

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

In the Matter of:

Abbott Vascular, Inc.
400 Saginaw Drive
Redwood City, California 94063

EPA ID: CAR000091850

Respondent.

Docket HWCA 2008-1822

Consent Order

Health and Safety Code
Section 25187

1. INTRODUCTION

1.1. Parties. The California Department of Toxic Substances Control (Department) and Abbott Vascular, Inc. (Respondent) enter into this Consent Order (Order) and agree as follows:

1.2. Site. Respondent generates, handles, stores, and/or disposes of hazardous waste at the following site: 400 Saginaw Drive, Redwood City, California 94063 (Site).

1.3. Inspection. The Department inspected the Site on July 29, 2008.

1.4. Authorization Status. Respondent is a large quantity generator.

Respondent generates the following hazardous waste: liquid isopropyl alcohol and hydro-gel liquid coatings ("liquid ignitable waste"), isopropyl alcohol wipes (IPA wipes), spent adhesives, waste oil, and caustic wastes.

///

///

Abbott Vascular, Inc.

Docket HWCA 2008-1822
Consent Order

1.5. Jurisdiction. Health and Safety Code, section 25187, authorizes the Department to order action necessary to correct violations and to assess a penalty when the Department determines that any person has violated specified provisions of the Health and Safety Code or any permit, rule, regulation, standard, or requirement issued or adopted pursuant thereto.

1.6. Full Settlement. A dispute exists regarding the violations alleged below pertaining to the Site. The Parties wish to avoid the expense of litigation and ensure prompt compliance. By their respective signatures below, the Parties, and each of them, agree that this Order, and all of the terms contained herein, are fair, reasonable, and in the public interest. This Order shall constitute full settlement of the violations alleged below. By agreeing to this Order, the Department does not waive any right to take further enforcement actions within its jurisdiction and involving either the Respondent(s) or the Site, except to the extent provided in this Order.

1.7. Hearing. Respondent waives any and all rights to a hearing in this matter.

2. VIOLATIONS ALLEGED

2. The Department alleges the following violations pertaining to the Site:

2.1. Respondent violated Health & Safety Code, section 25201, subdivision (a), in that, on or about July 29, 2008, Respondent stored a container of corrosive (pH>12.5) hazardous waste (caustic) on site for more than 90 days without permit or grant of authorization.

2.2. Respondent violated California Code of Regulations, title 22, section 66265.16, subdivision (a)(2), and section 66265.16, subdivision (c), in that, on or about

Abbott Vascular, Inc.

Docket HWCA 2008-1822
Consent Order

July 29, 2008, Respondent's hazardous waste training program was not directed by a person adequately trained in hazardous waste procedures and relevant to employee job duties. A written job description of each position and amount of training that will be given to each employee was not available. Class room or on the job training was not offered to the employees including janitors; orientation information was read and signed by employees.

2.3. Respondent violated Health & Safety Code, section 25244.21, in that, on or about July 29, 2008, Respondent failed to retain a current SB14 review plan, plan summary, and report and report summary at the site and make it available for inspection. The facility did not make available for inspection plans to reduce the generation of hazardous waste at its source for the year 2006.

2.4. Respondent violated California Code of Regulations, title 22, section 66262.11, in that, on or about July 29, 2008, Respondent failed to make a hazardous waste determination on the following: a) metal fines; and b) oily absorbent.

2.5. Respondent violated California Code of Regulations, title 22, sections 66265.54 and 66265.55, in that, on or about July 29, 2008, Respondent failed to have an updated emergency coordinator list. The emergency coordinator's name did not appear in the Emergency Action Plan retained by the facility.

2.6. Respondent violated California Code of Regulations, title 22, sections 66265.31, and 66265.174 in that, on or about July 29, 2008, Respondent's general facility inspection logs, maintained as weekly checklists, did not correspond with the

actual conditions in the facility.

2.7. Respondent violated California Code of Regulations, title 22, section 66265.32, subdivision (c), in that, on or about July 29, 2008, Respondent failed to maintain all required spill control equipment in the Hazardous Waste storage area.

2.8. Respondent violated California Code of Regulations, title 22, section 66262.34, subdivision (f), in that, on or about July 29, 2008, Respondent failed to properly label containers holding waste alcohol wipes and adhesives. In addition, the facility failed to properly label used oil buckets in the machine room. Waste coolant and used oil containers were not marked in the hazardous waste storage area.

2.9. Respondent violated California Code of Regulations, title 22, section 66265.35, in that, on or about July 29, 2008, Respondent failed to maintain adequate aisle space in the hazardous waste storage area; access to the eye wash station was blocked..

2.10. Respondent violated California Code of Regulations, title 22, sections 66273.14, subdivision (c), 66273.15, subdivision (a); and, 66273.15, subdivision (c), in that, on or about July 29, 2008, Respondent failed to properly cover, label, and store universal lamp containers.

2.11. Respondent violated California Code of Regulations, title 22, section 66265.31, in that, on or about July 29, 2008, Respondent failed to maintain the facility to prevent spills.

3. SCHEDULE FOR COMPLIANCE

3.1. Respondent shall comply with the following at the Site:

Abbott Vascular, Inc.

Docket HWCA 2008-1822
Consent Order

3.1.1. Respondent shall provide all employees in the Controlled Environment Room (CER) with hazardous waste training relevant to their job responsibilities to ensure safe handling of hazardous waste. Respondent has identified three categories of employees who currently operate within the CER:

- (a) CER Operators, who may generate small quantities of hazardous waste within the CER and who may manage satellite accumulation containers;
- (b) Chemical Coordinators, who are responsible for consolidating waste within the CER; and,
- (c) Hazardous Waste Technicians, who remove waste from the CER and manage other facets of the facility's hazardous waste program.

If requested by the Department or the Certified Unified Program Agency (CUPA), Respondent shall submit a copy of the training plan and training materials for each category of CER employee to the Department or CUPA for review within fifteen (15) days of the request. All CER employees shall receive initial and annual refresher training, including hazardous waste and emergency procedures, as specified in the training plan.

3.1.2. Respondent has identified three hazardous waste streams that are currently generated within the CER: adhesive waste; liquid ignitable waste; and, used IPA laden wipes. Each of these hazardous waste streams shall be managed in strict compliance with the requirements of California Code of Regulations, title 22, section

66262.34, and as indicated below¹:

(a) Adhesive wastes shall be managed in a satellite accumulation area near the initial accumulation point within the CER in one drum of 55 gallons or less. The drum will be labeled and dated with the date that the waste is first placed in the drum and the drum will be moved to the central 90-day accumulation area within 3 days of reaching the 55 gallon accumulation limit. The drum label will also contain the date when the drum was moved to the central accumulation area.

(b) Liquid ignitable waste shall be collected in individual containers in satellite accumulation areas at no more than two separate initial accumulation points within the CER depending on operations. A single container for the initial accumulation of this waste stream may not be practical as the waste must be collected very near the generation point to minimize the potential for spills and to ensure safe handling of the waste. Thus, the distance between these initial accumulation points and operational constraints may prevent the consolidation of this waste stream in a single container. The volume of liquid ignitable waste collected in a satellite accumulation area shall not exceed 55 gallons. Each container shall be labeled and dated with the date that the waste is first placed in the container and the container or contents thereof will be moved to the central accumulation area within 3 days of being filled. Containers in the central

¹ In the event of any conflict between this Order and any provision of California Code of Regulations, the provisions of the California Code of Regulations shall control.

accumulation area holding liquid ignitable waste shall be labeled and dated with the date that waste was first placed in the container in the central accumulation area or the date that the container or the contents thereof were moved into the central accumulation area, whichever occurs first.

(c) IPA-laden wipes are generated at multiple locations within the CER.

Respondent will manage waste wipes as a hazardous waste unless Respondent determines that such wipes do not meet the hazardous waste criteria. Such waste determination shall be made in accordance with California Code of Regulations, title 22, sections 66261.21 and 66261.24. Documentation of the waste determination(s) shall be maintained at the facility in accordance with California Code of Regulations, title 22, section 66262.40. While the IPA wipes are being managed as a hazardous waste, each location where IPA laden wipes are generated will be equipped with a closable waste-compatible container in good condition. The container lid shall remain completely closed at all times except as specified by California Code of Regulations, title 22, section 66265.173, subdivision (a). The containers may be equipped with a foot peddle operated or other manner of self-closing lid in order to allow CER operators to continue manufacture without interrupting the workflow process or leaving their workstation unattended. These containers will be continuously reused for the accumulation of the same waste stream and will be emptied daily (i.e., consolidated within the CER and transferred to the central accumulation area at the end of each work shift). The containers will be labeled with "recurring use"

labels and the phrase "emptied daily" will be used in the date area of the label as provided in the Department's January 2002 Fact Sheet entitled "Hazardous Waste Generator Requirements." The containers will be inspected in the Site's weekly inspection program.

(d) The Department understands that Respondent's operations in the CER may change in the future which may require modification to these procedures. Any future modification of these procedures shall comply with all applicable regulations in California Code of Regulations, title 22, Div. 4.5. Respondent shall notify the Department within 30 days of any such modification. Any modification regarding use of separate containers for compatible waste streams in a satellite accumulation area is subject to the review and approval of the Department.

3.1.3. (a) In addition to any other required training, Respondent shall send its employees who direct the Site's hazardous waste training program to California Compliance School, Modules I - V, and submit to the Department, within 180 days of the effective date of this Consent Order, Certificates of Satisfactory Completion thereof.

(b) Further, Respondent shall ensure that, at all times hereafter, all employees who direct the Site's hazardous waste training program and all employees who are designated to act as emergency coordinators, have successfully completed California Compliance School, Modules I - V or an equivalent hazardous waste management instructional program within six (6) months of their hire or assignment to the position. Certificates of Satisfactory Compliance or other documentation of completion for all of the above designated employees shall be kept on file as part of Respondent's training

records and in accordance with applicable regulations.

3.1.4. Respondent shall make all payments at the time(s) and in accord with any other conditions set forth in Section 5 (Penalty) below.

3.2. Submittals. All submittals from Respondent pursuant to this Order shall be sent to:

Charles A. McLaughlin
Performance Manager
State Oversight and Enforcement Branch
Enforcement and Emergency Response Program
Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, California 95826-3200

3.3. Communications. All approvals and decisions of the Department made regarding such submittals and notifications shall be communicated to Respondent in writing by the appropriate Branch Chief, or his/her designee. No informal advice, guidance, suggestions, or comments by the Department shall relieve Respondent of its obligation to obtain such required formal approvals.

3.4. Department Review and Approval. If the Department determines that any report, plan, schedule, or other document submitted for approval pursuant to this Order fails to comply with this Order or fails to protect public health or safety or the environment, the Department may:

- (a) Modify the document and approve the document as modified, or
- (b) Return the document to Respondent with recommended changes and a date by which Respondent must submit to the Department a revised document

incorporating the recommended changes.

3.5. Compliance with Applicable Laws. Respondent shall carry out this Order in compliance with all local, State, and federal requirements, including but not limited to requirements to obtain permits and to assure worker safety.

3.6. Endangerment during Implementation. In the event that the Department determines that any circumstance or activity (whether or not pursued in compliance with this Order) is creating an imminent or substantial endangerment to the health or welfare of people on the Site, in the surrounding area, or to the environment, the Department may order Respondent to stop further implementation of this Order for such period of time as is needed to abate the endangerment. Any deadline in this Order directly affected by a Stop Work Order under this section shall be extended by the term of such Stop Work Order.

3.7. Liability. Nothing in this Order shall constitute or be construed as a satisfaction or release from liability for any conditions or claims arising as a result of Respondent's operations, except as provided in this Order. Notwithstanding compliance with the terms of this Order, Respondent may be required to take such further actions as are necessary to protect public health or welfare, or the environment.

3.8. Site Access. Access to the Site shall be provided at all reasonable times to employees, contractors, and consultants of the Department, and any other agency having jurisdiction. The Department and its authorized representatives shall have the authority to enter and move freely about all property at the Site at all reasonable times for purposes including but not limited to: inspecting records, operating logs, and

contracts relating to the Site; reviewing the progress of Respondent in carrying out the terms of this Order; and conducting such tests as the Department may deem necessary in order to carry out the terms of the Order. Nothing in this Order is intended to limit in any way the right of entry or inspection that any agency may otherwise have by operation of any law.

3.9. Sampling, Data, and Document Availability.

3.9.1. Respondent shall permit the Department and/or its authorized representatives to inspect and copy all sampling, testing, monitoring, and/or other data (including, without limitation, the results of any such sampling, testing and monitoring) generated by Respondent, or on Respondent's behalf, in any way pertaining to work undertaken pursuant to this Order.

3.9.2. Respondent shall allow the Department and/or its authorized representatives to take duplicates or splits of any samples collected by Respondent pursuant to this Order. Respondent shall maintain a central depository of the data, reports, and other documents prepared pursuant to this Order. All such data, reports, and other documents shall be preserved by Respondent for a minimum of six years after the conclusion of all activities under this Order.

3.9.3. If the Department requests that some or all of these documents be preserved for a longer period of time, Respondent shall either:

- (a) comply with that request,
- (b) deliver the documents to the Department, or
- (c) notify the Department in writing at least six months prior to destroying any

documents prepared pursuant to this Order and permit the Department to copy the documents prior to destruction.

3.10. Government Liabilities. Neither the State of California nor the Department shall be liable for injuries or damages to persons or property resulting from acts or omissions by Respondent, or related parties, in carrying out activities pursuant to this Order. Neither the State of California nor the Department shall be held as a party to any contract entered into by Respondent or its agents in carrying out activities pursuant to the Order.

3.11. Extension Requests. If Respondent is unable to perform any activity or submit any document within the time required under this Order, the Respondent may, prior to expiration of the time, request an extension of time in writing. The extension request shall include a justification for the delay.

3.12. Extension Approvals. If the Department determines that good cause exists for an extension, it will grant the request and specify in writing a new compliance schedule.

4. OTHER PROVISIONS

4.1. Penalties for Noncompliance. Failure to comply with the terms of this Order may subject Respondent to costs, penalties and/or damages, as provided by Health and Safety Code, section 25188, and other applicable provisions of law.

4.2. Parties Bound. This Order shall apply to and be binding upon Respondent and its officers, directors, agents, employees, contractors, consultants, receivers, trustees, successors, and assignees, including but not limited to individuals, partners,

and subsidiary and parent corporations, and upon the Department and any successor agency that may have responsibility for and jurisdiction over the subject matter of this Order.

4.3. Privileges. Nothing in this Agreement shall be construed to require any party to waive any privilege. However, the assertion of any privilege shall not relieve any party of its obligations under this Order.

4.4. Time Periods. "Days" for the purpose of this Order means calendar days.

4.5. Captions and Headings. Captions and headings used herein are for convenience only and shall not be used in construing this Order.

4.6. Severability. If any provision of this Order is found by a court of competent jurisdiction to be illegal, invalid, unlawful, void or unenforceable, then such provision shall be enforced to the extent that it is not illegal, invalid, unlawful, void, or unenforceable, and the remainder of this Order shall continue in full force and effect.

4.7. Entire Agreement. This Order contains the entire and only understanding between the Parties regarding the subject matter contained herein and shall supersede any and all prior and/or contemporaneous oral or written negotiations, agreements, representations and understandings and may not be amended, supplemented, or modified, except as provided in this Order. The Parties understand and agree that in entering into this Order, the Parties are not relying on any representations not expressly contained in this Order.

4.8. Counterparts. This Order may be executed and delivered in any number of counterparts (including facsimile or electronic mail), each of which when executed and

delivered shall be deemed to be an original, but such counterparts shall together constitute one and the same document.

4.9. Non-Waiver. The failure by one party to require performance of any provision shall not affect that party's right to require performance at any time thereafter, nor shall a waiver of any breach or default of this Contract constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

4.10. Modification. Either Party to this Order may request a modification to the Schedule for Compliance, paragraph 3.1, and any part thereof. Any such request shall only become effective upon the written approval of both parties to this Order.

5. PENALTY

5.1. Respondent shall pay the Department the total sum of \$90,000 in penalties.

5.2. Payment is due within 45 days from the effective date of this Order.

5.3. Respondent's check(s) shall be made payable to Department of Toxic Substances Control, shall identify the Respondent and Docket Number, as shown in the caption of this case, and shall be delivered together with the attached Payment Voucher to:

Department of Toxic Substances Control
Accounting Office
1001 I Street, 21st floor
P. O. Box 806
Sacramento, California 95812-0806

A photocopy of the check(s) shall be sent to:

Charles A. McLaughlin

Performance Manager
State Oversight and Enforcement Branch
Enforcement and Emergency Response Program
Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, California 95826-3200

and

Richard Sherwood
Assistant Chief Counsel
Office of Legal Counsel
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812

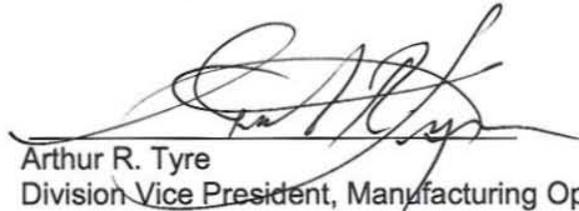
5.4. If Respondent fails to make payment as provided above, Respondent agrees to pay interest at the rate established pursuant to Health and Safety Code section 25360.1 and to pay all costs incurred by the Department in pursuing collection including attorney's fees.

6. EFFECTIVE DATE

6. The effective date of this Order is the date it is signed by the Department.

Dated: 19 JULY 2010

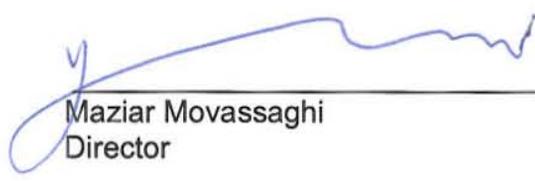
Respondent, Abbott Vascular, Inc.



Arthur R. Tyre
Division Vice President, Manufacturing Operations

Dated: 7/28/10

Department of Toxic Substances Control



Maziar Movassaghi
Director

///
///
///