



International Alliance for
Biological Standardization

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Title: Shelf-Life Estimation and Internal Release Limits accounting for a Series of Storage Excursions through Bayesian Modeling

In this presentation, a Bayesian kinetic hierarchical model is proposed to be fitted to real time and accelerated studies together to estimate both the shelf-life and internal release limits for a target shelf-life considering a series of excursions.

Creation of an experimental design for the accelerated stability study will be illustrated. Accelerated stability data can either be used to provide prior information to the real time stability model or the two data sets can be fitted together. In either case, a posterior probability of the reaction rates and other associated regression parameters can be jointly estimated for all conditions, which can be directly used to derive the shelf-life and internal release limits accounting for storage excursions. In the examples shown in this talk, data were generated based on an Arrhenius equation with pre-identified excursions in the real-time stability data.

