

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Region 2

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG.111  
2012 JAN 12 A 11:38  
REGIONAL CLERK  
HEARING

**In the Matter of:**

**TAPI Puerto Rico, Inc.**  
Highway 3, km 76.3  
C Street, Humacao Industrial Park  
Humacao, PR 00791

**Respondent**

Proceeding under Section 113  
of the Clean Air Act, 42 U.S.C. § 7413

Docket No. CAA-02-2011-1204

**Administrative Complaint under  
Section 113 of the Clean Air Act,  
42 U.S.C. § 7413**

**COMPLAINANT'S INITIAL PREHEARING EXCHANGE**

Pursuant to the request made by Hon. Susan L. Biro, Chief Administrative Law Judge, in the Prehearing Scheduling Order dated November 29, 2011, the Complainant in the above captioned matter hereby submits its Initial Pre-Hearing Exchange.

1.

(A) **a list of names of the expert or other witnesses intended to be called at hearing, identifying each as a fact witness or an expert witness, a brief narrative summary of each witness expected testimony, and a curriculum vitae or resume for each identified expert witness, or a statement that no witnesses will be called;**

- i. **Carlos M. Rivera-Velázquez**  
Environmental Scientist  
Multimedia Permits and Compliance Branch  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency, Region 2  
1492 Ponce De León Avenue, Suite 417  
San Juan, P.R. 00907-4127

Mr. Carlos M. Rivera-Velázquez has been working with EPA, Region 2, since November 2001, as an Environmental Scientist. Since November 2002, and at the time of the Inspection, and Issuance of the present Complaint, Mr. Rivera had been handling Clean Air Act inspections in the former Enforcement and Superfund Branch and now under the Multimedia Permits and Compliance Branch. Mr. Rivera has a Bachelor Degree with a Major in Environmental

Sciences and a Minor Degree in Chemistry from the Pontifical Catholic University of Puerto Rico where he graduated in 2000.

Mr. Rivera will testify about the CAA Section 112(r) regulations and how they apply to Respondent's facility. He will testify as to the Inspection he conducted at Respondent's facility and the findings that lead to the issuance of the penalty complaint, including the violations alleged in the Complaint. He will also testify with regard to his knowledge and experience in calculating civil penalties for violations of the CAA Section 112(r) program and about the specific facts and circumstances in this case and how they were considered in supporting the calculation of the penalty assessed in the complaint (the reasoning behind the calculation of said assessed penalty and the appropriateness of the penalty according to the CAA statutory factors and applicable penalty policy). In his expected testimony, Mr. Rivera is expected to discuss and explain the significance of various exhibits Complainant intends to offer.

- ii. **Neil Mulvey**  
EPA Contractor  
NPM Environmental & Safety, Inc.  
Lauren Court  
Manalapan, NJ 07726

Mr. Mulvey has 26 years of experience in environmental management and control, in the last 19 years specializing in process risk management and process safety. Mr. Mulvey has extensive experience in governmental and regulatory affairs at both the state and federal level, including risk management and process safety, emergency response, right-to-know, and air pollution control. Mr. Mulvey also has over 4 years experience in environmental affairs while working at a mid-size organic and inorganic chemical manufacturing facility. Mr. Mulvey was responsible for establishing the nation's first accidental release prevention program, the New Jersey Toxic Catastrophe Prevention Act (TCPA). The TCPA program was used as a model in developing other state risk management programs, including the states of California, Delaware, and Nevada. The Occupational Safety and Health Administration (OSHA) and U.S. Environmental Protection Agency (EPA) also used the TCPA program as a model in developing their respective Process Safety Management (PSM) and Risk Management Program (RMP) regulations. Mr. Mulvey has a Bachelors Degree in Environmental Science from Cook College, Rutgers University and graduated in 1979. Also, Mr. Mulvey posses a Masters Degree in Environmental Engineering from the New Jersey Institute of Technology where he graduated in 1982. Mr.

Mulvey will testify about the inspection conducted at the facility and the findings of the inspection, including the violations alleged in the Complaint and his experience with the Risk Management Program and the regulations at 40 C.F.R. Part 68. Mr. Mulvey is expected to discuss and explain the significance of various exhibits Complainant intends to offer.

Complainant intends to call Mr. Mulvey as an expert witness.

- iii. **Francisco Claudio**  
Chemical Engineer  
Multimedia Permits and Compliance Branch  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency, Region 2  
1492 Ponce De León Avenue, Suite 417  
San Juan, P.R. 00907-4127

Mr. Francisco Claudio has been working with EPA, Region 2, since April 17, 1997, as an Environmental Engineer. Since April 1997, and at the time of the inspections, and issuance of the present Complaint, Mr. Claudio had been handling Clean Air Act inspections in the former Enforcement and Superfund Branch and now under the Multimedia Permits and Compliance Branch. Prior to working at EPA, Mr. Claudio served from 1989 to 1997 as the Director of the Air Quality Area at the Puerto Rico Environmental Quality Board. Mr. Claudio has a Bachelor Degree in Chemical Engineering from the University of Puerto Rico.

Mr. Claudio will testify about the CAA Section 112(r) regulations and how they apply to Respondent's facility. He will testify as to the follow up inspections he conducted at Respondent's facility and the findings that lead to the issuance of the penalty complaint, including the violations alleged in the Complaint. He will also testify with regard to his knowledge and experience in calculating civil penalties for violations of the CAA Section 112(r) program and about the specific facts and circumstances in this case and how they were considered in supporting the calculation of the penalty assessed in the complaint (the reasoning behind the calculation of said assessed penalty and the appropriateness of the penalty according to the CAA statutory factors and applicable penalty policy). In his expected testimony, Mr. Claudio is expected to discuss and explain the significance of various exhibits Complainant intends to offer.

Complainant reserves the right, and nothing herein is intended or is to be construed to prejudice or waive any such right, to call or not to call any of the

aforementioned potential witnesses, and to expand or otherwise modify the scope, extent and/or areas of the testimony of any of the above-named potential witnesses, where appropriate. In addition, Complainant reserves the right to list and to call additional potential hearing witnesses, including expert witnesses, to answer and/or rebut evidence (testimonial or documentary) listed by Respondent in its prehearing exchange or on matters arising as a consequence of such evidence.

**(B) copies of all documents and other exhibits intended to be introduced into evidence, identified as Complainant's or Respondent's Exhibits, as appropriate, and numbered with Arabic numerals**

***Complainant's Exhibit 1*** - Administrative Complaint, Docket No. CAA-02-2011-1227 with attachments, including the penalty calculation and the EPA Combined Enforcement Policy for Section 112(r) of the Clean Air Act.

***Complainant's Exhibit 2*** - Respondent's Answer to the Complaint, with attachment, dated October 20, 2011.

***Complainant's Exhibit 3*** - Report of USEPA Risk Management Program (RMP) Inspection of the TAPI Puerto Rico, Inc. facility, date of Inspection September 10, 2008, with attachments.

***Complainant's Exhibit 4*** - Report of USEPA Risk Management Program (RMP) Inspection of the TAPI Puerto Rico, Inc. facility, date of Inspection March 22, 2010.

***Complainant's Exhibit 5*** - Civil Monetary Penalty Inflation Adjustment Rule; Final Rule, published on February 13, 2004, in the Federal Register (69 FR 7121).

**(C) a statement explaining its view as to the place for the hearing and the estimated amount of time needed to present its direct case. Also, state whether translation services are necessary in regard to the testimony of any witness, and if so, state the language to be translated.**

Pursuant to 40 C.F.R. §§ 22.21(d) and 22.19(d), the hearing should be held in the county where the Respondent conducts business which the hearing concerns, in the city in which the relevant Environmental Protection Agency Regional office is located, or in Washington, D.C. Complainant requests that the hearing be held in San Juan, where the relevant Environmental Protection Agency Regional office is located. This location is convenient for both parties

and witnesses, the TAPI Puerto Rico, Inc. facility is close to the metropolitan area and we foresee no problem for Respondent's witnesses to attend the hearing. The Complainant can assist by providing the Regional Hearing Clerk with information on facilities which may be available for purposes of holding the hearing.

Complainant estimates it will need one day and a half to present its direct case.

Translation services will not be necessary.

2.

**(A) a copy of any documents in support of each of the factual allegations in Paragraphs 35-47 of the Complaint, to the extent they have been denied or otherwise not admitted by Respondent in the Answer**

Please see Complainant's Exhibit 3 (Report of USEPA Risk Management Program (RMP) Inspection of the TAPI Puerto Rico, Inc. facility, date of Inspection September 10, 2008, with attachments); and Complainant's Exhibit 4 (Report of USEPA Risk Management Program (RMP) Inspection of the TAPI Puerto Rico, Inc. facility, date of Inspection March 22, 2010).

**(B) Complainant shall submit a statement explaining in detail how the proposed penalty was determined, including a description of how the specific provisions of any Agency penalty or enforcement policies and/or guidelines were applied in calculating the penalty.**

The proposed civil penalty in this matter has been determined in accordance with the "Combined Enforcement Policy for CAA Section 112(r) Risk Management Program," dated August 15, 2001 ("Section 112(r) Penalty Policy"). A copy of the Section 112(r) Penalty Policy is attached to the Complaint [Exhibit 1] as Attachment 1. Also attached to the Complaint, as Attachment 2, is a Penalty Calculation Worksheet which shows how the proposed penalty was calculated using the Section 112(r) Penalty Policy.

In determining the amount of any penalty to be assessed, Section 113(e) of the Clean Air Act, 42 U.S.C. § 7413(e), requires EPA to take into consideration the size of Respondent's business, the economic impact of the proposed penalty on Respondent's business, Respondent's full compliance history and good faith efforts to comply, the duration of the violations as established by any credible evidence, payment by Respondent of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the

violations. The proposed penalty reflects a presumption of Respondent's ability to pay the penalty and to continue in business based on the size of its business and the economic impact of the proposed penalty on its business.

Respectfully submitted. In San Juan, Puerto Rico, January 11, 2012.



Carolina Jordán-García  
Assistant Regional Counsel  
U.S. Environmental Protection Agency, Region 2  
Centro Europa Bldg., Suite 417  
1492 Ponce de León Ave.  
San Juan, PR 00907-4127  
phone: (787) 977-5834  
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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**Respondent**

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CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing **Complainant's Prehearing Exchange**, dated January 11, 2012, and bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and copy by **Overnight Mail** to:

**Karen Maples**  
Regional Hearing Clerk  
Region II  
U.S. Environmental Protection Agency  
290 Broadway, 16<sup>th</sup> Floor  
New York, NY 10007-1866

Copy by **Certified Mail, Return Receipt Requested** to:

Attorney for Respondent:  
**Gretchen Méndez, Esq.**  
Goldman, Antonetti & Córdoba, P.S.C.  
PO Box 70364  
San Juan, PR 00936-8364

Copy by **Overnight Mail** to:

**The Honorable Susan L. Biro**  
**Chief, Administrative Law Judge**  
Office of Administrative Law Judges  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

01/11/2012  
Date

A handwritten signature in black ink, appearing to read "Susan L. Biro". The signature is written in a cursive style with a large, sweeping initial "S".



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**Respondent**

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**Docket No. CAA-02-2011-1204**

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42 U.S.C. § 7413**

**ADMINISTRATIVE COMPLAINT**

**I. JURISDICTION**

1. This Complaint ("Complaint") initiates an administrative action for the assessment of a civil penalty pursuant to Section 113(d) of the Clean Air Act ("the Act"), 42 U.S.C. § 7413(d). The Complainant in this action is the Director of the Caribbean Environmental Protection Division of the United States Environmental Protection Agency ("EPA"), Region 2, who has been delegated the authority to institute this action.

2. EPA and the U.S. Department of Justice have determined, pursuant to Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), that EPA may pursue this matter through administrative enforcement action.

**II. APPLICABLE STATUTES AND REGULATIONS**

3. Section 113(d) of the Act, 42 U.S.C. § 7413(d), provides for the assessment of penalties for violations of Section 112(r) of the Act, 42 U.S.C. § 7412(r).

4. Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), requires the Administrator to promulgate release prevention, detection, and correction requirements regarding regulated substances in order to prevent accidental releases of regulated substances. EPA promulgated regulations in 40 C.F.R. Part 68 to implement Section 112(r)(7) of the Act, which set forth the requirements of risk management programs that must be established and implemented at affected stationary sources. The regulations at 40 C.F.R. Part 68, Subparts A through G, require owners and operators of stationary sources to, among other things, develop and implement: (1) a management system to oversee the implementation of the risk management program elements; and (2) a risk management program that includes, but is not limited to, a hazard assessment, a prevention program, and an emergency response program. Pursuant to 40 C.F.R. Part 68, Subparts A and G, the risk management program for a stationary source that is subject to these requirements is to be described in a risk management plan ("RMP") that must be submitted to EPA.

5. Sections 112(r)(3) and (5) of the Act, 42 U.S.C. §§ 7412(r)(3) and (5), require the Administrator to promulgate a list of regulated substances, with threshold quantities. EPA promulgated a regulation known as the List Rule, at 40 C.F.R. Part 68, Subpart F, to implement Section 112(r)(3) of the Act, 42 U.S.C. § 7412(r)(3), which lists the regulated substances and their threshold quantities.

6. Pursuant to Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), and 40 C.F.R. §§ 68.10(a), 68.12, and 68.150, an owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process shall comply with the requirements of 40 C.F.R. Part 68 (including, but not limited to, submission of an RMP to EPA), no later than June 21, 1999, or three years after the date on which such regulated substance is first listed under 40 C.F.R. § 68.130, or the date on which the regulated substance is first present in a process above the threshold quantity, whichever is latest.

7. The regulations at 40 C.F.R. Part 68 separate the covered processes into three categories, designated as Program 1, Program 2, and Program 3. A covered process is subject to Program 3 requirements, as per 40 C.F.R. § 68.10(d), if the process: a) does not meet one or more of the Program 1 eligibility requirements set forth in 40 C.F.R. § 68.10(b); and b) is listed in one of the specific North American Industry Classification System codes found at 40 C.F.R. § 68.10(d)(1) or is subject to the United States Occupational Safety and Health Administration ("OSHA") process safety management standard set forth in 29 C.F.R. § 1910.119.

8. 40 C.F.R. § 68.12(d) requires that the owner or operator of a stationary source with a Program 3 process undertake certain tasks, including, but not limited to, development and implementation of a management system (pursuant to 40 C.F.R. § 68.15), the implementation of prevention program requirements, which include mechanical integrity (pursuant to 40 C.F.R. §§ 68.65-68.87), the development and implementation of an emergency response program (pursuant to 40 C.F.R. §§ 68.90-

68.95), and the submission of additional information on prevention program elements regarding Program 3 processes (pursuant to 40 C.F.R. § 68.175).

9. Pursuant to Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), and 40 C.F.R. § 68.190(b), an owner or operator of a stationary source shall revise and update the RMP submitted pursuant to 40 C.F.R. § 68.150 at least once every five years from the date of its initial submission or most recent update required by 40 C.F.R. § 68.190(b)(2)-(7), whichever is later.

### III. DEFINITIONS

10. 40 C.F.R. § 68.3 defines "hot work" as work involving electric or gas welding, cutting, brazing, or similar flame or spark-producing operations.

11. 40 C.F.R. § 68.3 defines "mechanical integrity" as the process of ensuring that process equipment is fabricated from the proper materials of construction and is properly installed, maintained, and replaced to prevent failures and accidental releases.

12. 40 C.F.R. § 68.3 defines "stationary source" in relevant part, as any buildings, structures, equipment, installations, or substance-emitting stationary activities which belong to the same industrial group, which are located on one or more contiguous properties, which are under the control of the same person (or persons under common control), and from which an accidental release may occur.

13. 40 C.F.R. § 68.3 defines "threshold quantity" as the quantity specified for regulated substances pursuant to Section 112(r)(5) of the Act as amended, listed in 40 C.F.R. § 68.130, and determined to be present at a stationary source as specified in 40 C.F.R. § 68.115.

14. 40 C.F.R. § 68.3 defines "regulated substance" as any substance listed pursuant to Section 112(r)(3) of the Act in 40 C.F.R. § 68.130.

15. 40 C.F.R. § 68.3 defines "process" in relevant part, as any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances, or combination of these activities.

16. 40 C.F.R. § 68.3 defines "covered process" as a process that has a regulated substance present in more than a threshold quantity pursuant to 40 C.F.R. § 68.115.

### IV. FINDINGS OF VIOLATIONS

17. Respondent is, and at all times referred to herein was, a "person" as defined by Section 302(e) of the Act, 42 U.S.C. § 7602(e).

18. Respondent owned and operated a bulk pharmaceutical manufacturing plant located at Highway 3, km 76.3, C Street, Humacao Industrial Park Humacao, Puerto Rico, (hereinafter referred to as the "Facility").
19. Respondent temporarily ceased its operations at the Facility on March 31<sup>st</sup>, 2010.
20. The Facility was a "stationary source" pursuant to Section 112(r)(2)(C) of the Act and 40 C.F.R. § 68.3.
21. Fluorine is a "regulated substance" pursuant to Section 112(r)(2) and (3) of the Act and 40 C.F.R. § 68.3. The threshold quantity for fluorine as listed in 40 C.F.R. § 68.130, Table 1, is 1,000 pounds.
22. The Facility is currently registered under the RMP program as "TAPI Puerto Rico, Inc."
23. The Facility's current owner is Teva Group, Inc. Teva Group, Inc. purchased the Facility in April, 2008, from Archimica Puerto Rico, Inc.
24. The Facility is located in a commercial/industrial section of the Municipality of Humacao.
25. Respondent filed to the EPA Reporting Center its initial RMP for the Facility on August 24, 1999, at that time, the Facility was owned by Archimica, Inc.
26. On June 22, 2004, the RMP was resubmitted by Clariant Puerto Rico LSM. A corrected version of the RMP was submitted on November 17, 2008, changing the name from Clariant LSM Puerto Rico, Inc. to TAPI Puerto Rico, Inc.
27. EPA conducted an inspection of the Facility on September 10, 2008, (the "Inspection"), to assess compliance with Section 112(r) of the Clean Air Act.
28. During the Inspection, Respondent's representative informed EPA that the Facility was dedicated exclusively to the production of 5-Fluorouracil, a drug used to treat cancer.
29. 5-Fluorouracil is a mixture containing the regulated substance fluorine in a concentration above one percent by weight of the mixture and with a partial pressure of more than 10 millimeters of mercury.
30. Fluorine gas is received at the Facility in a tube trailer. Each trailer contains eight fluorine tube cylinders. Each tube cylinder contains 20% fluorine and 80% nitrogen. There are approximately 225-lbs. of fluorine in each tube cylinder.
31. The Facility reported that it had a maximum of two fluorine tube trailers on-site at any time. This was consistent with the reported registration quantity of 3,600-lbs.

32. Based on the findings of the September 10, 2008 inspection, EPA found Respondents in violation of the CAA, and issued an Administrative Compliance Order, Docket Number CWA-02-2009-1016, against Respondents.

33. EPA conducted a second inspection (the "Follow up Inspection") of the Facility on February 24, 2010.

34. From the findings of the follow up inspection, EPA concluded that TAPI took the necessary steps to comply with the regulatory requirements under Part 68.

#### COUNT 1

35. During the Inspection, Respondent did not have a written description of its RMP management system and other persons responsible for implementing individual requirements of the RMP with defined lines of authority, as required by 40 C.F.R. § 68.15(a) and (c).

36. During the Inspection, Respondent did not produce process safety information pertaining to the equipment in the process required by 40 C.F.R. § 68.65(d), including: electrical classification, ventilation system design, design codes and standards, and description of safety systems.

37. During the Inspection, Respondent did not produce any documentation stating that the equipment complies with recognized and generally accepted good engineering practices as required by 40 C.F.R. 68.65(d)(2).

38. During the Inspection, Respondent did not produce documentation that it had resolved the Process Hazard Analysis ("PHA") recommendations in a timely manner, as required by 40 C.F.R. § 68.67(e).

39. During the Inspection, Respondent did not have a record of annual certification of Standard Operating Procedures ("SOPs"), as required by 40 C.F.R. § 68.69(c).

40. During the Inspection, Respondent did not have a complete mechanical integrity program, as required by 40 C.F.R. § 68.73. The Facility Manager reported that the Pressure Safety Valves (PSVs) maintenance inspection was not performed in 2006, 2007 and 2008.

41. During the Inspection, Respondent did not have documentation to identify the date of each inspection and test that has been performed on process equipment, the name of the person who performed the inspection or test, the serial number or other identifier of the equipment on which the inspection or test was performed, a description of the inspection or test performed, and the results of the inspection or test, as required by 40 C.F.R. § 68.73(d)(4).

42. During the Inspection, EPA reviewed the Change Control Procedure (SOP-API-012; July, 17, 2007) and concluded that it does not explicitly address the safety and health review of changes, as required by 40 C.F.R. § 68.75(b)(2).
43. During the Inspection, Respondent did not have updated process safety information after changes covered by 40 C.F.R. § 68.75, as required by 40 C.F.R. § 68.75(d).
44. During the Inspection, Respondent did not have a Pre-startup Review completed for all changes involving the need to update PSI, as required by 40 C.F.R. § 68.77.
45. During the Inspection, Respondent did not have records of completed RMP compliance audits, as required by 40 C.F.R. § 68.79.
46. During the Inspection, Respondent did not have a written employee participation plan available for review, as required by 40 C.F.R. § 68.83(a). Respondent's failure to comply with the requirements of 40 C.F.R. Part 68 as described above in Paragraphs 34-45 constitutes a violation of Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7). Respondent is therefore subject to the assessment of penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d).
47. Respondent's failure to comply with the requirements of 40 C.F.R. Part 68, as described above, constitutes a violation of Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7). Respondent is therefore subject to the assessment of penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d).

#### V. NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY

Pursuant to Section 113(d) of the Act, 42 U.S.C. § 7413(d), and 40 C.F.R. Part 19, Adjustment of Civil Monetary Penalties for Inflation, EPA is authorized to assess civil penalties not to exceed \$27,500 per day for each violation of Section 112 of the Act, 42 U.S.C. § 7412, that occurred on or after January 30, 1997 through March 15, 2004, and \$32,500 per day for each violation of Section 112 of the Act that occurred after March 15, 2004 through January 12, 2009, and up to \$37,500 for violations that occurred after January 12, 2009. Civil penalties under Section 113 of the Act may be assessed by Administrative Order. On the basis of the violations of the Act described above, Complainant alleges that Respondent is subject to penalties for violating Section 112(r) of the Act, 42 U.S.C. § 7412(r).

The proposed civil penalty in this matter has been determined in accordance with the "Combined Enforcement Policy for CAA Section 112(r) Risk Management Program," dated August 15, 2001 ("Section 112(r) Penalty Policy") and the September 21, 2004 memorandum from Thomas V. Skinner, Acting Assistant Administrator, to the Regional Administrators. A copy of the Section 112(r) Penalty Policy accompanies this Complaint. A Penalty Calculation Worksheet which shows how the proposed penalty was calculated is included as Attachment 1.

In determining the amount of any penalty to be assessed, Section 113(e) of the Act, 42 U.S.C. § 7413(e), requires EPA to take into consideration the size of Respondent's business, the economic impact of the proposed penalty on Respondent's business, Respondent's full compliance history and good faith efforts to comply, the duration of the violations as established by any credible evidence, payment by Respondent of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violations.

In accordance with Section 113(d) of the Act, 40 C.F.R. Part 19, and the Section 112(r) Penalty Policy, and based on the facts alleged in this Complaint, Complainant proposes to assess a civil penalty of \$136,364 against Respondent.

Payment of a civil penalty shall not affect Respondent's ongoing obligation to comply with the Act and other applicable federal, state or local laws.

The proposed penalty reflects a presumption of Respondent's ability to pay the penalty and to continue in business based on the size of its business and the economic impact of the proposed penalty on its business. Respondent may submit appropriate documentation to rebut this presumption.

## VI. PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

The rules of procedure governing this civil administrative litigation are entitled, "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits" (hereinafter, the "Consolidated Rules"), and are codified at 40 C.F.R. Part 22. A copy of the Consolidated Rules accompanies this Complaint.

### Notice of Opportunity to Request a Hearing and Answering the Complaint

To request a hearing, Respondent must file an Answer to the Complaint, pursuant to 40 C.F.R. §§ 22.15(a)-(c). Pursuant to 40 C.F.R. § 22.15(a), such Answer must be filed within 30 days after service of the Complaint.

An Answer is also to be filed, pursuant to 40 C.F.R. § 22.15(a), if Respondent contests any material fact upon which the Complaint is based, contends that the proposed penalty is inappropriate, or contends that Respondent is entitled to judgment as a matter of law. If filing an Answer, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written Answer to the Complaint. The address of the Regional Hearing Clerk of EPA, Region 2, is:

Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 2  
290 Broadway, 16th floor  
New York, New York 10007-1866

Respondent shall also serve one copy of the Answer to the Complaint upon Complainant and any other party to the action, 40 C.F.R. § 22.15(a). Complainant's copy of Respondent's Answer, as well as a copy of all other documents that Respondent files in this action, shall be sent to:

Carolina Jordán-García  
Office of Regional Counsel  
U.S. Environmental Protection Agency - Region 2  
1492 Ponce de León Ave.  
Centro Europa Building, Suite 417  
Santurce, Puerto Rico 00907- 4127  
Email: jordan-garcia.carolina@epa.gov  
Tel.: (787) 977-5834  
Fax: (787) 729-7748

Pursuant to 40 C.F.R. § 22.15(b), Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations contained in the Complaint with regard to which Respondent has any knowledge. Where Respondent lacks knowledge of a particular factual allegation and so states in its Answer, the allegation is deemed denied, pursuant to 40 C.F.R. § 22.15(b). The Answer shall also set forth: (1) the circumstances or arguments that are alleged to constitute the grounds of defense; (2) the facts which Respondent disputes; (3) the basis for opposing any proposed relief; and (4) whether Respondent requests a hearing.

If Respondent fails in its Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation, pursuant to 40 C.F.R. § 22.15(d).

Respondent's failure to affirmatively raise in the Answer facts that constitute or that might constitute the grounds of its defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a hearing.

Any hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. § 22.21(d). A hearing of this matter will be conducted in accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of 40 C.F.R. Part 22.

Failure to Answer



If Respondent fails to file a timely answer to the Complaint, EPA may file a Motion for Default pursuant to 40 C.F.R. §§ 22.17(a) and (b), which may result in the issuance of a default order assessing the proposed penalty pursuant to 40 C.F.R. § 22.17(c). If a default order is issued, any penalty assessed in the default order shall become due and payable by Respondent without further proceedings 30 days after the default order becomes final. If necessary, EPA may then seek to enforce such final order of default against Respondent, and to collect the assessed penalty amount, in federal court.

## VII. INFORMAL SETTLEMENT CONFERENCE

Whether or not Respondent requests a formal hearing, EPA encourages settlement of this proceeding consistent with the provisions and objectives of CERCLA and EPCRA and the applicable regulations, 40 C.F.R. § 22.18(b). At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in this Complaint, and Respondent may also provide whatever additional information that it believes is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged; (2) any information relevant to Complainant's calculation of the proposed penalty; (3) the effect the proposed penalty would have on Respondent's ability to continue in business; and/or (4) any other special facts or circumstances Respondent wishes to raise. Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists.

Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to the EPA Assistant Regional Counsel identified in Section VI, above.

Respondent's request for a formal hearing does not prevent it from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a hearing pursuant to 40 C.F.R. § 22.15(c).

A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. § 22.15. No penalty reduction will be made simply because an informal settlement conference is held.

In the event settlement is reached, its terms shall be recorded in a written Consent Agreement signed by the parties and incorporated into a Final Order, pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3).

Respondent=s entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in such Consent Agreement terminates this administrative litigation and the civil proceedings arising out of the allegations made in this Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

#### VIII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE

Instead of filing an Answer, Respondent may choose to pay the total amount of the proposed penalty within 30 days after receipt of the Complaint, provided that Respondent files with the Regional Hearing Clerk, Region 2 (at the address provided in Section VI.A., above), a copy of the check or other instrument of payment, as provided in 40 C.F.R. § 22.18(a). A copy of the check or other instrument of payment should be provided to the EPA Assistant Regional Counsel identified in Section VI, above. Payment of the penalty assessed should be made by sending a cashier's or certified check payable to the "Treasurer, United States of America," in the full amount of the penalty assessed in this Complaint to the following addressee:

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, MO 63197-9000

The check must be identified with a notation of the name and docket number of this case, set forth in the caption on the first page of this Complaint. Pursuant to 40 C.F.R. § 22.18(a)(3), upon EPA's receipt of such payment, a Final Order shall be issued. Furthermore, as provided in 40 C.F.R. § 22.18(a)(3), the making of such payment by Respondent shall constitute a waiver of Respondent's rights to contest the allegations made in the Complaint and to appeal the Final Order. Such payment does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable regulations and requirements, and to maintain such compliance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Region 2

**In the matter of:**

**TAPI Puerto Rico, Inc.**  
Highway 3, Km, 76.3  
C Street, Humacao Industrial Park  
Humacao, PR 00791.

**Respondent**

Proceeding under Section 113 of the  
Clean Air Act, 42 U.S.C. § 7413

Docket No.CAA-02-2011-1204

Administrative Complaint under Section 113  
of the Clean Air Act, 42 U.S.C. § 7413

**ANSWER TO ADMINISTRATIVE COMPLAINT**

**TO THE HONORABLE PRESIDING OFFICER:**

TAPI Puerto Rico, Inc. ("TAPI") respectfully answers the Complaint:

**STATUTORY AUTHORITY**

1. The allegations of paragraph one (1) and two (2) on the "Jurisdiction" section of the Administrative Complaint ("Complaint") (Section I) is the United States Environmental Protection Agency's ("EPA") interpretation on the nature of the action, and as such, do not require a responsive pleading. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint in reference to the bulk pharmaceutical manufacturing facility located at Highway 3, Km. 76.3, C Street, Humacao Industrial Park, Humacao, Puerto Rico ("the Facility").

2. The allegations of paragraphs three (3) through nine (9) on the "Applicable Statutes and Regulations" section of the Complaint (Section II) and paragraphs ten (10) through sixteen (16) of the "Definitions" Section (Section III) include statements of law upon which

EPA has elected to set forth its jurisdictional claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

### **FINDINGS OF VIOLATIONS**

3. The allegation included in paragraph number seventeen (17) of the Complaint includes statements of law upon which EPA has elected to set forth its jurisdictional claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

4. The allegations included in paragraph number eighteen (18) of the Complaint are admitted. It is affirmatively alleged that TAPI continues to own and operate the Facility.

5. The allegation included in paragraph number nineteen (19) of the Complaint is admitted.

7. The allegation included in paragraph number twenty (20) of the Complaint is admitted.

6. The allegations included in paragraph number twenty one (21) of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

8. The allegations included in paragraph number twenty two (22) of the Complaint are admitted.

9. The allegations included in paragraph number twenty three (23) of the Complaint are hereby denied, as drafted.

10. The allegations included in paragraph number twenty four (24) of the Complaint are hereby denied, as drafted.

11. The allegations included in paragraph number twenty five (25) of the Complaint are hereby denied, as drafted.

12. The allegations included in paragraph number twenty six (26) of the Complaint are hereby denied, for lack of information or knowledge with respect to the veracity and/or mendacity of such allegations.

13. The allegation included in paragraph number twenty seven (27) of the Complaint is admitted.

14. The allegation included in paragraph number twenty eight (28) of the Complaint is admitted.

15. The allegations included in paragraph number twenty nine (29) of the Complaint are denied, as drafted.

16. The allegations included in paragraph number thirty (30) of the Complaint are admitted.

17. The allegations included in paragraph number thirty one (31) of the Complaint are admitted.

18. The allegations included in paragraph number thirty two (32) of the Complaint it is admitted insofar as to that the EPA issued Administrative Compliance Order. The rest of the allegations of paragraph are denied, as drafted.

19. The allegations included in paragraph number thirty three (33) of the Complaint are admitted.

20. The allegations included in paragraph number thirty four (34) of the Complaint are admitted insofar as TAPI was in compliance with Part 68 at the time of the second inspection. The rest of the allegations in this paragraph are denied, as drafted.

**COUNT 1**

21. The allegations included in paragraph number thirty five (35) of the Complaint are denied.

22. The allegations included in paragraph number thirty six (36) of the Complaint are denied.

23. The allegations included in paragraph number thirty seven (37) of the Complaint are denied.

24. The allegations included in paragraph number thirty eight (38) of the Complaint are admitted.

25. The allegations included in paragraph number thirty nine (39) of the Complaint are admitted.

26. The allegations included in paragraph number forty (40) of the Complaint are denied.

27. The allegations included in paragraph number forty one (41) of the Complaint are denied.

28. The allegations included in paragraph number forty two (42) of the Complaint are admitted insofar as to EPA's review of the Change of Control Procedure. The rest of the allegations area denied, as drafted.

29. The allegation included in paragraph number forty three (43) of the Complaint is admitted.

30. The allegation included in paragraph number forty four (44) of the Complaint is admitted.

31. The allegation included in paragraph number forty five (45) of the Complaint is admitted.

32. The allegations included in paragraph number forty six (46) of the Complaint are denied, as drafted.

33. The allegations included in paragraph number forty seven (47) of the Complaint are denied, as drafted.

#### **NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY**

34. The first, second, third, fifth and sixth paragraphs of Section V of the Complaint includes statements and conclusions of law upon which EPA has elected to set forth its claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted. The fourth paragraph and proposed penalties for the allegations in the Complaint are hereby expressly denied.

#### **PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION**

35. The allegations included in Section VI of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

#### **INFORMAL SETTLEMENT CONFERENCE**

36. The allegations included in Section VII of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

**RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR  
CONFERENCE**

37. The allegations included in Section VIII of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

38. Unless otherwise specified, any and all allegations not expressly admitted in connection to the Complaint should be deemed denied for all practical and legal matters.

**AFFIRMATIVE DEFENSES**

1. TAPI realleges all of its responsive pleadings, as included in this document, and incorporates the same to this section of affirmative defenses.

2. The Complaint was not served to a officer, partner a managing or general agent or other personal authorized by Federal or Commonwealth law to receive service of process for TAPI in violation of Section 22.5(b)(1)(ii)(A) of Title 40 of the Code of Federal Regulations (C.F.R.) relative to the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits.

3. The Complaint was not served together with a copy of the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits in violation of Section 22.5(b)(1)(i) of 40 C.F.R.

4. The Complaint fails to state facts and a claim upon which relief may be granted as claimed by EPA therein and against TAPI.

5. Penalties alleged in the Complaint are improper and/or unwarranted.

6. EPA is not entitled to the penalties requested in the Complaint and/or to any other type of penalties.



7. TAPI respectfully reserves the right to amend the Answer to the Complaint and to include one or more affirmative defenses, after conducting proper discovery procedures which shall include written interrogatories, request for production and inspection of documents and the taking of several depositions.

8. TAPI expressly reserves the right to raise additional defenses and/or to amend those already raised upon completion of the discovery proceedings in the instant case.

**WHEREFORE**, the TAPI respectfully requests this Honorable Presiding Officer, to take notice of the aforementioned, deny and dismiss the Complaint in all its parts given the insufficiency of service of process required by Section 22.5(b)(1)(ii)(A) of the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits. In the alternative, TAPI hereby respectfully requests a hearing.

**RESPECTFULLY SUBMITTED.**

**I HEREBY CERTIFY:** That on this same date, a true and exact copy of the foregoing document was sent, through regular mail, to; Carolina Jordán-García, Office of Regional Counsel, U.S. Environmental Protection Agency, Region 2, 1492 Ponce de León Ave., Centro Europa Building, Suite 417, Santurce, Puerto Rico 00907-4127.

In San Juan, Puerto Rico, this 20<sup>th</sup> day of October, 2011.

**GOLDMAN ANTONETTI & CORDOVA, P.S.C.**  
P.O. BOX 70364  
SAN JUAN, PUERTO RICO 00936-8364  
TEL. (787) 759-8000  
FAX. (787) 474-2407

  
\_\_\_\_\_  
GRETCHEN MENDEZ-VILELLA  
USDC #207904

**CLEAN AIR ACT SECTION 112(r) INSPECTION REPORT**

***Clariant LSM (Puerto Rico) Inc.***

***Humacao, Puerto Rico***

**GENERAL INFORMATION**

<b>Stationary Source</b>	<b>Clariant LSM (Puerto Rico) Inc.</b>
<b>Date of Inspection</b>	September 10, 2008
<b>USEPA Inspector</b>	Carlos Rivera, USEPA – Region II, Caribbean Office, Enforcement
<b>Contract Auditor</b>	Neil Mulvey, Sullivan Group (Subcontractor)
<b>Description of Activities</b>	<ul style="list-style-type: none"> <li>• Opening meeting with facility representative.</li> <li>• Program audit.</li> <li>• Closing meeting with facility representatives.</li> </ul> Program audit consisted of the following activities: Document review. Field verification. Personnel interviews

**STATIONARY SOURCE INFORMATION**

<b>EPA Facility ID #</b>	1000 0015 8679
<b>Date of Latest Submission (used for RMP inspection)</b>	Receipt Date: June 22, 2004 (Re-submission)  Anniversary Date: June 18, 2009
<b>Facility Location</b>	Highway 3, km 76.3 C Street, Humacao Industrial Park Humacao, PR 00791  Tel. (787) 485-5544
<b>Number of Employees</b>	<i>RMP*Submit</i> states 11 employees. Non-union.

<b>Description of Surrounding Area</b>	The facility conducts business on a 2.1 acre site located in a commercial / industrial section of Humacao (Humacao Industrial Park). The facility is immediately bordered by either other industrial companies or open space.
<b>Participants</b>	<p>Participants included representatives from:</p> <p>Carlos Rivera, USEPA – Region II, Caribbean Office          Neil P. Mulvey, USEPA Contractor – Sullivan Group          Santiago Hernandez, Site Manager, Clariant LSM*          Anal I. Tirado, EHS Associate Director, TAPI PR Inc.</p> <p>* Lead representative for Clariant LSM</p>

## REGISTRATION INFORMATION

<b>Process ID #</b>	51941
<b>Program Level (as reported in RMP)</b>	Program 3
<b>Process Chemicals</b>	Fluorine @ 3,600-lbs. (Registered quantity)
<b>NAICS Code</b>	32541 (Pharmaceutical and Medicine Manufacturing)

## GENERAL COMMENTS

### NOTE:

The facility is registered under the RMP program as “Clariant LSM (Puerto Rico) Inc. Since their latest submission in June 2004, the facility has undergone two name changes. In July 2006 the facility was purchased by Archimica Puerto Rico Inc. In April 2008, the facility was purchased by the TEVA Group. The facility currently operates under the name “TAPI Puerto Rico,” a member of the TEVA Group. However, since the current registration lists the name Clariant LSM (Puerto Rico) Inc., this report will utilize that name.

The facility produces pharmaceutical ingredients for sale to pharmaceutical manufacturing companies. The Humacao facility is fully dedicated to the production of an anti-cancer ingredient called 5-Fluorouracil (a white crystalline powder).

The facility uses fluorine gas in the production of 5-Fluorouracil. Fluorine gas is received in a tube trailer. Each trailer contains eight fluorine tube cylinders. Each tube cylinder contains 20% fluorine and 80% nitrogen. There is approximately 225-lbs. of fluorine in each tube cylinder. The facility reported that there is a maximum of two fluorine tube trailers on-site at any time. This is consistent with the registration quantity of 3,600-lbs. (225-lbs./tube cylinder x 8 tube cylinders/trailer x 2 tube trailers).

Typical pressure in a fluorine tube cylinder is 2200 PSIG. This pressure is regulated down to approximately 45 PSIG for delivery to the reactor system. Pressure is regulated down in two stages: 2200 PSIG to 150 PSIG and 150 PSIG to 45 PSIG.

The batch production occurs in a five-step process. Fluorine is used in the first step for a fluorination reaction. The entire batch cycle time is five days. There are three reactors (estimated 30-gallons each) utilized at the facility which typically run simultaneous fluorination reactions. The fluorination reaction is exothermic and takes approximately four hours. After completion of the fluorination reaction, the material is transferred into another reactor (R-7). The facility typically completes three simultaneous fluorination reactions four consecutive times. A total of 12 reaction batches are therefore collected in R-7. The batch material is then fed downstream for further processing, including centrifugation.

A typical fluorination reaction utilizes approximately 19 – 21-lbs. of fluorine at a feed rate of 4.5 – 5.0 lbs./hour. Fluorine gas is fed to the bottom of the reactor via ten ¼” feed lines. The rate of reaction is controlled by a combination of fluorine feed rate, reactor mix speed, and cooling water flow. All of these parameters are manually controlled. Operators monitor temperature in the fluorination reactor as an indication of a possible runaway reaction. A primary safeguard therefore is a high temperature alarm on the reactor and operator response.

PSVs in the system are designed to vent to a scrubber, rather than directly to the atmosphere.

## **RMP DOCUMENTATION**

The facility has a “PSM Manual” dated 12/11/92 originally compiled to address OSHA PSM compliance. The facility also maintains a “SOP Manual,” which includes written programs and procedures for various RMP required items, as well as other safety, environmental, maintenance, and operational procedures. Documentation includes written programs and procedures as described below.

### **Management System [40 CFR 68.15] & Registration**

The Site Manager has overall responsibility for implementation of the RMP program. The EHS Associate Director provides support as necessary. Facility management demonstrated an understanding of RMP program requirements and company programs and procedures designed to maintain compliance.

There was no written description of a management system.

The RMP\*Submit registration lists Clariant LSM (Puerto Rico) Inc. as the facility name. The current facility name is TAPI Puerto Rico, a member of the TEVA Group.

### **Hazard Assessment**

See the RMP Checklist for information regarding hazard assessment.

### **Process Safety Information (PSI) [40 CFR 68.65]**

PSI available for review included:

- Description of process chemistry
- Block Flow Diagram (BFD)
- MSDS for fluorine
- PI&D – Fluorine Tube Trailer; Dwg. No. 201-0-002; Rev. J; 3/2/04
- PI&D – R-101 Uracil Fluorine; Dwg. No. 201-0-003; Rev. G; 3/2/04
- PSV data including sizing, relief set points, MAWP, flow capacity

The following PSI documentation was not available for review:

- Electrical classification
- Ventilation system design
- Design codes and standards
- Description of safety systems

There was no documentation available regarding whether existing equipment complies with recognized and generally accepted good engineering practices.

### **Process Hazard Analysis (PHA) [40 CFR 68.67]**

PHA documentation available for review included:

- HAZOP worksheets from August 1992 sessions
- Record of a PHA Revalidation, report dated 4/8/99. Included description of PHA study team, HAZOP worksheet documentation, and a report on the resolution of PHA recommendations.
- Record of a PHA Revalidation – “Fluorine / Fluorination Reaction PHA Revalidation #2, May 2004.” Team sessions were held on May 19-20, 2004.

Team participation included a corporate engineer, Plant Manager, and Production/Maintenance Supervisor. There was no hourly operator on the study team. This PHA revalidation included the following:

- Review of previous incidents
- Review of MOCs
- Checklist review of facility siting
- Checklist review of human factors
- List of PSI documents
- Copies of the two previous PHA reports.

The May 2004 PHA Revalidation identified 24 recommendations. All of these recommendations were scheduled for resolution by 12/31/04. Eighteen recommendations remain unresolved.

### **Standard Operating Procedures (SOPs) [40 CFR 68.69]**

Written SOPs included:

- Procedure to Handle a Spill from Fluorinator Recirculation Line; SOP-PR-056; 1/5/07.
- Fluorine Trailer & Delivery system & Reactors Procedures. These procedures included step-by-step instruction for the following activities:
  - Connection to truck and prepare for usage
  - Changing from one truck to another
  - Disconnect truck and prepare for transport
  - Start-up operations of the system
  - System shutdown
  - Pre-startup procedure/operations
  - Identifying and responding to small fluorine leaks
  - Procedure to prepare for maintenance and repairs
  - Procedures to change from one tube to another tube on trailer
  - Procedures for power failure
  - Procedure to handle low pressure in tube (i.e., when tube is emptying)
  - Emergency Shutdown Procedure (two ESD switches)
  - Reactor preparation procedures
  - Reactor operation procedures

There was no record of annual certification of SOPs.

Safe work practice procedures included:

- Procedure for Hot Work
- Lock-out Procedure
- Procedure for Permit Required Confined Spaces

### **Training [40 CFR 68.71]**

The facility has a written Chemical Operator Training Procedure (SOP-OPS-006; 1/5/07). The training procedure includes detailed requirements for operator training, including initial and refresher training. Refresher training is performed annually, with the most recent refresher training completed in November 2007. Verification that operators understand training received includes verbal and written tests. Training procedures include specific requirements for operators.

The training records for an employee hired in August 1995 was reviewed. Documentation included:

- Verification of PSM training
- Verification of training in the fluorine process and reaction
- Verification of training in SOPs, including shutdown procedures, emergency shutdown procedures, and proper connections.
- Documentation on written tests to verify operator understanding of training received.

#### **Mechanical Integrity [40 CFR 68.73]**

The facility has a written Mechanical Integrity of Equipment Procedure (SOP-OPS-008; 1/5/07). This mechanical integrity procedure is well written and includes:

- Training requirements
- Inspection and test schedules
- Procedures for addressing equipment deficiencies
- Quality Assurance procedures

Other written procedures include:

- Instrument Calibration/Maintenance Logbook (SOP-G—023; 1/5/07)
- Maintenance Personnel Training Program (SOP-OPS-009; 1/5/07)
- Preparation for Performing Maintenance and/or Repairs in the Fluorine Reactors (SOP-PR-027; 1/5/07)
- Fluorine Flow Meter Calibration Procedure (SOP-PR-055; 1/5/07)
- Inspection of Teflon and Glass Lined Vessels (SOP-PR-032; 1/5/07)
- Above Ground Pipe Inspection (SOP-PR-035; 1/5/07)
- Preventive Maintenance Program (SOP-PR-036; 1/5/07)
- Calibration of Fluorine Pressure Gauges (SOP-PR-047; 1/5/07)

A check of inspection records required under the “Inspection of Teflon and Glass Lined Vessels” (SOP-PR-032; 1/5/07) procedure included documentation of quarterly inspections conducted of R-7 (June 2008, April 2008, February 2008, October 2007). However, documentation does not use the checklist form described in the procedure. Rather, documentation includes only a general statement. Note that the three fluorination reactors are made of polyethylene, not Teflon or glass.

Reviewed records to confirm that inspections and tests as required under the following procedures were completed:

Above Ground Pipe Inspection (SOP-PR-035; 1/5/07)

Record of monthly visual inspection of fluorine feed lines.

Preventive Maintenance Program (SOP-PR-036; 1/5/07)

Check records for:

- Fluorine tube trailer
- Pressure control manifold
- Fluorine piping
- Plastic Uracil slurry trays
- Reactor (R1, R2, R3)
- Flow meters N2
- Flow meters F2
- Vanton centrifugal pumps
- Fluorine regulators

Calibration of Fluorine Pressure Gauges (SOP-PR-047; 1/5/07)

Confirmed that bi-annual (e.g., every 6 months) calibration of the fluorine pressure gauges were completed (confirmed for 9/4/08 and 1/24/08 for Station #1 and #2).

Facility Management confirmed that PSVs are scheduled to be removed and inspected / replaced annually. Management reported that this maintenance inspection was not performed in 2006, 2007 and 2008.

**Management of Change (MOC) [40 CFR 68.75] & Pre-Startup Review (PSR) [40 CFR 68.77]**

The facility has a written procedure for management of change, "Change Control Procedure," (SOP-API-012; 7/17/07). The Change Control Procedure addresses equipment and procedural changes, uses a form to document changes, and includes necessary authorizations. The Change Control Procedure does not explicitly address the safety and health review of changes.

Facility management reported that there have been no changes to the process therefore there were no completed MOC reviews on file for review. The May 2004 PHA Revalidation however noted that the facility did not follow their MOC procedures regarding a change involving installation of valves in the fluorination reactor vent lines and in the drain line in the scrubber header and that P&IDs were not updated to reflect this change. This change was reviewed during the May 2004 PHA Revalidation however the P&IDs still have not been updated.



The facility has a written Pre-Startup Safety Review Procedure (SOP-OPS-007; 1/5/07). The PSSR Procedure addresses changes requiring an update to PSI and any changes that trigger a MOC review. The PSSR includes a checklist form to document review and appropriate authorizations. There was no PSSR review completed for the change involving installation of valves in the fluorination reactor vent lines and in the drain line in the scrubber header.

#### **Compliance Audits [40 CFR 68.79]**

There was no record of completed RMP compliance audits.

#### **Incident Investigation [40 CFR 68.81]**

Completed incident investigation reports were on file for fluorine incidents which occurred on 10/16/03 and 8/6/01. The reports were complete and included corrective actions to prevent reoccurrence.

#### **Employee Participation [40 CFR 68.83]**

There was no written employee participation plan available for review, however there was evidence of operator participation in development of SOPs and participation in PHAs.

#### **Hot Work Permit [40 CFR 68.85]**

The facility has a Procedure for Hot Work Permits (SOP-PR-028; 1/5/07). The procedure appears to be consistent with the requirements of 29 CFR 1910.252(a). Reviews are documented on a HWP form.

#### **Contractor Safety [40 CFR 68.87]**

The facility has a written contractor procedure, "Contractors at Archimica Puerto Rico Inc." (SOP-PR-031; 1/5/07). The procedure includes requirements for contractor selection, contractor orientation, and performance evaluation. The procedure includes a Contractor Evaluation Checklist form. Contractor work is managed through a "Contractors' Work Permit." Facility management reported that they do not use outside contractors to work on/near the process and therefore have no contractor files for review.

#### **Emergency Response [40 CFR 68.90 – 68.95]**

Evaluated by USEPA inspector.

### **FACILITY TOUR**

Several items noted during the facility tour include:

- ❑ There are no fluorine detectors in use at the facility. The most recent PHA study (May 2004) identified a recommendation to consider installation of fluorine detectors with interlock shutdown just downstream of the fluorine trailer, with an expected completion date of 12/31/04. This item remains unresolved. Facility management reported that there is a plan to install three detectors by 10/1/08. Plans are to install fluorine detectors at the PCM panel, at the scrubber, and in the fluorine reactor room. Additionally, the May 2004 PHA identified a recommendation to consider installation of a fluorine detector in the scrubber header with alarm and interlock shutdown just downstream of the fluorine trailer, with an expected completion date of 12/31/04. This item also remains unresolved. **Since these PHA recommendations are over four years old, and in accordance with 40 CFR 68.67(e), the facility should immediately resolve recommendations related to installation of fluorine detectors with shutdown interlocks.**
- ❑ Field cross-check between the P&IDs and installed equipment identified several valve / equipment tags that are no longer legible, particularly in the Pressure Control Manifold (PCM) panel. **The facility should ensure that all valve / instrument / equipment tags are legible, in accordance with good engineering practice.**
- ❑ Field check of installed equipment / instruments against the P&IDs did not identify any inconsistencies.
- ❑ The facility uses a retail-purchased Craftsman® drill as a mixer in the three fluorine reactors. **The facility should review and verify whether use of this drill as a mixer is consistent with good engineering practices and is suitable for its intended purpose.**
- ❑ An emergency shutdown switch and sign were observed in the production area. Facility management stated that this switch was no longer used for emergency shutdown. **The facility should remove the emergency shutdown switch and sign, since it is no longer in-service.**
- ❑ The rate of reaction in the fluorine reactors is controlled by a combination of fluorine feed rate, reactor mix speed, and cooling water flow to coils in the reactor. The fluorination reaction is exothermic. All of these parameters are manually controlled. Operators monitor temperature in the fluorination reactor as an indication of a possible runaway reaction. A primary safeguard therefore is a high temperature alarm on the reactor and operator response. Each reactor is equipped with a temperature element, temperature recorder and high temperature alarm (TAH). There was no record available of inspections / tests on the reactor TAHs. **Since the TAHs are important safeguards, the facility should establish an inspection / test schedule to confirm instrument integrity. Additionally, the facility should evaluate whether automatic controls / interlocks should be installed in response**

**to high temperature in the reactor, in place of, or in addition to, operator response.**

## FINDINGS/RECOMMENDATIONS

### Management System [40 CFR 68.15]

- ❑ **The facility must prepare a written description of its RMP management system and document other persons responsible for implementing individual requirements of the RMP with defined lines of authority, as required by 40 CFR 68.15(a) and (c).**

### Registration Information

- ❑ **The RMP\*Submit registration lists Clariant LSM (Puerto Rico) Inc. as the facility name. The current facility name is TAPI Puerto Rico, a member of the TEVA Group. The facility should update the RMP\*Submit registration reflecting the correct facility name and owner / operator.**

### Process Safety Information (PSI) [40 CFR 68.65]

- ❑ **The following PSI documentation was not available for review: electrical classification, ventilation system design, design codes and standards, and description of safety systems. The facility should compile all necessary PSI, including electrical classification (40 CFR 68.65(d)(1)(iii)), ventilation system design (40 CFR 68.65(d)(1)(v)), design codes and standards (40 CFR 68.65(d)(1)(vi)), and description of safety systems (40 CFR 68.65(d)(1)(viii)).**
- ❑ **There was no documentation available regarding whether existing equipment complies with recognized and generally accepted good engineering practices. The facility must document that equipment complies with recognized and generally accepted good engineering practices as required by 40 CFR 68.65(d)(2).**

### Process Hazard Analysis (PHA) [40 CFR 68.67]

- ❑ **The May 2004 PHA Revalidation identified 24 recommendations. All of these recommendations were scheduled for resolution by 12/31/04. Eighteen recommendations remain unresolved. The facility should resolve the 18 open**

**recommendations from the May 2004 PHA Revalidation, in accordance with 40 CFR 68.67(e).**

**Standard Operating Procedures (SOPs) [40 CFR 68.69]**

- There was no record of annual certification of SOPs. **The facility should annually certify operating procedures to confirm that they are current and accurate, in accordance with 40 CFR 68.69(c).**

**Mechanical Integrity [40 CFR 68.73]**

- A check of inspection records required under the "Inspection of Teflon and Glass Lined Vessels" (SOP-PR-032; 1/5/07) procedure included documentation of quarterly inspections of R-7, however, documentation does not use the checklist form described in the procedure. Rather, documentation includes only a general statement. **The facility should adhere to the procedure and use the checklist form rather than general documentation as it is more detailed and required per its written procedure.**
- Facility Management confirmed that PSVs are scheduled to be removed and inspected / replaced annually. Management reported that this maintenance inspection was not performed in 2006, 2007 and 2008. **The facility should adhere to the schedule for annual inspection / replacement of PSVs per its written procedure and as required by 40 CFR 68.73(d)(1).**

**Management of Change (MOC) [40 CFR 68.75] & Pre-Startup Review (PSR) [40 CFR 68.77]**

- The Change Control Procedure (SOP-API-012; 7/17/07) does not explicitly address the safety and health review of changes. **The facility should ensure that the Change Control Procedure includes a review of the impact of the change on safety and health, as required by 40 CFR 68.75(b)(2).**
- The May 2004 PHA Revalidation however noted that the facility did not follow their MOC procedures regarding a change involving installation of valves in the fluorination reactor vent lines and in the drain line in the scrubber header and that P&IDs were not updated to reflect this change. This change was reviewed during the May 2004 PHA Revalidation however the P&IDs still have not been updated. **The facility should ensure that their Change Control Procedure is followed for all changes and should update P&IDs to reflect changes involving installation of valves in the fluorination reactor vent lines and in the drain line in the scrubber header, as required by 40 CFR 68.75(d).**

- There was no Pre-startup Review completed for the change involving installation of valves in the fluorination reactor vent lines and in the drain line in the scrubber header. **The facility should ensure that a Pre-startup Review is completed for all changes involving the need to update PSI, as required by 40 CFR 68.77.**

**Compliance Audits [40 CFR 68.79]**

- There were no records of completed RMP compliance audits. **The facility must complete RMP compliance audits at least once every three years, as required by 40 CFR 68.79.**

**Employee Participation [40 CFR 68.83]**

- There was no written employee participation plan available for review, however there was evidence of operator participation in development of SOPs and participation in PHAs. **The facility must develop a written employee participation plan as required by 40 CFR 68.83(a).**

**RMP Program Level 3 Process Checklist**

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**CARIBBEAN OFFICE &**  
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*(NOTE: Hazard Assessment evaluation completed by Rohit*  
*Shirpewar, Sullivan Group)*  
**FINAL**

**Section A – Management [68.15]**

Management system developed and implemented as provided in 40 CFR 68.15? S M U N/A

Comments: \_\_\_\_\_

Has the owner or operator: \_\_\_\_\_

1. Developed a management system to oversee the implementation of the risk management program elements? [68.15(a)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
2. Assigned a qualified person or position that has the overall responsibility for the development, implementation, and integration of the risk management program elements? [68.15(b)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
3. Documented other persons responsible for implementing individual requirements of the risk management program and defined the lines of authority through an organization chart or similar document? [68.15(c)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A

**Section B: Hazard Assessment [68.20-68.42]**

Hazard assessment conducted and documented as provided in 40 CFR 68.20-68.42? S M U N/A

Comments: \_\_\_\_\_

**Hazard Assessment: Offsite consequence analysis parameters [68.22]**

1. Used the following endpoints for offsite consequence analysis for a worst-case scenario: [68.22(a)] <input checked="" type="checkbox"/> For toxics: the endpoints provided in Appendix A of 40 CFR Part 68? [68.22(a)(1)] <input type="checkbox"/> For flammables: an explosion resulting in an overpressure of 1 psi? [68.22(a)(2)(i)]; or <input type="checkbox"/> For flammables: a fire resulting in a radiant heat/exposure of 5 kw/m <sup>2</sup> for 40 seconds? [68.22(a)(2)(ii)] <input type="checkbox"/> For flammables: a concentration resulting in a lower flammability limit, as provided in NFPA documents or other generally recognized sources? [68.22(a)(2)(iii)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A  Note: should be noted in RMP.
2. Used the following endpoints for offsite consequence analysis for an alternative release scenario: [68.22(a)] <input checked="" type="checkbox"/> For toxics: the endpoints provided in Appendix A of 40 CFR Part 68? [68.22(a)(1)] <input type="checkbox"/> For flammables: an explosion resulting in an overpressure of 1 psi? [68.22(a)(2)(i)] <input type="checkbox"/> For flammables: a fire resulting in a radiant heat/exposure of 5 kw/m <sup>2</sup> for 40 seconds? [68.22(a)(2)(ii)] <input type="checkbox"/> For flammables: a concentration resulting in a lower flammability limit, as provided in NFPA documents or other generally recognized sources? [68.22(a)(2)(iii)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
3. Used appropriate wind speeds and stability classes for the release analysis? [68.22(b)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
4. Used appropriate ambient temperature and humidity values for the release analysis? [68.22(c)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
5. Used appropriate values for the height of the release for the release analysis? [68.22(d)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

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**FINAL**

6. Used appropriate surface roughness values for the release analysis? [68.22(e)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
7. Do tables and models, used for dispersion analysis of toxic substances, appropriately account for dense or neutrally buoyant gases? [68.22(f)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
8. Were liquids, other than gases liquefied by refrigeration only, considered to be released at the highest daily maximum temperature, based on data for the previous three years appropriate for a stationary source, or at process temperature, whichever is higher? [68.22(g)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A

**Hazard Assessment: Worst-case release scenario analysis [68.25]**

9. Analyzed and reported in the RMP one worst-case release scenario estimated to create the greatest distance to an endpoint resulting from an accidental release of a regulated toxic substance from covered processes under worst-case conditions? [68.25(a)(2)(i)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
10. Analyzed and reported in the RMP one worst-case release scenario estimated to create the greatest distance to an endpoint resulting from an accidental release of a regulated flammable substance from covered processes under worst-case conditions? [68.25(a)(2)(ii)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
11. Analyzed and reported in the RMP additional worst-case release scenarios for a hazard class if the worst-case release from another covered process at the stationary source potentially affects public receptors different from those potentially affected by the worst-case release scenario developed under 68.25(a)(2)(i) or 68.25(a)(2)(ii)? [68.25(a)(2)(iii)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
12. Has the owner or operator determined the worst-case release quantity to be the greater of the following: [68.25(b)] <input checked="" type="checkbox"/> If released from a vessel, the greatest amount held in a single vessel, taking into account administrative controls that limit the maximum quantity? [68.25(b)(1)] <input type="checkbox"/> If released from a pipe, the greatest amount held in the pipe, taking into account administrative controls that limit the maximum quantity? [68.25(b)(2)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
13.a. Has the owner or operator for <u>toxic substances</u> that are <u>normally gases</u> at ambient temperature and handled as a <u>gas or liquid under pressure</u> :			
13.a.(1) Assumed the whole quantity in the vessel or pipe would be released as a gas over 10 minutes? [68.25(c)(1)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
13.a.(2) Assumed the release rate to be the total quantity divided by 10, if there are no passive mitigation systems in place? [68.25(c)(1)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
13.b. Has the owner or operator for <u>toxic gases</u> handled as <u>refrigerated liquids</u> at ambient pressure:			
13.b.(1) Assumed the substance would be released as a gas in 10 minutes, if not contained by passive mitigation systems or if the contained pool would have a depth of 1 cm or less? [68.25(c)(2)(i)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.b.(2) If released substance would be contained by passive mitigation systems in a pool with a depth > 1 cm; <input type="checkbox"/> Assumed the quantity in the vessel or pipe (as determined per 68.25(b)) would be spilled instantaneously to form a liquid pool? [68.25(c)(2)(ii)] <input type="checkbox"/> Calculated the volatility rate at the boiling point of the substance and at the conditions specified in 68.25(d)? [68.25(c)(2)(ii)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A

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13.c. Has the owner or operator for toxic substances that are normally liquids at ambient temperature:

13.c.(1) Assumed the quantity in the vessel or pipe would be spilled instantaneously to form a liquid pool? [68.25(d)(1)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.c.(2) Determined the surface area of the pool by assuming that the liquid spreads to 1 cm deep, if there is no passive mitigation system in place that would serve to contain the spill and limit the surface area, or if passive mitigation is in place, was the surface area of the contained liquid used to calculate the volatilization rate? [68.25(d)(1)(i)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.c.(3) Taken into account the actual surface characteristics, if the release would occur onto a surface that is not paved or smooth? [68.25(d)(1)(ii)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.c.(4) Determined the volatilization rate by accounting for the highest daily maximum temperature in the past three years, the temperature of the substance in the vessel, and the concentration of the substance if the liquid spilled is a mixture or solution? [68.25(d)(2)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.c.(5) Determined the rate of release to air from the volatilization rate of the liquid pool? [68.25(d)(3)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.c.(6) Determined the rate of release to air by using the methodology in the RMP Offsite Consequence Analysis Guidance, any other publicly available techniques that account for the modeling conditions and are recognized by industry as applicable as part of current practices, or proprietary models that account for the modeling conditions may be used provided the owner or operator allows the implementing agency access to the model and describes model features and differences from publicly available models to local emergency planners upon request? [68.25(d)(3)]  What modeling technique did the owner or operator use? [68.25(g)] _____	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A

13.d. Has the owner or operator for flammables:

13.d.(1) Assumed the quantity in a vessel(s) of flammable gas held as a gas or liquid under pressure or refrigerated gas released to an undiked area vaporizes resulting in a vapor cloud explosion? [68.25(e)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.d.(2) For refrigerated gas released to a contained area or liquids released below their atmospheric boiling point, assumed the quantity volatilized in 10 minutes results in a vapor cloud? [68.25(f)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
13.d.(3) Assumed a yield factor of 10% of the available energy is released in the explosion for determining the distance to the explosion endpoint, if the model used is based on TNT-equivalent methods? [68.25(e)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
14. Used the parameters defined in 68.22 to determine distance to the endpoints? [68.25(g)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
15. Determined the rate of release to air by using the methodology in the RMP Offsite Consequence Analysis Guidance, any other publicly available techniques that account for the modeling conditions and are recognized by industry as applicable as part of current practices, or proprietary models that account for the modeling conditions may be used provided the owner or operator allows the implementing agency access to the model and describes model features and differences from publicly available models to local emergency planners upon request? [68.25(g)]  What modeling technique did the owner or operator use? [68.25(g)] <u>Areal Locations of Hazardous Atmospheres [ALOHA(R)]</u>	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
16. Ensured that the passive mitigation system, if considered, is capable of withstanding the release event triggering the scenario and will still function as intended? [68.25(h)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A



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17. Considered also the following factors in selecting the worst-case release scenarios: [68.25(i)] <input type="checkbox"/> Smaller quantities handled at higher process temperature or pressure? [68.25(i)(1)] <input type="checkbox"/> Proximity to the boundary of the stationary source? [68.25(i)(2)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
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**Hazard Assessment: Alternative release scenario analysis [68.28]**

18. Identified and analyzed at least one alternative release scenario for each regulated toxic substance held in a covered process(es) and at least one alternative release scenario to represent all flammable substances held in covered processes? [68.28(a)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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19. Selected a scenario: [68.28(b)] <input checked="" type="checkbox"/> That is more likely to occur than the worst-case release scenario under 68.25? [68.28(b)(1)(i)] <input type="checkbox"/> That will reach an endpoint off-site, unless no such scenario exists? [68.28(b)(1)(ii)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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20. Considered release scenarios which included, but are not limited to, the following: [68.28(b)(2)] <input type="checkbox"/> Transfer hose releases due to splits or sudden hose uncoupling? [68.28(b)(2)(i)] <input checked="" type="checkbox"/> Process piping releases from failures at flanges, joints, welds, valves and valve seals, and drains or bleeds? [68.28(b)(2)(ii)] <input type="checkbox"/> Process vessel or pump releases due to cracks, seal failure, or drain, bleed, or plug failure? [68.28(b)(2)(iii)] <input type="checkbox"/> Vessel overfilling and spill, or overpressurization and venting through relief valves or rupture disks? [68.28(b)(2)(iv)] <input type="checkbox"/> Shipping container mishandling and breakage or puncturing leading to a spill? [68.28(b)(2)(v)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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21. Used the parameters defined in 68.22 to determine distance to the endpoints? [68.28(c)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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22. Determined the rate of release to air by using the methodology in the RMP Offsite Consequence Analysis Guidance, any other publicly available techniques that account for the modeling conditions and are recognized by industry as applicable as part of current practices, or proprietary models that account for the modeling conditions may be used provided the owner or operator allows the implementing agency access to the model and describes model features and differences from publicly available models to local emergency planners upon request? [68.28(c)]  What modeling technique did the owner or operator use? [68.25(g)] <u>Areal Locations of Hazardous Atmospheres [ALOHA(R)]</u>	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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23. Ensured that the passive and active mitigation systems, if considered, are capable of withstanding the release event triggering the scenario and will be functional? [68.28(d)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
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24. Considered the following factors in selecting the alternative release scenarios: [68.28(e)] <input type="checkbox"/> The five-year accident history provided in 68.42? [68.28(e)(1)] <input type="checkbox"/> Failure scenarios identified under 68.50? [68.28(e)(2)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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**Hazard Assessment: Defining off-site impacts–Population [68.30]**

25. Estimated population that would be included in the distance to the endpoint in the RMP based on a circle with the point of release at the center? [68.30(a)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
26. Identified the presence of institutions, parks and recreational areas, major commercial, office, and industrial buildings in the RMP? [68.30(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
27. Used most recent Census data, or other updated information to estimate the population? [68.30(c)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
28. Estimated the population to two significant digits? [68.30(d)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

**Hazard Assessment: Defining off-site impacts–Environment [68.33]**

29. Identified environmental receptors that would be included in the distance to the endpoint based on a circle with the point of release at the center? [68.33(a)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
30. Relied on information provided on local U.S.G.S. maps, or on any data source containing U.S.G.S. data to identify environmental receptors? [Source may have used LandView to obtain information] [68.33(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

**Hazard Assessment: Review and update [68.36]**

31. Reviewed and updated the off-site consequence analyses at least once every five years? [68.36(a)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
32. Completed a revised analysis and submit a revised RMP within six months of a change in processes, quantities stored or handled, or any other aspect that might reasonably be expected to increase or decrease the distance to the endpoint by a factor of two or more? [68.36(b)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A

**Hazard Assessment: Documentation [68.39]**

33. For worst-case scenarios: a description of the vessel or pipeline and substance selected, assumptions and parameters used, the rationale for selection, and anticipated effect of the administrative controls and passive mitigation on the release quantity and rate? [68.39(a)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
34. For alternative release scenarios: a description of the scenarios identified, assumptions and parameters used, the rationale for the selection of specific scenarios, and anticipated effect of the administrative controls and mitigation on the release quantity and rate? [68.39(b)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
35. Documentation of estimated quantity released, release rate, and duration of release? [68.39(c)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
36. Methodology used to determine distance to endpoints? [68.39(d)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
37. Data used to estimate population and environmental receptors potentially affected? [68.39(e)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

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**Hazard Assessment: Five-year accident history [68.42]**

38. Has the owner or operator included 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? [68.42(a)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
39. Has the owner or operator reported the following information for each accidental release: [68.42(b)] <ul style="list-style-type: none"> <li><input type="checkbox"/> Date, time, and approximate duration of the release? [68.42(b)(1)]</li> <li><input type="checkbox"/> Chemical(s) released? [68.42(b)(2)]</li> <li><input type="checkbox"/> Estimated quantity released in pounds and percentage weight in a mixture (toxics)? [68.42(b)(3)]</li> <li><input type="checkbox"/> NAICS code for the process? [68.42(b)(4)]</li> <li><input type="checkbox"/> The type of release event and its source? [68.42(b)(5)]</li> <li><input type="checkbox"/> Weather conditions (if known)? [68.42(b)(6)]</li> <li><input type="checkbox"/> On-site impacts? [68.42(b)(7)]</li> <li><input type="checkbox"/> Known offsite impacts? [68.42(b)(8)]</li> <li><input type="checkbox"/> Initiating event and contributing factors (if known)? [68.42(b)(9)]</li> <li><input type="checkbox"/> Whether offsite responders were notified (if known)? [68.42(b)(10)]</li> <li><input type="checkbox"/> Operational or process changes that resulted from investigation of the release? [68.42(b)(11)]</li> </ul>	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A

**Section C: Prevention Program**

Implemented the Program 3 prevention requirements as provided in 40 CFR 68.65 - 68.87? 
 S     M     U     N/A

Comments:

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**Prevention Program- Safety information [68.65]**

<p>1. Has the owner or operator compiled written process safety information, which includes information pertaining to the hazards of the regulated substances used or produced by the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process, before conducting any process hazard analysis required by the rule? [68.65(a)]</p> <p>Does the process safety information contain the following for hazards of the substances: [68.65(b)]</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Material Safety Data Sheets (MSDS) that meet the requirements of the OSHA Hazard Communication Standard [29 CFR 1910.1200(g)]? [68.48(a)(1)]</li> <li><input checked="" type="checkbox"/> Toxicity information? [68.65(b)(1)]</li> <li><input checked="" type="checkbox"/> Permissible exposure limits? [68.65(b)(2)]</li> <li><input checked="" type="checkbox"/> Physical data? [68.65(b)(3)]</li> <li><input checked="" type="checkbox"/> Reactivity data? [68.65(b)(4)]</li> <li><input checked="" type="checkbox"/> Corrosivity data? [68.65(b)(5)]</li> <li><input checked="" type="checkbox"/> Thermal and chemical stability data? [68.65(b)(6)]</li> <li><input checked="" type="checkbox"/> Hazardous effects of inadvertent mixing of materials that could foreseeably occur? [68.65(b)(7)]</li> </ul>	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
<p>2. Has the owner documented information pertaining to technology of the process?</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> A block flow diagram or simplified process flow diagram? [68.65(c)(1)(i)]</li> <li><input checked="" type="checkbox"/> Process chemistry? [68.65(c)(1)(ii)]</li> <li><input checked="" type="checkbox"/> Maximum intended inventory? [68.65(c)(1)(iii)]</li> <li><input checked="" type="checkbox"/> Safe upper and lower limits for such items as temperatures, pressures, flows, or compositions? [68.65(c)(1)(iv)]</li> <li><input checked="" type="checkbox"/> An evaluation of the consequences of deviation? [68.65(c)(1)(iv)]</li> </ul>	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
<p>3. Does the process safety information contain the following for the equipment in the process: [68.65(d)(1)]</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Materials of construction? 68.65(d)(1)(i)]</li> <li><input checked="" type="checkbox"/> Piping and instrumentation diagrams [68.65(d)(1)(ii)]</li> <li><input type="checkbox"/> Electrical classification? [68.65(d)(1)(iii)]</li> <li><input checked="" type="checkbox"/> Relief system design and design basis? [68.65(d)(1)(iv)]</li> <li><input type="checkbox"/> Ventilation system design? [68.65(d)(1)(v)]</li> <li><input type="checkbox"/> Design codes and standards employed? [68.65(d)(1)(vi)]</li> <li><input type="checkbox"/> Material and energy balances for processes built after June 21, 1999? [68.65(d)(1)(vii)]                      N/A</li> <li><input type="checkbox"/> Safety systems? [68.65(d)(1)(viii)]</li> </ul>	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A  <p style="font-size: 1.2em; font-weight: bold;">PARTIAL</p>
<p>4. Has the owner or operator documented that equipment complies with recognized and generally accepted good engineering practices? [68.65(d)(2)]</p>	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A

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**CARIBBEAN OFFICE &**  
**NEIL MULVEY, SULLIVAN GROUP (Subcontractor)**  
*(NOTE: Hazard Assessment evaluation completed by Rohit*  
*Shirpewar, Sullivan Group)*  
**FINAL**

5. Has the owner or operator determined and documented that existing equipment, designed and constructed in accordance with codes, standards, or practices that are no longer in general use, is designed, maintained, inspected, tested, and operating in a safe manner? [68.65(d)(3)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
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**Prevention Program- Process Hazard Analysis [68.67]**

6. Has the owner or operator performed an initial process hazard analysis (PHA), and has this analysis identified, evaluated, and controlled the hazards involved in the process? [68.67(a)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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7. Has the owner or operator determined and documented the priority order for conducting PHAs, and was it based on an appropriate rationale? [68.67(a)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
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8. Has the owner used one or more of the following technologies to conduct process PHA: [68.67(b)] <input type="checkbox"/> What-if? [68.67(b)(1)] <input checked="" type="checkbox"/> Checklist? [68.67(b)(2)] <input type="checkbox"/> What-if/Checklist? [68.67(b)(3)] <input checked="" type="checkbox"/> Hazard and Operability Study (HAZOP) [68.67(b)(4)] <input type="checkbox"/> Failure Mode and Effects Analysis (FMEA) [68.67(b)(5)] <input type="checkbox"/> Fault Tree Analysis? [68.67(b)(6)] <input type="checkbox"/> An appropriate equivalent methodology? [68.67(b)(7)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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9. Did the PHA address: <input checked="" type="checkbox"/> The hazards of the process? [68.67(c)(1)] <input checked="" type="checkbox"/> Identification of any incident that had a likely potential for catastrophic consequences? [68.67(c)(2)] <input checked="" type="checkbox"/> Engineering and administrative controls applicable to hazards and interrelationships? [68.67(c)(3)] <input checked="" type="checkbox"/> Consequences of failure of engineering and administrative controls? [68.67(c)(4)] <input checked="" type="checkbox"/> Stationary source siting? [68.67(c)(5)] <input checked="" type="checkbox"/> Human factors? [68.67(c)(6)] <input checked="" type="checkbox"/> An evaluation of a range of the possible safety and health effects of failure of controls? [68.67(c)(7)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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10. Was the PHA performed by a team with expertise in engineering and process operations and did the team include appropriate personnel? [68.67(d)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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11. Has the owner or operator established a system to promptly address the team's findings and recommendations; assured that the recommendations are resolved in a timely manner and documented; documented what actions are to be taken; completed actions as soon as possible; developed a written schedule of when these actions are to be completed; and communicated the actions to operating, maintenance, and other employees whose work assignments are in the process and who may be affected by the recommendations? [68.67(e)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
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12. Has the PHA been updated and revalidated by a team every five years after the completion of the initial PHA to assure that the PHA is consistent with the current process? [68.67(f)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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**MP Program Level 3 Process Checklist**

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*(NOTE: Hazard Assessment evaluation completed by Rohit*  
*Shirpewar, Sullivan Group)*  
**FINAL**

**Prevention Program - Training [68.71]**

9. Has each employee involved in operating a process, and each employee before being involved in operating a newly assigned process, been initially trained in an overview of the process and in the operating procedures? [68.71(a)(1)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
10. Did initial training include emphasis on safety and health hazards, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks? [68.71(a)(1)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
11. In lieu of initial training for those employees already involved in operating a process on June 21, 1999, an owner or operator may certify in writing that the employee has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities as specified in the operating procedures [68.71(a)(2)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
12. Has refresher training been provided at least every three years, or more often if necessary, to each employee involved in operating a process to assure that the employee understands and adheres to the current operating procedures of the process? [68.71(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
13. Has owner or operator ascertained and documented in record that each employee involved in operating a process has received and understood the training required? [68.71(c)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
14. Does the prepared record contain the identity of the employee, the date of the training, and the means used to verify that the employee understood the training? [68.71(c)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

**Prevention Program - Mechanical Integrity [68.73]**

15. Has the owner or operator established and implemented written procedures to maintain the on-going integrity of the process equipment listed in 68.73(a)? [68.73(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
16. Has the owner or operator trained each employee involved in maintaining the on-going integrity of process equipment? [68.73(c)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
17. Performed inspections and tests on process equipment? [68.73(d)(1)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
	<b>PARTIAL</b>		
18. Followed recognized and generally accepted good engineering practices for inspections and testing procedures? [68.73(d)(2)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
19. Ensured the frequency of inspections and tests of process equipment is consistent with applicable manufacturers' recommendations, good engineering practices, and prior operating experience? [68.73(d)(3)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
20. Documented each inspection and test that had been performed on process equipment, which identifies the date of the inspection or test, the name of the person who performed the inspection or test, the serial number or other identifier of the equipment on which the inspection or test was performed, a description of the inspection or test performed, and the results of the inspection or test? [68.73(d)(4)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
21. Corrected deficiencies in equipment that were outside acceptable limits defined by the process safety information before further use or in a safe and timely manner when necessary means were taken to assure safe operation? [68.73(e)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

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**FINAL**

32. Assured that equipment as it was fabricated is suitable for the process application for which it will be used in the construction of new plants and equipment? [68.73(f)(1)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
33. Performed appropriate checks and inspections to assure that equipment was installed properly and consistent with design specifications and the manufacturer's instructions? [68.73(f)(2)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
34. Assured that maintenance materials, spare parts and equipment were suitable for the process application for which they would be used? [68.73(f)(3)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

**Prevention Program - Management Of Change [68.75]**

35. Has the owner or operator established and implemented written procedures to manage changes to process chemicals, technology, equipment, and procedures, and changes to stationary sources that affect a covered process? [68.75(a)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
36. Do procedures assure that the following considerations are addressed prior to any change: [68.75(b)] <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> The technical basis for the proposed change? [68.75(b)(1)]</li> <li><input type="checkbox"/> Impact of change on safety and health? [68.75(b)(2)]</li> <li><input checked="" type="checkbox"/> Modifications to operating procedures? [68.75(b)(3)]</li> <li><input checked="" type="checkbox"/> Necessary time period for the change? [68.75(b)(4)]</li> <li><input checked="" type="checkbox"/> Authorization requirements for the proposed change? [68.75(b)(5)]</li> </ul>	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A  <b>PARTIAL</b>
37. Were employees, involved in operating a process and maintenance, and contract employees, whose job tasks would be affected by a change in the process, informed of, and trained in, the change prior to start-up of the process or affected parts of the process? [68.75(c)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
38. If a change resulted in a change in the process safety information, was such information updated accordingly? [68.75(d)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
39. If a change resulted in a change in the operating procedures or practices, had such procedures or practices been updated accordingly? [68.75(e)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A

**Prevention Program - Pre-startup Safety Review [68.77]**

40. If the facility installed a new stationary source, or significantly modified an existing source, (as discussed at 68.77(a)) did it perform a pre-startup safety review prior to the introduction of a regulated substance to a process to confirm: [68.77(b)] <ul style="list-style-type: none"> <li><input type="checkbox"/> Construction and equipment was in accordance with design specifications? [68.77(b)(1)]</li> <li><input type="checkbox"/> Safety, operating, maintenance, and emergency procedures were in place and were adequate? [68.77(b)(2)]</li> <li><input type="checkbox"/> For new stationary sources, a process hazard analysis had been performed and recommendations had been resolved or implemented before startup? [68.77(b)(3)]</li> <li><input type="checkbox"/> Modified stationary sources meet the requirements contained in management of change? [68.77(b)(3)]</li> <li><input type="checkbox"/> Training of each employee involved in operating a process had been completed? [68.77(b)(4)]</li> </ul>	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
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**FINAL**

**Prevention Program - Compliance audits [68.79]**

41. Has the owner or operator certified that the stationary source has evaluated compliance with the provisions of the prevention program at least every three years to verify that the developed procedures and practices are adequate and being followed? [68.79(a)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
42. Has the audit been conducted by at least one person knowledgeable in the process? [68.79(b)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
43. Are the audit findings documented in a report? [68.79(c)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A
44. Has the owner or operator promptly determined and documented an appropriate response to each of the findings of the audit and documented that deficiencies had been corrected? [68.79(d)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> N/A
45. Has the owner or operator retained the two most recent compliance reports? [68.79(e)]	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N <input type="checkbox"/> N/A

**Prevention Program - Incident investigation [68.81]**

46. Has the owner or operator investigated each incident that resulted in, or could reasonably have resulted in a catastrophic release of a regulated substance? [68.81(a)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
47. Were all incident investigations initiated not later than 48 hours following the incident? [68.81(b)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
48. Was an accident investigation team established and did it consist of at least one person knowledgeable in the process involved, including a contract employee if the incident involved work of a contractor, and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident? [68.81(c)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
49. Was a report prepared at the conclusion of every investigation? [68.81(d)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
50. Does every report include: [68.81(d)] <input checked="" type="checkbox"/> Date of incident? [68.81(d)(1)] <input checked="" type="checkbox"/> Date investigation began? [68.81(d)(2)] <input checked="" type="checkbox"/> A description of the incident? [68.81(d)(3)] <input checked="" type="checkbox"/> The factors that contributed to the incident? [68.81(d)(4)] <input checked="" type="checkbox"/> Any recommendations resulting from the investigation? [68.81(d)(5)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
51. Has the owner or operator established a system to address and resolve the report findings and recommendations, and are the resolutions and corrective actions documented? [68.81(e)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
52. Was the report reviewed with all affected personnel whose job tasks are relevant to the incident findings including contract employees where applicable? [68.81(f)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
53. Has the owner or operator retained incident investigation reports for at least five years? [68.81(g)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

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**FINAL**

**Section D - Employee Participation [68.83]**

1. Has the owner or operator developed a written plan of action regarding the implementation of the employee participation required by this section? [68.83(a)]	<input type="checkbox"/> Y	<input checked="" type="checkbox"/> N	<input type="checkbox"/> N/A
2. Has the owner or operator consulted with employees and their representatives on the conduct and development of process hazards analyses and on the development of the other elements of process safety management in chemical accident prevention provisions? [68.83(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
3. Has the owner or operator provided to employees and their representatives access to process hazards analyses and to all other information required to be developed under the chemical accident prevention rule? [68.83(c)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

**Section E - Hot Work Permit [68.85]**

1. Has the owner or operator issued a hot work permit for each hot work operation conducted on or near a covered process? [68.85(a)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
2. Does the permit document that the fire prevention and protection requirements in 29CFR 1910.252(a) have been implemented prior to beginning the hot work operations? [68.85(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
3. Does the permit indicate the date(s) authorized for hot work and the object(s) upon which hot work is to be performed? [68.85(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
4. Are the permits being kept on file until completion of the hot work operations? [68.85(b)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A

**Section F - Contractors [68.87]**

1. Has the owner or operator obtained and evaluated information regarding the contract owner or operator's safety performance and programs when selecting a contractor? [68.87(b)(1)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
2. Informed contract owner or operator of the known potential fire, explosion, or toxic release hazards related to the contractor's work and the process? [68.87(b)(2)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
3. Explained to the contract owner or operator the applicable provisions of the emergency response or the emergency action program? [68.87(b)(3)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A
4. Developed and implemented safe work practices consistent with §68.69(d), to control the entrance, presence, and exit of the contract owner or operator and contract employees in the covered process areas? [68.87(b)(4)]	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> N/A
5. Periodically evaluated the performance of the contract owner or operator in fulfilling their obligations (as described at 68.87(c)(1) – (c)(5))? [68.87(b)(5)]	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> N/A

**Section G - Emergency Response [68.90 - 68.95]**

*Evaluated by USEPA inspector.*

Developed and implemented an emergency response program as provided in 40 CFR 68.90-68.95?  S  M  U  N/A

Comments:

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**FINAL**

1. Is the facility designated as a "first responder" in case of an accidental release of regulated substances?"	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
1.a. If the facility is not a first responder:	
1.a.(1) For stationary sources with any regulated substances held in a process above threshold quantities, is the source included in the community emergency response plan developed under 42 U.S.C. 11003? [68.90(b)(1)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
1.a.(2) For stationary sources with only regulated flammable substances held in a process above threshold quantities, has the owner or operator coordinated response actions with the local fire department? [68.90(b)(2)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
1.a.(3) Are appropriate mechanisms in place to notify emergency responders when there is need for a response? [68.90(b)(3)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
2. An emergency response plan is maintained at the stationary source and contains the following? [68.95(a)(1)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
<input type="checkbox"/> Procedures for informing the public and local emergency response agencies about accidental releases? [68.95(a)(1)(i)] <input type="checkbox"/> Documentation of proper first-aid and emergency medical treatment necessary to treat accidental human exposures? [68.95(a)(1)(ii)] <input type="checkbox"/> Procedures and measures for emergency response after an accidental release of a regulated substance? [68.95(a)(1)(iii)]	
3. The emergency response plan contains procedures for the use of emergency response equipment and for its inspection, testing, and maintenance? [68.95(a)(2)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
4. The emergency response plan requires, and there is documentation of, training for all employees in relevant procedures? [68.95(a)(3)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
5. The owner or operator has developed and implemented procedures to review and update, as appropriate, the emergency response plan to reflect changes at the stationary source and ensure that employees are informed of changes? [68.95(a)(4)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
6. Did the owner or operator use a written plan that complies with other Federal contingency plan regulations or is consistent with the approach in the National Response Team's Integrated Contingency Plan Guidance ("One Plan")? If so, does the plan include the elements provided in paragraph (a) of 68.95, and also complies with paragraph (c) of 68.95? [68.95(b)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
7. Has the emergency response plan been coordinated with the community emergency response plan developed under EPCRA? [68.95(c)]	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

**Section II – Risk Management Plan [40 CFR 68.190 – 68.195]**

1. Does the single registration form include, for each covered process, the name and CAS number of each regulated substance held above the threshold quantity in the process, the maximum quantity of each regulated substance or mixture in the process (in pounds) to two significant digits, the five- or six-digit NAICS code that most closely corresponds to the process and the Program level of the process? [68.160(b)(7)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
2. Did the facility assign the correct program level(s) to its covered process(es)? [68.160(b)(7)]	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

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**FINAL**

<p>3. Has the owner or operator reviewed and updated the RMP and submitted it to EPA [68.190(a)]?                  Reason for update:</p> <p><input checked="" type="checkbox"/> Five-year update. [68.190(b)(1)]</p> <p><input type="checkbox"/> Within three years of a newly regulated substance listing. [68.190(b)(2)]</p> <p><input type="checkbox"/> At the time a new regulated substance is first present in an already regulated process above threshold quantities. [68.190(b)(3)]</p> <p><input type="checkbox"/> At the time a regulated substance is first present in a new process above threshold quantities. [68.190(b)(4)]</p> <p><input type="checkbox"/> Within six months of a change requiring revised PHA or hazard review. [68.190(b)(5)]</p> <p><input type="checkbox"/> Within six months of a change requiring a revised OCA as provided in 68.36. [68.190(b)(6)]</p> <p><input type="checkbox"/> Within six months of a change that alters the Program level that applies to any covered process. [68.190(b)(7)]</p>	<p><input checked="" type="checkbox"/> Y    <input type="checkbox"/> N    <input type="checkbox"/> N/A</p>
<p>4. If the owner or operator experienced an accidental release that met the five-year accident history reporting criteria (as described at 68.42) subsequent to April 9, 2004, did the owner or operator submit the information required at 68.168, 68.170(j) and 68.175(l) within six months of the release or by the time the RMP was updated as required at 68.190, whichever was earlier. [68.195(a)]</p>	<p><input type="checkbox"/> Y    <input type="checkbox"/> N    <input checked="" type="checkbox"/> N/A</p>
<p>5. If the emergency contact information required at 68.160(b)(6) has changed since June 21, 2004, did the owner or operator submit corrected information within thirty days of the change? [68.195(b)]</p>	<p><input type="checkbox"/> Y    <input type="checkbox"/> N    <input checked="" type="checkbox"/> N/A</p>
<p>Totals</p>	<p>\$ 0.00</p>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2



MEMORANDUM

**DATE:** March 22, 2010

**SUBJECT:** Enforcement Inspection at TAPI-Humacao

**FROM:** Francisco Claudio, Environmental Engineer  
Multimedia Permits and Compliance Branch

**TO:** Mrs. Teresita Rodriguez, Chief  
Multimedia Permits and Compliance Branch

**Purpose:**

To conduct a re-inspection to determine if TAPI is been operated in compliance with 40 CFR Part 68 Risk Management Plan (RMP) requirements.

**Findings:**

On February 24, 2010, I conducted an RMP inspection to TAPI Puerto Rico located in PR Highway 3, km 76.3 C Street, Humacao Industrial Park 00791. Once I was allowed to the premises, I showed my EPA credentials to Eng. Santiago Hernandez, Site Manager and Eng. Samuel Laguna, Environmental Engineer at Guayama Site. Mr. Hernandez indicated that since their operations has been reduced due to the relocation of their processes to Guayama, only two (2) operators and one (1) Supervisor remain on site during the week. Eng. Hernandez informed me that his personnel are trained to respond to any emergency. I was able to verify the type of emergency training given to the personnel. Additionally, they have one guard to monitor the daily operations and during night time and weekends, they monitored the plan through a closed circuit camera that sends the signal to the Guayama site.

I informed Eng. Hernandez and Eng. Laguna that we intended to conduct an RMP evaluation as a follow-up of EPA's previous inspections conducted by Carlos M. Rivera and Neil Mulvey on September 10, 2008 and as part of the agreement to evaluate if all the changes were completed to have a full implemented RMP Program. Additionally, once TAPI responded to EPA's Order on December 23, 2009, we intended to define if their response to paragraph 49 of the Order and their position assumed in response to paragraph 33 to 45 has been implemented and all regulatory areas of the RMP were fulfilled.

TAPI was formerly owned by Clariant, LSM. The facility conducts business on a 2.1 acre site located in a commercial / industrial section of Humacao (Humacao Industrial Park). The facility is immediately bordered by either other industrial companies or open space.

The facility is registered under the RMP program as "Clariant LSM (Puerto Rico) Inc. Since

their latest submission in June 2004, the facility has undergone two name changes. In July 2006 the facility was purchased by Archimica Puerto Rico Inc. In April 2008, the facility was purchased by the TEVA Group. The facility currently operates under the name "TAPI Puerto Rico," a member of the TEVA Group.

The facility produces pharmaceutical ingredients for sale to pharmaceutical manufacturing companies. The Humacao facility is fully dedicated to the production of an anti-cancer ingredient called 5-Fluorouracil (a white crystalline powder). The facility uses fluorine gas in the production of 5-Fluorouracil. Fluorine gas is received in a tube trailer. Each trailer contains eight fluorine tube cylinders. Each tube cylinder contains 20% fluorine and 80% nitrogen. There are approximately 225-lbs. of fluorine in each tube cylinder. The facility reported that there is a maximum of two fluorine tube trailers on-site at any time. This is consistent with the registration quantity of 3,600-lbs. (225-lbs. /tube cylinder x 8 tube cylinders/trailer x 2 tube trailers).

Typical pressure in a fluorine tube cylinder is 2200 PSIG. This pressure is regulated down to approximately 45 PSIG for delivery to the reactor system. Pressure is regulated down in two stages: 2200 PSIG to 150 PSIG and 150 PSIG to 45 PSIG.

The batch production occurs in a five-step process. Fluorine is used in the first step for a fluorination reaction. The entire batch cycle time is five days. There are three reactors (estimated 30-gallons each) utilized at the facility which typically run simultaneous fluorination reactions. The fluorination reaction is exothermic and takes approximately four hours. After completion of the fluorination reaction, the material is transferred into another reactor (R-7). The facility typically completes three simultaneous fluorination reactions four consecutive times. A total of 12 reaction batches are therefore collected in R-7. The batch material is then fed downstream for further processing, including centrifugation.

A typical fluorination reaction utilizes approximately 19 – 21-lbs. of fluorine at a feed rate of 4.5 – 5.0 lbs. /hour. Fluorine gas is fed to the bottom of the reactor via ten ¼" feed lines. The rate of reaction is controlled by a combination of fluorine feed rate, reactor mix speed, and cooling water flow. All of these parameters are manually controlled. Operators monitor temperature in the fluorination reactor as an indication of a possible runaway reaction. A primary safeguard therefore is a high temperature alarm on the reactor and operator response. PSVs in the system are designed to vent to a scrubber, rather than directly to the atmosphere.

### **Findings on TAPI RMP Plan**

Eng. Santiago Hernandez and Eng. Samuel Laguna explain that the plant has reduced operations since EPA's last inspection and confirmed that the operations will be transfer to the Guayama Site. The Humacao Plant will be closed and all employees will be relocated. Eng. Hernandez indicated that the last operation will take place on March 5, 2010. Actually, they have around 850 lbs of fluoride stored in the tank trucks and they expect to consume all the fluorides stored and the tank trucks will be transfer also to Guayama.

The plant presently has installed three (3) fluorides detectors that use potassium iodide as the

reactive and each detector activates an alarm when the fluoride concentration reaches 1 ppm. Two (2) detectors and alarms are located at the loading rack and one alarm is located on an area closed to the tank trucks. In case of any release, the alarms will actuated a valve closing any transfer from the tank truck and only releasing what is left on the line. The plant has 4 video monitors which are interconnected with the Guayama Site where they monitor the operations. In case of any release they will be advice but is unclear how the neighbors are notified as well as the other commercial buildings, schools and the community.

Eng. Hernandez only confirmed that, as of today, only a table drill exercise was conducted by their personnel but no governmental official from the Fire Department, Police Department or the Civil Defense were present or has participated. We asked Eng. Hernandez about the SARA Title III Program and Eng. Hernandez showed no knowledge of the LEPC structure and that the Puerto Rico Environmental Quality Board (PREQB) Representative at the Humacao Regional Office is actually the President of the Humacao LEPC. However, apparently Eng. Hernandez has not had any previous contact with the LEPC. It is our concern that in case of any release or emergency, TAPI will not contact immediately PREQB, and will be unable to get response assistance from them. Additionally, since no representatives from the neighbors and industries nearby have participated in any drill, it will be hard to determine if a fast response and evacuation can be obtained without previous knowledge of their activities.

The operations start at TAPI from 6:30am until 11:00pm and only 5 people are present during week days. On weekends and holidays no personnel are present and any response depends solely on the response initiated from the Guayama Site. Eng. Hernandez responded that they will call 911 in case of any emergency and some of the employees live nearby and are able to respond. I asked Eng. Hernandez of any event to respond in case of any electrical blackout and he said that the plant has a 1500 kW diesel engine for backup with automatic transfer switch.

#### **Management System-40 CFR Part 68.10(b)**

Eng. Hernandez-Site Manager has overall responsibility for implementation of the RMP program. The EHS Associate Director provides support as necessary. Eng. Hernandez demonstrated an understanding of RMP program requirements and company programs and procedures designed to maintain compliance. However, if the facility continues their operation, they still will need to develop the written description of a management system. Once they de-register and provide us with a copy of the notification, then they will not be subject to RMP. Eng. Hernandez showed that their RMP Registration was updated on November 17, 2008 reflects TAPI as their actual name.

#### **Process Safety Management-40 CFR Part 68.65(d)**

Eng. Hernandez stated that their operation has not change since 1992 when the first process safety management plan was developed under PCR, Inc. and that the document was available all the time. TAPI reviewed and developed a new plan dated December 24, 2009. The plan was included as Exhibit 2 on their response. We have reviewed the new plan and it contains all the necessary elements to describe the safety mechanism to handle fluoride, among which electrical

classification (40 CFR 68.65(d) (1) (iii)), ventilation system design (40 CFR 68.65(d) (1) (v)), design codes and standards (40 CFR 68.65(d) (1) (vi)), and description of safety systems (40 CFR 68.65(d) (1) (viii)).

We advise Eng. Hernandez that the same requirements for electrical classification, ventilation system design, design codes and standards, and description of safety systems will apply if the new process to be relocated in Guayama exceeds the threshold for fluorides and become subject to RMP under Section 112r.

**Process Hazard Analysis- 40 CFR Part 68.67(c) (2)**

Eng. Hernandez has indicated that the compliance audit conducted in 2004 were discussed internally and resolved by the TAPI management. Exhibit #4 includes the 17 recommendations presented to TAPI and how TAPI was able to resolve them. Nevertheless, on 2008, TAPI hired Eng. Arlene Pagan, APM Consulting, PSC to conduct another compliance audit for process hazard analysis and she presented 26 recommendations. These same recommendations constitute the core of the findings made by EPA personnel.

Our review of the documents developed for TAPI indicates that they have corrected all their SOP's and have corrected the implementation issues. The involvement of their employees on site is continuous procedure since the employees are also member of their response group. However any future issues related with safety and hazards will not be resolve once the plant shutdown. It is highly recommended that for the new location in Guayama, EPA should request copies of all documentation to make sure the new operation is conducted safely in Guayama. This should include mechanical integrity tests of al pipelines.

**SOP Annual Certification- 40 CFR Part 68.69©**

Eng. Hernandez showed us a copy of their April 20, 2009 annual certification conducted to 17 SOPs developed in house. The document included as Exhibit 5 is signed by Eng. Hernandez himself. We mentioned to him that such SOPs should be review by an outside contractor to make it more reliable. He understood our recommendation.

**Mechanical Integrity-40 CFR Part 68.73(d) (4)**

The tank trucks belong to Linde Company. They conduct mechanical integrity tests to the bullets in the truck and certified their integrity. Copies of the most recent tests were shown to us. In terms of the integrity of the pipeline presently at the plant, no records show that such pipelines have been tested recently. Eng. Hernandez showed documents indicating that TAPI has conducted pressure test at their lines with nitrogen and has monitored the pressure. Such tests do not constitute a mechanical integrity or similar structural tests. During our inspection, we observed that most of the pipeline is old and some portions are corroded based on the paint stains. We inquire to Eng. Hernandez about it and he informed they intended to use new pipeline in their new site.



In EPA Order, EPA addresses that some of the pressure safety valves were not inspected since 2006. Eng. Santiago identified in Exhibit 7 that TAPI developed new SOPs for mechanical integrity for pressure vessels, piping systems, relief valves and vent systems, among others, and is implementing them. Examples of the new inspections forms were included as Exhibit 8 and 9.

Eng. Hernandez indicated and showed us that two new pressure relief valves were installed on January 10, 2010.

**Management of Change- 40 CFR Part 68.75(b)(2)**

EPA Order addresses that TAPI failed to address in their Change Control Procedure SOP the health and safety review of changes when implementing changes in their process, of their operating equipment or facilities. TAPI responded that the SOP developed initially by Arquimica, previous owner, identifies all the changes that will be reviewed with their Environmental, Health and Safety Department any changes to identify any modification of the SOP. TAPI did recognize that a new management of Change procedure was needed and developed it and identify as Exhibit 11. This new SOP is more explanatory and details the actions to be taken. It has been implemented since March 6, 2009.0

**Hot Works and Contract Permits-**

Eng. Hernandez indicated that they have developed a hot permit SOP that requires several signatures and training prior to approval. Outside contractors are required to sign the forms and prove their qualifications for hot areas.

**PSI documentation- 40 CFR Part 68.75(d)(4)**

Eng. Hernandez and Eng. Laguna addressed that the process safety information for the fluoride operation has always been available under the name of the companies in charged. However, TAPI developed it recently for their ownership and intents to clarify any doubts.

We review the document and although it contains most of the information in the previous records, the new document is clearer and addresses all the safety issues concerning equipment, pipeline, valves, ventilation and operations.

**Pre-Startup Review- 40 CFR Part 68.77**

EPA address in the Order that TAPI did not have a Pre-Startup Review document to evaluated any changes in equipment, materials, pipeline, etc. that could affect their operation or the safety of the workers. Eng. Hernandez indicated that Exhibit 12 included the document developed by TAPI as SOP (SS-022-05) that became effective on April 9, 2009. Our review of the SOP indicated that TAPI is implementing a good procedure as well as using the appropriate forms to identify any impact prior to a formal startup.

We should emphasize that TAPI should continue the use of the same forms for their new operation in Guayama.

**Compliance Audits- 40 CFR Part 68.79**

EPA Order addressed that no compliance audits were conducted by TAPI. Eng. Hernandez provided a copy of the last compliance audit conducted by ADM Consulting that took place in November 2008. During such audit, several recommendations were made and an analysis of those indicates the same recommendations made by EPA in their inspection audit back in September 2008.

Eng. Hernandez did address that he certified compliance in Dec 1, 2008 but was unable to provide any documentation to backup his findings. If the facility continues their present operation, EPA will recommend that any future audit be completed by an outside contractor.

**Employee Participation Plan- 40 CFR Part 68.83(a)**

EPA Order address that TAPI did not have a written employee participation plan that indicates that in all aspects of the RMP, TAPI consulted their employees to get feedback of the most relevant portions related with safety and health issues. TAPI responded with a new document which provides the guidelines to get the employee participation and is making those documents available for their employees. The documents provide the steps when the Safety Committee will seek feedback from all employees via their Union management Board directly involved in the operation of Fluoride.

We believed that in addition to the training provided to employees, TAPI should implement a task force with member of all areas including employees that should review and analyze regularly the SOPs developed for RMP. During their meetings, an Agenda should be developed and an assistance sign sheet should be recorded. This will provide a better participation of their employees

**Conclusion and Recommendations:**

- 1- EPA considers that TAPI took the necessary steps to revise and developed new documents to comply with the regulatory requirements under Part 68.
- 2- TAPI's shutdown of their facility in Humacao constitutes the finalization of their involvement within RMP.
- 3- EPA should issued a Complaint to address the penalty to be impose for the following past violations:
  - a. Failure to develop and maintain an appropriate Management System-40 CFR Part 68.10(b)
  - b. Failure to develop and maintain accessible an updated Process Safety Management-40 CFR Part 68.65(d)
  - c. Failure to develop and maintain accessible an updated Process Hazard Analysis- 40 CFR Part 68.67(e)(2)

- d. Failure to prepare and implement a Standard Operating Procedure (SOP) to conduct Annual Certification- 40 CFR Part 68.69C
  - e. Failure to conduct regularly a mechanical integrity evaluation on their equipment -40 CFR Part 68.73(d)(4)
  - f. Failure to develop and update regularly a process safety information on all changes implement at the facility- 40 CFR part 68.75(d)(4)
  - g. Failure to developed and implement at the facility a Pre-Startup Review- 40 CFR Part 68.77
  - h. Failure to develop an Standard Operating Procedure to conduct regularly the Compliance Audits- 40 CFR Part 68.79
  - i. Failure to developed and implement an Employee Participation Plan to assure the employee involvement in the implementation of their RMP- 40 CFR Part 68.83(a)
- 4- EPA will determine the penalty to be imposing using the penalty guideline developed for RMP violations.

Employees (subpart A of 29 CFR part 2602) by removing all provisions other than those dealing with outside employment. These outside employment provisions, which are now codified at 29 CFR part 4904, have been superseded by OGE's government-wide regulations. Accordingly, the PBGC is removing part 4904 from its regulations.

Because this rule involves agency management and personnel (5 U.S.C. 553(a)(2)), general notice of proposed rulemaking and a delayed effective date are not required (5 U.S.C. 553(b), (d)).

Because no general notice of proposed rulemaking is required, the Regulatory Flexibility Act does not apply (5 U.S.C. 601(2)).

**List of Subjects in 29 CFR Part 4904**

Conflict of interests, Government employees, Penalties, Political activities (Government employees), Production and disclosure of information, Testimony.

■ For the reasons set forth above, 29 CFR chapter XL is amended as follows:

**PART 4904—ETHICAL CONDUCT OF EMPLOYEES**

■ 1. The authority citation for part 4904 continues to read as follows:

Authority: 29 U.S.C. 1302(b); E.O. 11222, 30 FR 6469; 5 CFR 735.104.

**PART 4904—[REMOVED]**

■ 2. Part 4904 is removed.

Issued in Washington, DC this 10th day of February, 2004.

**Steven A. Kandarian,**  
*Executive Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 04-3246 Filed 2-12-04; 8:45 am]

BILLING CODE 7708-01-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 19 and 27**

[FRL-7623-5]

**Civil Monetary Penalty Inflation Adjustment Rule**

**AGENCY:** Environmental Protection Agency (EPA)

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency ("EPA") is issuing this final Civil Monetary Penalty Inflation Adjustment Rule, as mandated by the Debt Collection Improvement Act of 1996, to adjust EPA's civil monetary penalties ("CMPs") for inflation on a periodic basis. The Agency is required

to review its penalties at least once every four years and to adjust them as necessary for inflation according to a formula specified in the statute. A complete version of Table 1 from the regulatory text, which lists all of the EPA's civil monetary penalty authorities, appears near the end of this rule.

**EFFECTIVE DATE:** March 15, 2004.

**FOR FURTHER INFORMATION CONTACT:** David Abdalla, Office of Regulatory Enforcement, Special Litigation and Projects Division, Mail Code 2248A, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 564-2413.

**SUPPLEMENTARY INFORMATION:**

**Background**

Pursuant to section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. 3701 note, ("DCIA"), each federal agency is required to issue regulations adjusting for inflation the maximum civil monetary penalties that can be imposed pursuant to such agency's statutes. The purpose of these adjustments is to maintain the deterrent effect of CMPs and to further the policy goals of the laws. The DCIA requires adjustments to be made at least once every four years following the initial adjustment. The EPA's initial adjustment to each CMP was published in the **Federal Register** on December 31, 1996, at (61 FR 69360) and became effective on January 30, 1997.

This rule adjusts the amount for each type of CMP that EPA has jurisdiction to impose in accordance with these statutory requirements. It does so by revising the table contained in 40 CFR 19.4. The table identifies the statutes that provide EPA with CMP authority and sets out the inflation-adjusted maximum penalty that EPA may impose pursuant to each statutory provision. This rule also revises the effective date provisions of 40 CFR 19.2 to make the penalty amounts set forth in 40 CFR 19.4 apply to all applicable violations that occur after the effective date of this rule.

The DCIA requires that the adjustment reflect the percentage increase in the Consumer Price Index between June of the calendar year preceding the adjustment and June of the calendar year in which the amount was last set or adjusted. The DCIA defines the Consumer Price Index as the Consumer Price Index for all urban consumers published by the Department of Labor ("CPI-U"). As the initial adjustment was made and published on

December 31, 1996, the inflation adjustment for the CMPs set forth in this rule was calculated by comparing the CPI-U for June 1996 (156.7) with the CPI-U for June 2003 (183.7), resulting in an inflation adjustment of 17.23 percent. In addition, the DCIA's rounding rules require that an increase be rounded to the nearest multiple of: \$10 in the case of penalties less than or equal to \$100; \$100 in the case of penalties greater than \$100 but less than or equal to \$1,000; \$1,000 in the case of penalties greater than \$1,000 but less than or equal to \$10,000; \$5,000 in the case of penalties greater than \$10,000 but less than or equal to \$100,000; \$10,000 in the case of penalties greater than \$100,000 but less than or equal to \$200,000; and \$25,000 in the case of penalties greater than \$200,000.

The amount of each CMP was multiplied by 17.23 percent (the inflation adjustment) and the resulting increase amount was rounded up or down according to the rounding requirements of the statute. Certain CMPs were adjusted for the first time and were increased by only 10 percent without being subject to the rounding procedures as required by the DCIA. The table below shows the inflation-adjusted CMPs and includes only the CMPs as of the effective date of this rule. EPA intends to readjust these amounts in the year 2008 and every four years thereafter, assuming there are no further changes to the mandate imposed by the DCIA.

On June 18, 2002, the EPA published a direct final rule and a parallel proposed rule in the **Federal Register** (67 FR 41343). The direct final rule would have amended the Civil Monetary Penalty Inflation Adjustment Rule, as mandated by the DCIA, to adjust EPA's civil monetary penalties for inflation. EPA stated in the direct final rule that if we received adverse comment by July 18, 2002, EPA would publish a timely notice of withdrawal on or before the August 19, 2002 effective date, and then address that comment in a subsequent final action based on the parallel proposal published at (67 FR 41363). EPA subsequently received one adverse comment on the direct final rule from the General Accounting Office ("GAO"), which asserted that EPA had misinterpreted the rounding formula provided in the DCIA. Accordingly, EPA withdrew the direct final rule on August 19, 2002 (67 FR 53743).

The formula for the amount of the penalty adjustment is prescribed by Congress in the DCIA and these changes are not subject to the exercise of discretion by EPA. However the

rounding requirement of the statute is subject to different interpretations. Some agencies rounded the increase based on the amount of the current penalty before adjustment, while other agencies have rounded the increase based on the amount of the increase resulting from the CPI percentage calculation. Still other agencies first added the CPI increase to the amount of the current penalty and then rounded the total based on the amount of the increased penalty. The penalties in EPA's direct final rule were rounded based on the amount of the increase resulting from the CPI percentage increase because this approach appears to achieve the intent of the DCIA by steadily tracking the CPI over time. However, the GAO's adverse comment asserts that a strict reading of the DCIA requires rounding the CPI increase based on the amount of the current penalty before adjustment.

On July 3, 2003, EPA published a proposed rule that appeared in the **Federal Register** at (68 FR 39882), entitled "Civil Monetary Penalty Inflation Adjustment Rule," as mandated by the Debt Collection Improvement Act of 1996, to adjust EPA's civil monetary penalties for inflation on a periodic basis. EPA subsequently published a technical correction in the **Federal Register** on August 4, 2003 at (68 FR 45788) to correct errors in the language of the proposal that mistakenly referred to the proposed effective date as July 3, 2003. EPA proposed to adopt GAO's interpretation of the DCIA rounding rules and, thus, proposed to round the CPI increases in the proposed rule based on the amount of the current penalty before adjustment.

In accordance with the DCIA, EPA's proposed rule used the CPI-U from June 2002 to calculate the penalty adjustments. EPA also stated in the proposal that it intends to use this formula for calculating future adjustments to the CMPs and will not provide additional comment periods at the time future adjustments are made. EPA received comments on the proposed rule from two commenters.

One commenter supported the "greatest legal increase possible" to discourage polluters from treating the fines as just a "cost of doing business." This final rule enables EPA to impose the maximum fines provided under the law, but is not intended to address when a maximum fine is appropriate. Instead, EPA makes that decision on a case-by-case basis, and considers numerous factors in determining the appropriate penalty in each case, including the gravity of the violation

and the extent to which the violator gained an economic benefit as a result of violating the law.

Another commenter argued that any ambiguity in the rounding requirement of the statute was due to a "scrivener's error." This commenter supported an interpretation that penalties be rounded based on the amount of the increase resulting from the CPI adjustment, rather than the amount of the penalty. However, we determined after carefully considering GAO's comment and examining the practices of other agencies, that following the plain meaning of the statutory language is appropriate. As GAO's adverse comment states "[n]othing in the plain language of the statute, nor the legislative history, permits an agency to use the size of the increase to determine the appropriate category of rounding." This commenter also noted that EPA had not published this second round of adjustments within four years of the initial adjustments as set forth in the statute. EPA's earlier direct final rulemaking was delayed due to EPA's need to analyze and reconcile the potential ambiguities arising from the statutory language including review of other agencies rulemakings under DCIA and discussions with other agencies regarding their approaches to interpreting the DCIA. Prior to GAO's involvement in the process, no federal agency had assumed a leadership in providing guidance on how the DCIA rounding rule should be implemented. Since the time that GAO became involved in the process, including the submission of its adverse comment on EPA's direct final rule, EPA has worked with GAO and other agencies to resolve the appropriate interpretation of the statutory language. Finally, the commenter also suggested that all of the penalties should be adjusted from their original base and not their adjusted base. The statute does not provide for a return to the original base penalty in calculating the adjustment but provides that the adjustment "shall be determined by increasing the maximum civil penalty \* \* \* by the cost-of-living adjustment."

As discussed above, EPA's proposed rule used the CPI-U from June 2002 because EPA proposed the rule in 2003. However, since EPA is issuing the final rule in 2004 and DCIA requires EPA to use the CPI-U for June of the calendar year preceding the adjustment, the penalty adjustments in this final rule use the CPI-U for June 2003 which result in an inflation adjustment of 17.23 percent rather than the 14.8 percent adjustment in the proposed rule. Thus, to derive the CMPs for this

final rule, the amount of each CMP was multiplied by 17.23 percent and the resulting increase was rounded according to the rounding rules of DCIA as EPA proposed and is adopting in this final rule. As a result of using the June 2003 CPI-U, some of the adjusted CMPs in this final rule are different than those in the July 2003 proposed rule. However, this difference results solely from the requirement in DCIA to use the June 2003 CPI-U and application of the same rounding rules that EPA proposed in July 2003.

Under 5 U.S.C. 553(b)(B), EPA finds that there is good cause to promulgate this rule without providing for further public comment even though the rule uses a CPI-U value different than the CPI-U value used in the proposal. EPA already provided an opportunity for public comment on the rounding rules that EPA has used in this final rule and the DCIA requires that an agency use the CPI-U from June of the year prior to the adjustment. Therefore, further public comment is unnecessary because EPA has no discretion to do other than to use the June 2003 CPI-U.

#### Statutory and Executive Order Review

##### *Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 12866, [58 FR 51,735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866, and is therefore not subject to review by the Office of Management and Budget.

*Paperwork Reduction Act*

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Burden means the total time, effort, financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as (1) a small business as defined in the Small Business Administration regulations at 13 CFR Part 121; (2) a small governmental jurisdiction that is a government of a city, county, town school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA is required by the DCIA to adjust

civil monetary penalties for inflation. The formula for the amount of the penalty adjustment is prescribed by Congress and is not subject to the exercise of discretion by EPA. EPA's action implements this statutory mandate and does not substantively alter the existing regulatory framework. This rule does not affect mechanisms already in place, including statutory provisions and EPA policies, that address the special circumstances of small entities when assessing penalties in enforcement actions.

Although this rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. Small entities may be affected by this rule only if the federal government finds them in violation and seeks monetary penalties. EPA's media penalty policies generally take into account an entity's "ability to pay" in determining the amount of a penalty. Additionally, the final amount of any civil penalty assessed against a violator remains committed to the discretion of the federal judge or administrative law judge hearing a particular case.

*Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "federal mandates" that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a

small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This rule contains no federal mandates (under the regulatory provisions of Title II of the UMRA) for state, local, or tribal governments or the private sector because the rule implements mandate(s) specifically and explicitly set forth by the Congress without the exercise of any policy discretion by EPA. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

*Executive Order 13132: Federalism*

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in executive Order 13132. Thus, Executive Order 13132 does not apply to this rule.

*Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." As this rule will not have substantial direct effects on tribal

governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, Executive Order 13175 does not apply to this rule.

*Executive Order 13045: Protection of Children From Environmental Health & Safety Risks*

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Because this action does not involve technical standards, EPA did not consider the use of any voluntary consensus standards under the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note).

*Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

*National Technology Transfer Advancement Act*

Section 12(d) of the National Technology Transfer Advancement Act

of 1995 ("NTTAA"), Public Law 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards. Because this action does not involve technical standards, EPA did not consider the use of any voluntary consensus standards under the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note).

*Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

*Congressional Review Act*

The Congressional Review Act, 5 U.S.C. § 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**.

This action is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 19*

Environmental protection, Administrative practice and procedure, Penalties.

*40 CFR Part 27*

Administrative practice and procedure, Assessments, False claims, False statements, Penalties.

Dated: February 8, 2004.

**Michael O. Leavitt,**

*Administrator, Environmental Protection Agency.*

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

■ 1. Revise part 19 to read as follows:

**PART 19—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION**

**Sec.**

19.1 Applicability.

19.2 Effective Date.

19.3 [Reserved].

19.4 Penalty Adjustment and Table.

**Authority:** Pub. L. 101-410, 28 U.S.C. 2461 note; Pub. L. 104-134, 31 U.S.C. 3701 note.

**§ 19.1 Applicability.**

This part applies to each statutory provision under the laws administered by the Environmental Protection Agency concerning the maximum civil monetary penalty which may be assessed in either civil judicial or administrative proceedings.

**§ 19.2 Effective Date.**

The increased penalty amounts set forth in this part apply to all violations under the applicable statutes and regulations which occur after March 15, 2004.

**§ 19.3 [Reserved].**

**§ 19.4 Penalty Adjustment and Table.**

The adjusted statutory penalty provisions and their maximum applicable amounts are set out in Table 1. The last column in the table provides the newly effective maximum penalty amounts.

TABLE 1 OF SECTION 19.4.—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. code citation	Civil monetary penalty description	Penalties effective between January 30, 1997 and March 15, 2004	New maximum penalty amount
7 U.S.C. 136l(a)(1)	FEDERAL INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT CIVIL PENALTY—GENERAL—COMMERCIAL APPLICATORS, ETC.	\$5,500	\$6,500
7 U.S.C. 136l(a)(2)	FEDERAL INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT CIVIL PENALTY—PRIVATE APPLICATORS—FIRST AND SUBSEQUENT OFFENSES OR VIOLATIONS.	\$550/\$1000	\$650/\$1,200
15 U.S.C. 2615(a)	TOXIC SUBSTANCES CONTROL ACT CIVIL PENALTY	\$27,500	\$32,500
15 U.S.C. 2647(a)	ASBESTOS HAZARD EMERGENCY RESPONSE ACT CIVIL PENALTY	\$5,500	\$6,500
15 U.S.C. 2647(g)	ASBESTOS HAZARD EMERGENCY RESPONSE ACT—CONTRACTOR VIOLATIONS.	\$5,000	\$5,500
31 U.S.C. 3802(a)(1)	PROGRAM FRAUD CIVIL REMEDIES ACT/VIOLATION INVOLVING FALSE CLAIM.	\$5,500	\$6,500
31 U.S.C. 3802(a)(2)	PROGRAM FRAUD CIVIL REMEDIES ACT/VIOLATION INVOLVING FALSE STATEMENT.	\$5,500	\$6,500
33 U.S.C. 1319(d)	CLEAN WATER ACT VIOLATION/CIVIL JUDICIAL PENALTY	\$27,500	\$32,500
33 U.S.C. 1319(g)(2)(A)	CLEAN WATER ACT VIOLATION/ADMINISTRATIVE PENALTY PER VIOLATION AND MAXIMUM.	\$11,000/\$27,500	\$11,000/\$32,500
33 U.S.C. 1319(g)(2)(B)	CLEAN WATER ACT VIOLATION/ADMINISTRATIVE PENALTY PER VIOLATION AND MAXIMUM.	\$11,000/ \$137,500.	\$11,000/ \$157,500
33 U.S.C. 1321(b)(6)(B)(i)	CLEAN WATER ACT VIOLATION/ADMIN PENALTY OF SEC 311(b)(3)&(j) PER VIOLATION AND MAXIMUM	\$11,000/\$27,500	\$11,000/\$32,500
33 U.S.C. 1321(b)(6)(B)(ii)	CLEAN WATER ACT VIOLATION/ADMIN PENALTY OF SEC 311(b)(3)&(j) PER VIOLATION AND MAXIMUM.	\$11,000/ \$137,500.	\$11,000/ \$157,500
33 U.S.C. 1321(b)(7)(A)	CLEAN WATER ACT VIOLATION/CIVIL JUDICIAL PENALTY OF SEC 311(b)(3)—PER VIOLATION PER DAY OR PER BARREL OR UNIT.	\$27,500 or \$1,100 per barrel or unit.	\$32,500 or \$1,100 per barrell or unit
33 U.S.C. 1321(b)(7)(B)	CLEAN WATER ACT VIOLATION/CIVIL JUDICIAL PENALTY OF SEC 311(c)&(e)(1)(B).	\$27,500	\$32,500
33 U.S.C. 1321(b)(7)(C)	CLEAN WATER ACT VIOLATION/CIVIL JUDICIAL PENALTY OF SEC 311(j).	\$27,500	\$32,500
33 U.S.C. 1321(b)(7)(D)	CLEAN WATER ACT VIOLATION/MINIMUM CIVIL JUDICIAL PENALTY OF SEC 311(b)(3)—PER VIOLATION OR PER BARREL/UNIT.	\$110,000 or \$3,300 per barrel or unit.	\$130,000 or \$4,300 per barrel or unit.
33 U.S.C. 1414b(d)	MARINE PROTECTION, RESEARCH & SANCTUARIES ACT VIOL SEC 104b(d).	\$660	\$760
33 U.S.C. 1415(a)	MARINE PROTECTION RESEARCH AND SANCTUARIES ACT VIOLATIONS—FIRST & SUBSEQUENT VIOLATIONS.	\$55,000/ \$137,500.	\$65,000/ \$157,500
42 U.S.C. 300g-3(b)	SAFE DRINKING WATER ACT/CIVIL JUDICIAL PENALTY OF SEC 1414(b).	\$27,500	\$32,500
42 U.S.C. 300g-3(c)	SAFE DRINKING WATER ACT/CIVIL JUDICIAL PENALTY OF SEC 1414(c).	\$27,500	\$32,500
42 U.S.C. 300g-3(g)(3)(A)	SAFE DRINKING WATER ACT/CIVIL JUDICIAL PENALTY OF SEC 1414(g)(3)(a).	\$27,500	\$32,500
42 U.S.C. 300g-3(g)(3)(B)	SAFE DRINKING WATER ACT/ MAXIMUM ADMINISTRATIVE PENALTIES PER SEC 1414(g)(3)(B).	\$5,000/\$25,000	\$6,000/\$27,500
42 U.S.C. 300g-3(g)(3)(C)	SAFE DRINKING WATER ACT/THRESHOLD REQUIRING CIVIL JUDICIAL ACTION PER SEC 1414(g)(3)(C).	\$25,000	\$27,500
42 U.S.C. 300h-2(b)(1)	SDWA/CIVIL JUDICIAL PENALTY/VIOLATIONS OF REQS—UNDERGROUND INJECTION CONTROL (UIC).	\$27,500	\$32,500
42 U.S.C. 300h-2(c)(1)	SDWA/CIVIL ADMIN PENALTY/VIOLATIONS OF UIC REQS—PER VIOLATION AND MAXIMUM.	\$11,000/ \$137,500.	\$11,000/ \$157,500
42 U.S.C. 300h-2(c)(2)	SDWA/CIVIL ADMIN PENALTY/VIOLATIONS OF UIC REQS—PER VIOLATION AND MAXIMUM.	\$5,500/\$137,500	\$6,500/\$157,500
42 U.S.C. 300h-3(c)(1)	SDWA/VIOLATION/OPERATION OF NEW UNDERGROUND INJECTION WELL.	\$5,500	\$6,500
42 U.S.C. 300h-3(c)(2)	SDWA/WILLFUL VIOLATION/OPERATION OF NEW UNDERGROUND INJECTION WELL.	\$11,000	\$11,000
42 U.S.C. 300i(b)	SDWA/FAILURE TO COMPLY WITH IMMINENT AND SUBSTANTIAL ENDANGERMENT ORDER.	\$15,000	\$16,500
42 U.S.C. 300i-1(c)	SDWA/ATTEMPTING TO OR TAMPERING WITH PUBLIC WATER SYSTEM/CIVIL JUDICIAL PENALTY.	\$22,000/\$55,000	\$100,000/ \$1,000,000
42 U.S.C. 300j(e)(2)	SDWA/FAILURE TO COMPLY W/ORDER ISSUED UNDER SEC 1441(c)(1).	\$2,750	\$2,750
42 U.S.C. 300j-4(c)	SDWA/REFUSAL TO COMPLY WITH REQS. OF SEC. 1445(a) OR (b)	\$27,500	\$32,500
42 U.S.C. 300j-6(b)(2)	SDWA/FAILURE TO COMPLY WITH ADMIN. ORDER ISSUED TO FEDERAL FACILITY	\$25,000	\$27,500
42 U.S.C. 300j-23(d)	SDWA/VIOLATIONS/SECTION 1463(b)—FIRST OFFENSE/REPEAT OFFENSE.	\$5,500/\$55,000	\$6,500/\$65,000



TABLE 1 OF SECTION 19.4.—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. code citation	Civil monetary penalty description	Penalties effective between January 30, 1997 and March 15, 2004	New maximum penalty amount
42 U.S.C. 4852d(b)(5)	RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992, SEC 1018—CIVIL PENALTY.	\$11,000	\$11,000
42 U.S.C. 4910(a)(2)	NOISE CONTROL ACT OF 1972—CIVIL PENALTY	\$11,000	\$11,000
42 U.S.C. 6928(a)(3)	RESOURCE CONSERVATION & RECOVERY ACT/VIOLATION SUBTITLE C ASSESSED PER ORDER.	\$27,500	\$32,500
42 U.S.C. 6928(c)	RES. CONS. & REC. ACT/CONTINUED NONCOMPLIANCE OF COMPLIANCE ORDER.	\$27,500	\$32,500
42 U.S.C. 6928(g)	RESOURCE CONSERVATION & RECOVERY ACT/VIOLATION SUBTITLE C.	\$27,500	\$32,500
42 U.S.C. 6928(h)(2)	RES. CONS. & REC. ACT/NONCOMPLIANCE OF CORRECTIVE ACTION ORDER.	\$27,500	\$32,500
42 U.S.C. 6934(e)	RES. CONS. & REC. ACT/NONCOMPLIANCE WITH SECTION 3013 ORDER.	\$5,500	\$6,500
42 U.S.C. 6973(b)	RES. CONS. & REC. ACT/VIOLATIONS OF ADMINISTRATIVE ORDER	\$5,500	\$6,500
42 U.S.C. 6991e(a)(3)	RES. CONS. & REC. ACT/NONCOMPLIANCE WITH UST ADMINISTRATIVE ORDER.	\$27,500	\$32,500
42 U.S.C. 6991e(d)(1)	RES. CONS. & REC. ACT/FAILURE TO NOTIFY OR FOR SUBMITTING FALSE INFORMATION.	\$11,000	\$11,000
42 U.S.C. 6991e(d)(2)	RCRA/VIOLATIONS OF SPECIFIED UST REGULATORY REQUIREMENTS.	\$11,000	\$11,000
42 U.S.C. 14304(a)(1)	BATTERY ACT VIOLATIONS	\$10,000	\$11,000
42 U.S.C. 14304(g)	BATTERY ACT/VIOLATIONS OF CORRECTIVE ACTION ORDERS	\$10,000	\$11,000
42 U.S.C. 7413(b)	CLEAN AIR ACT/VIOLATION/OWNERS & OPERATORS OF STATIONARY AIR POLLUTION SOURCES—JUDICIAL PENALTIES.	\$27,500	\$32,500
42 U.S.C. 7413(d)(1)	CLEAN AIR ACT/VIOLATION/OWNERS & OPERATORS OF STATIONARY AIR POLLUTION SOURCES—ADMINISTRATIVE PENALTIES PER VIOLATION & MAX.	\$27,500/ \$220,000	\$32,500/ \$270,000
42 U.S.C. 7413(d)(3)	CLEAN AIR ACT/MINOR VIOLATIONS/STATIONARY AIR POLLUTION SOURCES—FIELD CITATIONS.	\$5,500	\$6,500
42 U.S.C. 7524(a)	TAMPERING OR MANUFACTURE/SALE OF DEFEAT DEVICES IN VIOLATION OF 7522(a)(3)(A) OR (a)(3)(B)—BY PERSONS.	\$2,750	\$2,750
42 U.S.C. 7524(a)	VIOLATION OF 7522(a)(3)(A) OR (a)(3)(B)—BY MANUFACTURERS OR DEALERS; ALL VIOLATIONS OF 7522(a)(1),(2), (4),&(5) BY ANYONE.	\$27,500	\$32,500
42 U.S.C. 7524(c)	ADMINISTRATIVE PENALTIES AS SET IN 7524(a) & 7545(d) WITH A MAXIMUM ADMINISTRATIVE PENALTY.	\$220,000	\$270,000
42 U.S.C. 7545(d)	VIOLATIONS OF FUELS REGULATIONS	\$27,500	\$32,500
42 U.S.C. 9604(e)(5)(B)	SUPERFUND AMEND. & REAUTHORIZATION ACT/NONCOMPLIANCE W/REQUEST FOR INFO OR ACCESS.	\$27,500	\$32,500
42 U.S.C. 9606(b)(1)	SUPERFUND/WORK NOT PERFORMED W/IMMINENT, SUBSTANTIAL ENDANGERMENT.	\$27,500	\$32,500
42 U.S.C. 9609(a)&(b)	SUPERFUND/ADMIN. PENALTY VIOLATIONS UNDER 42 U.S.C. SECT. 9603, 9608, OR 9622.	\$27,500	\$32,500
42 U.S.C. 9609(b)	SUPERFUND/ADMIN. PENALTY VIOLATIONS—SUBSEQUENT	\$82,500	\$97,500
42 U.S.C. 9609(c)	SUPERFUND/CIVIL JUDICIAL PENALTY/VIOLATIONS OF SECT. 9603, 9608, 9622.	\$27,500	\$32,500
42 U.S.C. 9609(c)	SUPERFUND/CIVIL JUDICIAL PENALTY/SUBSEQUENT VIOLATIONS OF SECT. 9603, 9608, 9622.	\$82,500	\$97,500
42 U.S.C. 11045(a)&(b)(1),(2)&(3).	EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT CLASS I & II ADMINISTRATIVE AND CIVIL PENALTIES.	\$27,500	\$32,500
42 U.S.C. 11045(b)(2)&(3)	EPCRA CLASS I & II ADMINISTRATIVE AND CIVIL PENALTIES—SUBSEQUENT VIOLATIONS.	\$82,500	\$97,500
42 U.S.C. 11045(c)(1)	EPCRA CIVIL AND ADMINISTRATIVE REPORTING PENALTIES FOR VIOLATIONS OF SECTIONS 11022 OR 11023	\$27,500	\$32,500
42 U.S.C. 11045(c)(2)	EPCRA CIVIL AND ADMINISTRATIVE REPORTING PENALTIES FOR VIOLATIONS OF SECTIONS 11021 OR 11043(b).	\$11,000	\$11,000
42 U.S.C. 11045(d)(1)	EPCRA—FRIVOLOUS TRADE SECRET CLAIMS—CIVIL AND ADMINISTRATIVE PENALTIES.	\$27,500	\$32,500

**PART 27—[AMENDED]**

■ 2. The authority citation for Part 27 continues to read as follows:

Authority: 31 U.S.C. 3801–3812; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note;

Pub. L. 104–134, 110 Stat. 1321, 31 U.S.C. 3701 note.

■ 3. Section 27.3 is amended by revising paragraphs (a)(1)(iv) and (b)(1)(ii) to read as follows:

**§ 27.3 Basis for civil penalties and assessments.**

(a) \* \* \*

(1) \* \* \*

(iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be

subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$6,500<sup>1</sup> for each such claim [The regulatory penalty provisions of this part effective on January 30, 1997 remain in effect for any violation of law occurring between January 30, 1997 and March 15, 2004.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than 6,500<sup>2</sup> for each such statement.

\* \* \* \* \*

[FR Doc. 04-3231 Filed 2-12-04; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[FL-91-200323(a); FRL-7622-1]

#### Approval and Promulgation of Implementation Plans; Florida: Southeast Florida Area Maintenance Plan Update

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The EPA is approving revisions to the State Implementation Plan (SIP) submitted by the Florida Department of Environmental Protection (FDEP) on December 20, 2002. This SIP revision satisfies the requirement of the Clean Air Act (CAA) for the second 10-year update for the Southeast Florida area (Dade, Broward, and Palm Beach Counties) 1-hour ozone maintenance plan. For transportation purposes, EPA 101-410, 104 Stat. 890), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134, 110 Stat. 1321).

<sup>1</sup> As adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410, 104 Stat. 890), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134, 110 Stat. 1321).

unless EPA receives adverse comment by March 15, 2004. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Comments may be submitted by mail to: Heidi LeSane, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Comments may also be submitted electronically, or through hand delivery/courier. Please follow the detailed instructions described in Part I.B.1. through 3 of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Heidi LeSane, Air, Pesticides & Toxics Management Division, Air Planning Branch, Regulatory Development Section, U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Mrs. LeSane's phone number is 404-562-9035. She can also be reached via electronic mail at [lesane.heidi@epa.gov](mailto:lesane.heidi@epa.gov) or Lynorae Benjamin, Air, Pesticides & Toxics Management Division, Air Planning Branch, Air Quality Modeling & Transportation Section, U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Ms. Benjamin's phone number is 404-562-9040. She can also be reached via electronic mail at [benjamin.lynorae@epa.gov](mailto:benjamin.lynorae@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

##### *A. How Can I Get Copies of This Document and Other Related Information?*

include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Regulatory Development Section, Air Planning

Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 9 to 3:30, excluding Federal holidays.

2. Copies of the State submittal and EPA's technical support document are also available for public inspection during normal business hours, by appointment, at the State Air Agency, Florida Department of Environmental Protection, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida 32399-2400.

3. Electronic Access. You may access this **Federal Register** document electronically through the Regulation.gov Web site located at <http://www.regulations.gov> where you can find, review, and submit comments on Federal rules that have been published in the **Federal Register**, the Government's legal newspaper, and are open for comment.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.