



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

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**VIRGINIA WASTE MANAGEMENT BOARD
ENFORCEMENT ACTION - ORDER BY CONSENT
ISSUED TO
AMERICAN INTERNATIONAL BIOTECHNOLOGY, LLC
FOR
AI BIOTECH
EPA ID No. VAR000012419**

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code § 10.1-1455, between the Virginia Waste Management Board, and American International Biotechnology, LLC, regarding AI Biotech for the purpose of resolving certain violations of the Virginia Waste Management Act and the applicable regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "AI Biotech" means American International Biotechnology, LLC, a limited liability company authorized to do business in Virginia and its members, affiliates, partners, and subsidiaries. AI Biotech is a "person" within the meaning of Va. Code § 10.1-1400.
2. "Board" means the Virginia Waste Management Board, a permanent citizens' board of the Commonwealth of Virginia, as described in Va. Code §§ 10.1-1184 and -1401.
3. "CFR" means the Code of Federal Regulations, as incorporated into the Regulations.
4. "CO" means the Central Office of DEQ, located in Richmond, Virginia.

5. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia, as described in Va. Code § 10.1-1183.
6. "Director" means the Director of the Department of Environmental Quality, as described in Va. Code § 10.1-1185.
7. "Facility" or "Site" means AI Biotech's Facility located at 601 Biotech Drive in Richmond, Virginia.
8. "Generator" means person who is a hazardous waste generator, as defined by 40 CFR § 260.10.
9. "Hazardous Waste" means any solid waste meeting the definition and criteria provided in 40 CFR § 261.3.
10. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1455.
11. "Order" means this document, also known as a "Consent Order" or "Order by Consent."
12. "Regulations" or "VHWMR" means the Virginia Hazardous Waste Management Regulations, 9 VAC 20-60-12 *et seq.* Sections 20-60-14, -124, -260 through -266, -268, -270, -273, and -279 of the VHWMR incorporate by reference corresponding parts and sections of the federal Code of Federal Regulations (CFR), with the effective date as stated in 9 VAC 20-60-18, and with independent requirements, changes, and exceptions as noted. In this Order, when reference is made to a part or section of the CFR, unless otherwise specified, it means that part or section of the CFR as incorporated by the corresponding section of the VHWMR. Citations to independent Virginia requirements are made directly to the VHWMR.
13. "Solid Waste" means any discarded material meeting the definition provided in 40 CFR § 261.2.
14. "SQG" means a small quantity generator, a hazardous waste generator that generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month and meets other restrictions. *See* 40 CFR § 262.34(d)-(f).
15. "Va. Code" means the Code of Virginia (1950), as amended.
16. "VAC" means the Virginia Administrative Code.
17. "Virginia Waste Management Act" means Chapter 14 (§ 10.1-1400 *et seq.*) of Title 10.1 of the Va. Code. Article 4 (Va. Code §§ 10.1-1426 through 10.1-1429) of the Virginia Waste Management Act addresses Hazardous Waste Management.

SECTION C: Findings of Fact and Conclusions of Law

1. AI Biotech leases and operates the Facility in Richmond, Virginia. The Facility is a clinical laboratory and research organization. Operations at the Facility are subject to the Virginia Waste Management Act and the Regulations.
2. AI Biotech submitted a RCRA Subtitle C Site Identification Form (received October 29, 1998) that gave notice of regulated waste activity at the Facility as an LQG of hazardous waste. AI Biotech was issued EPA ID No. VAR000012419 for the Facility. In a subsequent form (received September 13, 2001), AI Biotech gave notice as an SQG of hazardous waste at the Facility.
3. At the Facility, AI Biotech generates the following hazardous wastes which are also solid wastes. Each waste is listed with associated waste codes as described in 40 CFR § 261.21, 261.24 and 261.31. Hazardous wastes, including those listed below, are accumulated in containers at the Facilities after generation.

Used oil

Universal waste lamps

Acetonitrile and methanol (HPLC waste) - D001

Corrosive wastes- D002

Other lab waste- D001, D022, F002, F003, F005

Expired chemicals- many waste codes including U154, U108, U080

Mercury waste- D009

Expired sodium cyanide- P080

4. On April 14, 2016, Department staff inspected the Facility for compliance with the requirements of the Virginia Waste Management Act and the Regulations. Based on the inspection and follow-up information, Department staff made the following observations:
 - a. The Facility could not determine generator status and was not tracking its waste. DEQ personnel observed an undetermined amount of 4-gallon or smaller bottles containing waste, hazardous waste, expired chemicals, and unexpired chemicals commingled throughout the Facility. The volume of the mixed waste currently being stored was unknown.

40 CFR §262.10. Purpose, scope, and applicability.

a) These regulations establish standards for generators of hazardous waste.

(b) 40 CFR 261.5(c) and (d) must be used to determine the applicability of provisions of this part that are dependent on calculations of the quantity of hazardous waste generated per month.

40 CFR §261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators:

(c) When making the quantity determinations of this part and 40 CFR part 262, the generator must include all hazardous waste that it generates, except hazardous waste ... (that meets an exception).

(d) In determining the quantity of hazardous waste generated, a generator need not include: (1) Hazardous waste when it is removed from on-site storage; or (2) Hazardous waste produced by on-site treatment (including reclamation) of his hazardous waste, so long as the hazardous waste that is treated was counted once; or (3) Spent materials that are generated, reclaimed, and subsequently reused on-site, so long as such spent materials have been counted once.

- b. DEQ staff observed the different labs at AI Biotech during the inspection. Many of the labs are no longer operational as a result of contracts expiring and work stoppage as long ago as last summer and as recently as three weeks prior to the inspection. In the labs that are no longer being used, wastes have been allowed to remain along with discarded, expired chemicals and abandoned chemicals. AI Biotech has not properly made a hazardous waste determination in the laboratories. In addition, expired chemicals are placed in a cabinet labeled "R&D", identified as Research and Development. However, according to facility representatives, no R&D is being performed at this facility.

40 CFR §262.11 states in part: "A person who generates a solid waste, as defined in 40 CFR 261.2, must determine if that waste is a hazardous waste using the following method..."

- c. AI Biotech accumulated waste on-site for more than 180 days without a permit. Hazardous waste was shipped off-site on June 26, 2015 and not again until January 6, 2016.
- 40 CFR §262.34(f) [as referenced by 9 VAC 20-60-262] states in part: "A generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month and who accumulates hazardous waste in quantities exceeding 6000 kg or accumulates hazardous waste for more than 180 days (or for more than 270 days if he must transport his waste, or offer his waste for transportation, over a distance of 200 miles or more) is an operator of a storage facility and is subject to the requirements of 40 CFR parts 264, 265 and 267, and the permit requirements of 40 CFR part 270 unless he has been granted an extension to the 180-day (or 270-day if applicable) period..."
- d. DEQ personnel reviewed the hazardous waste manifests for the last three years. It was noted that hazardous waste manifest #001007142 dated January 6, 2016,

manifest #000873757 dated December 1, 2014, and manifest #000776673VES dated June 23, 2014 were not signed by the destination facility.

40 CFR §262.40 [as referenced by 9 VAC 20-60-262] states in part: “(a) A generator must keep a copy of each manifest signed in accordance with §262.23(a) for three years or until he receives a signed copy from the designated facility which received the waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.”

- e. DEQ personnel observed an unknown quantity of hazardous waste, expired chemicals and unexpired chemicals in bottles commingled throughout the facility. It could not be determined at the time of the inspection how much hazardous waste was on-site, and how long it had been present at the facility. Accumulation start dates were not observed on any hazardous waste containers.

40 CFR § 262.34(a) [as referenced by 9 VAC20-60-262] states: “Except as provided in paragraphs (d), (e), and (f) of this section, a generator may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status provided that: (2) The date upon which each period of accumulation begins is clearly marked and visible for inspection on each container;...”

- f. DEQ personnel observed an unknown quantity of hazardous waste, expired chemicals and unexpired chemicals in bottles commingled throughout the facility. Hazardous Waste labels were not observed on any hazardous waste containers.

40 CFR § 262.34(a) [as referenced by 9 VAC20-60-262] states: “Except as provided in paragraphs (d), (e), and (f) of this section, a generator may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status provided that: (3) While being accumulated on-site, each container and tank is labeled or marked clearly with the words, ‘Hazardous Waste.’”

- g. DEQ staff reviewed the facility training records, which are kept in computer file format. AI Biotech was unable to provide a written description of the training being provided at the Facility and documentation that employees had received hazardous waste management training.

40 CFR §262.34(d)(5)(iii) states in part: “The generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies...”

40 CFR 262.34(d)(2) states in part: (d) A generator who generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status provided that: (2) The generator complies with the requirements of subpart I of part 265 of this chapter..."

40 CFR §265.16 states in part: (a)(1) Facility personnel must successfully complete a program of classroom instruction or on-the-job training that teaches them to perform their duties in a way that ensures the facility's compliance with the requirements of this part. The owner or operator must ensure that this program includes all the elements described in the document required under paragraph (d)(3) of this section.

(d) The owner or operator must maintain the following documents and records at the facility:

(3) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph (d)(1) of this section;

(4) Records that document that the training or job experience required under paragraphs (a), (b), and (c) of this section has been given to, and completed by, facility personnel.

(e) Training records on current personnel must be kept until closure of the facility. Training records on former employees must be kept for at least three years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

h. AI Biotech was unable to provide documentation that it had attempted to arrange agreements with local authorities.

§265.37 Arrangements with local authorities.

(a) The owner or operator must attempt to make the following arrangements, as appropriate for the type of waste handled at his facility and the potential need for the services of these organizations:

(1) Arrangements to familiarize police, fire departments, and emergency response teams with the layout of the facility, properties of hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes;

(2) Where more than one police and fire department might respond to an emergency, agreements designating primary emergency authority to a specific police and a specific fire department, and agreements with any others to provide support to the primary emergency authority;

(3) Agreements with State emergency response teams, emergency response contractors, and equipment suppliers; and

(4) Arrangements to familiarize local hospitals with the properties of hazardous waste handled at the facility and the types of injuries or illnesses which could result from fires, explosions, or releases at the facility.

(b) Where State or local authorities decline to enter into such arrangements, the owner or operator must document the refusal in the operating record.

- i. AI Biotech staff was unable to provide written documentation of weekly inspections of all of their hazardous waste accumulation areas. Only monthly inspections were taking place in the main hazardous waste storage area.

40 CFR 265.174 [as referenced by 9VAC 20-60-265] Inspections - At least weekly, the owner or operator must inspect areas where containers are stored, except for Performance Track member facilities, that must conduct inspections at least once each month, upon approval by the Director. To apply for reduced inspection frequency, the Performance Track member facility must follow the procedures described in §265.15(b) (5) of this part. The owner or operator must look for leaking containers and for deterioration of containers caused by corrosion or other factors.

- j. AI Biotech had one accumulation area for universal waste located in the chemical storage area. DEQ staff observed one 4' cardboard cylinder containing both 4' lamps and 8' universal waste lamps. The cardboard cylinder was not closed.

40 CFR §273.13(d) states: "A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows: (1) A small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions."

- k. AI Biotech had one accumulation area for universal waste located in the chemical storage area. DEQ staff observed one cardboard container (cylinder) containing universal waste lamps. Only the lid of the container (cylinder) was labeled; however, the lid was not on the cylinder, therefore the container was not labeled.

40 CFR §273.14 states: "A small quantity handler of universal waste must label or mark the universal waste to identify the type of universal waste as specified below: (e) Each lamp or container or package in which such lamps are contained

must be labeled or marked clearly with one of the following phrases: "Universal Waste—Lamp(s)," or "Waste Lamp(s)" or "Used Lamp(s)."

1. AI Biotech had one accumulation area for universal waste located in the chemical storage area. DEQ staff observed one cardboard cylinder containing universal waste lamps. The universal waste container was not dated and AI Biotech could not demonstrate the length of time the universal waste lamps had been accumulated.

40 CFR §273.15(c) states in part: "A small quantity handler of universal waste who accumulates universal waste must be able to demonstrate the length of time that the universal waste has been accumulated from the date it becomes a waste or is received..."

- m. DEQ staff reviewed AI Biotech's training records. AI Biotech was unable to provide documentation that all staff members handling universal waste have been trained on universal waste management.

40 CFR 273.16 [as referenced by 9VAC 20-60-273] states: "Employee training - A small quantity handler of universal waste must inform all employees who handle or have responsibility for managing universal waste. The information must describe proper handling and emergency procedures appropriate to the type(s) of universal waste handled at the facility."

5. On April 25, 2016, a Request for Information was sent to AI Biotech. The request asked for a complete and accurate inventory of all wastes, expired chemicals and unexpired chemicals stored at the facility at the time of the inspection, including the material identification, quantity, and location.
6. On July 13, 2016, based on the inspection, the Department issued Notice of Violation No. 2016-07-PRO-602 to AI Biotech for the violations described in paragraphs C(4)(a) through C(4)(m), above.
7. On August 8, 2016, Department staff met with representatives of AI Biotech to discuss the violations.
8. On September 7, 2016, AI Biotech submitted documentation to DEQ in response to DEQ's Request for Information.
9. On August 7, 2017, AI Biotech informed DEQ that it had closed all business lines as of March 31, 2017 and is in the process of closing the lab and remediating the site.
10. Based on the results of the April 14, 2016 inspection, the August 8, 2016 meeting, and the documentation submitted on September 7, 2016, the Board concludes that AI Biotech has violated 40 CFR 262.10, 40 CFR 262.11, 40 CFR 262.34(a)(2), 40 CFR 262.34(a)(3), 40 CFR 262.34(d)(2), 40 CFR 262.34(d)(5)(iii), , 40 CFR 262.34(f), 40 CFR 262.40, 40

CFR 262.42, 40 CFR 265.15, 40 CFR 265.37(a) and (b), 40 CFR 265.174, 40 CFR 273.13, 40 CFR 273.14, 40 CFR 273.15, and 40 CFR 273.16, as described in paragraphs C(a) through C(m), above.

11. AI Biotech has submitted documentation that verifies that the violations described in paragraphs C(a), (b), (d-f), and (i-l), above, have been corrected.

SECTION D: Agreement and Order

Accordingly, by virtue of the authority granted it in Va. Code § 10.1-1455, the Board orders AI Biotech, and AI Biotech agrees to:

1. Pay a civil charge of \$32,500 in settlement of the violations cited in this Order. The civil charge shall be paid in accordance with the following schedule:

Due Date	Amount
November 1, 2017	\$3,750 or balance
February 1, 2018	\$3,750 or balance
May 1, 2018	\$3,750 or balance
August 1, 2018	\$3,750 or balance
November 1, 2018	\$3,750 or balance
February 1, 2019	\$3,750 or balance
May 1, 2019	\$3,750 or balance
August 1, 2019	\$3,750 or balance
October 1, 2019	\$2,500

2. If the Department fails to receive a civil charge payment pursuant to the schedule described above, the payment shall be deemed late. If any payment is late by 30 days or more, the entire remaining balance of the civil charge shall become immediately due and owing under this Order, and the Department may demand in writing full payment by AI Biotech. Within 15 days of receipt of such letter, AI Biotech shall pay the remaining balance of the civil charge. Any acceptance by the Department of a late payment or of any payment of less than the remaining balance shall not act as a waiver of the acceleration of the remaining balance under this Order.
3. All payments shall be made by check, certified check, money order or cashier's check payable to the "Treasurer of Virginia," and delivered to:

Receipts Control
Department of Environmental Quality
Post Office Box 1104
Richmond, Virginia 23218

4. AI Biotech shall include its Federal Employer Identification Number (FEIN) with the civil charge payment and shall indicate that the payment is being made in accordance with the requirements of this Order for deposit into the Virginia Environmental Emergency Response Fund (VEERF). If the Department has to refer collection of moneys due under this Order to the Department of Law, AI Biotech shall be liable for attorneys' fees of 30% of the amount outstanding.

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend this Order with the consent of AI Biotech for good cause shown by AI Biotech, or on its own motion pursuant to the Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, after notice and opportunity to be heard.
2. This Order addresses and resolves only those violations specifically identified in Section C of this Order and in NOV No.2016-07-PRO-602 dated July 13, 2016. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to: (1) taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations; (2) seeking subsequent remediation of the facility; or (3) taking subsequent action to enforce the Order.
3. For purposes of this Order and subsequent actions with respect to this Order only, AI Biotech admits the jurisdictional allegations, findings of fact, and conclusions of law contained herein.
4. AI Biotech consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.
5. AI Biotech declares it has received fair and due process under the Administrative Process Act and the Virginia Waste Management Act and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein. Nothing herein shall be construed as a waiver of the right to any administrative proceeding for, or to judicial review of, any action taken by the Board to modify, rewrite, amend, or enforce this Order.
6. Failure by AI Biotech to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority.
7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.
8. AI Biotech shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other unforeseeable circumstances beyond its control and not due to a

lack of good faith or diligence on its part. AI Biotech shall demonstrate that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. AI Biotech shall notify the DEQ Regional Director verbally within 24 hours and in writing within three business days when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:

- a. the reasons for the delay or noncompliance;
- b. the projected duration of any such delay or noncompliance;
- c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and
- d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

Failure to so notify the Regional Director verbally within 24 hours and in writing within three business days, of learning of any condition above, which the parties intend to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto and any successors in interest, designees and assigns, jointly and severally.
10. This Order shall become effective upon execution by both the Director or his designee and AI Biotech. Nevertheless, AI Biotech agrees to be bound by any compliance date which precedes the effective date of this Order.
11. This Order shall continue in effect until:
 - a. The Director or his designee terminates the Order after AI Biotech has completed all of the requirements of the Order;
 - b. AI Biotech petitions the Director or his designee to terminate the Order after it has completed all of the requirements of the Order and the Director or his designee approves the termination of the Order; or
 - c. The Director or Board terminates the Order in his or its sole discretion upon 30 days' written notice to AI Biotech.

Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve AI Biotech from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. Any plans, reports, schedules or specifications attached hereto or submitted by AI Biotech and approved by the Department pursuant to this Order are incorporated into this Order. Any non-compliance with such approved documents shall be considered a violation of this Order.
13. The undersigned representative of AI Biotech certifies that he or she is a responsible official authorized to enter into the terms and conditions of this Order and to execute and legally bind AI Biotech to this document. Any documents to be submitted pursuant to this Order shall also be submitted by a responsible official of AI Biotech.
14. This Order constitutes the entire agreement and understanding of the parties concerning settlement of the violations identified in Section C of this Order, and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this Order.
15. By its signature below, AI Biotech voluntarily agrees to the issuance of this Order.

And it is so ORDERED this 30 day of November, 2017.


Jefferson D. Reynolds, Enforcement Director
Department of Environmental Quality

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American International Biotechnology, LLC voluntarily agrees to the issuance of this Order.

Date: 10/12/2017 By: David G. Bastwick Owner
(Person) (Title)
American International Biotechnology, LLC

Commonwealth of Virginia
City/County of Chesterfield

The foregoing document was signed and acknowledged before me this 12th day of October, 2017, by David G. Bastwick who is Owner of American International Biotechnology, LLC, on behalf of the company.

Margo Jean Vogel
Notary Public

7730303

Registration No.

My commission expires: 2/28/21

Notary seal:

