

COMPANY STATEMENT



Oct. 17, 2019

BD Response to Georgia EPD Statement

We are surprised and deeply concerned by Georgia Environmental Protection Division's (EPD) new position that BD did not properly disclose the unintended release of ethylene oxide (EtO). That is simply not accurate and misleading based on our prior communications with EPD and other stakeholders (see attached timeline). We provided a voluntary verbal report to Georgia EPD on September 25. We provided a similar verbal update to the City of Covington on September 26. On September 27, we issued a formal, written report to EPD, City of Covington and Governor Brian Kemp's staff (see attached emails). The unintended release of ethylene oxide (EtO) at BD's Covington facility was below the reportable threshold of 10 lbs. per 24-hour period. However, BD voluntarily and properly disclosed the unintended release as soon as we had confirmed the amount and cause.

Voluntarily reporting the release is consistent with BD's approach of transparency to all stakeholders, which has also included opening our facility to tours to more than a dozen elected officials and media outlets to help educate on the process and science behind the safe use of EtO for medical device sterilization. We have repeatedly invited Mayor Johnston, EPD leadership and the Governor's staff to tour our operations so that they can see our approach to sterilization firsthand.

Our highly educated and skilled Covington employees, with the full support of BD corporate resources, operate a facility that is safe for both employees and the community. We would not operate a facility that was not in compliance with all laws and regulations.

Our tenured workforce, many with more than 25 years at BD, is a testament to the safety of our facility. It is worth noting that BD has been recognized as a top corporate citizen year after year and the company has received accolades for its approach to transparency. Doing the right thing is part of our core values and how we conduct business.

Because of our commitment to safety, the company has taken a proactive approach to make the facility even safer, including our \$8 million voluntary technology upgrades to capture fugitive emissions and our recently completed voluntary stack test that showed a 99.999% EtO destruction efficiency for our emission control technology.

In addition, BD is the only entity to engage board-certified toxicologists to analyze the results of air monitoring performed by BD and the City of Covington to base EtO discussions on science and facts. Toxicologists are scientists trained to understand the relationship of chemicals to human health. They take into account the type of chemical and the amount of the chemical that would be needed to create a toxic effect on human health.

We provided both BD's and the City of Covington's air monitoring results to three, separate, independent toxicologists for review at our expense. All three toxicologists stated that the most appropriate way to analyze the results from this very limited sample is to average all measurements from any single monitoring location to get a view of average exposure levels for that location. To scientifically compare risk levels to regulatory limits or risk screening values, scientists look at the average (typically a geometric mean) of all points at the same location. That's because long-term risk is defined as consistent exposure 24 hours per day, 365 days a year for a lifetime, which is defined as

70 years. Taking only one value from one location, high or low, and comparing to regulatory limits is not grounded in science. These experts have built their careers on protecting human health, and they take that responsibility very seriously. None of them believe that either data set show short- or long-term health risks when properly viewed in their entirety.

In addition, Georgia EPD stated today that initial results from two days of their EtO air monitoring in four locations in Covington show three of eight samples lower than the detection limit and a range from non-detectable to 2.13 $\mu\text{g}/\text{m}^3$. Their initial sample from a rural state park in southern Georgia was 0.5 $\mu\text{g}/\text{m}^3$, 25 times higher than the EPA screening level, another example that EtO is all around us, even when far away from any medical sterilization facilities.

Neither the City of Covington nor Georgia EPD provided any scientific explanation as to why they are raising concerns with the same data that was reviewed by our toxicology experts. This is a complex issue and needs more context than soundbites. The residents of Covington and Georgia deserve the facts.

What has not received enough attention is the millions of patients that rely on BD devices that are sterilized in Georgia. We would not trade employee or community safety for patient safety but knowing that the science has revealed the safety of our operations, we must advocate for the patients around the world who use the more than 250 million devices each year that are sterilized by BD in Georgia. Creating public hysteria with no basis in science does not serve the public interest and is putting millions of patients at risk worldwide.

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Timeline of relevant correspondence between BD and Georgia Environmental Protection Division (EPD)

November/ December 2018	EPD contacted BD to have a meeting (late Nov.). BD hosted at our facility in Covington (so as to provide a tour) on Dec. 4th. EPD discussed redoing modeling for emissions from the facility. BD agreed to any data requests the EPD may have. In the days following the meeting EPD provided BD with a data request for air modeling purposes.
1/2/19	BD provided facility information to EPD via letter. BD and EPD agree that BD will perform additional analysis on product for fugitive emissions information.
5/3/19	BD provides letter to EPD with additional emissions information for modeling
6/19/19	BD receives call from EPD to review results of modeling. EPD delivers results of modeling memo. BD asks if there are any actions to take. EPD states no actions requested, and that we should wait to see what Federal EPA does with revised NESHAP rule.
7/22/19	BD holds call with EPD where EPD requests BD to start thinking of improvements for emissions.
7/24/19	EPD contacts BD to discuss willingness to commit to voluntary emission reductions. BD commits to making voluntary reductions.
8/5/19	BD meets with EPD leadership and Governor Brian Kemp's staff ahead of Covington City Council meeting.
8/20/19	BD leadership meets with Governor Brian Kemp and EPD leadership.
9/25/19	BD contacted EPD to voluntarily report unintended EtO release due to valve issue. Notified EPD of all details known to date (issue identified and determined under reporting limit; working to determine accurate amounts using engineering information). EPD provided follow up call 1 hour later letting BD know that EDP passed the information along to another unit who would document the report on EPD's end. Site should expect to hear from that person at EPD.
9/25/19	EPD reaches out to BD to have a call with the site team regarding release. Call included a summary of the release. EPD asked that BD send an e-mail with summary of the incident by end of the week. BD agreed. EPD asked about GC levels and quantification of release amount. BD explained due to dynamics of situation and conditions that correlation of GC readings and release would not give valid results. Call concluded with EPD expressing appreciation for our time and response and would likely be back in touch once incident report was received.
9/27/19	BD emails incident report to EPD. BD attorney shortly after emails incident report to the City's attorneys

9/30/19	EPD emails BD about placing EPD sampling canisters on property. They speak by phone on Oct. 1 st and set up time for Oct. 2 nd where EPD visits the site about cannister placement.
10/1/19	BD has regular update call with EPD. Asks about any questions from the incident report on the valve. EPD says it's with EPD unit who was appreciative of the level of detail in the report. EPD staff on the phone had not heard of any questions from EPD unit. BD subsequently forwards incident report to EDP staff on the phone via email, as they had stated they had not seen the actual report.
10/2/19	BD submits stack test report to EPD.
10/10/19	BD emails EPD for a time on the 11 th to provide a regular update on upgrades and other EtO related events.
10/15/19	BD receives a call from EPD. EPD was in process of closing the release report and had question about how BD calculated the numbers in the table BD sent them. Explained to EPD how we calculated and EPD seemed satisfied. EPD said they should close the report that day. BD asked if we needed to do anything further. EPD responded that there should be no further required from us.
10/16/19	BD calls EPD to inform that BD is releasing its air monitoring results (duplicates from city sampling). BD subsequently forwards statement to EPD via email. Second email to EPD shortly after to provide a link to the Advamed Montrose Report on emission levels of common sources of EtO.
10/16/19	BD receives a call from EPD regarding the release report. EPD had received a question from a reporter and was preparing a response. EPD asked if the nitrogen wash phase was typically routed through the vacuum exhaust valve to the roof. BD stated the vacuum exhaust valve would be closed for all post exposure phases, including nitrogen wash, and vacuum pump exhaust is directed to the RTO.
10/16/19	BD emails BD's letter to the Mayor to Rick Dunn, Karen Hayes, Mary Walker (EPA Region 4) and Black Ashbee (EPA Region 4).

From: [John LaMontagne](#)
To: james.cooley@dnr.ga.gov
Cc: [Ron Pasdon](#); [Boone Brothers](#)
Subject: BD Covington Incident Summary
Date: Friday, September 27, 2019 5:07:23 PM
Attachments: [image001.png](#)
[Incident Report Cov 27.sept.19 EPD.pdf](#)

Jim,

Attached is the summary of the incident we discussed.

Please contact me with any questions.

Regards,

John LaMontagne



John LaMontagne

BD UCC and Critical Care

John.LaMontagne@crbard.com

8195 Industrial Blvd.
Covington, GA, 30014
US

t: +1.770.784.6186

c: 770.652.2049

f: 770.788.5519

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From: [Oakes, Les](#)
To: [Frank Turner](#); [Quintrell, Randy](#)
Cc: [Ellen Kondracki](#); [Mary Gerdes](#); [Michelle Quinn](#); [Ron Pasdon](#)
Subject: BD Covington Incident Summary
Date: Friday, September 27, 2019 6:30:23 PM
Attachments: [image001.png](#)
[Incident Report Cov 27.sept.19 EPD.pdf](#)

Gentlemen: as Ellen Kondracki promised the mayor yesterday, attached is the EtO incident summary that BD submitted to EPD earlier this afternoon.

Les Oakes

T: +1 404 572 3314 | E: loakes@kslaw.com | www.kslaw.com

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King & Spalding LLP
1180 Peachtree Street, NE
Suite 1600
Atlanta, GA 30309

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From: [Elizabeth Woody](#)
To: [Broce, Candice](#)
Cc: [Sam Khichi](#); [Fleming, Tim](#); [Smith, Lorri](#); [Dove, David](#)
Subject: BD Update
Date: Friday, September 27, 2019 5:42:00 PM
Attachments: [image001.jpg](#)
[Incident Report Cov 27.sept.19 EPD.PDF](#)

Hi Candice,

We want to share the following update with you, Tim, Lorri and David:

- Early next week, we expect ESCI (third party testing firm) to issue the final results of our stack test performed on September 11th and 12th. We will share the results with you as soon as they have been finalized by ECSI.
- Newton County Commissioners Stan Edwards and Nancy Schulz visited our Covington facility on Tuesday of this week and both Commissioners found the tour to be a helpful way to understand our sterilization operations. We would welcome the opportunity for you to have the same experience at your convenience. Next week, we will have two expert toxicologists on site to meet with selected stakeholders, and we would be pleased to connect you with them with as well.
- We notified Georgia EPD and the City of Covington that a valve on one of the sterilization chambers in our Covington facility was discovered not to be fully in the closed position, which resulted in a release that did not trigger the reporting requirement of 10 pounds in a 24 hour period. The release was detected through the automated safety systems as they are designed to operate, and the valve was identified and determined that it could be permanently decommissioned to avoid any future release. There were no injuries or evacuations, and no further actions were required at the site. Although the amount released was lower than the required reporting requirements, we voluntarily reported the release. Please find attached a detailed summary that we provided to EPD today.
- This week, work was initiated on the design for the upgrades that we will make at our Madison facility that are aligned with the upgrades we are making in Covington.

We will continue to keep you updated on our progress in executing against our commitments and please do not hesitate to contact us with any questions.

Elizabeth



Elizabeth K. Woody

Vice President, Public Affairs

elizabeth.woody@bd.com

700 6th Street, NW, Suite 400
Washington, DC 20001 US

t: 202.777.1585

c: 202.669.8651

bd.com