> <li></li> </ul>				

	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>B. Hazard Analysis of Significant Changes</b>				
B1. When purchasing new materials or equipment, or implementing new processes, what types of analyses are performed to determine their impact on safety and health? Is it adequate?	Y	X		X
<ul style="list-style-type: none"> <li>The hazards of the individual ingredients, rather than the product as a whole, are used for hazard assessment assuming worst case scenario</li> </ul>				
B2. When implementing/introducing non-routine tasks, materials or equipment, or modifying processes, what types of analyses are performed to determine their impact on safety and health? Is it adequate?	Y	X		X
<ul style="list-style-type: none"> <li>The hazards of the individual ingredients, rather than the product as a whole, are used for hazard assessment assuming worst case scenario. An example is the "bag-in, bag-out" procedure for changing filter media in the exhaust systems, which avoids exposure.</li> </ul>				

	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>C. Hazard Analysis of Routine Activities</b>				
C1. Is there at least a minimally effective hazard analysis system in place for routine operations and activities? MR⊙.	Y	X	X	X
<ul style="list-style-type: none"> <li></li> </ul>				
C2. Does hazard identification and analysis address both safety and health hazards, if appropriate? If not, please explain.	Y	X	X	X
<ul style="list-style-type: none"> <li></li> </ul>				
C3. What hazard analysis technique(s) are employed for routine operations and activities (e.g., job hazard analysis, HAZ-OPS, fault trees)? Are they adequate?	Y	X		X
<ul style="list-style-type: none"> <li>Job Hazard Analysis</li> </ul>				
C4. Are the results of the hazard analysis of routine activities adequately documented? If not, please explain.	Y	X		X

•

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>D. Routine Inspections</b>				
D1. Does the site have a minimally effective system for performing safety and health inspections (i.e., a minimally effective system identifies hazards associated with normal operations)? If not, please explain. MR⊙.	Y	X	X	X
•				
D2. Are routine safety and health inspections conducted monthly, with the entire site covered at least quarterly (for construction: entire site weekly)?	Y	X		X
•				
D3. How do inspections use information discovered through the baseline hazards analysis, job hazard analysis, accident/incident analysis, employee concerns, sampling results, etc.?		X		X
• Batch Production Records (BPR) – describes precautions and PPE needed for chemical processing				
D4. Are those personnel conducting inspections adequately trained in hazard identification? If not, please explain.	Y	X		X
•				
D5. Is the routine inspection system written, including documentation of results? If not, please explain.	Y	X		X
•				
D6. Do the written routine inspection reports clearly indicate what needs to be corrected, by whom, and by when? If not, please explain.	Y	X		X
•				
D7. Did the VPP team find hazards that should have been found through self-inspection? If so, please explain.	Y		X	
• Fall hazards, eyewash location, struck by hazard at lift in Pilot Room				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>E. Hazard Reporting</b>				
E1. Does the site have a reliable system for employees to notify appropriate management personnel in writing about safety and health concerns? Please describe.	Y	X		X
• Employees report directly to management or safety committee members				
E2. Do the employees agree that they have an effective system for reporting safety and health concerns? If not, please explain.	Y	X		
•				
E3. Is there a minimally effective means for employees to report hazards and have them addressed? If not, please explain. MR⊙.	Y	X		X

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	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>F. Hazard Tracking</b>				
F1. <i>Does the hazard tracking system address hazards found by employees, hazard analysis of routine and non-routine activities, inspections, and accident or incident investigations? If not, please explain.</i>	Y	X		X
•				
F2. <i>Does the tracking system result in hazards being corrected and provide feedback to employees for hazards they have reported. If not, please explain.</i>	Y	X		X
•				
F3. <i>Does the tracking system result in timely correction of hazards with interim protection established when needed? Please describe.</i>	Y	X		
• Employees stated that corrective actions were taken by the employer in a timely manner				
F4. <i>Does a minimally effective tracking system exist that results in hazards being controlled? If not, please explain. MR⊙.</i>	Y	X		X
•				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section II: Worksite Analysis</b>				
<b>G. Accident/Incident Investigations</b>				
G1. <i>Is there a minimally effective system for conducting accident/incident investigations, including near-misses? If not, please explain. MR⊙.</i>	Y	X		X
•				
G2. <i>Are those conducting the investigations trained in accident/incident investigation techniques? If not, please explain.</i>	Y	X		X
•				
G3. <i>Describe how investigations discover and document all the contributing factors that led to an accident/incident.</i>		X		X
• The affected employee is interviewed				
• The supervisor investigates and makes a recommendation				
• The safety committee reviews the findings and determines if additional safeguards or procedural changes need to be implemented				
G4. <i>Were any hazards discovered during the investigation previously addressed in any prior hazard analyses (e.g., baseline, self-inspection)? If not, please explain.</i>	N			X
• A review of the previous investigations revealed that no hazards discovered went uncorrected				

How Assessed

Section II: Worksite Analysis	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>H. Safety and Health Program Evaluation</b>				
H1. Briefly describe the system in place for conducting an annual evaluation. • The evaluations are conducted by top management and the EHS Officer		X		X
H2. Does the annual evaluation cover the aspects of the safety and health program including the elements described in the Federal Register? If not, please explain. •	Y	X		X
H3. Does the annual evaluation include written recommendations in a narrative format? If not, please explain. • Annual evaluations should include appropriate recommendations or a statement that none are needed.	Y	X		X
H4. Is the annual evaluation an effective tool for assessing the success of the site's safety and health system? Please explain. • The report has the ability to document and evaluate hazards as well as mechanisms for reporting corrections and timeframes.	Y			X
H5. What evidence demonstrates that the site responded adequately to the recommendations made in the annual evaluation? • The report lists the corrective actions that were taken				X

Section II: Worksite Analysis	How Assessed			
	Yes or No	Interview	Observation	Doc Review
<b>I. Trend Analysis</b>				
I1. Does the site have a minimally effective means for identifying and assessing trends? MRØ. •	Y	X		X
I2. Have there been any injury and/or illness trends over the last three years? If so, please explain. •	N	X		X
I3. If there have been injury and/or illness trends, what courses of action have been taken? Are they adequate? • N/A – no trends	N	X		X
I4. Does the site assess trends utilizing data from hazard reports or accident/incident investigations to determine the potential for injuries and illnesses? If not, please explain. • N/A – no trends	Y	X		

<b>Section II: Worksite Analysis</b>
<b>Merit Goals:</b> (Include cross reference to section, subsection, and question, e.g., II.B2)
1.

**90-Day Items:** (Delete this section for final transmittal to National Office)

1.

**Best Practices:**

1.

**Comments including Recommendations** *(optional)*

1. Additional hazard recognition training is recommended for any individual that participates in worksite safety and health evaluations
2. Annual evaluations should include appropriate recommendations or a statement that none are needed

**Documents Referenced, Programs Reviewed** *(optional):*

1.

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section III: Hazard Prevention and Control</b>				
<b>A. Hazard Prevention and Control</b>				
A1. Does the site select at least minimally effective controls to prevent exposing employees to hazards. MR☉.	Y	X	X	X
•				
A2. When the site selects hazard controls, does it follow the preferred hierarchy (engineering controls, administrative controls, work practice controls [e.g., lockout/tag out, bloodborne pathogens, and confined space programs], and personal protective equipment) to eliminate or control hazards? Please provide examples, such as how exposure to health hazards were controlled.	Y	X	X	X
• PPE				
• Evaluation for ergonomic issues				
• Hearing protection for mechanical room if present for an extended period of time				
• Local ventilation is used for all open chemical transfer				
• Monitor for oxygen and flammable atmospheres				
A3. Describe any administrative controls used at the site to limit employee exposure to hazards (for example, job rotation).		X		
• Pregnant employees are not permitted to work with toxic chemicals				
• They have a Chemical Hygiene Plan for laboratories				
A4. Do the work practice controls and administrative controls adequately address those hazards not covered by engineering or administrative controls? If not, please explain.	Y	X	X	
•				
A5. Are the work practice controls (e.g. lockout/tag out, blood born pathogens, and confined space programs) recommended by hazard analyses implemented at the site? If not, please explain.	Y	X	X	X
•				
A6. Are follow-up studies (where appropriate) conducted to ensure that hazard controls were adequate? If not, please explain.	Y	X	X	X
•				
A7. Are hazard controls documented and addressed in appropriate procedures, safety and health rules, inspections, training, etc.? Provide examples.	Y	X	X	X
• Batch Production Records				
• Training and procedures are in place to prevent accidents				
• Internal Operating Procedures are in place for nearly every conceivable activity				
A8. Are there written worker safety procedures including a disciplinary system? Describe the disciplinary system.	Y	X		X
• There is a disciplinary system in place which includes verbal and written warnings which could lead to dismissal				
A9. Has the disciplinary system been enforced equally for both management and employees, when appropriate? If not, please explain.	Y	X		X
•				
A10. Does the site have minimally effective written procedures for emergencies (TED 3-16 3h)? MR☉.	Y	X		X
•				

A11. Are emergency drills held at least annually? •	Y	X		X
A12. Does the site have a written preventative/predictive maintenance system? If not, please explain. •	Y	X		X
A13. Did the hazard identification and analysis (including manufacturers' recommendations) identify hazards that could result if equipment is not maintained properly? If not, please explain. •	Y	X		X
A14. Does the preventive maintenance system adequately detect hazardous failures before they occur? If not, please explain. •	Y	X		X
A15. How does the site select Personal Protective Equipment (PPE)? • Written procedures based on sampling to identify the hazards employees are exposed • Information from MSDS • Internal standards for highly toxic materials		X	X	X
A16. Do employees understand the limitations and uses of PPE? If not, please explain. •	Y	X		X
A17. Did the team observe employees using, storing, and maintaining PPE properly? If not, please explain. •	Y		X	
A18. Is the site covered by the Process Safety Management Standard (29 CFR 1910.119)? If not, skip to section B. •	N	X		
A19. Which chemicals that trigger the Process Safety Management (PSM) standard are present? •				
A20. Please describe the PSM elements in place at the site (do not duplicate if included elsewhere in the report, such as under contractors, preventive maintenance, emergency response, or hazard analysis). •				

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section III: Hazard Prevention and Control</b>				
<b>B. Occupational Health Care Program and Record-keeping</b>				
B1. Describe the occupational health care program (including availability of physician services, first aid, and CPR/AED) and special programs such as audiograms or other medical tests used. • Contract with offsite health care provider • Medical evaluations for respirator users		X		X
B2. How are licensed occupational health professionals used in the site's hazard identification and analysis, early recognition and treatment of illness and injury, and the system for limiting the severity of harm that might result from workplace illness or injury? Is this use appropriate? • Contract healthcare provider is advised of high hazard procedures and toxicological risk assessments for compounds handled	Y	X		

B3. Is the occupational health program adequate for the size and location of the site, as well as the nature of hazards found here? If not, please explain.

Y	X	X	X
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### Section III: Hazard Prevention and Control

**Merit Goals:** (Include cross reference to section, subsection, and question, e.g., I.B2)

1.

**90-Day Items:** (Delete this section for final transmittal to National Office)

1.

**Best Practices:**

1. The labeling of piping in the Pilot and Kilo area were exceptionally clear with content and flow direction indicated.

**Comments including Recommendations** (optional)

1.

**Documents Referenced, Programs Reviewed** (optional):

1.

	Yes or No	How Assessed		
		Interview	Observation	Doc Review
<b>Section IV: Safety and Health Training</b>				
<b>A. Safety and Health Training</b>				
A1. <i>What are the safety and health training requirements for managers, supervisors, employees, and contractors?</i>		X		X
<ul style="list-style-type: none"> <li>• New employee orientation</li> <li>• Annual refresher training is prescribed for all employees</li> <li>• Employer has prepared an extensive list of required training</li> </ul>				
A2. <i>Who delivers the training?</i>		X		X
<ul style="list-style-type: none"> <li>• Supervisor</li> <li>• EHS Officer</li> </ul>				
A3. <i>How are the safety and health training needs for employees determined?</i>				X
<ul style="list-style-type: none"> <li>• Based on job title and department</li> </ul>				
A4. <i>Does the site provide minimally effective training to educate employees regarding the known hazards of the site and their controls? If not, please explain. MR○.</i>	Y	X		X
•				
A5. <i>What system is in place to ensure that all employees and contractors have received and understand the appropriate training?</i>				X
<ul style="list-style-type: none"> <li>• There is a computerized tracking system</li> </ul>				
A6. <i>Who is trained in hazard identification and analysis?</i>		X		X
<ul style="list-style-type: none"> <li>• All employees have some level of training in hazard recognition</li> </ul>				
A7. <i>Is training in hazard identification and analysis adequate for the conditions and hazards of the site? If not, please explain.</i>	Y	X		X
•				
A8. <i>Does management have a thorough understanding of the hazards of the site? Provide examples that demonstrate their understanding.</i>	Y	X	X	X
<ul style="list-style-type: none"> <li>• The preventative measures that have been implemented demonstrate management's understanding of the hazards inherent to the site</li> </ul>				

## Section IV: Safety and Health Training

**Merit Goals:** (Include cross reference to section, subsection, and question, e.g., I.B2)

1.

**90-Day Items:** (Delete this section for final transmittal to National Office)

1.

**Best Practices:**

1.

**Comments including Recommendations** (optional)

1. It is recommended that those employees performing inspections receive additional hazard recognition training to better identify the safety and health hazards common in this operation

**Documents Referenced, Programs Reviewed (optional):**

1.

**VPP TEAM COMPOSITION DATA SHEET**

Name of Company: Hovione LLC  
 Site Address: 40 Lake Drive, East Windsor, NJ 08520  
 Small Employer (<250 employees onsite AND < 500 employees corporate wide): X  
 Region: 2 Dates of Onsite: 12/19-20/2006  
 Check One: Preapproval Visit: X Evaluation Visit:   
 Reported Drafted Onsite: Yes: X No:

TEAM COMPOSITION			
NAME	ID	ROLE	SGE
Phil Mannheim		Team Leader	
Mike Yarnell		Backup Team Leader	<input type="checkbox"/>
Kristine Logue		Industrial Hygienist	<input type="checkbox"/>
Martin Davis		Safety	<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

**BEST PRACTICES CHECKLIST**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Ergo Program       | <input type="checkbox"/> Confined Space Program                       | <input type="checkbox"/> LO/TO Program       |
| <input type="checkbox"/> PSM                | <input type="checkbox"/> Hazard Analysis                              | <input type="checkbox"/> Contractor Program  |
| <input type="checkbox"/> Medical Program    | <input type="checkbox"/> Self-Inspections                             | <input type="checkbox"/> Accountability      |
| <input type="checkbox"/> Industrial Hygiene | <input type="checkbox"/> Employee Involvement                         | <input type="checkbox"/> Tracking of Hazards |
| <input type="checkbox"/> Pre-Job Analysis   | <input checked="" type="checkbox"/> Other: Labeling of Piping systems |  |

**STRATEGIC PLAN**

**High Hazard Industries**

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Landscaping – 078             | <input type="checkbox"/> Oil/Gas – 138                        | <input type="checkbox"/> Fruits/Vegetables 203           |
| <input type="checkbox"/> Concrete/Gypsum/Plaster – 327 | <input type="checkbox"/> Blast Furnace/Steel Production – 331 | <input type="checkbox"/> Ship/Boat Building/Repair – 373 |
|  | <input type="checkbox"/> Wholesale Storage – 422              |  |

**Hazards**

- |   |   |                                 |
|---|---|---------------------------------|
| <input type="checkbox"/> Ergo                       | <input type="checkbox"/> Lead                           | <input type="checkbox"/> Silica |
| <input type="checkbox"/> Amputations – Construction | <input type="checkbox"/> Amputations – General Industry |                                 |

**VPP Corporate Tracking**

	Application Review	Onsite Prep	Onsite	Report Writing	Total
Team Hours Spent (est.)					