permitting—will necessitate the reconfiguration of an 12,000 square foot warehouse space. As this work cannot be completed before the April 2026 deadline, Trinity will have to shut down its operations after that date while these upgrades are completed. Details regarding the impact that this disruption will have on Trinity's sterilization operation is detailed below.

- There is also a scarcity of engineers and consultants capable of this type of work within the short time frame permitted under the current rule. It is also unknown what technology EPA will recommend after it reconsiders this rule. Therefore, it cannot be determined at this point whether that technology is currently available for this facility.
- Finally, the medical devices that Trinity assembles must be sterilized according to specific protocols and can only be sterilized at Trinity's Salisbury facility. Outsourcing sterilization would take more than twelve months and may be impossible, as all other facilities capable of sterilizing Trinity's products are at capacity. Likewise, there is no guarantee that there will be capacity at other sterilizers for Trinity's products after the rule's implementation.

2. **National Security Interests:**
   - Trinity manufactures critical medical devices that are essential for patient care across the United States. These devices are distributed to over 4,000 institutions, including hospitals, homecare facilities and military bases. Any interruption in sterilization operations due to this rule's implementation could result in severe disruptions to the supply of these devices. Trinity estimates that it manufactures and distributes nearly 25,000,000 medical kits a year, as well as over an additional 6,000,000 surgical instruments. Trinity will likely have to shut-down sterilization operations for at least year in order to implement PTE. For that year, those 25,000,000 kits and 6,000,000 instruments will not be available to the care providers that need them to perform necessary procedures on millions of patients. Ensuring the continuous availability of sterilized medical devices is vital for national health security and public safety.
   - Without this exemption, Trinity may be forced to permanently shut down its onsite sterilizer, or even stop manufacturing operations completely due to the lack of available sterilizer capacity at other facilities and the lengthy process of establishing sterilization protocols and completing validation. Trinity also provides assembly and manufacturing services for other entities, and these delays would also impact those entities, likely forcing them to go out-of-business entirely. Granting this exemption is also in the national security interests of the United States, as it will avoid any unnecessary delays if these standards change after the EPA reconsiders this rule.

An appropriate delegation of authority by Trinity to submit this request is enclosed. Trinity reserves the right to amend this application based on any subsequent guidance, rulemaking, or change in law.

We look forward to your favorable consideration of this request.