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February 25, 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 the application materials submitted regarding the proposed facility expansion project located at 425 Whitney Street Northborough, Massachusetts to facilitate installation and operation of a M4-H X-Ray Pallet Bunker unit for sterilizing medical products.

The materials consulted for this review include the following:

- 105 CMR 120 Massachusetts Regulations for the Control of Radiation
- Steris response to email from Environmental Partners
- MEVEX Corporation Report, Radiation Calculations, M4-H X-ray Pallet Bunker
- Building Expansion Floor Plan for 425 Whitney Street
- Locus Plan map for 425 Whitney Street
- Letter to Kathy Joubert from Stephen Madaus re: 425 Whitney Street – Application for Site Plan Review
- Training Requirements for Operators
- Steris Applied Sterilization Technologies Irradiator Operating and Emergency Procedure List

BACKGROUND

The project includes the expansion of the property located at 425 Whitney Street Northborough, Massachusetts. We understand the proposed use of the building expansion will include the installation of a M4-H X-Ray Pallet Bunker using particle accelerators containing two (2) X-Ray systems each with electron energy up to 7.5 MeV and beam power up to 500 kW. C. N. Associates, Inc. has the following comments regarding the planned



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installation and these units.

105 CMR 120.000: THE CONTROL OF RADIATION

105 CMR 120 is the Massachusetts code for the control of radiation. The Department of Public Health (Agency) is responsible for enforcement of these regulations. This section of the code addresses a broad spectrum of subjects related to various uses of radioactive material and the operation of radiation machines. The accelerators planned for this project are considered radiation machines and fall under this regulatory code.

105 CMR 120 contains the following rules regarding radiation machines and control of radiation in general:

120.021: Purpose and Scope

- (A) 105 CMR 120.020 through 120.040 provides for the registration of radiation machine facilities and for the registration of persons providing radiation machine installation, servicing, and/or services to Department registrants or registrable facilities. For the purposes of 105 CMR 120.020, particle accelerators, whether used primarily for x-ray production or other purposes, shall be considered a radiation machine facility. (emphasis added)
- (B) In addition to the requirements of 105 CMR 120.020 through 120.040, all registrants are subject to the applicable provisions of other parts of 105 CMR 120.000.

Installation of the planned sterilization machines will require registration in accordance with these sections of the code. We understand that application for registration has not yet been made.

120.024: Plan Review

- (A) Prior to construction, the floor plans and equipment arrangements of all new installations, or modifications of existing installations, utilizing ionizing radiation for diagnostics or therapeutic purposes shall be submitted to the



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Agency for review and approval. The installation shall meet the requirements of 105 CMR 120.420: Appendix A and 105 CMR 120.422: Appendix C unless specifically exempted. Additional shielding and design requirements are specified elsewhere in 105 CMR 120.000.

- (B) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval. (emphasis added)
- (C) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.

Installation of the planned sterilization machines falls under the plan review requirements of these sections of the code. We understand that the Plan Review information has not yet been submitted to the Agency.

Shielding calculation results were provided to C.N. Associates by Steris. These calculations were prepared by MEVEX, an accelerator technology company, and include calculations of radiation dose external to the M4-H bunker. These calculations include the expected radiation dose rate at a number of locations on the outside of the bunker where the dose rates are expected to be the highest.

The calculations make the assumption that there are up to two x-ray systems, each with an electron energy up to 7.5MeV and an electron beam power up to 500 kW. The maximum energy of 7.5 MeV precludes the production of neutron radiation, which is therefore not considered in the report.

The calculated radiation dose rates for every calculation point assumed there were two operational beams at 7.5 MeV, 500 kW. The design goal for the bunker is to meet radiation dose rate limits for the general public at all points outside the shield by limiting dose rates to 0.5 micro-Sieverts/hour.

The maximum dose rate provided in the calculation summary was 0.41 micro-Sieverts/hour at two locations. The majority of locations were much lower than this, and many locations were reported as <0.01 micro-Sieverts/hour.

Massachusetts regulations provide both hourly and annual limits for the radiation dose to which members of the public may be exposed:



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120.221: Dose Limits for Individual Members of the Public

(A) Each licensee or registrant shall conduct operations so that:

- (1) the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.540, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 105 CMR 120.253; and
- (2) the dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with 105 CMR 120.540, does not exceed 0.02 millisievert (0.002 rem) in any one hour; and
- (3) the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5mSv (0.5 rem).

At a radiation dose rate of 0.5 micro-Sieverts/hour, a person would need to stay at a location for 40 hours/week for 50 weeks/year to receive a dose of 1000 micro-Sieverts (1000 micro-Sieverts is equal to 1 milli-Sievert (0.1 rem)).

Actual dose rates less than 0.5 micro-Sieverts/hour would result in dose rates and doses to the general public that will be less than Massachusetts regulatory limits. Actual dose rates will be measured during initial operation to verify design dose rate criteria are met.

Massachusetts regulations further state:

120.703: General Requirements for the Issuance of a Registration for Particle Accelerators

In addition to the requirements of 105 CMR 120.020 or 120.100, a registration application for use of a particle accelerator will be approved only if the Agency determines that:



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(A) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with 105 CMR 120.700, 120.200 and 120.750 in such a manner as to minimize danger to public health and safety or property;

(B) The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(C) The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 105 CMR 120.704;

(D) The applicant has appointed a radiation safety officer;

(E) The applicant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

(F) The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and,

(G) The applicant has an adequate training program for operators of particle accelerators.

Steris provided C. N. Associates with a description of Training Requirements for Operators and a listing of Operating and Emergency Procedures that included:

1. Radiation Detection Instruments
2. Ventilation System
3. Irradiator Safety Features
4. Radiation Protection Program
5. Operational Safety Checks
6. Surveys of the Shield
7. Contamination Detection and Analysis
8. Irradiator Shutdown
9. Irradiator Entry
10. Irradiator Startup
11. Notification of Incidents
12. Radiation Alarms
13. Overexposure to Radiation



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- 14. Fires or Explosions
- 15. Natural Disasters

In summary, the information provided is consistent, both in content and in quality, with state regulations and is acceptable. Massachusetts Regulations for the Control of Radiation provide an extensive array of controls for the operation of particle accelerators. These regulations begin in the application process and continue to govern the process through the installation and operation of individual facilities. The design documents made available to C. N. Associates are indicative of a standard design for a particle accelerator bunker arrangement that can be operated in accordance with regulations. The process of approval through the Massachusetts regulatory process would be expected to ensure all requirements are met.

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