A Systematic Method to Model Natural Variability and Uncertainty in Diffusive Transport

Martin L. Tanaka College of Engineering and Technology Western Carolina University Cullowhee, NC USA

John Wagaman Department of Mathematics & Computer Science Western Carolina University Cullowhee, NC USA

> David M. Saylor US Food and Drug Administration Silver Spring, MD, USA

Abstract

Implanted polymeric medical devices have the potential to leach hazardous materials into the body. Often the worst-case conditions are used to approximate the amount of material that could be released. However, this approach only yields a single scalar value. A more clinically relevant approach is to model the input parameters as probability density functions. Our approach includes dividing the parameter space into an *n* dimensional grid where *n* is the number of input parameters. Each combination of the grid was then evaluated systematically by calculating both the quantitative value of material released and the likelihood for each grid combination. These results were compared to results obtained using a Monte Carlo simulation. Analysis showed the systematic approach to yield densely represented data over the entire range of input parameter values while the Monte Carlo simulation becomes sparse at extreme values of the input parameters. Thus, this systematic approach may be advantageous when results over the entire range of input parameters.