



ESTADO LIBRE ASOCIADO DE
P U E R T O R I C O
ENVIRONMENTAL QUALITY BOARD

**STATEMENT OF BASIS – TITLE V FINAL PERMIT
ABBOTT HEALTHCARE (PUERTO RICO) LTD.
PFE-TV-2833-09-1096-0011-B**

The Environmental Quality Board (EQB) is issuing a Title V permit pursuant to Title 40 of the Code of Federal Regulations (CFR), Part 70 and with Part VI of the Regulations for the Control of Atmospheric Pollution (RCAP) for Abbott Healthcare (Puerto Rico) Ltd. (Abbott). The facility is located on Road #2 Km. 58.2 Cruce Dávila in Barceloneta, P.R. EQB received a Title V permit application on October 31, 1996. On January 29, 2004 a public hearing was held with the intention to issue the operating permit for Abbott. However, a final permit was not issued. On January 1, 2013 Abbott completed the legal separation of its operations between two companies, Abbott Healthcare and Abbvie, Ltd. On January 2, 2013, we received an amended application on behalf of Abbott Healthcare, including only equipment belonging to Abbott Healthcare.

Abbott is a company dedicated to the manufacture of bulk active ingredients for the production of pharmaceuticals. The company has two subsidiaries, both under common control of Abbott: Abbott Healthcare (PR) Ltd. (AHL) and Abbott Diagnostics International (ADI). AHL operates in the south complex of Abbvie, while ADI operates in the north complex. Abbvie, who owns the property, offers Abbott utilities services such as steam, electricity, etc. Emissions of volatile organic compounds (VOC) and hazardous air pollutants (HAP) are controlled by a thermal oxidizer, connected to a caustic gases scrubber. As backup control equipment, Abbott has an enclosed flare, known as an *Enclosed Flame Vapor Combustor System* (EFVCS). Storage tanks and solvent recovery operations are also connected to these control equipment. Moreover, Abbott Diagnostics is engaged in the manufacturing of surgical guide wires.

Abbott is required to have an operating Title V permit because it is subject to the National Emission Standards for Pharmaceuticals Production (MACT for Pharmaceutical Production), included in 40 CFR Part 63, Subpart GGG, although emissions of hazardous air pollutants (HAP) do not exceed the major source threshold. The Environmental Protection Agency (EPA) determined on October 22, 2013 that the pharmaceutical production MACT continues to apply to the process of Clarithromycin and the thermal oxidizer. Abbott also becomes a minor source for criteria pollutants and greenhouse gases (GHG) expressed as CO₂e.

Emission Units

The Emission Units section lists the significant emission units, the associated control equipment, and fuel type. This section is an overview of the facility. The emission units are the following:



EU-01: Chemical Synthesis of Pharmaceuticals - This emission unit includes manufacturing of bulk pharmaceuticals. Abbott currently manufactures two products in the facility: Clarithromycin, which emits HAP, and Feno Acid. The unit uses the thermal oxidizer/scrubber and EFVCS as control equipment. Dust collectors are also used for operations emitting particulate matter.

EU-14: Loading, unloading and storage of chemicals - This unit includes storage tanks for virgin, used and waste chemicals that are used to support the activities of chemical synthesis of pharmaceuticals. They use the thermal oxidizer/gas scrubber and EFVCS as control equipment.

EU-18: Solvent recovery operations -This emission unit includes used solvent recovery activities for reuse. The solvent is recovered through mass transfer steps and separation, including vaporization and distillation. They use the thermal oxidizer/gas scrubber and EFVCS as control equipment.

EU-25: Guide Wires Manufacturing - This operation consists of manufacturing surgical guide wires at the Abbott Diagnostics facilities.

Combustion control equipment (Thermal Oxidizer and EFVCS) - These control devices are in themselves sources of emissions since they use fuel to destroy VOC and HAP emissions. The thermal oxidizer uses diesel and LPG as fuel. The EFVCS, used as a backup equipment, uses diesel as fuel.

Emissions Limits¹

The emissions described in the following table represent the emission limits at the time of the permit application. According to RCAP Rule 610(a), when **Abbott** requests a modification, administrative change or minor modification to its Title V permit, the source will pay only those charges related with any emission increase (if any) per ton, based on the change and not based on the previous total charges in accordance with RCAP Rule 610(a). The emission limits were based on the limitations contained in emission units building permits.

Pollutants	Emissions (ton/year)
PM	33.171
SO ₂	8.256
NO _x	3.938
CO	1.511
VOC	47.395
HAP (Includes Acetonitrile and Methyl Bromide)	6.332

¹ Includes fugitive and Abbott Diagnostics emissions.

Pollutants	Emissions (ton/year)
CO ₂ e	4,215.38

According to EQB Resolution RI-06-02², the emissions calculations will be based on the actual emissions of **Abbott**, however calculations based on allowable emissions of the facility will be accepted. If **Abbott** decides to perform the calculations based on potential emissions, **Abbott** shall pay the same charge per ton as the facilities that decide to do the calculations based on actual emissions.

Applicable Requirements

National Emission Standards for Pharmaceuticals Production, 40 CFR Part 63, Subpart GGG

This subpart applies to pharmaceutical manufacturing operations, as defined in §63.1251 of the 40 CFR. This regulation applies to process vents, storage tanks, wastewater streams, and equipment leaks. Currently Clarithromycin is the only Abbott process subject to this regulation. Abbott has implemented a program of leak detection and repair (LDAR), required by §63.1255 of the 40 CFR to control fugitive emissions.

As a MACT compliance strategy, Abbott complies with section 63.1254(a)(1) of 40 CFR (93% reduction³) for process vents, using the Thermal Oxidizer/Gas Scrubber and the flare as backup equipment. This strategy differs from that which was presented in the Pre-Compliance MACT Report, submitted on April 19, 2002. On that occasion, Abbott indicated it would comply as a primary strategy with the provisions of pollution control (Pollution Prevention) included in §63.1252(e) of 40 CFR, and as a secondary strategy it would comply with §63.1254(a)(3) 40 CFR (98% of control). At that time, EPA did not accept for the parameters of the control equipment to be established through a design evaluation, and determined that the parameters should be established through a stack test. In this situation, Abbott changed its compliance strategy (to comply with §63.1254(a)(1) of 40 CFR), which was notified in the MACT Compliance Report, submitted on March 20, 2003. Abbott said that the control equipment would control less than 10 ton/year of HAPs, therefore classified as small control equipment. §63.1258(b)(3) of the 40 CFR allows operating parameters to be established by a design evaluation.

²EQB Resolution - Payment procedure for Title V operating charges and Title V permit renewal charges, issued on March 20, 2006.

³ The regulation requires a 93% reduction for hazardous air pollutants. However, Abbott must comply with an efficiency of 99%, as required by the permit PFE-09-0193-0057-I-II-C.

The following requirements are not applicable to Abbott:

- Equipment for burning fuel, RCAP Rule 406 (thermal oxidizer and EFVCS) - Rule 406 applies to fuel burning equipment primarily to produce heat or power by indirect heat conduction. The primary purpose of these equipment is to destroy VOC and HAP emissions.
- Chemical accident prevention provisions, 40 CFR Part 68 - Not applicable to Abbott since it does not store any substances regulated by this regulation.

The frequency of reporting for compliance certification for this source should be annual. However, Abbott shall submit semiannual reports of any required monitoring. Unless specifically stated, all terms and conditions of the Title V permit, including provisions designed to limit the potential emission of the source, are enforceable by EPA and the citizens under the Federal Clean Air Act. The terms and conditions designated as state enforceable only, as indicated by the permit, are enforceable only by the EQB.

The EQB has determined that this Title V Operating Permit satisfies the requirements under RCAP Part VI.

ml