PRION INACTIVATION

- Prions are proteins (not microorganisms) and far more resistant than all germs used for evaluation of disinfection and sterilization processes. There are no international standards for prion inactivation but recognized tests methods (in vitro + in vivo) exist.

DISINFECTANT (VARIOUS TEST METHODS)

- Claims by category of micro-organism * (bacteria, yeast, virus, mycobacteria, fungal spores).
- Various test methods in suspension and carriers (EN, AOAC, ASTM) and log reduction objectives.

HIGH LEVEL DISINFECTANT (VARIOUS DEFINITIONS)

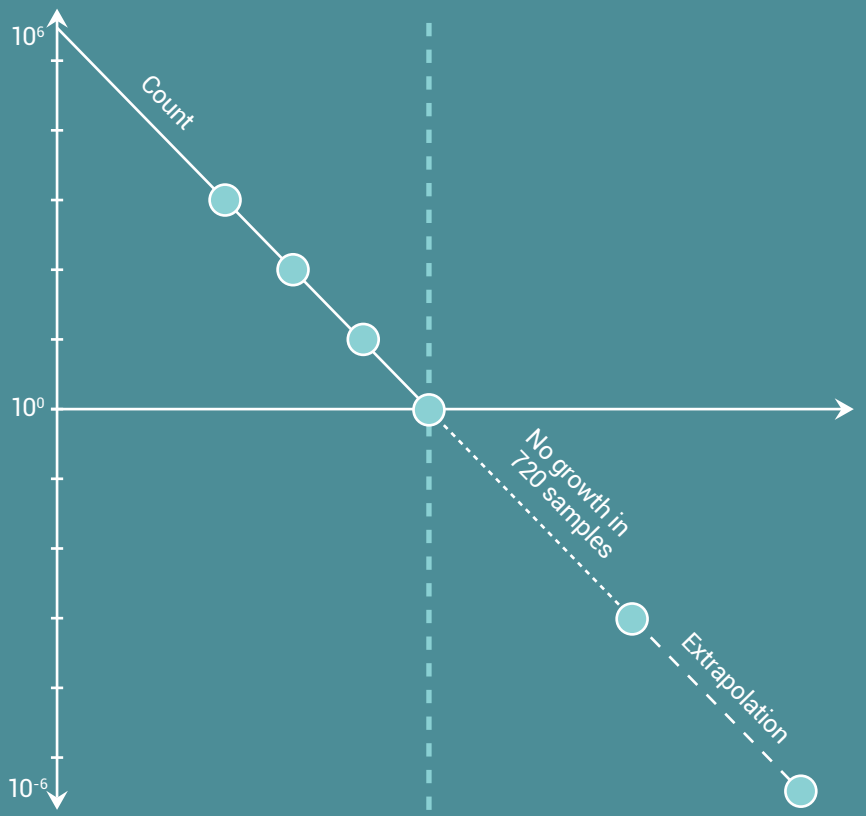
- Same as Disinfectant + some sporicidal activity.
- Various test methods and criteria: For example, for FDA, an HLD must be a « sterilant » (see below) at higher exposure time.

STERILANT (SPECIFIC TO FDA)

AOAC 966.04: 2 carriers, 2 Germs, 60 samples x 3 lots of sterilant solution i.e. a total of 720 samples with no growth.

TERMINAL STERILIZATION (UNIVERSAL)

- Sterility Assurance Level of 10-6 with most resistant germ (spore).
- ISO standards per modality or ISO 14937 and packaging.
- For hospital: overkill approach.



DETERGENT

- Evaluation of cleaning process (i.e. combination of mechanical, thermal and chemical effects) according to methods and thresholds defined by ISO 15883-5.