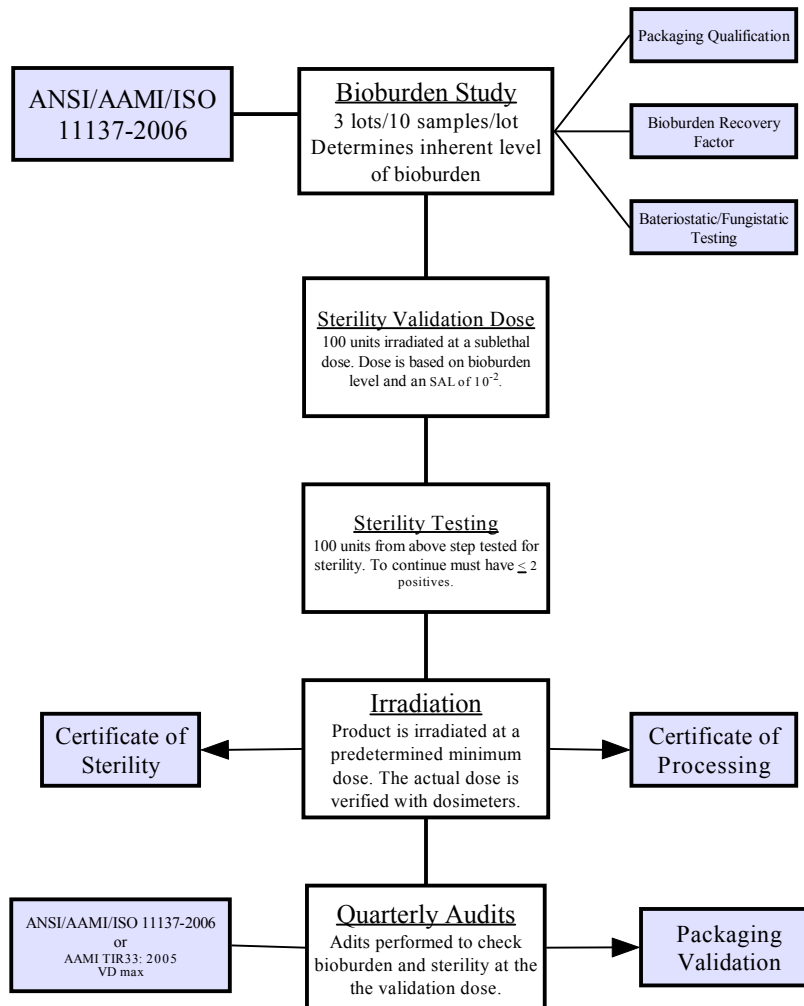


Sterilization Validation Process



Definitions:

- Bioburden: population of viable microorganisms on a product.
- Sterility Assurance Level (SAL): probability of a viable organism being present on a product unit after sterilization. Expressed as 10^{-n} . A SAL of 10^{-6} is the probability of one non-sterile unit in one million.
- Dosimeter: device which can be used to measure the absorbed dose in a given material.