

Abstract

This is the report of a project carried out to determine the microbial-kill characteristics of saturated steam plus hydrogen peroxide (H₂O₂) using a specially-constructed test apparatus. Spores on stainless-steel planchets were inserted into a flowing gaseous atmosphere of steam plus H₂O₂ for a timed exposure to the lethal agent. The specially-designed test apparatus and its operating parameters are described. *Geobacillus stearothermophilus* (former name, *Bacillus stearothermophilus*) spore-death rates were evaluated in several spore-planchet handling modes. Enumeration microbial recovery methods were used. The data were analyzed using survivor-curve methods; D-values were calculated using the initial number of spores per planchet and the number of spores surviving the process. Extensive tests were carried out using *Geobacillus stearothermophilus* spores; limited tests were carried out using *Bacillus smithii* ATCC 51232 (former name, *Bacillus coagulans*), *Bacillus macerans*, and *Bacillus subtilis*, *subtilis* ATCC 35021 spores (former name, *Bacillus subtilis*, CCC 5230, Kerns 15U). For *G. stearothermophilus* spores subjected to steam plus H₂O₂ and recovered using the 2B procedure (planchets deposited in sterile, 100-mL bottles containing 50.0 mL of buffer immediately after they were subjected to the steam-H₂O₂ condition; 11 experiments), the mean D-value was 0.48 min at 2,500 ppm and 0.22 min at 7,500 ppm. The application of steam plus H₂O₂ to the sterilization of barrier isolator enclosures is discussed.