I – W – 1A: "Process/Design Excellence for Small and Medium Sized Enterprises"

Quality Improvement Tools and Techniques in UK Manufacturing Companies: an empirical study

Professor Jiju Antony
Department of DMEM, University of Strathclyde
E-mail: jiju.antony@strath.ac.uk

This paper presents the findings from a research which investigated the use of quality improvement tools and techniques, their success factors and barriers within UK manufacturing companies. The findings are based on empirical data generated from two questionnaire surveys and semi-structured interviews. A literature review was carried out and from its findings a primary questionnaire was designed and sent out to 500 manufacturing companies throughout the UK. 70 useful responses were received from companies within Scotland and Wales. A more detailed questionnaire was also designed, largely based on results from the primary questionnaire. Finally, a semi-structured interview was designed to verify and validate data from the questionnaires. Three of the respondent companies were visited and, in total, eight employees were interviewed.

Design for Six Sigma: An Application

Ronald J.M.M. Does, Jeroen de Mast and Gerjan Diepstraten
Department of Quantitative Economics, IBIS UvA, Amsterdam, The Netherlands
Email: R.J.M.M.Does@uva.nl

Printed circuit assemblies can be found in all kinds of electrical and electronic products, including cars, mobiles, airplanes, computers, and tools. The components are attached to the assemblies with solder; these solder connections or joints are both electrical and physical. A conventional way of creating these solder joints is through the use of what is known as a wave soldering process. In such a process the printed circuit board is moved across a flowing wave of molten solder. The molten solder contacts the surfaces to be joined – components to the circuit board itself – and forms solder joints and a functional assembly.

Before these boards can be soldered the surface has to be cleaned and prepared with a chemistry called flux. Once the flux is applied, the board is heated to evaporate the solvent of the flux and to bring energy into the board. Then the board is ready to be soldered. The amount of flux that is applied is critical to the soldering process. In this real life example we discuss the design of a closed loop flux control. The problem definition in this case study is: Design and implement a new methodology of measuring and controlling the amount of flux in the machine. The methodology used in this example is Design for Six Sigma. The new device was introduced in the market by a small sized enterprise.

Application of Design of Experiments for optimising an Injection Moulding Process

J.W.J. Timans (Werner Timans)
Stenden University, The Netherlands
E-mail jwj.timans@home.nl

Injection moulding processes are influenced by a number of process parameters that are controllable on a injection moulding machine and also by some parameters which are uncontrollable during production. A case study of the optimisation of an injection moulding process using DOE is presented. Special attention is given to the demands on the quality of the measuring processes used to collect data on critical to quality product-characteristics. Also proposals are presented to implement DOE as a standard tool in Injection Moulding SMEs.

An outline is given for further DOE-based improvement of process optimisation using information from pressure- and temperature-curves delivered by sensors which are placed in the walls of the mould, close to the melt of the polymer injected into the mould.

I – W – 1B: "Statistical Engineering"

What do I want to be when I grow up – Applied Statistician or Statistical Engineer?

Stephanie P DeHart
Consulting Statistician & MBB, DuPont
Email: stephanie.p.dehart@usa.dupont.com

Recent statistical and quality journal articles on the topic of statistical engineering have sparked much discussion among industrial statisticians. Many are asking: "How is this different from applied statistics and what I do today?" Others are asking: "What is the benefit? Is this more than just a marketing gimmick?" Whether or not it has been labeled as such, we argue that many industrial statisticians have long been practicing statistical engineering while industry and society have reaped the benefits. We will review the definition of statistical engineering and compare it to applied statistics through examples. We will also discuss that while the label may be debatable, the benefits of formalizing the discipline are clear.

Is Our Sigma Too Lean?

Jim Rutherford
Chevron Oronite Company, LLC, Consulting Statistician
Email: jaru@chevron.com

The first version of the Lubricant Test Monitoring System (LTMS) was the result of efforts of the American Chemistry Council (ACC) Statistical Engine Test Work Group (SETWG) of the ACC Product Approval Protocol Task Group (PAPTG). The SETWG applied a logical and data based analytical approach to available ASTM (American Society for Testing and Materials) calibration test data in the

development of the LTMS. This system of managing lubricant engine test severity (bias) and precision was presented to the ASTM Technical Guidance Committee of the Test Monitoring Board in October, 1991 by the ACC PAPTG. The LTMS was subsequently adopted for use by ASTM Performance Test Surveillance Panels.
This Second Edition was initiated by the ASTM LTMS Task Force, and, specifically, the Statistics Task Group of the LTMS Task Force which included statisticians and others from the engine oil industry as well as representatives of independent test laboratories and the ASTM Test Monitoring Center. Stakeholders provided input through various venues including Surveillance Panels and internal company communications.

The first version was based on simple SPC principals with ad hoc modifications to address issues unique to this situation. Over the past 2 decades there were additional modifications meant to alleviate specific problems and address specific concerns raised by stakeholders. Some of these problems and concerns were technical in nature and some were intended to reduce industry testing costs. The second edition recognizes inappropriateness of standard SPC assumptions and the dangers of short term cost reductions. It is based on a system more in line with what Box1,2 called "Statistical Control by Monitoring and Adjustment" or Bisgaard's "Using a Time Series Model for Process Adjustment and Control"3.

Theory, simulations, and review of historical data indicate improvements in test result variability for commercial candidate engine oils for the proposed Second Edition. However, convincing industry groups and garnering agreement by stakeholders has been a slow process. The need for better training in statistical thinking and competing business objectives among organizations are difficult but not insurmountable obstacles.

PopPK Modeling for Oncology Drug Vorinostat with D-optimal Design Guided Sparse Sampling

Xiaoli Shirley Hou
Merck Research Labs, Senior Biometrician
Email: xiaoli_hou@merck.com

(Co-Authors: Wendy Ankrom Comisar & Nancy Agrawal, Merck Research Laboratoires and Bo Jin, Pfizer)

Vorinostat is an oncology drug approved in the U.S. in 2006 as a monotherapy for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma who have progressive, persistent or recurrent disease on or following two systemic therapies. The pharmacokinetics of vorinostat are highly variable and data were somewhat limited (given that all clinical studies need to be conducted in patients rather than healthy subject), which complicated the development of population PK models. Additionally, a sparse pharmacokinetic sampling scheme that should be convenient for the patient population was needed for the Phase II/III studies. This sparse sampling scheme needed to enable us to successfully obtain posthoc parameter estimates for patients in Phase II/III studies. With

all of these factors in mind, we were able to fit a first-pass model to the Phase I data, which characterized the PK parameters fairly well. Based on this model, we used a D-optimal Design to strategically identify an appropriate sparse sampling scheme for the Phase II/III studies, which was critical since the quality of population PK parameter estimates is a function of the experimental design, including the number of concentrations measured per subject, the timing of each blood sample, and the number of subjects.

I – W – 2A: "Multivariate and Autocorrelated Data"

Multivariate Process Capability Indices—A graphical approach

Kerstin Vännman
Umeå University and Luleå University of Technology, Sweden
Email: Kerstin.Vannman@ltu.se

(Based on joint work with Ingrid Tano, University West, Sweden.)

Univariate process capability indices have been in use for more than 20 years to characterize process performances. However, the quality of a process is often determined by several quality characteristics, some of which are correlated. For these circumstances, multivariate process capability indices (MPCI:s) have been elaborated. To start with the MPCI:s were derived as theoretical quantities to define the process capability using, mostly, one number and suitable estimates were suggested. More recently statistical theory for some of these estimated indices have been derived and confidence intervals or tests have been suggested. This means that conclusions about the process capability can be drawn, based on a random sample, at a given confidence level or significance level. This presentation review and compare some of these MPCI:s and their corresponding confidence intervals or tests. Some advantages and disadvantages of these MPCI:s will be discussed. Furthermore, a new graphical approach to MPCI will be presented and exemplified by using data from a Swedish industry.

Multivariate Process Control with Autocorrelated Data

Murat Kulahci
Technical University of Denmark
Email: mk@imm.dtu.dk

As sensor and computer technology continues to improve, it becomes a normal occurrence that we confront with high dimensional data sets. As in many areas of industrial statistics, this brings forth various challenges in statistical process control and monitoring. This new high dimensional data often exhibit not only cross-correlation among the quality characteristics of interest but also serial dependence as a consequence of high sampling frequency and system dynamics. In practice, the most common method of monitoring multivariate data is through what is called the Hotelling's T2 statistic. For high dimensional data with excessive amount of cross correlation, practitioners are often

recommended to use latent structures methods such as Principal Component Analysis to summarize the data in only a few linear combinations of the original variables that capture most of the variation in the data. In this paper, we discuss the effect of autocorrelation (when it is ignored) on multivariate control charts based on these methods and provide some practical suggestions and remedies to overcome this problem.

Multivariate design space – building a capable process

Johan Trygg
Computational Life Science Cluster, Department of Chemistry, Umeå University, Sweden
Email: johan.trygg@chem.umu.se

Pharmaceutical production quality is still guaranteed by controlling the purity of the final product. Achieving better control throughout the process, as a means for improving product quality is within the concept of quality by design (QbD) to minimize risk and maximize process understanding. Here, the use of design of experiments (DoE) and multivariate methods have proven to be successful. The physical state of a pharmaceutical process can be measured with for example, pH and temperature. Non-invasive spectroscopic methods, for example, ultraviolet (UV) and near infrared (NIR), give additional chemical information compared to the process variables. Hence, combining process and spectroscopic variables into one MSPC model will enhance the possibilities of fault detection and outlier detection, and provide easier diagnosis of possible process deviations. In this presentation OPLS methodology (OPLS and O2PLS) was implemented to facilitate a combined analysis of spectroscopic and process data in a batch process. This enables assessment of both the joint and uniquely complementary variations in the respective data sets over time. By combining data, a deeper understanding of process interactions was gained. The results gave an improved understanding of the process, and DoE derived the important factors that control it, which is in line with QbD. This methodology can also be extended to more than two data tables and hence it nicely fits into the framework of a multi-block approach.

I – W – 2B: "Statistical Issues in Aerospace/Aeronautics"

Applying DOE in Large Organizations – Military Test and Evaluation

Alex Sewell, Jim Simpson and Greg Hutto
Eglin Airforce Base
Email: houston.sewell@eglin.af.mil

Can a methodology (DOE) typically taught only to statistics and industrial engineering graduate students be effectively employed as the default method of test in large organizations? This talk addresses the vital aspects of designed experiments applied to military test and evaluation throughout the weapon system acquisition cycle. We consider each of the essential components from duties/placement of statisticians/analysts, to DOE training, to practical application and mentoring, to

test policy, and finally methods research. The primary emphasis of the discussion will be excellence in a DOE training program including: general experiment philosophy, depth of topic coverage, critical tools, the diversity of the student customers, and what needs to follow training for the program to be effective. The heart of this message will be a strategy for building and sustaining your training program, especially train the trainer. Difficult questions regarding content - the right methods and techniques, will also be addressed.

Statistical Challenges and Opportunities in the Aerospace Industry

Stephen Jones
The Boeing Company
Email: stephen.p.jones@boeing.com

The aerospace industry offers some unique challenges and opportunities to the professional statistician. Product development of a new commercial airliner, for instance, requires understanding the needs of a small number of customers (airlines) and a large number of the customers' customers (passengers). The manufactured product is fabricated in relatively small quantities and embodies the complex integration of expertise from many scientific and engineering disciplines. The consequences of inadequate quality can be catastrophic and the statistician has an important role in quantifying risk and guiding decision-makers.

In this presentation we will describe some of the unique challenges for a statistician in the aerospace industry. We will also present some opportunities for research in statistical methods and application development that would be relevant to the challenges of the industry.

Aerospace Measurement System Characterization

Peter Parker
NASA
Email: Peter.A.Parker@nasa.gov

Characterization of complex measurement systems is a critical component of NASA's aerospace missions. These applications typically involve custom-developed measurement systems with very low noise responses that are characterized as a function of multiple variables, which are often challenging to experimentally set and measure. Some applicable statistical approaches include classical calibration regression and response surface methodology. However, neither approach fully meets the unique requirements found in many aerospace applications. For example, the classical calibration formulation assumes that a known, traceable standard is available, and is often restricted to simple linear regression. Alternatively, response surface methods are well suited for modeling higher-order effects of multiple factors, however their design and analysis methods were developed for industrial optimization applications rather than estimating high-fidelity prediction models that require inverse estimation. This presentation includes motivating case studies from NASA programs, highlights statistical challenges, and presents research to adapt and extend existing methods.

I – W – 3A: "Industrial Statistics Research from Latin America"

Ways to reduce the effect of the autocorrelation on chart performance

Antonio F. B. Costa
Department of Production, Sao Paulo State University, Brasil
Email: fbranco@feg.unesp.br

Autocorrelation often exists in quality control applications. The autocorrelation has an adverse effect on the chart's performance. To counteract the undesired effect of the autocorrelation we present two strategies: a) to build up the samples with non-neighbor items, according to the time they were produced, b) to build up the sample with items that were taken from the process in different sampling times; for instance, if four items are taken at each half hour, we build up the current sample with the last two produced items and with two others that were selected from the production line half hour earlier. The strategy of skipping items and the strategy of mixing the samples with items from different rational subgroups reduces the adverse effect of the autocorrelation on the chart's performance.

Bayesian Analysis of Very Small Unreplicated Experiments

Víctor Aguirre-Torres
Statistics Department, Instituto Tecnológico Autónomo de México (ITAM)
Email: aguirre@itam.mx

Román de la Vara
Quality Engineering Department, Centro de Investigación en Matemáticas (CIMAT)
Email: delavara@cimat.mx

There are situations when resources are scarce or experimental runs are expensive to get and very small unreplicated experiments are used. For example fractions with 8 or 4 experimental runs. Unreplicated experiments are typically analyzed using the Daniel plot of the effects. For small fractions the Daniel plot could be hard to interpret even if there are significant effects. For this reason we propose the use of two Bayesian tools for analyzing this kind of experiments: posterior probabilities that the effects are active, and the posterior density of the effects. The first tool is implemented in R for normal or generalized linear models to allow for non-normal responses, and the second tool is obtained using Winbugs. Examples and simulations are given to support the use of these tools.

I – W – 3B: "Design of Experiments in the U.S. Department of Defense"

Examining Improved Experimental Designs for Wind Tunnel Testing Using Monte Carlo Sampling Method

Raymond R. Hill
Air Force Institute of Technology
Email: Raymond.Hill@afit.edu

(Based on joint work with Derek A. Leggio, Shay R. Capehart, August G. Roesener)

Wind tunnels are used in the design and testing of a wide variety of systems and products. Wind tunnel test campaigns involve a large number of experimental data points, can take a long time to accomplish, and can consume tremendous resources. Design of Experiments is a systematic, statistically based approach to experimental design and analysis that has the potential to improve the efficiency and effectiveness of wind tunnel testing. In Defense Acquisition, wind tunnel testing of aircraft systems may require years of effort to fully characterize the system of interest. We employ data from a fairly large legacy wind tunnel test campaign and compare that data's corresponding response surface to the response surfaces derived from data generated using smaller, statistically motivated experimental design strategies. The comparison is accomplished using a Monte Carlo sampling methodology coupled with a statistical comparison of the system's estimated response surfaces. Initial results suggest a tremendous opportunity to reduce wind tunnel test efforts without losing test information.

A Case Study of Design of Experiments in Army Test and Evaluation

Paul Roche
Army Test and Evaluation Command
Email: paul.roche@us.army.mil

Casey Turner
Army Test and Evaluation Command
Email: Casey.N.Turner@us.army.mil

Two test events for a projectile system will be discussed to illustrate an application of Design of Experiments (DOE) in Army Test and Evaluation (T&E) along with some current challenges to implementing DOE. Design of Experiments first took root in the early 20th century and has since become a widely used tool. The numerous stakeholders in Army Acquisition require an iterative team approach to implementing DOE to ensure all requirements are met across the developmental and operational testing. The increasing demands for test efficiencies require an expanded use of split-plot designs. While challenges remain, continued support and development of design of experiments in Army T&E will result in more rigorous system evaluations.

DOE Power Analysis for Continuous and Discrete Response Variables

Swala Burns
Marine Corps Operational Testing and Evaluation Activity (MCOTEA)
Email: swala.burns@usmc.mil

This presentation will review methods for calculating the power of a test design with continuous and discrete (including binary) response variables. The mathematics behind the methods will be illustrated and discussed briefly in order to keep the presentation within time and difficulty-level constraints. The difference in power for the continuous output and discrete output variables will be illustrated with real-world examples. Some SAS JMP software slide demonstrations will also be shown.

I – T – 1A: "Multivariate Tools for Quality Improvement"

Multivariate Analysis and the Quality by Design Initiative in Pharmaceutical Industry

Theodora Kourti
GlaxoSmithKline
Email: kourtit@mcmaster.ca

The pharmaceutical industry has entered a new phase. Attention is now being paid to real time process monitoring, real time process control, continuous improvement of processes, and quick product technology transfer. Terms like Quality by Design, Design Space, Control Strategy, Process Analytical technology, Process Signature are now used to reflect the current state. Multivariate Statistical Analysis has played an integral part in several industries, enabling process understanding, utilization of real time analysers and Real Time Product release. It is therefore appropriate to see it as an integral part of the pharmaceutical industry effort to address issues like Design Space, Control Strategy, real time process signature monitoring, process understanding and correct technology transfer. In this work it is demonstrated that multivariate, data based statistical methods play a very critical role in providing solutions to these issues. From determining the acceptability of raw material entering the plant to ensuring quality of the product that leaves the plant, the multivariate analysis philosophy should govern all the operations that take that raw material and convert it to a final product in a cost efficient way, while meeting safety and environmental constraints, from development to manufacturing to site transfer.

Modeling and Robust Parameter Optimization of Profile Response Experiments

Hussam Alshraideh
Dept. of Industrial and Manufacturing Engineering, The Pennsylvania State University
Email: haa134@psu.edu

Enrique del Castillo
Dept. of Industrial and Manufacturing Engineering, The Pennsylvania State University
Email: exd13@psu.edu

Profile response experiments arise in a variety of applications in practice. In these experiments, it is frequent to desire a particular shape of the profile response which in turn defines desired properties of the product or process. In this paper, we propose a spatio-temporal Gaussian Process model for such profile response systems. The modeling approach is Bayesian and allows to optimize the shape of the profile response in robust parameter design scenarios, i.e., it allows to maximize the probability the profile is within a given specification band when environmental or noise factors exist, in addition to the controllable factors. The proposed model and optimization method is applied to data sets obtained from the literature. Preliminary results show that the proposed approach provides optimal process settings that yield higher probability of conformance of the resulting profiles compared to other methods available.

A Comparative Study of Different Methodologies for Fault Diagnosis in Multivariate Quality Control

Santiago Vidal-Puig
Dept. of Applied Statistics, O.R. and Quality Universidad Politécnica de Valencia (Spain)
Email: svidalp@eio.upv.es

Alberto Ferrer
Dept. of Applied Statistics, O.R. and Quality Universidad Politécnica de Valencia (Spain)
Email: aferrer@eio.upv.es

Different methodologies for fault diagnosis in multivariate quality control have been proposed in the last years in the literature. These methods work in the scale of the original measured variables and have performed reasonably well when there is a reduced number of mildly correlated quality and/or process variables with a well-conditioned covariance matrix. These approaches have been introduced by emphasizing their positive or negative virtues, generally on an individual base, so it is not clear for the practitioner which method should be used in a particular context. This paper provides a more comprehensive comparison study of the performance of those approaches under a wide number of different simulated scenarios. The goal is to highlight the weaknesses and strong points of all of them, clarifying their relationships and the requirements for their implementation in practice.

I – T – 1B: "DOE for Computer Experiments"

Sliced Latin Hypercube Designs

Xinwei Deng
Virginia Tech

Bridge Designs for Modeling Systems with Small Error Variance

Bradley Jones
SAS Institute
Email: Bradley.Jones@jmp.com

(Co-authors: Rachel T. Johnson, Naval Postgraduate School, Douglas C. Montgomery, Arizona State University)

A necessary characteristic of designs for deterministic computer simulations is that they avoid replication. This characteristic is also necessary for one-dimensional projections of the design, since it may turn out that only one of the design factors has any non-negligible effect on the response. Latin Hypercube designs have uniform one-dimensional projections, but are not efficient for fitting low order polynomials when there is a small error variance. D-optimal designs are very efficient for polynomial fitting but have substantial replication in projections. We propose a new class of designs that bridge the gap between Latin Hypercube designs and D-optimal designs. These designs guarantee a minimum distance between points in any one-dimensional projection. Subject to this constraint they are D-optimal for any pre-specified model.

Non-collapsing Spacing-filling Designs for Bounded Polygonal Regions

Angela M. Dean
The Ohio State University
Email: dean.9@osu.edu

(Joint work with Danel Draguljic and Thomas Santner)

Many physical processes can be described via mathematical models implemented as computer codes. A computer experiment is a set of runs of a computer code which obtains outputs for selected sets of input values (design points). Since a computer code may take hours or days to produce a single output, a cheaper surrogate model (emulator) may be fitted for exploring the region of interest. The performance of the emulator depends on the "space-filling" properties of the design; that is, how well the design points are spread throughout the experimental region. The output from many computer codes is deterministic, in which case no replications

are required at, or near, any design point to estimate error variability. In addition, designs that do not replicate any value for any single input ("non-collapsing" designs) are the most efficient when one or more inputs turn out to have little effect on the response. An algorithm is described for constructing space-filling and non-collapsing designs for computer experiments when the input region is bounded.

I – T – 2A: "Robust Design and Design of Experiments for Time Series Data"

A Re-interpretation of the Loss Function Reasoning

Stefano Barone
Chalmers University of Technology, Goteborg (Sweden)
Email: stefano.barone@chalmers.se

Bo Bergman
Chalmers University of Technology, Goteborg (Sweden)

Based on Taguchi's idea of loss function, researchers have been more concerned on developing different analytical models of loss than clarifying the reasoning behind the loss function idea. This is a missing link necessary for a complete interpretation and more profitable use of the loss function. For example, an issue still open in the statistical engineering literature is the tolerance allocation, i.e. the way to set specification limits for critical characteristics or performances of interest of a system under study. A common approach to tolerance allocation is based on the idea of Loss function initially developed by Taguchi. Unfortunately, some obstacles prevent from a full exploitation of the Taguchi approach, since despite its clarity, it is poorly operational. In this presentation the authors will show a method to operatively build loss functions from field data and to finally set tolerance limits, starting from an elicitation of the rationale hidden behind the loss function concept. An illustrative example completes the paper.

Towards Improved Analysis Methods for Two-Level Factorial Experiments with Time Series Responses

Erik Vanhatalo

Luleå University of Technology (Sweden)
Email: erik.vanhatalo@ltu.se

Many industrial processes are dynamic, exhibiting a time-delay between a disturbance and the resulting process response. Hence, it becomes necessary to acknowledge, for example, transition times when planning and analyzing experiments in dynamic processes. Combined with measurement systems using high frequency sampling, dynamic process behavior results in autocorrelated time series responses. A basic "textbook analysis" normally ignores the autocorrelation in the response series which can lead to ineffective analysis procedures, such as underestimation of location effects and overestimation of dispersion effects.

This presentation explores and compares different methods to estimate location effects for two-level factorial experiments with time series responses. Particularly, a method based on intervention-noise modeling to estimate the effects is suggested as a possible improvement compared with an "easy and quick" method using the average of the response in each run to calculate the effects. Results from simulated experiments using a dynamic continuous process model are presented.

The results indicate that although the effect estimates for the compared analysis methods are similar, intervention-noise models are more comprehensive, render fewer spurious effects, find more of the active effects for unreplicated experiments, and provide the possibility to model transition periods during the experiment.

Non-regular Designs: Properties and Analysis

John Sølve Tyssedal
Department of Mathematical Sciences, NTNU, Norway
Email: tyssedal@stat.ntnu.no

For screening many factors in few runs under the assumption of factor sparsity, non-regular two-level designs are very useful. This is due to their remarkable projection properties. One of the reasons why these designs are not used as often as they should is the lack of good available software to do the analysis. Focusing on that the main purpose of screening is to identify the subspace of active factors we compare properties of non-regular to the ones of regular designs and demonstrates some useful techniques than can be used in their analysis.

I – T – 2B: "Topics in Statistical Process Control"

The Use of Control Charts with Image Data

Fadel M. Megahed William H. Woodall
Industrial and Systems Engineering, Virginia Tech

Email: fmegahed@vt.edu

William H. Woodall
Department of Statistics, Virginia Tech
Email: bwoodall@vt.edu

Jaime A. Camelio
Industrial and Systems Engineering, Virginia Tech
Email: jcamelio@vt.edu

Machine vision systems are increasingly being used in industrial applications due to their ability to provide not only dimensional information, but also information on product geometry, surface defects, surface finish, and other product and process characteristics. There are a number of applications of control charts for these high dimensional image data to detect changes in process performance and to increase process efficiency. We review control charts which have been proposed for use with image data in industry, and in some medical device applications, and discuss their advantages and disadvantages in some cases. In addition, we highlight some application opportunities available in the use of control charts with image data and provide some advice to practitioners.

Business Analytics, Data Quality, and Statistical Process Control: Opportunities for Collaboration

L. Allison Jones-Farmer
Auburn University
Email: joneall@auburn.edu

Erik Brynjolfsson (MIT) states "*We're rapidly entering a world where everything can be monitored and measured, but the big problem is going to be the ability of humans to use, analyze and make sense of the data.*" An industry-driven field, Business Analytics, can be considered a process by which data are collected and stored; retrieved and processed; summarized and analyzed; and communicated. At each step in this process, there are many sub-processes, the quality of each depending on the quality of the preceding step. The quality of the data affects the quality of the analysis and decisions made from the data. Considering the data gathering, storage, and retrieval as a process, and the data as the output of that process, quality control methods may be applicable to monitoring and improving data quality. This talk will discuss ways to operationalize measurements of the data quality dimensions. Further, we will discuss the applicability of multivariate modeling and statistical process control methods to establishing the Phase I state of in-control, and to monitor for Phase II departures from the in-control state of the data quality.

A Robust Standard Deviation Control Chart

Marit Schoonhoven
University of Amsterdam
Email: M.schoonhoven@uva.nl

Ronald J.M.M. Does
IBIS UvA, University of Amsterdam, The Netherlands
R.J.M.M.Does@uva.nl

This presentation discusses the robustness of Phase I estimators for the standard deviation control chart. A Phase I estimator should be efficient in the absence of contaminations and resistant to disturbances. Most of the robust estimators proposed in the literature so far are robust against either diffuse disturbances, i.e. outliers spread over the samples, or localized disturbances, which affect an entire sample. We compare various robust estimators and we propose a simple algorithm that is robust against both types of disturbances. The algorithm is intuitive in its use and is the best estimator in terms of overall performance. We also study the effect of using robust estimators from Phase I on monitoring in Phase II.

I – T – 3A: "Advances in Reliability and Design"

A Comparison of Maximum Likelihood and Median Rank Regression for Weibull Estimation

William Q. Meeker
Iowa State University
Email: wqmeeker@iastate.edu

The Weibull distribution is frequently used in reliability applications. Many different methods of estimating the parameters and important functions of the parameters (e.g. quantiles and failure probabilities) have been suggested. Maximum likelihood and median rank regression methods are most commonly used today. Largely because of conflicting results from different studies that have been conducted to investigate the properties of these estimators, there are sharp differences of opinion on which method should be used. The purpose of this paper is to report on the results of our simulation study, to provide insight into the differences between the competing methods, and to resolve the differences among the previous studies.

Sequential Design for Improved Reliability Estimation

Christine Anderson-Cook
Statistical Sciences Group, Los Alamos National Laboratory
Email: candcook@lanl.gov

The reliability of a system is often estimated using multiple sources of data collected over multiple years. What data to collect in a new time period to maximally improve the precision of the reliability estimate can be based on current understanding of the system and its components from previous analyses, and the quality of estimation. Resource allocation is an approach which leverages current understanding to guide new data collection in a sequential designed experiment setting. The approach will be illustrated with an example.

Experiments for Reliability Achievement

Steven Rigdon
Southern Illinois University at Edwardsville
Email: srigdon@siue.edu

Co-authors: Brandon R. Fish, Steven E. Rigdon Southern Illinois University Edwardsville; Rong Pan, Connie M. Borror, Douglas C. Montgomery, Arizona State University

When the response variable in a designed experiment is a lifetime, we must typically apply a distribution other than the normal. The Weibull distribution is the most common distribution used in life testing. We study several examples of how designed experiments can be used to achieve reliability and we discuss the concept of optimal design for life testing experiments. We also show how genetic algorithms can be used to find optimal designs.

I – T – 3B: "Measurement Systems and Uncertainty"

The metRology Package in R: Tools for Statistical Metrology and Uncertainty Analysis

William Guthrie
National Institute of Standards and Technology
Email: william.guthrie@nist.gov

Co-authors: Alan Heckert, Hung-kung Liu, Antonio Possolo, Daniel Samarov, and James Yen, National Institute of Standards and Technology, Gaithersburg, MD, USA; Stephen Ellison, LGC Limited, Teddington, Middlesex, UK

This talk describes the development and use of the R package metRology that offers specialized functions for carrying out statistical tasks common in metrological applications. The functionality of the package will be demonstrated both directly in R and using a spreadsheet interface based on the software RExcel. The interface makes it easy for scientists, engineers, and metrologists who need to carry out statistical analyses to harness the power of R with fewer of the overhead costs associated with learning a new software package.

Schemes for Gauge Matching in an Industrial Environment

Di Michelson
SEMATECH
Email: Di.Michelson@ismi.sematech.org

(Co-authors: Ben Bunday and Victor Vartanian, SEMATECH)

Forthcoming…

Measurement System Analysis of a Capable Process – Do I continue to reject good parts, improve my gauge or improve my process?

Woody Santy
Industrial Quality Consultants
Email: iqcWoody@instructor.net

(Co-author: James Stevenson, James Stevenson Consulting)

One of the often overlooked issues when conducting a Measurement System Analysis (MSA) is the estimation of misclassifying bad parts as good or good parts as bad. The articles in literature that do address this only show examples of low capability systems. When capable processes were examined using Monte Carlo simulation, the results were unexpected. We then examined the misclassification probabilities for capable systems from a Monte Carlo simulation and theoretical viewpoint.

One of the most frequently used outputs from MSA is the percent of tolerance consumed by the measurement system. Generally accepted guidelines (i.e. 10%, 20% and 30%) do not provide insight into the estimate of the probability of accepting bad parts (called Missed Faults) and rejecting good parts (called False Faults). Monte Carlo simulation for a capable process (Cpk=1.33) produced unexpected results. A search of the literature produced integral equations which were solved using numerical computations and arrived at similar results. Results are tabulated for a range of process capabilities and range of MSA values.

When the process is capable (Cpk >= 1.33), from the consumer's point of view, the gage capability (percent of tolerance consumed) can significantly exceed 30% (often up to 80%) and the consumer is protected. From the producer's point of view, the number of good parts rejected can increase significantly thus they can make a tradeoff between the cost of rejecting good parts, improving the gage or improving the process.

I – T – 4A: "Prognostics and Field Reliability"

An Analytical Approach to Assessing Maintenance Cost and Scheduling Proactive Repair

Brock Osborn
GE Global Research, Applied Statistics Lab
Email: osborn@ge.com

(Based on joint work with Michael Graham, Harish Agarwal)

One of the most powerful applications of Reliability in the industrial setting is in the area of proactive repair modeling. Owners and operators of large pieces of equipment (locomotives, aircraft engines, power generation equipment, etc.) are interested in extending the time between maintenance actions and seek strategies that, although may cost more in the short term, will ultimately result in reduced costs in the long term. Historically, reliability modeling and simulation have been used to explore the effectiveness of work scope alternatives in cost reduction. However, as equipment becomes more reliable, strategies need to be developed to optimize over longer time horizons, typically 20 to 30 years or more. Simulation proves to be inadequate in addressing this task, and an analytical solution must be developed in its place.

This talk will describe an analytical approach to modeling proactive repair and will provide an optimal solution to this problem. Examples from industry will be discussed to demonstrate the effectiveness of the solution.

A general framework for predicting the remaining useful life of a single unit under time-varying operating conditions

Haitao Liao
Department of Industrial and Information Engineering, Department of Nuclear Engineering
University of Tennessee
Email: hliao4@utk.edu

Product reliability in the field is important for a wide variety of critical applications such as manufacturing, transportation, power generation, and healthcare. In particular, the propensity of achieving zero-downtime emphasizes the need for remaining useful life (RUL) prediction for a single unit. The task is quite challenging when the unit is subject to time-varying operating conditions. This research provides a general framework for predicting the RUL of a single unit under time-varying operating conditions by incorporating the results of both accelerated degradation testing (ADT) and in-situ condition monitoring. For illustration purposes, the underlying degradation process is modeled as a Brownian motion evolving in response to the operating conditions. The model is combined with in-situ degradation measurements of the unit and the operating conditions to predict the unit's RUL through a Bayesian technique. When the operating conditions are piecewise constant, statistical approaches using a conjugate prior distribution and Markov Chain Monte Carlo (MCMC) are developed for cases involving linear and nonlinear degradation-stress relationships, respectively. Simulation experiments and a case study for ball bearings are used to verify the prediction capability and practicality of the framework. In the case study, a quantile regression technique is proposed to handle load-dependent failure threshold values in RUL prediction.

Degradation Models, Data Analyses and an Application in Service Life Prediction

Yili Hong
Department of Statistics, Virginia Tech
Email: yilihong@vt.edu

(Based on joint work with William Q. Meeker and Luis A. Escobar)

For products/systems requiring high reliability or availability, reliability assessment and maintenance actions are often needed in a timely manner. For these systems/products, information on system state and performance can be collected over the system's operating time, providing what is known as degradation data. With appropriate models and data analysis techniques, degradation data are converted to system reliability information and this information is useful for short and long-term reliability assessment and for planning maintenance actions. This presentation provides a review of degradation data models and methods that have been used successfully in this area. A new application in service life prediction will also be presented. Commonly used methods for analyzing degradation data, general path models and stochastic models are introduced. Models and methods for analyzing data from accelerated degradation tests and accelerated destructive degradation tests are also discussed. Dynamic condition monitoring based on degradation data is covered. Examples are used to illustrate the models and methods covered in this presentation. The conclusion of this

talk provides a discussion of test planning, software implementation and the future of degradation data analysis.

I – T – 4B: "Measurement Systems Analysis"

Assessing a Binary Measurement System with Varying Misclassification Rates and a Random Effects Model

Stefan H. Steiner
Business and Industrial Statistics Research Group (BISRG)
Dept. of Statistics and Actuarial Sciences, University of Waterloo
Email: shsteine@math.uwaterloo.ca

(Based on joint work with Oana Danila and R. Jock MacKay)

Binary measurement systems (BMS) are commonly used as diagnostic tools in medicine and inspection systems in industry. Understanding their properties is essential to making correct decisions with these systems. In this talk we consider the situation where no gold standard measurement is available and we must use a latent class model to assess the BMS and estimate the misclassification rates. This context has been previously considered by Danila et al. (2010), Van Wieringen and De Mast (2008), Boyles (2005) and Van Weiringen and Van den Heuvel (2005) in an industrial context and Pepe (2003), Walter and Irwing (1988) and Qu et al. (1996) in a medical setting. In this talk we propose a novel analysis of binary measurement system investigation data using a random effects model that allows the misclassification rates to vary from part to part. This modeling approach is more realistic than the usual assumption that all good (bad) parts have the same misclassification rate since, in practice, there are usually some parts that are easy to correctly classify while other parts are more difficult. We examine the performance of the analysis assuming a standard fixed effects model, i.e. with constant misclassification rates, when in fact the misclassification rates vary from part to part and, conversely, the performance of the analysis using the random effects model when the

misclassification rates are constant. Since the fixed effects model is a limiting case of the random effects model, we also provide a test of significance to assess if there is variation in the misclassification rates.

Measurement system analysis for binary inspection: Continuous versus dichotomous measurands

Jeroen de Mast

Tashi P. Erdmann
University of Amsterdam, the Netherlands
Email: t.p.erdmann@uva.nl

Wessel N. van Wieringen

We review methods for assessing the reliability of binary measurements, such as accept/reject inspection in industry. A highly relevant factor in deciding which method to use is whether the underlying property, the *measurand*, is continuous or truly dichotomous. In many practical situations, continuous measurands are treated, in a measurement system evaluation, as though they were dichotomous. Such a *false dichotomy* creates complications which are underappreciated in the literature and in practice. In particular, it introduces an intrinsic reason for the assumption of conditional i.i.d. to be violated. We think that continuous measurands are far more common than truly dichotomous measurands and, therefore, complications for false dichotomies are a ubiquitous problem. A related issue is that many guidelines offered in industry are in conflict with our conclusion that random sampling is in many cases crucial.

Understanding Measurement Systems and Their Impact on Statistical Analysis

Joanne R. Wendelberger
Statistical Sciences Group, Los Alamos National Laboratory
Email: joanne@lanl.gov

Understanding data often requires careful analysis of the measurement system used to collect the data. Even elementary statistical methods must be thought through carefully in the presence of variability inherent in measurement systems. Failure to consider errors associated with the measurement system can result in misleading analyses. This presentation will discuss concepts associated with measurement systems that are important but often ignored. Failure to consider errors associated with measurement systems can result in misleading analyses. Examples of data obtained from different measurement systems will be provided to illustrate the complexities that can arise in the collection of data.

I – F – 1A: "Quality Issues in the Pharmaceutical Industry"

Assessing Measures of Precision for Method Transfer Studies when Random Effects are Sampled from Finite Populations

Jorge Quiroz
Merck Research Laboratory, Nonclinical Statistics
Email: jorge.quiroz@merck.com

In method transfer studies based on measures of precision, it is necessary to determine whether the measures of precision are consistent with validated limits. A common practice is to estimate the precisions using mixed effect designs assuming that the laboratories are sampled from an infinite population. This assumption may not be supported by the data since the laboratories are selected from a finite population. Models with laboratories as random effects provide confidence intervals on the measures of precision that are too wide, and fixed effects models underestimate the true precisions. In this presentation, we compare alternative methods for modeling precisions in a method transfer study.

Reducing Variability in Biological Assays

Tom Steinmetz
Viral Vaccine Technology & Engineering, Merck & Co., Inc.
Email: thomas_steinmetz@merck.com

Julia O'Neill
Merck & Co., Inc.
Email: julia_oneill@merck.com

Manufacturing biological products, such as vaccines, depends on producing consistent output from inherently variable processes such as cell growth and virus propagation. Often process control systems are based on inputs from biological assays. The assays themselves rely on inherently variable biological processes, as well as standard measurement techniques such as dilution and image analysis.

A biological assay was scrutinized at the deepest level of detail to gain understanding of the sources of variation with greatest impact on results. This deeper understanding enabled dramatic improvements in assay precision and accuracy, which in turn enabled improvements in the long-term capability of the process and assay. The connections between statistical methodology, biological understanding and quality improvement will be illustrated with a case study from a vaccine potency assay.

Change Point Analysis: Looking Back at What Happened

Rebecca Elliott
Research Scientist, Eli Lilly & Company
Email: rjelliott@lilly.com

In manufacturing drug substances and drug products, normal process monitoring techniques, like control charting, help identify special cause events as they occur. In some cases, investigations into what happened in the past need different techniques to help identify changes in processes. Change Point Analysis, as described by Dr. Wayne A. Taylor, provides a way to identify when these changes occurred and provides a statistical confidence for those changes. In this talk, some background contrasting control chart and change point techniques will be given with examples of how change point analysis has helped identify process shifts.

I – F – 1B: "Modeling and Analysis of System Reliability"

Selecting an Optimal Consumption Strategy based on Multiple Reliability Criteria Utilizing a Pareto Frontier

Lu Lu
Los Alamos National Laboratory
Email: lulu@lanl.gov

Managers are often faced with difficult decisions about how to balance multiple competing objectives when selecting a best strategy to consume units in their inventory or stockpile. We propose a two-phase decision-making process using a Pareto frontier approach to identify a good consumption strategy for a population of units which age over time, and are to be used in fixed time intervals. The approach selects several good strategies for a subset of representative

units in the first phase and then projects the consumption patterns back to the original population and uses them as the starting point to search for a fine-tuned final solution. The Pareto front optimization approach and graphical tools to facilitate improved decision-making are used in both phases of the proposed process. The complete decision-making process is illustrated for a population of single–use nonrepairable units, such as missiles or batteries, while balancing three competing objectives: most consistent reliability for units used across all time intervals, lowest uncertainty to estimate reliability, and highest average reliability.

Bayesian Model Selection for Good Prediction of Future Reliability Using a Generalized Linear Model

Adam L. Pintar
National Institute of Standards & Technology
Email: apintar@iastate.edu

Christine M. Anderson-Cook
Los Alamos National Laboratory
Email: candcook@gmail.com

Huaiqing Wu
Iowa State University
Email: isuhwu@iastate.edu

Generalized linear models such as probit and logit regression are important tools for assessing reliability; however, what explanatory variables to include is an important consideration. In the Bayesian paradigm, if unimportant explanatory variables are included, posterior distributions will have inflated variance. If important explanatory variables are excluded, posterior distributions can be biased and miss their (true, but unknown) target. Several model selection methodologies currently exist for this setting, including selection of the model with smallest deviance information criterion, the model with largest posterior probability, or the model containing all terms with posterior probability greater than 0.5. A common theme to all of these methodologies is that they consider only the observed data. However, if one is interested in predicting future reliability, a different strategy is suggested because it is possible that the best model for prediction is dependent on age range. We propose a model selection methodology that focuses on good prediction over a user-specified distribution on the covariate space. The methodology quantifies the prediction ability of all models under consideration at covariate points sampled from the user-specified distribution. Then, a best

model is identified by graphically comparing the distributions of prediction abilities. The methodology is illustrated via an example, and a simulation study highlighting its performance is presented.

Negative Log-Gamma Modeling for Reliability Trends in Series Systems

Roger Zoh
Iowa State University
Email: rszoh@iastate.edu

Alyson Wilson
Iowa State University

Modeling system reliability over time when binary data are collected both at the system and component level has been the subject of many papers. In a series system, it is often assumed that component reliability is linear in time through some link function. Often little or no prior information exists on the parameters of the linear regression, and in a Bayesian analysis they are modeled using very diffuse priors.This can have unintended consequences for the analysis, specifically in the prediction of system reliability. In this work, we consider negative log-gamma distributions as means of specifying prior information on reliability. We first show how our method can be implemented in modeling the reliability of a series system at a given time and then extend to the case where we are interested in modeling reliability over time.

I – F – 2A: "Choice Experiments"

Optimal Stated Choice Designs

Fangfang Sun
The Ohio State University
Email: sun.238@osu.edu

(This is a joint work with Angela M. Dean)

Stated choice experiments are widely used for studies in areas such as marketing research, city and transportation planning and health care. In such studies, subjects are presented with a series of choice sets containing two or more options and asked to select one of the options within each choice set. The options are composed of attributes, which may be at different levels. An objective of the study is often to estimate the main effects of those attributes and possibly their interactions. The experimental design selected for the study should give the smallest possible variance of the effect estimators. However, under MNL model, the best design depends on the "attractiveness" of the options.

This talk deals with choice sets of size 2, where each attribute has two levels. A lower bound for the average variance of the estimators is given when equal attractiveness beliefs are held on the options. The situation of unequal prior beliefs on the options' attractiveness is also discussed. Some examples of designs achieving the bound are given.

I-Optimal Designs for Mixture Experiments with Linear Inequality Constraints

Laura Lancaster
SAS
Email: Laura.Lancaster@jmp.com

(Joint work with Chris Gotwalt)

Predictive capability is an important objective of many mixture experiments. Because they minimize the average prediction variance over the design region, I-optimal designs would be a natural approach in mixture design situations. However, until now they have not been investigated because creating I-optimal designs for mixture experiments with linear inequality constraints on the factors is particularly challenging in two regards. First, the objective function involves a moments matrix whose calculation requires several integrals over a linearly constrained region. The other challenge involves finding the optimal design in the presence of linear inequality constraints, as nonlinear programming methods are needed for the optimization. We will show how a Monte Carlo method for generating random uniform points over an arbitrary linearly constrained region can be used to calculate the moments matrix and how the Wolfe reduced gradient method can be used for optimizing the design. In addition, we demonstrate the improved predictive capacity of I-optimal mixture designs by comparing them with other methods for generating mixture designs. This method will be demonstrated with an applied ratings based choice experiment.

Bayesian Optimal Design of Discrete Choice Experiments for Large Numbers of Attributes

Roselinde Kessels
Universiteit Antwerpen
Email: roselinde.kessels@ua.ac.be

(Joint work with Peter Goos & Bradley Jones)

Discrete choice experiments are widely used to study people's preferences in various areas in economics where behaviors of interest involve discrete responses or qualitative choices (e.g. transportation mode choices, consumer goods choices). Typically, respondents choose among hypothetical (occasionally real) options or alternatives presented in choice sets where the alternatives are described by levels of a set of predefined attributes. Respondents can find it difficult to trade off prospective goods when every attribute of the offering changes for each comparison. Especially in studies involving many attributes, respondents get overloaded by the complexity of the choice task. To overcome respondent fatigue, it is better to simplify the comparison by holding some of the attributes constant in every choice set. However, keeping the choice tasks manageable for the respondents through the use of constant attributes comes at a loss of information on the parameters of the underlying choice model. In case the number of levels for each attribute differs between the attributes, it makes sense to hold an attribute with fewer levels constant more often than an attribute with a larger number of levels to obtain similar amounts of information on each type of effect. In this talk, we describe a Bayesian optimal design approach to constructing discrete choice experiments with constant attributes and show how to account for homogeneous as well as heterogeneous numbers of levels for the attributes.

I – F – 2B: "Mary Natrella Session"

Generalized Likelihood Ratio Cusum based on a Nonparametric Kernel Density Estimation

Tatevik Ambartsoumian

We use the Generalized Likelihood Ratio CUSUM to detect a change in the distribution of the incoming observations when both the in-control and the out-of-control densities are unknown. We assume that there is enough historical data to estimate the in-control density using a proper nonparametric Kernel Density Estimation method. Additionally, we assume that the out-of-control density of the observations can be characterized from the in-control density through a suitable shift or a scale transformation. We propose an algorithm for tuning the threshold parameter, H, in order to achieve the specified Average Run Length when the distribution is in control. We illustrate our results under several different scenarios.

Comparisons to the Early Aberration Reporting System's W2count Method

John L. Szarka, III
Department of Statistics, Virginia Tech

Email: szarkajl@vt.edu

The Centers for Disease Control and Prevention (CDC) established the BioSense program with the intent of providing real-time biosurveillance for early event detection. The CDC's Early Aberration Reporting System (EARS) has been implemented in hundreds of hospitals and public health departments across the United States to determine whether or not syndromic outbreaks have occurred. The W2count (W2c) method is used for alerting whether a daily syndromic count at a health facility is large relative to a baseline of recent counts. An adaptive threshold method is presented as an alternative to the W2c approach, where a parametric distribution can be fit to the baseline data. An exponentially weighted moving average (EWMA) method is also implemented for each monitoring technique. We consider yearly seasonal patterns for Poisson and negative binomial data to represent the distribution of syndromic counts. The effectiveness of these surveillance methods is evaluated by injecting outbreaks into our data streams and determining the detection rates for each method.