UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

JAN 14 2020

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Camille I. Farhat
Chief Executive Officer
RTI Surgical, Inc.
11621 Research Circle
Alacha, Florida 32616-2650

SUBJ: Request for Information
RTI Surgical East - EPA ID#FLR000086892
RTI Surgical West - EPA ID#FLR000110635

Dear Mr. Farhat:

On November 20, 2019, the U.S. Environmental Protection Agency, along with the Florida Department of Environmental Protection, conducted a RCRA compliance evaluation inspection (CEI) at the RTI Surgical East and RTI Surgical West facilities located in Alachua, Florida to determine the facilities' compliance status with the Resource Conservation and Recovery Act (RCRA) and Chapter 403 of the Florida Statutes (Fla. Stat.), Fla. Stat. § 403.702 *et seq. et seq.* and applicable regulations.

Pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927, RTI Surgical, Inc. is hereby directed to respond, fully and truthfully, within thirty (30) calendar days of receipt of this letter, to the Information Request enclosed herein as Enclosure C (subject to the Instructions in Enclosure A, and the Definitions in Enclosure B). Compliance with this request for information is mandatory, and information provided by RTI Surgical, Inc. may be used by the EPA in future enforcement actions. Failure to respond fully and truthfully to each and every question or information request within thirty (30) calendar days of receipt of this letter, or to adequately justify such failure to respond, may result in further enforcement action against RTI Surgical, Inc. by the EPA pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928.

Your response to this request for information should be mailed to:

Kimberly L. Bingham
Acting Chief, Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division
U.S. EPA, Region 4
61 Forsyth St., SW
Atlanta, Georgia 30303.

The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets. RTI Surgical, Inc. may, if desired, assert a business confidentiality claim covering part or all of the information requested, in the manner described in 40

C.F.R. § 2.203(b), by attaching to such information, at the time it is submitted, a suitable notice employing language such as trade secret or proprietary or company confidential. Information covered by such a claim will be disclosed by the EPA only to the extent and only by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. If no such claim accompanies the information when it is received by the EPA, it may be made available to the Public by the EPA without further notice to RTI Surgical, Inc. The EPA will construe the failure to furnish a confidentiality claim with your response to this letter as a waiver of that claim. RTI Surgical, Inc. should read the above-cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim.

This Information Request is not subject to the approval requirement of the Paper Reduction Act of 1980, 44 U.S.C. § 3501 et seq.

Should you have any questions on this matter, please contact Daryl R. Himes, of my staff, by phone at (404) 562-8614 or by email at himes.daryl@epa.gov.

Sincerely,

Kimberly L. Bingham
Acting Chief
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division

Enclosures

ENCLOSURE A

INFORMATION REQUEST

Instructions:

1. Identify the person(s) responding to these Information Requests on behalf of Respondent.

2. A separate response must be made to each of the Information Requests set forth herein.

3. Precede each answer with the number of the Information Request to which it corresponds.

4. In answering each Information Request question, identify all documents and persons consulted, examined, or referred to in the preparation of each response and provide true and accurate copies of all such documents.

5. If information not known or not available to you as of the date of submission of a response to this Information Request should later become known or available to you, you must supplement your response to the EPA. Moreover, should you find at any time after the submission of its response that any portion of the submitted information is false or misrepresents the truth; you must notify the EPA thereof as soon as possible.

6. For each document produced in response to this Information Request, indicate on the document, or in some other reasonable manner, the number of the question to which it responds.

7. Where specific information has not been memorialized in a document, but is nonetheless responsive to the Request, you must respond to the question with a written response.

8. If information responsive to this Information Request is not in your possession, custody or control, then identify the person from whom such information may be obtained.

9. If you have reason to believe that there may be persons able to provide a detailed or complete response to any Information Request question or who may be able to provide additional responsive documents, identify such persons and the additional information or documents that they may have.

10. The information requested herein must be provided even though the Respondent may contend that it includes possibly confidential information or trade secrets. You may, if you desire, assert a confidentiality claim covering part or all of the information requested, pursuant to Section 3007(b) of RCRA, 42 U.S.C. Section 6927(b), Sections 104(e)(7)(E) and (F) of CERCLA, 42 U.S.C. Sections 9604(e)(7)(E) and (F), and 40 C.F.R. Section 2.203(b), by attaching to such information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as trade secret, or proprietary, or company confidential. Information covered by such a claim will be disclosed by the EPA only to the extent, and only by means, of the procedures set forth in statutes and regulation set forth above. If no such claim accompanies the information when it is received by the EPA, it may be made available to the public by the EPA without further notice to you. You should read the above cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim.

ENCLOSURE B

INFORMATION REQUEST

Definitions:

The following definitions shall apply to the following words as they appear in this Enclosure.

1. The terms AND and OR shall be construed either disjunctively or conjunctively as necessary to bring within the scope of this Information Request any information which might otherwise be construed to be outside their scope.

2. The term DISPOSAL shall mean the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any water, including groundwater.

3. The term DOCUMENT and DOCUMENTS shall include writings of any kind, formal or informal, whether or not wholly or partially in handwriting (including by way of illustration and not by way of limitation), any invoice, receipt, endorsement, check, bank draft, canceled check, deposit slip, withdrawal slip, order, correspondence, record book, minutes, memorandum of telephone and other conversations including meetings, agreements and the like, diary calendar, desk pad, scrapbook, notebook, bulletin, circular, form, pamphlet, statement, journal, postcard, letter, telegram, telex, report, notice, message, analysis, comparison, graph, chart, inter-office or intra-office communications, photostat or other copy of any documents, microfilm or other film record, photograph, sound recording on any type of device, punch card, disc or disc pack, tape or other type of memory generally associated with computers and data processing (together with the programming instructions and other written material necessary to use punch card, disc, disc pack, tape or the type of memory) including; (a) every copy of each document which is not an exact duplicate of a document which is produced, (b) every copy which has any writing, figure, notation, annotation, or the like of it, (c) drafts, (d) attachments to or enclosures with any document, and (e) every document referred to in any other document.

4. The term FACILITIES shall mean RTI Surgical East located at 11621 Research Circle, Alachua, Florida and RTI Surgical West located at 13709 Progress Boulevard #19, Alachua, Florida.

5. The term GENERATION shall mean any act or process which produces hazardous waste as identified or listed in 40 C.F.R. Part 261 or an act which first causes a hazardous waste to become subject to regulation.

6. The term HAZARDOUS SUBSTANCE means: (a) any substance designated pursuant to Section 311(b)(2)(A) of the Federal Water Pollution Control Act; (b) any element, compound, mixture, solution, or substance designated pursuant to Section 102 of CERCLA; (c) any hazardous waste having the characteristics identified under or listed pursuant to Section 3001 of RCRA (but not including any waste the regulation of which under RCRA has been suspended by Act of Congress); (d) any toxic pollutant listed under Section 307(a) of the Federal Water Pollution Control Act; (e) any hazardous air pollutant listed under Section 112 of the Clean Air Act; and (f) any imminently hazardous chemical substance or mixture with respect to which the Administrator of the EPA has taken action pursuant to Section 7 of the Toxic Substances Control Act. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise

specifically listed or designated as a hazardous substance under subparagraphs (a) through (f) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). HAZARDOUS SUBSTANCE shall include any mixtures of such hazardous substances with any other substances including petroleum products.

7. The term HAZARDOUS WASTE means a hazardous waste as defined in 40 C.F.R. § 261.3.

8. The term IDENTIFY means, with respect to a natural person, to set forth the person's name, present or last known business address and business telephone number, present or last known home address and home telephone number, and present or last known job title, position or business.

9. The term IDENTIFY means, with respect to a corporation, partnership, business trust or other associate of a business entity (including a sole proprietorship), to set forth its full name, address, legal form (e.g., corporation, partnership, etc.), organization, if any, and a brief description of its business.

10. The term IDENTIFY means, with respect to a document, to provide its customary business description, date, number, if any (invoice or purchase order number), the identity of the author, addressor, addressee and/or recipient, and the substance or the subject matter.

11. The term PERSON includes, in the plural as well as the singular, any natural person, firm, unincorporated associate partnership, corporation, trust or other entity.

12. The term POLLUTANT or CONTAMINANT shall include, but not be limited to, any element, substance, compound or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including a malfunction in reproduction) or physical deformation in such organisms or their offspring; except that the term POLLUTANT or CONTAMINANT shall not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (a) through (f) of Definition 5 above, and shall not include natural gas, liquefied natural gas, or synthetic gas of pipeline quality (or mixtures of natural gas and such synthetic gas). POLLUTANT or CONTAMINANT shall include any mixtures of such pollutant and contaminants with other substances, including petroleum products.

14. The term TRANSACTION or ARRANGEMENT shall mean every separate agreement, act, deal, instance or occurrence.

15. The term YOU or RESPONDENT shall mean the addressee of this Information Request, the addressee's officers, managers, employees, contractors, trustees, successors, assigns, and agents.

ENCLOSURE C

INFORMATION REQUEST

Background for Request Numbers 1-4

The U.S. Environmental Protection Agency Region 4 (EPA) conducted a compliance evaluation inspection (CEI) at the RTI Surgical, Inc. facilities located at 11621 Research Circle, Alachua, Florida (RTI Surgical East) and at 13709 Progress Boulevard #19, Alachua, Florida (RTI Surgical West) on November 20, 2019 to determine each of the facilities' compliance status with the RCRA.

Prior to conducting the CEIs at the facilities, the EPA received information from American Distillation Incorporated (ADI) located in Leland, North Carolina which indicated that ADI had received shipments from RTI Surgical East containinig isopropyl alcohol (IPA) and separate shipments containing acetone. The following are requests for information regarding the facilities generation and management of the isopropyl alcohol and acetone materials which were sent to ADI.

Request Number 1

Please provide copies of any and all documents which were used to make hazardous waste determinations in accordance with 40 CFR § 262.11 on the IPA and/or acetone which were previously shipped to ADI. In addition, please submit copies of any and all physical and/or chemical analysis performed on any shipment of IPA and/or acetone were shipped to ADI in the past five years.

Request Number 2

Please provide copies of any and all Bills of Lading, manifests, or other transportation related papers for all shipments of IPA and acetone from the facilities to ADI during past five years. Please exclude copies of Bills of Ladings for all shipments identified on a zip drive provided by Daryl Himes of the EPA to RTI Surgical, Inc. personnel present during the November 20, 2019 CEIs.

Request Number 3

For any and all shipments of IPA or acetone which have been shipped from the facilities to ADI during the past five years, please provide corresponding copies of any and all financial documents which reflect payments made for the transfer of the IPA or acetone. Please include a line item breakdown of the costs associated with the payments.

Request Number 4

Please provide copies of any and all Bills of Ladings, manifests, or other transportation related papers for all shipments of IPA and acetone from the facilities to any person other than ADI during past five years. In addition, please provide corresponding copies of any and all financial documents which reflect payments made for the transfer of the IPA or acetone to this person. Please include a line item breakdown of the costs associated with the payments.

ENCLOSURE C

Background for Request Number 5

On May 15, 2015, a letter from Barry White, Plant Manager, of ADI was sent to Lior Busel, Environmental, Heath & Safety Director or RTI Surgical, Inc. concerning future shipments from RTI Surgical, Inc. to ADI.

Request Number 5

Please provide any and all contractual documents, aggreements and correspondence between RTI Surgical, Inc. and ADI pertaining to the transfer of IPA and/or acetone during the past five years.

Requiest Number 6

Please provide copies of any and all hazardous waste manifests for shipments of hazarsdous waste from the facilities to an off-site facility during the past five years.

Request Number 7

Please provide copies of any any all documents which demonstrate that the facilities' hazardous waste contingency plans have been submitted to local hospitals, fire departments and police departments.

Requiest Number 8

Please provide copies of any and all documents which demonstrate when 55-gallon drums of acetone were transported from RTI Surgical West to RTI Surgical East prior to being transported to ADI during the past five years.

Requiest Number 9

Please state how acetone was moved from RTI Surgical West to RTI Surgical East prior to shipment to ADI.