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April 30, 2021

Ms. Kathy Joubert, Town Planner
Town of Northborough
Northborough Town Offices
63 Main Street
Northborough, MA 01532

**RE: Peer Review Letter – Facility Expansion Project
425 Whitney Street, Northborough, Massachusetts**

This letter is to advise that we have reviewed two response memorandums from Steris A.S.T addressed to the Northborough Planning Board dated January 28, 2020 and May 27, 2020, respectively. We conducted a point-by-point review of these memorandums and have commented as appropriate with available information. See attached response memorandums with our comments inserted. For references and background information we refer you to our previous letter dated February 25, 2021.

Donald Flahardy

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Donald T. Flahardy, CHP
Director of Operational Health Physics
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Attachments:

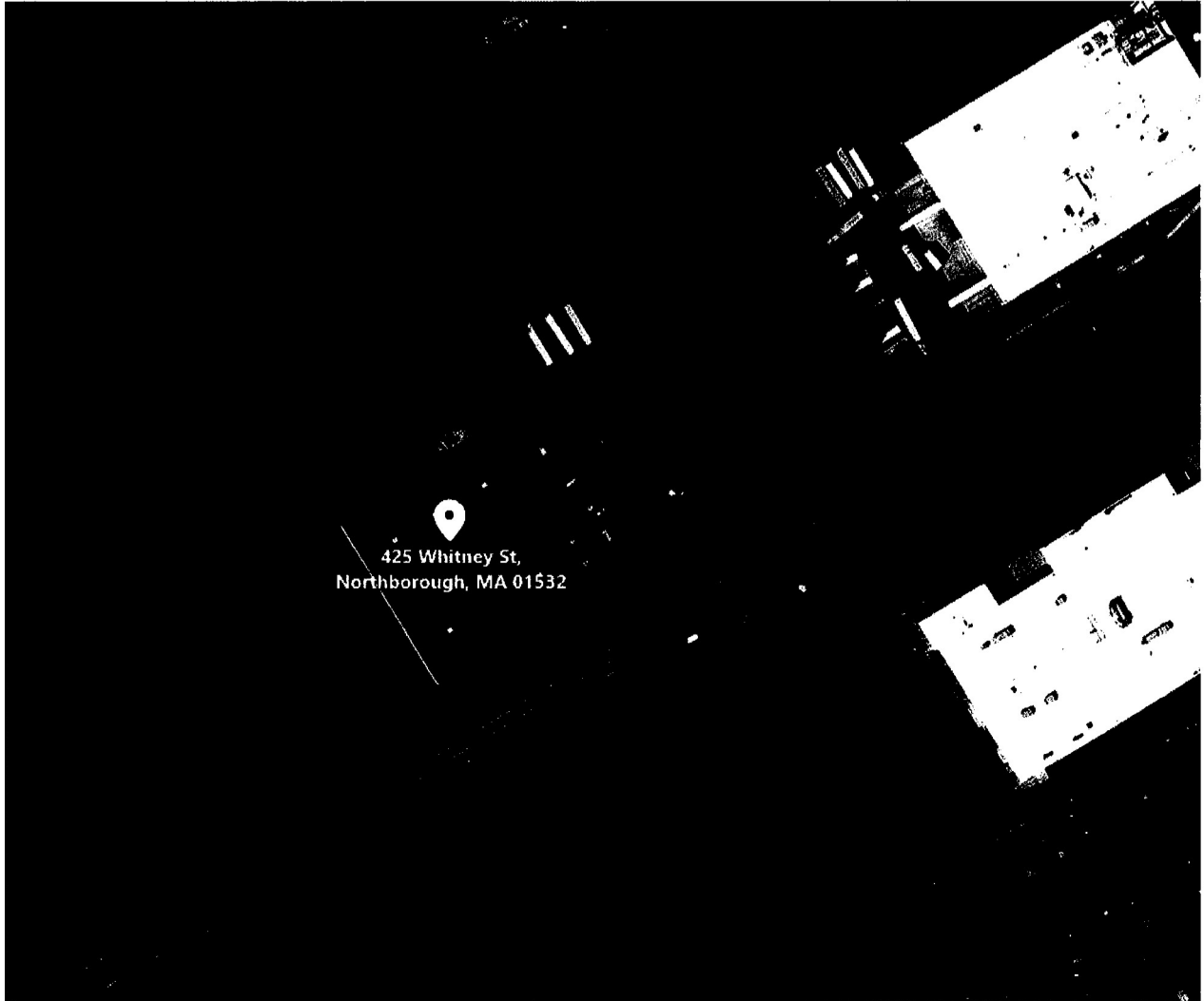
Response Memorandum from STERIS A.S.T. Response to Request for Additional Information. January 28, 202

Response to Northborough Planning Board's Second Request for Additional Information; Site Plan Approval - 425 Whitney Street May 27, 2020

Response Memorandum from STERIS A.S.T.


Northborough Planning Board

Re: 425 Whitney Street



Memorandum

TO: Ms. Kerri Martinek, Chair, Northborough Planning Board

FROM: Stephen F. Madaus, on behalf of STERIS, A.S.T. 

DATE: January 28, 2020

RE: Response to Request for Additional Information

This memorandum is in response to a letter received by STERIS A.S.T. (the "Applicant") from the Northborough Planning Board (the "Planning Board"), dated November 15, 2019. By its letter, the Planning Board requested additional information to assist the Board in its review of the Applicant's applications for Site Plan Approval (Section 07-03-050 of the Zoning Bylaw) and for a Special Permit pursuant to the Groundwater Protection Overlay District (Section 7-07010 of the Zoning Bylaw), concerning property located at 425 Whitney Street in Northborough (the "Property" or the "Site"). A copy of the Planning Board's letter is attached as Exhibit A.

To ensure a comprehensive response to the Planning Board's request for additional information, the Applicant cut and pasted each of the line items or topics listed in the Planning Board's letter and provided its response to each item in italics. The Applicant previously submitted with its applications a full Site Plan, entitled "Facility Expansion Project, 425 Whitney Street, Northborough, Massachusetts", prepared by VHB (the "Site Plan"). The proposed improvements to the Property, as shown on the Site Plan, are referred to herein as the "Project".

MIRICK O'CONNELL

Conformity with Section 7.2 Submission Requirements per the Planning Board's Rules and Regulations.

1 Application narrative in accordance with Section 7.2 B (1-11)

B. Application narrative. To assist the Planning Board with its review, the Applicant shall provide a concise narrative about the proposed project. At minimum, the narrative shall include the following information:

(1) *The proposed use(s).*

The Applicant 's proposed use involves receiving new products manufactured by others, such as medical devices, equipment and consumer products (e.g., paper products, plastic products, bandages, gauze) and to process these products through an X-Ray Pallet System, to sterilize the medical devices, equipment and consumer products. The medical devices, equipment and consumer products remain in their original packing (on pallets) during the processing. After processing, the medical devices, equipment and consumer products are shipped to their designated destinations.

C.N. Comments: The Steris description for the proposed use of the X-Ray Pallet System is consistent with the available literature that describes the purpose and use of these systems.

Application narrative sections 7.2B (2-11) are non-radiological in nature. C.N. has no comments

(2) The projected increase in traffic trips generated by the project.

See the "Transportation Impact Assessment", dated January 21, 2020, prepared by Mr. Jeffery Dirk, P.E., of Vanasse Associates, Inc. attached hereto as Exhibit B. The prior use of the existing building was for warehousing of wood and wood products for an architectural millwork company. See Table 2, "Traffic Volume Comparison ", in the Transportation Impact Assessment; it is estimated that the prior use generated 304 traffic trips per weekday. The Applicant 's proposed new use of the Property is estimated to generate 320 traffic trips per weekday. Accordingly, the net increase in traffic trips per weekday is estimated to be 16.

(3) The projected public water and sewer demand, if any.

The Applicant 's proposed use and occupancy of the existing building is estimated to result in a public water consumption 0/400-500 gallons per day. The existing water connection is sufficient for this' demand.

Relative to sewer service, the Applicant proposes 10 either extend the existing public sewer main in Whitney Street to serve the Property (if elevations allow), or to install a force main along Whitney Street which will connect to the existing gravity sewer system. The Applicant will remove the existing septic system in accordance with all applicable requirements and connect the building to the extended sewer line. The demand for sanitary sewer service for the Project is

estimated to be 400-500 gallons per day, based on 310 CMR 15.203, "System Sewage Flow Design Criteria "for a "Factory, Industrial Plant, Warehouse or Dry Storage Space " use.

(4) A list of all other required local, state and federal permits, and the status of each.

A dimensional variance is required from the Northborough Zoning Board of Appeals to allow for the construction of the proposed addition to the existing building within 20' of the side-yard property line, as shown on the Site Plan. The Northborough Zoning Board of Appeals voted to grant the requested dimensional variance at its meeting on August 27, 2019 and the decision was filed with the office of the Town Clerk on September 25, 2019. A neighboring property owner filed an appeal of the ZBA's decision with the Massachusetts Land Court on October 15, 2019. The litigation is pending in the Land Court.

An Order of Conditions from the Northborough Conservation Commission, pursuant to the Wetlands Protection Act, is required for the Project. EcoTec, Inc. prepared a Notice of Intent on behalf of the Applicant, which was filed with the Conservation Commission on September 24, 2019. The Conservation Commission held a public meeting to consider The Notice of Intent on October 7, 2019; at that meeting the Conservation Commission voted to approve an Order of Conditions. The Order of Conditions for the Project was issued on October 23, 2019.

A Special Permit pursuant to the Ground Water Protection Overlay District is required.

The Property is within the Groundwater Protection Overlay District, Area 3 as established by the Town's Zoning Map and Bylaw and, therefore, a special permit is required under Zoning Bylaw section 7-07-010. D (3)(c)[4]. In accordance with Zoning Bylaw section 7-07-010.D. (4)(a), the Applicant submitted a letter prepared by VHB dated September 13th, 2019 to document chemicals expected to be used and stored on-site. Since that letter was submitted to the Town's Groundwater Advisory Board, the Applicant recognized additional chemicals to be stored at the Property. The Applicant notified the Town's Groundwater Advisory Board of the additional chemicals that had not originally been anticipated. Accordingly, the Applicant's site engineer, VHB, submitted a revised letter dated January 22, 2020, documenting the latest chemical use and storage information, which is attached hereto as Exhibit C (without exhibits).

As further described herein, registration with the Massachusetts Department of Public Health (MA DPH), Radiation Control Program is required to operate the X-Ray Processing/Treatment System.

(5) The size of the proposed building(s) or addition.

As shown on the Site Plan, the existing building consists of approximately 45,753 sq. ft. The proposed additions to the existing building will add 20,100 sq. ft. and 3,400 sq. ft., respectively, for a total building size of approximately 69,253 sq. ft.

(6) The estimated number of employees for the project.

It is estimated that there will be 25 full time employee working at the Property, post completion of the Project.

(7) The number of parking spaces required to serve the use(s) in the project.

See the "Parking Summary Chart" on sheet C-2 of the Site Plan; the number of parking spaces required, according to the Zoning Bylaw, is 38 spaces and 38 parking spaces will be provided.

(8) The proposed methods of screening the premises and off-street parking from abutting property and the street.

As shown on sheet L-1, Planting Plan, of the Site Plan, the off-street parking area will be screened from abutting property in the Industrial Zoning District by a chain link fence and existing vegetation along the rear of the Property.

(9) Calculation of existing and proposed lot coverage.

As shown on sheet C-2 of the Site Plan, the existing lot coverage of the Property is 21%; the proposed lot coverage is 33%.

(10) For a project plan filed under an approved Industrial/Office Campus master plan special permit, the Applicant shall also provide written statements that the project for which a building permit is sought complies with (a) the master plan special permit, (b) the uses permitted within an IOCD and (c) all requirements of {7-10-030 of the Zoning Bylaw.

Not Applicable — the Project not part of an Industrial/Office Campus master plan.

(11) Any other information the Applicant believes will assist the Planning Board in reviewing and understanding the site plan application and making the required Northborough Planning Board determinations under Section 6.5 of these Regulations and 0703-050 of the Zoning Bylaw.

Applicant seeks to make use of an existing commercial warehouse building, constructed in 1980, in [the Town 's Industrial Zoning District. The Applicant 's proposed use is allowed as of right in the Industrial Zoning District as "Light Manufacturing: processing", as determined by the Town 's Building Inspector, in his capacity as enforcement officer under The Zoning Bylaw (Section 7-03-0080). The Project will comply with all requirements of the Zoning Bylaw.

2. Site design contents in accordance with Section 7.2. C. (1-20)

Section 7.2. C. (1-20) are non-radiological in nature. C.N. has no comments

C. Site plan contents. The site plan shall be at a scale of one inch equals forty feet (1 " = 40'), prepared and stamped by an architect, landscape architect, or professional engineer registered in the Commonwealth of Massachusetts, as applicable, and shall show the following:

- (1) Existing and proposed boundaries of the site.

Boundaries are as shown on sheet C-2 of the Site Plan. No changes to the boundaries of the Property are proposed.

- (2) Site area and zoning classification(s).

The Property is known as and located at 425 Whitney Street and consists of approximately 5 acres of land (217,800 sq. ft.) located in the Industrial (I) Zoning District. The Property is also located in the Groundwater District 3 Overlay District.

- (3) Ownership of abutting land.

As shown on the Site Plan, the Property is bound on two sides (the rear property line and the eastern sideline) by land of Anza Santo/429 Whitney Street Realty Trust and on one side (the western sideline) by land Consolidated Rail Corp. (a railroad line).

- (4) A north arrow and locus map showing the project within the Town at a scale of one (1) inch equals one hundred (100) feet, and the location and use of any building thereon within three hundred (300) feet of the boundary of the site. The Northborough Assessor Maps, as amended to the date of the site plan application, shall be acceptable to show the use and ownership information required herein.

See the Site Plan submitted by Applicant.

- (5) Location of the site in relation to the Groundwater Protection Overlay District as shown on the Northborough Zoning Map, on file with the Town Clerk.

See the Site Plan submitted by Applicant.

- (6) Location of site in relation to the Floodplain District under 7-07-020.

As indicated on the Federal Emergency Management Agency 's (FEMA) Flood Insurance Rate Map (FIRM) and the National Flood Hazard Layer FIRMette, the Property is not within the mapped Floodplain District.

- (7) Existing and proposed topographical contours of the site taken at two-foot (2') contour intervals by a registered engineer or registered land surveyor. The contours shall extend at least fifty (50) feet beyond the site boundaries, as estimated by the professional preparing the plan.

See sheet C-3, "Grading, Drainage, and Erosion Control Plan ", of the Site Plan submitted by the Applicant.

- (8) Location of all wetlands or water bodies on the site and within one hundred (100) feet of the perimeter of the development activity.

See sheet C-3, "Grading, Drainage, and Erosion Control Plan ", of the Site Plan submitted by the Applicant.

- (9) The nature, location, and size of all significant existing natural land features, including but not limited to tree, shrub, or brush masses, specimen trees and all other trees over ten (10) inches in diameter at breast height, grassed areas, and soil features.

See the "Existing Conditions Plan of Land" of the Site Plan submitted by the Applicant.

- (10) Engineering cross-sections of proposed new curbs and pavements, and vision triangles measured in feet from any proposed curb cut along the street on which access is proposed.

See sheet C-5, "Site Details I ", of the Site Plan submitted by the Applicant. No new curb cuts are proposed for the Property.

- (11) Proposed surface treatment(s) of paved areas and the location and design of drainage systems, with drainage calculations prepared by a registered civil engineer.

See sheets C-3, "Grading, Drainage and Erosion Control Plan " and C-4, "Utility Plan " of the Site Plan submitted by the Applicant.

- (12) Comprehensive parking and traffic circulation plan, showing location and dimensions of proposed parking spaces, dividers, bumper stops, required buffer areas and planting beds, the location and dimensions of proposed pedestrian walkways, and provisions for accessible parking and circulation for people with disabilities.

See the Site Plan submitted by Applicant, including Sheet C-2, "Layout and Materials Plan ", showing location of existing and proposed parking spaces and pedestrian walkways.

- (13) Location, height, elevation, interior and exterior dimensions and uses of all buildings or structures, both proposed and existing; location, number and area of floors; number and type of dwelling units or proposed leasable areas; location of emergency exits, retaining walls, existing and proposed signs.

See the Site Plan submitted by Applicant, including Sheet C-2, "Layout and Materials Plan", and Sheet A 201, 'Exterior Elevations'".

- (14) A table that summarizes all zoning requirements that apply to the project and demonstrates how the project complies with each such requirement.

See the "Zoning Summary Chart" on Sheet CO of the Site Plan submitted by the Applicant.

- (15) Provisions for waste disposal, drainage, dust, erosion control, and other utilities including the proposed water supply system showing proposed fire hydrant locations, and any proposed sewer, electric, telephone, gas and cable television utilities.

See Sheet C-4, " Utility Plan ", of the Site Plan submitted by the Applicant.

- (16) Plans and documents illustrating the proposed system of wastewater collection, treatment and disposal, along with documentation regarding the proposed treatment technology.

See Sheet C-4 of the Site Plan submitted by the Applicant, showing the connection of [the existing building to a new Sewer Force Main, to be constructed by Applicant in Whitney Street. See Note on Sheet C-4: "Existing ,, septic system to be removed. Sanitary sewer to be rerouted through building to force main.

- (17) Proposed stormwater management system, which shall be designed in accordance with the Massachusetts Department of Environmental Protection (DEP) Stormwater Management Policy Handbook and Technical Handbook as most recently amended, whether or not the proposed work falls within the jurisdiction of the Wetlands Protection Act, M.G.L. c. 131, 40.

See sheets C-3, "Grading, Drainage, and Erosion Control Plan ", and C-4 "Utility Plan " of the Site Plan and see the Stormwater Report submitted by the Applicant, entitled "Facility Expansion Project" prepared for Isomedix Operations Inc., 425 Whitney Street, Northborough, MA by VHB, dated September 2019, Revised October 2019 (copy attached hereto as Exhibit D, without Appendices). The Stormwater Report provides: "The rainfall-runoff of the Site under existing and proposed conditions was analyzed for storm events with recurrence intervals of 2-, 10-, 25-, and 100-years. The results of the analysis... indicated that the post-development net runoff volume does not exceed existing conditions

by more than fifteen percent (15%) for the 2-, 10-, 25-, and 100-year storm events. " The Stormwater Report was reviewed and approved by the Conservation Commission and the Town Engineer.

- (18) Lighting plan showing existing and proposed lighting, including intensity, pole height, design and direction. A photometric plan shall be submitted.

See the photometric plan prepared by Omni-Lite, Inc., dated September 13, 2019, showing the levels of illuminance on the Site. The plan is attached here[o as Exhibit E

- (19) Landscaping plan showing existing and proposed landscape features, including trees, signs, fences, walls, plantings, and walks, and the location, name, number and size of plant types, and the locations and elevation and/or height of planting beds, fences, walls, steps and paths.

See Sheet L-1, "Planting Plan " and Sheet L-2, "Planting Details ", of the Site Plan submitted by the Applicant.

- (20) Where the Zoning Bylaw requires the provision of open space, the Applicant's declaration of his choice of method or methods of dedicating the required open space, consistent with the provisions of the Zoning Bylaw, along with proposed covenants and restrictions to secure the permanent legal existence of the preserved open space and the proposed wording of any deed for transfer in fee to the Town or to a nonprofit organization.

Not Applicable.

3. Development impact analysis in accordance with Section 7.2 D (1) (a-d).

D. Additional requirements. The site plan application shall also include:

(1) Development impact analysis, including:

- (a) Traffic impact: projected total and peak-hour trip generations, capacity and pre- and post Project (buildout) level of service (LOS) of streets and intersections to be affected by the Project, existing and proposed traffic controls and sight lines at the intersections of proposed driveways and streets.

See the Transportation Impact Assessment prepared by Mr. Jeffery Dirk, P.E., of Vanasse & Associates, Inc., dated December 13, 2019, attached hereto as Exhibit B.

Traffic impact is non-radiological in nature. C.N. has no comments

(b) Environmental impact: written analysis of the project's potential impacts on the quality of air, surface water and groundwater; flooding potential; increases in impervious surfaces; stormwater management; compliance with Groundwater Protection Overlay District requirements; hazards from radioactive emissions or other hazardous materials; solar access to adjacent properties; and noise and light impacts.

The Project will comply with all applicable federal and state environmental regulations. Relative [o surface water, groundwater and flooding potential, see the Stormwater Report submitted by [he Applicant, entitled "Facility Expansion Project" prepared by Isomedix Operations Inc., 425 Whitney Street, Northborough, MA by VHB, dated September 2019, Revised October 2019, attached hereto as Exhibit D (without Appendices). The Stormwater Report was reviewed and approved by the Conservation Commission and the Town Engineer.

Relative to radioactive emissions, there will be no radioactive emissions or other hazardous materials released from the Property; the sterilization operation does not utilize or create radioactive material.

C. N. Comments: C.N. agrees with Steris that the operation of the pallet sterilizer does not use nor create radioactive material. C.N. agrees that there will be no radioactive emissions from the property.

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Relative to solar access, to the best of the Applicant's knowledge, no adjacent properties will be impacted by the Project for solar access.

Noise impacts will be shown on an acoustical study to be provided. The Applicant has retained Tech Environmental of Waltham, MA to provide the acoustical study.

Light impacts are as shown on the photometric plan prepared by Omni-Lite, Inc., dated September 13, 2019, attached hereto as Exhibit E.

(c) Fiscal impact: projections of costs rising from increased demand for public services and infrastructure; projections of benefits from increased tax revenues, employment and infrastructure improvements; and impacts on adjacent property values.

The Applicant's proposed use and occupancy of the Property is likely to enhance the tax revenue for the Town of Northborough because a viable business will take occupancy of a vacant warehouse building in the Industrial Zoning District. Furthermore, provided the dimensional variance is upheld, the Applicant will expand the square footage of the commercial building. There will be no perceivable increase in demand for public services arising from the Applicant's use of the Property. Furthermore, the traffic engineer, Vanasse and Associates, Inc., determined that based on its comparative analysis, "it is clear that the Project will result in comparable traffic volumes and impacts to those of the former architectural millwork company that occupied the Project site." The Applicant's proposed use will result in the establishment of approximately 25 full time employment positions in Northborough. There should be no impact on adjacent property values attributable to the Applicant's use and occupancy of a vacant commercial building in the Industrial Zoning District; the building has been in use for commercial/industrial purposes since 1980.

(d) Community impact: analysis of the project's impact on the surrounding neighborhood in terms of architectural character, pedestrian movement and overall character; impacts on nearby historic structures or sites; and an evaluation of the proposed project's consistency and compatibility with existing local and regional plans.

Relative to architectural character, the proposed addition to the building will be consistent with the design of the existing commercial building in the Industrial Zoning District. The Applicant is not aware of any potential impact of the Project on nearby historic structures or sites. The Project is consistent with the determination and intent of Northborough Town Meeting, when it voted (by a two-thirds vote) to designate the zoning for this Property as Industrial.

Light Manufacturing Use

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Provide data and facts that support that the operations meet the use criteria in accordance with Section 7-05-020 11).

Response: The Zoning Bylaw lists the following as an allowed use in the Industrial Zoning District:

1. Industrial uses.

(1) Light manufacturing: Fabrication, processing, packaging, or assembly operations, employing only electric or other substantially noiseless and inoffensive motor power, utilizing hand labor or quiet

machinery and processes, and free from neighborhood-disturbing agents such as odors, gas, fumes, smoke, cinders, refuse matter, electromagnetic radiation, heat, vibration, or noise; provided, that all operations are located entirely within an enclosed building and there is no outside storage of materials or finished goods.

The Applicant 's proposed use qualifies as "light manufacturing —processing. " The term processing is not defined in the Northborough Zoning Bylaw, so it must be given its common and usual meaning. The term "process " is defined as "a systematic series of actions directed to some end; a continuous action, operation, or series of changes taking place in a definite manner ". The verb of processing is defined as, "to treat or prepare by some particular process, as in manufacturing. " The American College Dictionary; 1969. The Applicant 's proposed use involves the receiving of products or goods in containers, which are then run through an x-ray system which sterilizes the material. The products or goods are then shipped out. This use is clearly a "systematic series of actions directed to some end.

The x-ray system is powered by electricity and is located is entirely within an enclosed building (surrounded by walls that are twelve-feet thick). The processing of goods and products is free from neighborhood disturbing agents — the processing will not emit odors, smoke, cinders, refuse matter, electromagnetic radiation, heat, vibration or noise. While some gas may be emitted from the processing operation, it is not at a detectible or reportable level and will not cause any neighborhood disturbing agents. " Accordingly, the Applicant 's proposed use qualifies as "light manufacturing" in the Industrial Zoning District.

Section 7-03-080 of the Zoning Bylaw, entitled "Enforcement", provides in Part A that the Building Inspector "shall be charged with the enforcement of this bylaw. " At meetings with [the Zoning Board of Appeals and with the Planning Board, the Building Inspector informed the boards of his determination that the Applicant 's proposed use falls within the definition of light manufacturing, a use that is allowed as of right in the Industrial Zoning District. The Applicant understands that Town Counsel also provided written correspondence to inform the Planning Board that Town Counsel agrees with the Building Inspector 's determination that the Applicant 's proposed use is allowed as of right

C.N. Comment: As previously commented there will be no radiation emissions from the property.

2. Provide data and facts that support the proposed use complies with all environmental performance standards in accordance with Section 7-05 -040 of the Northborough Zoning Bylaws for uses in an industrial district — including noise, light, emissions,

a. For all indoor and outdoor activity — buildings (both the addition and the original warehouse), chillers, and concrete plant.

Relative to noise, the Applicant has retained Tech Environmental of Waltham, MA to prepare an acoustical study of the Property and of the Applicant 's proposed operations.

Relative to lighting, see the Photometric Plan prepared by Omni-Lite, Inc., attached hereto as Exhibit E.

3. Provide the levels of radioactive emissions

There will be no radioactive emissions to either air or water and no radiation dose rates outside of the shield exceeding 2.0 mR/hr (105 CMR 120.221 (b) and no potential for a dose exceeding 0.1r in a year outside of the shield.

C.N. Comment: C.N. agrees with this response.

4. Provide the levels of electromagnetic radiation

Radiation levels outside of the shield will not exceed 2.0 mR/hr (105 CMR 120.2210) and no potential for a dose exceeding 0.1r in a year outside of the shield.

C.N. Comment: C.N. agrees with this response.

5. Details of the process and how it fits the use:

a. What is the equipment for the sterilization process including how many machines, noise, vibration and electromagnetic radiation produced?

The equipment for the sterilization process includes a radiation shield, a pallet conveyor, a modulator room, a control room, and an accelerator system. The Applicant will install two shields in the building. The equipment required for the sterilization process is explained in a document entitled "X-Ray Overview — Summary of the Technology and Application ", prepared by Mevex, attached hereto as Exhibit F.

C.N. Comment: C.N. agrees with the stated description of the equipment.

b. Describe the "treatment center" vs. other areas of production

The treatment center is the shield area in the building, where x-rays are applied to goods and products. The other areas are operations and controls and general warehousing.

C.N. Comment: C.N. agrees with the description of the treatment center.

c. Will there be an electron beam?

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There will be an electron beam used to create x-rays. The machine will be inside of a shield designed for such use and will be registered in accordance with 105 CMR 120.020 and will be designed and used in accordance with 105 CMR 120.700.

C.N. Comment: C.N. agrees with the statement regarding the electron beam and the registration per Commonwealth regulations.

d. List of hazardous materials to be permanently stored in the building and on-site, including amounts, descriptions, and hazards.

See Exhibit C letter from VHB to the Town Engineer and the Groundwater Advisory Board, dated January 22, 2020. The applicant reported the following chemicals (and quantities) may be stored on-site:

- *Gunk Brake Parts Cleaner (12) 20-ounce cans*
- *HydroForce Degreaser — (12) 20-ounce cans* ● *CRC Brakleen — (12) 20-ounce cans*
- *Liquid Wrench Universal Chain Lube — (12) 12-ounce cans*
- *Power Lube — (12) 12-ounce cans*
- *Krytox Lubricant — (12) 20-ounce cans*
- *Blaster Silicone Lubricant — (12) 20-ounce cans*
- *PB Blaster — (12) 20-ounce cans* ●
Air Tool Oil — (12) 8-ounce bottles
- *Chain Lube — (12) 20-ounce cans*
- *Renolit Syn 940 Grease — (12) 12-ounce tubes*
- *Loctite LB 8801 Silicone Lubricant — (12) 6-ounce tubes*
- *Acetone — (1) 1-gallon bottle*
- *Methanol (1) 1-gallon bottle*

C.N. Comment: None of the listed hazardous materials are radioactive. C.N. has no comments regarding non-radioactive hazardous materials.

Groundwater

1. Data and facts that support any requests made by Fred Litchfield, Town Engineer, on behalf of the Groundwater Advisory Committee for both the building and the concrete plant.

- a. Drainage, run-off, impact on surrounding land, any possible flooding.

See the Stormwater Report submitted by the Applicant, entitled "Facility Expansion Project" prepared for Isomedix Operations Inc., 425 Whitney Street, Northborough, MA by VHB, dated September 2019, Revised October 2019, attached hereto as Exhibit D (without Appendices). The Stormwater Report was reviewed and approved by [the Conservation Commission and the Town Engineer.

- b. Layout, description, and impact of the concrete plant on the surrounding land:

- i. Containment of stock piles. ii.
Water usage and source.
iii. Waste water containment and disposal.

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- iv. How will dust be controlled and contained to avoid spreading to residential areas?

These issues and concerns are addressed in the Order of Conditions issued by the Northborough Conservation Commission, attached hereto as Exhibit E. See the "Special Conditions ", No. 46, entitled "Temporary Concrete Plant", which states in part (a): "No site work on the temporary concrete plant shall begin until plans and specifications that include, but are not limited to, erosion control measures, construction sequencing, details on dewatering, mobilization, demobilization, and daily operation and maintenance are approved by the Commission or its agent and the Town Engineer. " And in part (c): "The drainage and stormwater system shall be cleaned and maintained after the complete demobilization of the temporary concrete plant. The maintenance and inspection report for this work shall be submitted to the office of the Conservation Commission. The Commission shall be notified before the maintenance activities occur and shall be afforded the opportunity to inspect the work."

C.N. Comment: There are no radiological materials generated by the operation of the X-Ray Pallet system therefore there are no radiological

impacts to groundwater. C.N. has no comments regarding other possible impacts.

Landscaping

1. Describe buffers for the facility during and after the use of the concrete plant

a. Possible sound wall barrier

None during construction. Applicant will adhere to limitation of hours of construction activity, as set forth in the Northborough Zoning Bylaw (limited to hours between 7:00 a.m. to 7:00 p.m.). Depending on the result of the acoustical study, the Applicant may install a sound barrier around the chiller equipment.

b. Visual barrier. *None during construction.*

C.N. has no comments regarding Landscaping

Traffic/Trucks (During construction of the additions and during the operation of the facility)

I. Impact of trucks traveling to site during construction and during day-to-day operations.

a. What will be the hours of operation of the temporary concrete plant including days of the week? *Applicant will adhere to limitation on construction activity as set forth in the Northborough Zoning Bylaw.*

b. What will be the hours of operation after construction and during day-to-day operations? *Once completed, the facility will operate (internal operations) 24-hours a day, seven days a week. External operations (shipping and receiving) will typically occur on Monday Friday, between the hours of 7:00 a.m. and 7:00 p.m.*

How many truck trips per day? It is estimated that there will be 15 — 20 truck [rips to or from the Property, each business' day.

2. What is the noise associated with the trucks? *Typical or usual noises associated with truck traffic will occur on the Property during the business day. The Applicant will adhere to all applicable state and federal regulations relative to the operation of motor vehicles. Note that the "Environmental Performance Standards, " concerning noise as set forth in Section 7-05-040(c) of the Zoning Bylaw, do not apply to: "Any noise produced by a registered motor vehicle; provided that such vehicle is equipped with all noise-suppression devices required for legal operation under such registration by the laws of the " Commonwealth.*

3. Will there be temporary lighting in place during construction? No. Describe type and levels of lighting, if applicable. *Not applicable.*

4. List of materials if stored in trucks overnight in the parking lot.

Typical materials that might be stored in trucks overnight at the Site are consumer products, such as bandages, or medical devices. The stored products are comprised of either metal, plastic, or cloth. There will be no hazardous materials stored overnight in trucks on the Site.

C.N. has no comments regarding Trucks/Traffic.

Peer Review of Application

1. Expert review of safety, levels of electromagnetic radiation, and the safeguards that should be in place during construction, testing and operation of the facility.

a. Is the thickness and positioning of the concrete walls, floor, and ceiling adequate?

Yes - the concrete shield (walls, ceiling and flooring) has been designed specifically for the sterilization operations by a company registered with the MA Department of Public Health for Shielding Design.

C.N. Comment: C.N. agrees that the design thickness of the concrete walls, floor, and ceiling are adequate to limit the radiation exposures as specified by Commonwealth regulations.

b. Decommissioning plans?

A Decommissioning Funding Plan is not necessary or required by regulation because no radioactive materials will be on site or used at the Properly.

C.N. Comment: C.N. agrees that a decommissioning fund is not required by Commonwealth regulations. Removal for transfer or disposal of the linear accelerators would be required when the devices are no longer needed. The cost of this would be minimal. Notice to the Commonwealth for disposal or transfer is required by regulations in accordance with 105 CMR 120.032

c. Safety plans in the event of an accident or disaster (100-year flood, earthquake/tornado, other natural disaster)?

The control system for the sterilization equipment includes a combination of manual and automatic shut offs. If the operators determine that the sterilization system must be shut down quickly, there are emergency stop buttons. If the operators are incapacitated, the system will automatically shut down.

C.N. Comment: C.N. has not reviewed design and operations manuals for the X-Ray Pallet system. As such we cannot comment regarding automatic or manual shutoffs.

d. Adequate cleanup plans if hazardous material is spilled, leaked, released into the environment?

The sterilization system does not create or cause opportunities for hazardous materials to spill, leak, or to be otherwise released from or at the Property. There will be no radioactive material on the Property.

C.N. Comment: C.N. agrees that the system does not create radioactive materials.

e. Review compliance with MA Executive Office of Health and Human Services, Department of Public Health, Bureau of Environmental Health, Radiation Control Program and any others as applicable or required by law.

The sterilization system will comply with all applicable regulations of the Commonwealth of Massachusetts.

C.N. Comment: The Commonwealth registration process for radiation machines is designed to ensure compliance with regulations.

f. Are there federal or state licensure regulations or mandatory certifications for personnel operating equipment and handling products?

Nuclear Regulatory Commission N/A (the Commonwealth of Massachusetts, through its Department of Public Health, enforces applicable standards of the NRC).

Commonwealth of Massachusetts:

1. 105 CMR 120.001-.016_General Provisions
2. 105 CMR 120.020-.040_Registration of Radiation Machine Facilities and Services
3. 105 CMR 120.200-.287 _Standards for Protection Against Radiation
4. 105 CMR 120.700-.711 _Radiation Safety Requirements for Particle Accelerators
5. 105 CMR 120.750-.760_Notices, Instructions and Reports to Workers: Inspections

C.N. Comment: C.N. agrees that the Commonwealth regulates the use of X-Ray machines.

g. Proper maintenance protocol for the concrete

- i. Degradation of concrete over time? What is the expectancy of concrete under these conditions?

There is no degradation of the concrete over time; there is no limitation on the "life expectancy" of the concrete.

- ii. How often does it need to be inspected, replaced, what type of reporting/records should be required?

C.N. is not an expert regarding concrete life expectancy but our experience with concrete used for radiation shielding is such that we would not expect degradation that would affect its shielding characteristics in this application.

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The shield will be inspected annually during the shield survey or after a natural disaster, such as an earthquake or other unlikely event which could cause damage to the shield.

- iii. Does the concrete need to be coated? *No. Does it require lead bricks? No.*

C.N. Comment: C.N. would agree that lead bricks would not be required.

h. What risks do we need to be aware of? What is the safe radius from the structure?

- i. Health risks

There are no health risks from the sterilization operations outside of the shield. Risks to employees inside the facility will be controlled by machine safety interlocks which immediately shut down power to the machine if activated.

C.N. Comment: see previous comment regarding machine safety interlocks for automatic shutdown.

ii. Explosion risks. *None.*

iii. Leakage risks

Initial shield surveys by a qualified expert will determine if additional shielding is needed prior to commencement of operations.

C.N. Comment: initial shield surveys are required by Commonwealth regulations

i. Environmental impact — what are the standards and how do we confirm that standards are met?

There are no specific environmental impact standards applicable to the sterilization technology; the sterilization system is designed so that radiation is contained within the shield(s). No radioactive material will be stored or used at the Property.

C.N. agrees with this response.

i. What are best practices in measuring compliance: what should be measured, how it should be measured, is there a specific device used to measure it

Applicant will adhere to monitoring requirements as set forth in regulations of the Massachusetts Department of Public Health, which require continuous radiation monitoring in the treatment/shield area.

C.N. Comment: C.N. agrees that Commonwealth regulations specify monitoring requirements for X-Ray device shielding and High Radiation Areas that could exist inside the treatment area.

2. Evaluation of the chillers

a. Level of noise, ground vibration

The Applicant retained Tech Environmental of Waltham, MA, a professional acoustical engineer, to prepare an acoustical study report for the Property.

b. Hours of Operation

The Applicant intends that the internal operations at the facility will occur twenty-four hours per day. External operations on the Property will typically occur from 7:00 a.m. to 7:00 p.m., Monday — Friday.

c. Inspection, maintenance and reporting

As needed; the chillers are required to operate the sterilization system, so it is in the Applicant's interest to monitor and maintain the chillers in good working order. The chillers will be air chilled, with circulating water (no anti-freeze).

C.N. has no comments regarding the chillers.

3. Potential impact on utilities possible impact on neighborhoods for power disruption

None; the local utility company 's power grid will support the facility.

C.N. has no comments regarding the power grid.

a. Levels of carbon dioxide emissions by large use of electricity

None at the Property.

C.N. has no comments regarding carbon dioxide emissions.

4. Radiation monitoring inside and outside the cell

See response to (b), below; with the monitoring inside the shield area, there is no need to monitor the outside of the facility.

a. Is there a device or instrument that can be installed on the exterior of the building that can monitor the radiation levels beyond the shield?

Yes, there is a device or instrument which would monitor radiation levels outside of the facility.

C.N. agrees that devices exist to monitor radiation levels outside of the facility.

b. How will it be recorded and reported, how often and to whom?

All high radiation areas, located behind interlocked doors inside the shield, will be continuously monitored for radiation per 105 CMR 120.710 (c). Portable radiation monitors will be available and required for entrance into high radiation areas as required

by 105 CMR 120. 710(a). The outside of the shield will be surveyed initially by a qualified expert acceptable to the MA DPH and then annually or if a change is made to the equipment that could affect the power of the machine or if an event, such as an earthquake, could have an effect on the shield.

C.N. Comment: The response provided above addresses how often radiation levels will be monitored inside and outside of the cell in accordance with regulations. The response does not address how that monitoring will be recorded and to whom it will be reported. (the response for the following item does state that shield surveys will be documented per internal procedure) but does not address reporting of results.

c. Proof this level of radiation is safe.

Shield surveys will be performed and documented per internal procedure as specified by 105 CMR 120. 710(b).

C.N. Comment: C.N. agrees with the above reference but suggests the entire section 120.710 (a) through (h) are applicable for radiation monitoring requirements for particle accelerators.

5. At ZBA hearing, stated: "Shield survey will be done annually to make sure not exceeding regulatory limits for what gets outside."

a. What is a shield survey, how often should it be performed, how and who performs the survey, who monitors it?

A shield survey is the process of using an appropriate and calibrated hand-held radiation survey instrument on the exterior surfaces of concrete walls and roof of the shield [o verify that any radiation levels, if present are below regulatory limits as specified in 105 CMR 120.211 and 221.

A survey is required to be performed when the accelerator is first capable of producing radiation (105 CMR 120. 706(a)) and when there have been any changes to the shielding, equipment, operation of the equipment or use of adjacent areas. In addition, the Applicant will voluntarily perform shield surveys on an annual schedule.

Required shield surveys must be performed by qualified expert acceptable to the state agency. These acceptable experts are registered with the MA DPH.

C.N. agrees with the above stated response.

6. Any other information that the peer reviewer determines is pertinent to the site, facility, and process, design, and construction. [Items for Peer Reviewer]

- a. Guidance on conditions that we should consider as part of the review
- b. Establishment of performance bonds or escrow? Account for decommissioning of the concrete plant and facility?

A Decommissioning Funding Plan is not required or necessary, because the Applicant will not be using radioactive materials.

See previous C.N. comment regarding decommissioning funds

- c. Review of backup plans — including generator and backup for "life support systems"
- d. High-level inquiry of other US locations with this exact process (Ohio and CA) to uncover any unforeseen issues or challenges in construction or operation.
- e. Review of all data and studies submitted by Steris including but not limited to: acoustics study by acoustics engineer, traffic study

Memorandum

TO: Kerri Martinek, Chair, Northborough Planning Board

FROM: Attorney Stephen F. Madaus, on behalf of STERIS, A.S.T. 

DATE: May 27, 2020

RE: Response to Northborough Planning Board's Second Request for Additional Information; Site Plan Approval 425 Whitney Street

This memorandum is in response to a second series of questions received by STERIS A.S.T. (the "Applicant") from the Northborough Planning Board (the "Planning Board"), in the form of a memorandum dated March 11, 2020. By way of background, on September 17, 2019 the Applicant filed an application for Site Plan Approval in accordance with Section 7-03-050 of the Northborough Zoning Bylaws. The Planning Board considered the Site Plan Application at its meetings on October 17, 2019, December 12, 2019, February 4, 2020, February 18, 2020, and March 10, 2020. The Planning Board issued its first memo requesting additional information on November 15, 2019 and the Applicant provided an 18-page response memo with exhibits, dated January 28, 2020.

Site Plan Approval Review Criteria

Preliminarily, we respectfully remind the Planning Board that the Applicant's proposed use is allowed as of right in the Industrial Zoning District. The use is not subject to a special permit. The review criteria for Site Plan Approval is set forth in Section 7-03-050 (C) (2), entitled "Decision criteria. " Note the first sentence in the decision criteria: "The Planning Board shall approve a site plan if it determines that:" (the review criteria in subparts (a), (b), and (c) are satisfied). Nothing in the review criteria concerns regulating or denying an applicant's proposed, allowed use, nor does the review criteria relate to or permit the regulation of the interior of a building.

Preemption by State Law

MIRICK O'CONNELL
A T T O R N E Y S A T L

The Planning Board's second set of questions concern, almost entirely, the technology to be used by the Applicant within its building. Despite the fact that the review criteria for Site Plan Approval does not concern the regulation of a use (and does not allow for regulating the interior use), the Applicant is providing answers to all of the Planning Board's questions. The Planning Board should be aware, however, that the regulation of radiation and of "machines which emit ionizing and nonionizing radiation" is an area occupied by the Commonwealth of Massachusetts, namely the Massachusetts Department of Public Health. See Section 5N of Chapter I II of the general laws:

The department (of Public Health) is hereby designated as the state radiation control agency. The department shall develop and, from time to time, after a public hearing, prescribe and establish rules and regulations, compatible or consistent, whichever appropriate, with federal rules and programs, necessary to implement a program for the evaluation and control of...machines which emit ionizing and nonionizing radiation and for the issuance, amendment, suspension and revocation of general and specific licenses by-product, source and special nuclear material or devices or equipment utilizing such material, for the purpose of protecting the general public and individuals against hazards associated with the possession, use, transportation, storage, packaging, sale, distribution, production, and disposal thereof

Furthermore, Section 5N provides:

The department "public health shall establish rules and regulations of the commonwealth insofar as they pertain to the health aspects of ionizing and nonionizing radiation. Such rules and regulations shall apply exclusively throughout the commonwealth.

The Massachusetts Department of Public Health promulgated regulations in accordance with its exclusive authority. The primary regulations are found at 105 CMR 120.000, et seq., entitled "Control of Radiation."

Under the Home Rule Amendment to Massachusetts Constitution, cities and towns may exercise any power or function which the general court has the power to confer upon them, "which is not inconsistent with the constitution or laws enacted by the general court." Section 6 of the Home Rule Amendment (emphasis added). By enacting MGL c. 111, Section 5N, the legislature determined that the Massachusetts Department of public Health shall establish the rules and regulations "insofar as they pertain to the health aspects of ionizing and nonionizing radiation." Most importantly, the legislature determined that, "such rules and regulations shall apply exclusively throughout the commonwealth,"

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A T T O R N E Y S A T L

The Massachusetts Supreme Judicial Court held: "In deciding whether under Section 6 of the Home Rule Amendment a municipal ordinance or bylaw is 'not inconsistent with the constitution or laws enacted by the general court'... we have said that the legislative intent to preclude local action must be clear." Town of Wendell v. Attorney General 394 Mass. 518, at 523 (1985), quoting Bloom v. Worcester, 363 Mass. 136 (1973). In this instance, it is clear that the legislature intended for the Massachusetts Department of Public Health to promulgate rules and regulations to govern and control, exclusively, the use of radiation and machines which emit ionizing radiation (such as the Applicant's technology). Accordingly, the Northborough Planning Board is preempted by state law from regulating or conditioning, through Site Plan review or any other means, the Applicant's use of ionizing machines and equipment.

The Applicant's answers to the Planning Board's questions are attached as Exhibit A. To ensure a comprehensive response to the Planning Board's questions, the Applicant cut and pasted each of the line items or topics listed in the Planning Board's memo and provided its response to each item in italics.

MIRICK O'CONNELL
ATTORNEYS AT LAW

EXHIBIT A

Questions relating to the facility:

Commercial medical x-ray sterilization facilities/equipment:

1. Internet search finds that there are less than five commercial medical X-ray sterilizers currently operating in the world. We are aware of only the one in Daniken, Switzerland. Are there any others?

In addition to its investment in Daniken, Switzerland and Northborough, the Applicant is investing in building similar electron beam and x-ray sterilization facilities in Ontario, CA, Libertyville, IL (already permitted), and Venlo, The Netherlands (already permitted).

In addition to the Applicant, a company named Steri-Tek operates an electron beam and x-ray sterilization facility in Fremont, CA and a company named Steri-Genics operates an electron beam and x-ray sterilization facility in Bridgeport, NJ, Internationally, a company named Ionisos operates an electron beam and x-ray sterilization facility in Biassono, near Milan, Italy and Medi-Scan, GmbH, operates two x-ray sterilization facilities in Austria.

C.N. has no comments regarding the total number of sterilizers operating in the world.

2. Including the Daniken, Switzerland facility, how long they have been operating? What type of equipment is used in each facility?

The Applicant 's sterilization facility in Daniken has been operating since late 2010. The x-ray sterilization facilities in Ontario, CA and Libertyville, IL are not yet operating. We have no direct knowledge relating to the operating timelines of facilities not owned by STERIS.

A review of the website for each company listed above may reveal the types of equipment employed in each facility, but the technology is the generally the same.

C.N. has no comments regarding how long various facilities have been in operation.

3. What is the MeV capacity of accelerator at the Daniken, Switzerland site?

The Daniken machine is 7 Me V.

C.N. has no information for the Daniken machine.

4. Will this same equipment be used at the Northborough MA facility?

Similar type equipment, but supplied by a different manufacturer.

C.N. has no information for the Daniken machine for comparison to the one planned for Northborough.

5. Do the accelerators operate continuously?

No, the equipment does not run continuously, but only when started by an authorized operator and it is shut down when not needed for processing.

C.N. Comment: the response is consistent with the available literature

6. Are there specialized electrical components such as cabling, parts, and brakes needed to operate this equipment?

Yes.

C.N. does not comment regarding electrical needs.

7. How is the equipment serviced and repaired?

The equipment will be serviced and repaired by trained STERIS personnel and by the manufacturer's representatives, who are registered technicians with the Commonwealth of Massachusetts.

C.N. confirms the regulatory reference: 120.025 (C) Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 105 CMR 120.026(D) to his radiation machine facility until such person provides evidence that he has been as a provider of services in accordance with 105 CMR 120.026.

8. Does the Switzerland facility have a single-row, double-sided system, or double-row, double sided?

The facility in Switzerland is a single-row, two-level, multi-pass system.

C.N. has not knowledge regarding the specifics of the Switzerland facility.

9. What system will be used at the Northborough MA facility?

The facility in Northborough will have a double-row, single level, multi-pass system.

C.N. finds this response consistent with the literature provided.

10. What issues or problems have been encountered with the site in Daniken, Switzerland?

None

C.N. has no information regarding the operation of the Switzerland facility.

11. How many x-ray sterilizers machines do they utilize in Daniken, Switzerland?

One

C.N. has no information regarding the design of the Switzerland facility.

12. How many x-ray sterilizers machines will there be at the Northborough MA facility?

C.N. finds this response consistent with the literature provided for the Northborough facility.

13. Is there potential or allowances, accommodations in the plans to add more?

No

C.N. has no information regarding Steris' plans for any additions other than what is stated in this response.

Chillers:

1. How do the chillers work?

Mechanical refrigeration system tht uses air for cooling.

2. What happens if the chillers breakdown?

The system shuts down automatically.

C.N. does not possess technical information to confirm automatic shutdown capabilities.

3. Is there a malfunction alarm or some sort of notification that the chillers are not working properly?

Yes.

C.N. does not possess the technical information regarding this issue.

Power/shut down/ backup generator:

1. Is there a manual emergency shut down for the entire x-ray processing system?

Yes; there is an emergency shut down system, with multiple locations (buttons, pull cords, keys, other) that will immediately shut down power to the equipment.

C.N. does not possess this technical design information.

2. Is there a manual emergency shut down for the accelerator?

Yes; see response to No. 1, above.

3. Will there be a generator for backup power and if so, where will it be located?

4. What is the source of power for the generator?

Not applicable.

Radiation emission dose measurements/monitoring/shields:

It is stated on page 11, question #4 of the response entitled Response Memorandum from STERS A-S.T. Northborough Planning Board RE: 425 Whitney Street, dated January 28, 2020 that "Radiation levels outside of the shield will not exceed 2.0 mR/hr and no potential for a dose exceeding 0.1 r in a year outside the shield".

1. Is it correct to state that this is only measured upon initial set up and then monitored annually, not continuously, as it is inside the shield?

Yes; the levels outside the shield will be surveyed initially and in accordance with regulations of the MA DPH.

C.N. agrees that this response meets MADPH regulations.

2. Are these measurements taken when accelerator is on, off or both?

Measurements (shield surveys) are conducted while the machine is on and at full power.

C.N. agrees with this response

3. Is there residual radiation?

No; the machine creates no radioactive contamination.

C.N. agrees with this response

4. Is there a potential for a dose exceeding 0.1 r/year and how is that evaluated?

Based on the shield design there is no potential that any member of the public would be exposed to more than 0.1 rem in a year. This will be evaluated by the initial shield survey at full power and then by periodic surveys thereafter.

C.N. agrees with this response

5. Is the potential for dose measurement a cumulative measurement? If so, over how long a period?

The 0.1 rem/year dose for members of the public is a cumulative dose over a 12-month period. The 2.0 mrem/hour is a dose rate that is measured at a single point in time:

- for shield surveys this would be while the machine is operating at full power;
- for other interlocks used for employee safety this would be measured continuously after the machine is off and prior to allowing entry into the shield/cell.

C.N. agrees with this response

6. What happens in the condition that it is being exceeded?

If during the initial shield survey, it was discovered that any point on the exterior of the shield exceeded acceptable limits additional shielding material would be added to that area and the surrounding area to ensure that levels are below required limits prior to resuming operations.

C.N. agrees with this response. Regulations require changes to the shielding if acceptable limits are not met.

7. Are the shields referenced on page I I of the January 28, 2020 response constructed with concrete walls and a concrete roof?

Yes; the walls and roof will be constructed with high density concrete.

C.N. agrees with this response.

8. Where will the two shields be located?

In the new addition to the existing building.

C.N. finds this response aligned with provided drawings.

9. Will these measurements be taken in the same spots every time or different spots?

The initial survey will encompass the entire shield; annual surveys will include any point indicating a dose rate reading above background levels during the initial survey. All surveys will be conducted in accordance with regulations of the Massachusetts Department of Public Health (MA DPH) and industry best practices.

C.N. Comment: C.N. agrees that previous locations of readings above background should be elements for subsequent surveys. C.N. would consider surveying additional points as a best practice.

10. How many areas?

Measurements will be conducted in accordance with state regulations and industry best practices.

C.N. Comment: See previous response regarding survey points.

11. Do these shields absorb radiation? Do they repel radiation?

The shields absorb the energy from the x-rays but do not become radioactive.

C.N. agrees with this response

12. Which direction will the electron beams be facing?

North.

C.N. agrees with this response

13. Page 17, #4 of the January 28, 2020 response, what does the term "cell" refer to?

A cell is another term for the area inside of the shield, where processing will take place.

C.N. agrees with this response

14. Regarding a device or instrument that will measure radiation outside the facility, is this something other facilities use and would it be possible to install at this site?

We do not know if other facilities use a device or instrument to measure radiation outside of a facility. There is neither a need nor a requirement to install such a device and there is no plan to do so.

C.N. Comment: C.N. has no information regarding external monitoring by other facilities. C.N. agrees that external monitoring is not needed assuming shield performance is as designed.

15. What are the costs/effort of deconstructing the 12-foot walls and ceiling to re-utilize the property in the future?

Not known. Unlike a Gamma machine which requires a decommissioning plan, the proposed facility will not use radioactive material to sterilize products and, therefore, a decommissioning plan is not required.

C.N. has no comments regarding costs for future use. C.N. agrees that a decommissioning plan is not required by regulations.

EMFs:

L Will the facility give off any EMFs outside of the facility or past the property line?

No.

C.N. has no comment regarding non-ionizing EM radiation (EMFs).

2, What is the gas emitted by the process?

The sterilization process creates ozone and the Applicant will comply with all applicable state regulatory limits.

C.N. has no comments regarding ozone emissions.

3. Level and type of any electromagnetic interference that is possible?

None.

C.N. has no comments regarding electromagnetic interference.

4. Any impact on radio frequencies — wireless, cellphone, tv or other?

No.

C.N. has no comments regarding electromagnetic interference.

5. Is the beam continuously generating x-rays [*No; only when turned on.*] and does the level or radiation or dose of radiation outside of the shield increase as number of electron beams increases? [*No.*] Currently noted as not to exceed 2mR/hour outside of the shield.

The machine generates x-rays only when it is intentionally turned on for processing. Each shield is designed for containment of the highest output of power to be used in that shield. Each shield will be designed for a maximum of 2 x-ray machines and will not physically fit any additional xray machines.

C.N. agrees with this response.

6. What triggers an automatic shutdown and how quickly does that trigger lead to the automatic shutdown?

Multiple machine parameters and safety interlocks will shut down the machine. The machine Will have power removed immediately upon activation of any such interlock.

C.N. has no details regarding interlocks to provide comment.

7. Is the "acceptable expert registered with the MA DPH" who does the initial shield survey and ongoing reporting an internal resource or an independent third-party resource?

The acceptable expert registered with MA DPH is the machine manufacturer.

C.N. does not possess information regarding the manufacturer's registration with the MA DPH to provide comment.

8. Are there permits that will need to be filed if the products being sterilized change to toxic or hazardous materials (used medical equipment/waste, infectious materials, etc.)? This could be a question for Bob.

As the Applicant previously reported, it does not process used medical equipment/waste or infectious materials.

C.N. has no comments regarding this matter.

Traffic/Trucks: (During construction of the additions and during the operation of the facility)

1. The traffic study appears to be based on generic information vs true study. How is this information statistically accurate given only three days were reviewed in November 2019?

The Applicant retained a qualified, professional traffic engineer, Mr. Jeffery Dirk, P.E, PTOE, of Vanasse & Associates, Inc., to prepare and submit the Traffic Impact Assessment (dated January 23, 2020). He determined that, in comparison to the former architectural millwork company that occupied the Project site, "the PrQject is expected to generate approximately 60 fewer vehicle trips on an average weekday and 196 fewer vehicle trips on a Saturday, with 2 fewer vehicle trips expected during the weekday morning peak-hour, 8 fewer vehicle trips expected during the weekday evening peak hour and 23 fewer vehicle trips expected during the Saturday midday peak hour. On balance, the Project will result in comparable traffic volumes and impacts to those of the former architectural millwork company that occupied the Project site. " The traffic engineer's determinations do not appear to be based on any seasonal study or data.

C.N. has no comments regarding trucks/traffic.