DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION
RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA725)
Current Human Exposures Under Control

Facility Name: **B. Braun Medical, Inc.**
Facility Address: **901 Marcon Boulevard, Allentown, Pennsylvania 18109**
Facility EPA ID #: **PAD982679169**

1. Has **all** available relevant/significant information on known and reasonably suspected releases to soil, groundwater, surface water/sediments, and air, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), and Areas of Concern (AOC)), been **considered** in this EI determination?

☒ If yes - check here and continue with #2 below.

☐ If no - re-evaluate existing data, or

☐ If data are not available, skip to #8 and enter "IN" (more information needed) status code.

BACKGROUND
Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EI developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of "Current Human Exposures Under Control" EI

A positive "Current Human Exposures Under Control" EI determination ("YE" status code) indicates that there are no "unacceptable" human exposures to "contamination" (i.e., contaminants in concentrations in excess of appropriate risk-based levels) that can be reasonably expected under current land- and groundwater-use conditions (for all "contamination" subject to RCRA corrective action at or from the identified facility (i.e., site-wide)).

Relationship of EI to Final Remedies

While Final remedies remain the long-term objective of the RCRA Corrective Action program the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, GPRA). The "Current Human Exposures Under Control" EI are for reasonably expected human exposures under current land- and groundwater-use conditions ONLY, and do not consider potential future land- or groundwater-use conditions or ecological receptors. The RCRA Corrective Action program's overall mission to protect human health and the environment requires that Final remedies address these issues (i.e., potential future human exposure scenarios, future land and groundwater uses, and ecological receptors).

Duration / Applicability of EI Determinations

EI Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

ED_006568_00000640-00001

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective risk-based "levels" (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

	Yes	No	?	Rationale / Key Contaminants
Groundwater		X		See rationale below.
Air (indoors)[2]		X		See rationale below.
Surface Soil (e.g., <2 ft)		X		See rationale below.
Surface Water		X		See rationale below.
Sediment		X		See rationale below.
Subsurf. Soil (e.g., >2 ft)		X		See rationale below.
Air (outdoors)		X		See rationale below.

☒ If no (for all media) - skip to #6, and enter "YE," status code after providing or citing appropriate "levels," and referencing sufficient supporting documentation demonstrating that these "levels" are not exceeded.

☐ If yes (for any media) - continue after identifying key contaminants in each "contaminated" medium, citing appropriate "levels" (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

☐ If unknown (for any media) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):

Facility Background Information:

B. Braun Medical, Inc. (B. Braun) is a privately-owned health care company that provides healthcare products, services and educational programs that enhance the care and safety of patients and healthcare professionals in the fields of drug delivery, IV therapy, pain control, clinical nutrition, dialysis and vascular intervention. B. Braun's products and services are used in hospitals, outpatient surgery centers and in the home care setting. B. Braun's facility (herein after referred to as "B. Braun," "Facility," or "Site") located at 901 Marcon Boulevard in Hanover Township, Lehigh County, Pennsylvania, manufactures, prepares and sterilizes plastic disposable medical devices, such as valves, adapters, piercing devices, stopcocks, infusion pumps and systems, syringes, cannulae, regional anesthesia, balloon catheters, fluid administration systems, interventional products, and safety products.

Footnotes:

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based "levels" (for the media, that identify risks within the acceptable risk range).

[2] Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest that unacceptable indoor air concentrations are more common in structures above groundwater with volatile contaminants than previously believed. This is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration necessary to be reasonably certain that indoor air (in structures located above (and adjacent to) groundwater with volatile contaminants) does not present unacceptable risks.

ED_006568_00000640-00002

The Facility is situated on 29.32-acres in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The Site is surrounded on all sides by office complex buildings, and an airport tarmac for the Lehigh Valley International Airport is located to the immediate northwest. The property was owned by Burron Medical, Inc. from 1984 to 1994. B. Braun purchased the property in 1994 and is the current owner of the Site. Structures on the Site include the original 285,000 square foot building which was constructed in 1985, in addition to a 75,000 square foot building constructed in 2009. Currently, B. Braun operates as a subsidiary of B. Braun Melsungen AG.

RCRA Regulatory Status:

With respect to the Facility's RCRA regulatory status, Burron Medical, Inc. filed an initial Notification of Hazardous Waste Activity with EPA in June 1990. The initial notification identified Burron as a Small Quantity Generator (SQG, less than 1,000 kilograms (kg) per month) of hazardous waste. As a result, Burron Medical, Inc. was issued the EPA Identification Number PAD982679169. On May 5, 1997, B. Braun submitted a subsequent Notification of Hazardous Waste Activity to EPA. The subsequent notification identified the Facility's name change from Burron Medical, Inc. to B. Braun and updated the Facility's (i.e., B. Braun) generator status to a Large Quantity Generator (LQG, greater than 1,000 kg per month) of hazardous waste. The EPA Hazardous Waste Codes identified on the subsequent notification included: D001 (ignitable), D002 (corrosive), D010 (selenium), D011 (silver), F002 (halogenated solvents), and F003 (non-halogenated solvents).

On April 30, 1997, B. Braun applied for a Permit By Rule (PBR) with the Pennsylvania Department of Environmental Protection (PADEP) for its neutralization process of Ethylene Glycol (25 Pa Code 265.433 – Neutralization Treatment Units). On June 6, 1997, PADEP notified B. Braun's of the Department's determination that the Facility's neutralization unit (referred to as a captive wastewater treatment unit by PADEP) qualifies for PBR.

On May, 2, 2011, Michael Jr. Baker, Inc. conducted an Environmental Indicator (EI) Inspection of B. Braun, on behalf of EPA. The findings of the EI Inspection are documented in a September 2011 EI Inspection Report for B. Braun Medical, Inc., prepared by Baker. Information gathered during the EI Inspection identified generation of the following hazardous wastes by B. Braun: D001 (spent isopropyl alcohol (IPA), ignitable), D008 (lead), D009, (mercury), D010 (selenium), D039 (tetrachloroethylene (PCE)), and F002 (spent methylene chloride (MeCl), spent halogenated solvents).

For additional information regarding the generation and management of hazardous waste by B. Braun, please refer to Section A of the September 2011 EI Inspection Report.

Solid Waste Management Units and Areas of Concern:

Summaries of historic and/or current Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs) present at the Site as a result of past or present operations are provided in the following paragraphs and are described in further detail in Section B of the of the EI Inspection Report.

Elementary Neutralization Unit: The Facility's elementary neutralization unit (ENU) is located within the southern portion of the main building (refer to Appendix B, Figure 2 – Facility Layout, of September 2011 EI Inspection Report) in the Deoxx Room. The ENU, which was installed and began operation in 1985, is used to neutralize ethylene glycol process wastewater generated by the Facility's closed-loop ethylene oxide sterilization emissions control system (deoxx scrubber system). Prior to neutralization using sodium hydroxide, the Facility's ethylene glycol process wastewater is hazardous for the characteristic of corrosivity (EPA Hazardous Waste Code D002). The neutralized process wastewater is shipped off-site to be reused in the manufacture of antifreeze. Both the Facility building and the ENU area are secure and require card access. The ENU consists of a 3,000-gallon aboveground storage tank (AST), two towers, and a reaction tank. The unit is enclosed on three sides by cinder block walls, a concrete curb that is approximately 1.5 feet high on the forth side, and a concrete floor. There have been no documented releases or violations on record relative to the Facility's ENU.

Former Hazardous Waste Accumulation Area: The Facility's Former Hazardous Waste Accumulation Area was located on the southeast side of the Facility, just outside of the main building. Between 1989 and 2002, the Facility used this area for the accumulation of hazardous waste with the EPA Hazardous Waste Codes D001 (ignitable), D002 (corrosive), D035 (methyl ethyl ketone), F002 (spent halogenated solvents), F003 (spent non-halogenated solvents), and P042 (epinephrine waste). The Former Hazardous Waste Accumulation Area consisted of a hazardous material storage shed constructed with secondary containment that was located within a fenced area to restrict access. There are no documented releases for this area.

Current Hazardous Waste Accumulation Area: The Facility's current hazardous waste accumulation area is located at the northeast end of the property adjacent to the main building. The area is surrounded by a six-foot high chain link fence with two gated and locked entrances. Two hazardous material storage sheds equipped with secondary containment are present within the accumulation area. Both of the units are approximately 10-feet by 20-feet in size. The southern unit is used for the storage of raw materials in 55-gallons drums, including various grades of IPA, MeCl, tetrahydrofuran (THF), cyclohexane, and MTM, a mixture (pre-mixed) of MeCl and THF. The northern unit is used to store both hazardous and non-hazardous wastes in 55-gallon drums. Hazardous wastes accumulate in this area include the EPA Hazardous Waste Codes D001 (ignitable), D002 (corrosive), D035 (methyl ethyl ketone), F002 (spent halogenated solvents), F003 (spent non-halogenated solvents), and P042 (epinephrine waste). All raw materials and wastes stored in the Current Hazardous Waste Accumulation Area are placed inside of the storage sheds; no raw materials or waste materials are stored outside. There have been no documented releases from the Facility's current hazardous waste accumulation area.

Empty Ethylene Oxide Drum Storage Area: The Facility receives ethylene oxide (EtO), a colorless, ignitable, high reactive gas, in pressurized drums. The raw material drums of ethylene oxide are stored in the Ethylene Oxide Room (or Gas Room), which is located within the main building, adjacent to the deoxx scrubber system. The EtO is used to sterilize medical devices in the Facility's eight (8) humidified rooms (i.e., sterilization units). Following sterilization, the medical devices are aerated in the aeration room to remove residual EtO. The EtO is directed to the deoxx scrubber system, which converts the EtO into ethylene glycol and water, which is stored in the 3,000-gallon AST associated with the Facility's ENU. EtO is also directed to the catalytic oxidizer located on the west side of the Facility, which converts EtO to carbon dioxide and water. The catalytic oxidizer is equipped with a heat recovery unit, and the heat is directed back into the aeration unit. Once "empty" (not to be confused with the term "RCRA Empty"), the EtO drums are stored in a fenced and locked storage area located outside of the EtO room until they are returned to the vendor as a hazardous material.

Emergency Catch Basin Underground Storage Tank (UST, Tank 001): Tank 001, which is located on the northwest side of the Facility, is a registered UST (Facility ID No. 39-37781) and regulated under PADEP's UST Program. Tank 001 was installed in April 1999, and is constructed of double-walled steel with a plastic jacket. The piping associated with Tank 001 is gravity fed and constructed of single-walled PVC plastic. Tank 001acts an emergency catch basin that is set up to receive ethylene glycol that is spilled or released to the floor drains located inside each sterilization unit, throughout the areas where EtO is used, and from the Facility's deoxx scrubber system. As indicated by B. Braun during Bakers' May 2011 site visit, approximately 200-400 gallons of liquid are removed from the UST routinely by the same company that empties the 3,000-gallon AST associated with the Facility's ENU, which contains an ethylene glycol and water mixture. The contents of Tank 001 and the 3,000-gallon AST are removed at the same time and comingled for off-site shipment to be reused in the manufacture of antifreeze. As a regulated UST, Tank 001 is equipped with an interstitial sensor that monitors the UST's interstitial space for leaks, in addition to an overfill alarm, that is monitored using an automatic tank gauging system (ATG). There have been no documented releases from Tank 001.

Potential Exposure Pathways:

Please note that there have been no known and/or reported releases at this Facility, and that the majority of the Site is covered with impermeable surfaces, such as, concrete slabs and asphalt paving.

1. *Groundwater*: Water and sewer are provided to the Facility and surrounding area by the Catasauqua Municipal Water Works, and in accordance with Chapter 235, Article III, Section 235-13.L., "all subdivisions and land developments located within the Borough of Catasauqua shall be served with public water and sanitary sewer facilities unless the Commission determines that such facilities are not required or that suitable alternate facilities meeting the requirements of the Pennsylvania Department of Environmental Protection shall be provided." According to the Catasauqua Borough's 2010 Annual Drinking Water Quality Report, drinking water is derived entirely from three (3) municipally owned and operated groundwater wells located within 1,200 feet of the water plant located at Walnut and St. Johns Streets in Catasauqua. The wells range in depth from 141 below ground surface (bgs) to 235 feet bgs. The water plant is located approximately 1.6 miles northwest of the Facility.

   There have been no known/documented releases to Site soils or groundwater relative to B. Braun's operations, and therefore, no detailed site-specific geologic or hydrogeologic studies have been conducted at the Site within a regulatory framework, nor is there evidence available to presume that such work is warranted.

2. *Indoor and Outdoor Air*: Generally, exposure to on-site workers via the indoor air pathway can be attributed to regular Facility operations due to the usage of solvents, paints, particulates, etc. B. Braun currently operates under

a Title V Air Permit (Permit No. 39-00055) which was issued on January 13, 2010, and is effective through January 12, 2015. Emission sources covered by the permit include two boilers, four emergency generators, two fire pumps, eight sterilizers, the aeration room, catalytic oxidizer, and the deoxx scrubber system. Thus, it is presumed that this exposure pathway was/is controlled by the applied air permitting control measures, in addition to compliance with OSHA regulations. Furthermore, information obtained from PADEP eFACTS website (2011) and the PADEP archives indicated that routine air quality inspections have been occurring at the Site from 1997 through 2011 with no cited violations.

Because there have been no known/documented releases to Site soils or groundwater relative to B. Braun's operations, subsurface investigation data to conduct a vapor intrusion assessment is not available, nor is it believed to be warranted based on the public information reviewed per the September 2011 EI Report.

3. *Surface Soils and Subsurface Soils*: There have been no known/documented releases to Site soils or groundwater relative to B. Braun's operations, and therefore, no detailed site-specific geologic or hydrogeologic studies have been conducted at the Site within a regulatory framework, nor is there evidence available to presume that such work is warranted.

4. *Surface Water and Sediment*: The nearest surface water body is a tributary to the Lehigh River located approximately 0.5 miles east of the Facility. The tributary is designated as a cold water fishery and is listed on the tentative streams integrated list as a non-attaining segment impaired for aquatic life resulting from siltation due to road runoff and storm sewers. The tributary flows to the southwest under US Route 22, where a portion of the stream (approximately 1,800 feet) was enclosed during development of a retail shopping center (Airport Center). The tributary discharges to the Lehigh River approximately 1.2 miles downstream of the Facility. At its closest point, the Lehigh River, a designated trout stocking fishery, is located approximately 0.8 miles west of the Facility.

   B. Braun has a Watershed Protection Permit (Permit No. 07-03) through the Borough of Catasauqua which is effective through November 9, 2012. The permit covers the Facility's disposal of industrial wastewater, including process and water treatment wastewaters, as well as sanitary wastewater, into the sanitary sewer. There have been no known violations of the Facility's Watershed Protection Permit. Surface water runoff from the Site is directed to storm sewer drains located throughout the property. There have been no known or documented releases to the tributary by B. Braun.

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

3. Are there **complete pathways** between "contamination" and human receptors such that exposures can be reasonably expected under the current (land- and groundwater-use) conditions?

Summary Exposure Pathway Evaluation Table

Potential **Human Receptors** (Under Current Conditions)

"Contaminated" Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food[3]
Groundwater							
Air (indoors)							
Soil (surface, e.g., <2 ft)							
Surface Water							
Sediment							
Soil (subsurface e.g., >2 ft)							
Air (outdoors)							

Instructions for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors' spaces for Media which are not "contaminated" as identified in #2 above.

2. enter "yes" or "no" for potential "completeness" under each "Contaminated" Media -- Human Receptor combination (Pathway).

Note: In order to focus the evaluation to the most probable combinations some potential "Contaminated" Media - Human Receptor combinations (Pathways) do not have check spaces ("___"). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

☐ If no (pathways are not complete for any contaminated media-receptor combination) - skip to #6, and enter "YE" status code, after explaining and/or referencing condition(s) in-place, whether natural or man-made, preventing a complete exposure pathway from each contaminated medium (e.g., use optional Pathway Evaluation Work Sheet to analyze major pathways).

☐ If yes (pathways are complete for any "Contaminated" Media - Human Receptor combination) - continue after providing supporting explanation.

☐ If unknown (for any "Contaminated" Media - Human Receptor combination) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):

[3] Indirect Pathway/Receptor (e.g., vegetables, fruits, crops, meat and dairy products, fish, shellfish, etc.)

ED_006568_00000640-00006

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be **"significant"**[4] (i.e., potentially "unacceptable" because exposures can be reasonably expected to be: 1) greater in magnitude (intensity, frequency and/or duration) than assumed in the derivation of the acceptable "levels" (used to identify the "contamination"); or 2) the combination of exposure magnitude (perhaps even though low) and contaminant concentrations (which may be substantially above the acceptable "levels") could result in greater than acceptable risks)?

☐ If no (exposures can not be reasonably expected to be significant (i.e., potentially "unacceptable") for any complete exposure pathway) - skip to #6 and enter "YE" status code after explaining and/or referencing documentation justifying why the exposures (from each of the complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

☐ If yes (exposures could be reasonably expected to be "significant" (i.e., potentially "unacceptable") for any complete exposure pathway) - continue after providing a description (of each potentially "unacceptable" exposure pathway) and explaining and/or referencing documentation justifying why the exposures (from each of the remaining complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

☐ If unknown (for any complete pathway) - skip to #6 and enter "IN" status code

Rationale and Reference(s):

[4] If there is any question on whether the identified exposures are "significant" (i.e., potentially "unacceptable") consult a human health Risk Assessment specialist with appropriate education, training and experience.

ED_006568_00000640-00007

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

5. Can the "significant" **exposures** (identified in #4) be shown to be within **acceptable** limits?

☐ If yes (all "significant" exposures have been shown to be within acceptable limits) - continue and enter "YE" after summarizing and referencing documentation justifying why all "significant" exposures to "contamination" are within acceptable limits (e.g., a site-specific Human Health Risk Assessment).

☐ If no - (there are current exposures that can be reasonably expected to be "unacceptable")- continue and enter "NO" status code after providing a description of each potentially "unacceptable" exposure.

☐ If unknown (for any potentially "unacceptable" exposure) - continue and enter "IN" status code.

Rationale and Reference(s):

ED_006568_00000640-00008

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI (event code CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

☒ YE - Yes, "Current Human Exposures Under Control" has been verified. Based on a review of the information contained in this EI Determination, "Current Human Exposures" are expected to be "Under Control" at the B. Braun Medical, Inc. Facility, EPA ID No. PAD982679169, located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109 under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

☐ NO - "Current Human Exposures" are NOT "Under Control."

☐ IN - More information is needed to make a determination.

Completed by (signature) _____ Date _____
(print) Jeanna R. Henry
(title) Remedial Project Manager

Supervisor (signature) _____ Date _____
(print) Paul Gotthold
(title) Associate Director
EPA Region III

Locations where References may be found:

US EPA Region III
Land & Chemicals Division
1650 Arch Street
Philadelphia, PA 19103

Contact telephone number and e-mail address:

(name) Jeanna R. Henry
(phone #) (215) 814-2820
(e-mail) henry.jeannar@epa.gov

ED_006568_00000640-00009