⟨1229.9⟩ PHYSICOCHEMICAL INTEGRATORS AND INDICATORS FOR STERILIZATION

INTRODUCTION

Physicochemical integrators provide some assessment of sterilization process efficacy and may be used in cases where validation of a sterilization process is not required—an exception is the validation and monitoring of radiation sterilization with dosimetry. The physicochemical indicator provides an immediate visual confirmation that an item has been exposed to a sterilization process. Performance standards both within and between lots of physicochemical integrators or indicators from a given manufacturer should be consistent. Integrators or indicators should not interact physically or chemically with any container or product when placed in the sterilizer load, and should not alter the strength, quality, or purity of the sterilized article. The integrator or indicator should be positioned such that it does not alter the effectiveness of the sterilization process. The principal usage of physicochemical integrators and indicators is to provide a rapid means of confirmation of sterilization cycle completion. This is especially important with single door sterilization chambers where a potential mix-up of nonsterilized and sterilized items is more likely. Aside from radiation sterilization where dosimetric data is accepted as definitive they should not be used as the sole proof of cycle efficacy (see *Radiation Sterilization* ⟨1229.10⟩).

PHYSICOCHEMICAL INTEGRATORS

A physicochemical integrator is defined as a device that responds to one or more sterilization process critical parameters, which results in a measurable value that can be correlated to microbial lethality. The manufacturers of physicochemical integrators should provide data to demonstrate that the labeled performance characteristics tests of the integrators are met.

Physicochemical integrators require precautions for use and the appropriate interpretive criteria to define their performance characteristics. Performance of the sterilization apparatus must be ascertained from records generated by calibrated instruments (temperature, pressure, exposure time, gas concentration, and others, as applicable). The integrator can demonstrate only inadequate or adequate exposure to a combination of sterilization parameters.

Physicochemical integrators for radiation sterilization are designed to react predictably to the delivered radiation dose and can provide primary evidence of sterilization process effectiveness. The use of dosimeters in radiation sterilization cycle development and routine process control is addressed in ANSI/AAMI/ISO 11137-3, Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects (*1*).

PHYSICOCHEMICAL INDICATORS

A physicochemical indicator is defined as a device that provides visual evidence of exposure to one or more critical sterilization parameters. Physicochemical indicators cannot provide primary evidence of sterilization efficacy.

REFERENCE

1. ANSI/AAMI/ISO 11137-3:2006/(R)2010, Sterilization of health care products—Radiation—Part 3: guidance on dosimetric aspects. New York: American National Standards Institute; 2010.