DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA750)
Migration of Contaminated Groundwater 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 the groundwater media, 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 "Migration of Contaminated Groundwater Under Control" EI

A positive "Migration of Contaminated Groundwater Under Control" EI determination ("YE" status code) indicates that the migration of "contaminated" groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original "area of contaminated groundwater" (for all groundwater "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 "Migration of Contaminated Groundwater Under Control" EI pertains ONLY to the physical migration (i.e., further spread) of contaminated ground water and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

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).

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2. Is **groundwater** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective "levels" (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

☐ If yes - continue after identifying key contaminants, citing appropriate "levels," and referencing supporting documentation.

☒ If no - skip to #8 and enter "YE" status code, after citing appropriate "levels," and referencing supporting documentation to demonstrate that groundwater is not "contaminated."

☐ If unknown - skip to #8 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.

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.

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 appropriate "levels" (appropriate for the protection of the groundwater resource and its beneficial uses).

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.

Groundwater:

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.

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.

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3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within "existing area of contaminated groundwater"[2] as defined by the monitoring locations designated at the time of this determination)?

☐ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the "existing area of groundwater contamination"[2]).

☐ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the "existing area of groundwater contamination"[2]) – skip to #8 and enter "NO" status code, after providing an explanation.

☐ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

[2] "existing area of contaminated groundwater" is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of "contamination" that can and will be sampled/tested in the future to physically verify that all "contaminated" groundwater remains within this area, and that the further migration of "contaminated" groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

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4. Does "contaminated" groundwater **discharge** into **surface water** bodies?

☐ If yes - continue after identifying potentially affected surface water bodies.

☐ If no - skip to #7 (and enter a "YE" status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater "contamination" does not enter surface water bodies.

☐ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

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5. Is the **discharge** of "contaminated" groundwater into surface water likely to be **"insignificant"** (i.e., the maximum concentration[3] of each contaminant discharging into surface water is less than 10 times their appropriate groundwater "level," and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or eco-systems at these concentrations)?

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☐ If yes - skip to #7 (and enter "YE" status code in #8 if #7 = yes), after documenting: 1) the maximum known or reasonably suspected concentration[3] of key contaminants discharged above their groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) provide a statement of professional judgement/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or eco-system.

☐ If no - (the discharge of "contaminated" groundwater into surface water is potentially significant) - continue after documenting: 1) the maximum known or reasonably suspected concentration[3] of each contaminant discharged above its groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) for any contaminants discharging into surface water in concentrations[3] greater than 100 times their appropriate groundwater "levels," the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

☐ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

[3] As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

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6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be "**currently acceptable**" (i.e., not cause impacts to surface water, sediments or eco-systems that should not be allowed to continue until a final remedy decision can be made and implemented[4])?

☐ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site's surface water, sediments, and eco-systems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR 2) providing or referencing an interim-assessment[5], appropriate to the potential for impact that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment "levels," as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

☐ If no - (the discharge of "contaminated" groundwater can not be shown to be "**currently acceptable**") - skip to #8 and enter "NO" status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or eco-systems.

☐ If unknown - skip to 8 and enter "IN" status code.

Rationale and Reference(s):

[4] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

[5] The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

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7. Will groundwater **monitoring** / measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the "existing area of contaminated groundwater?"

☐ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

☐ If no - enter "NO" status code in #8.

☐ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

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8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), 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, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the B. Braun Medical, Inc. Facility, EPA ID No. PAD982679169, located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109. This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

☐ NO - Unacceptable migration of contaminated groundwater is observed or expected.

☐ 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:

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