Course Title: Regulatory Science Principles – SCSC 634

Term

Meeting Location: Online

Credit Hours: 3

Course Description and Prerequisites

Regulatory tools, standards and practices to improve the protection and compliance of regulated systems; interdependence of regulatory agencies; models of risk analysis with emphasis on conducting a qualitative and quantitative risk assessment; and implications of compliance.

This course will address the following topics:

- Emerging Field of Regulatory Science
- Regulatory Policy
- Role of Risk Analysis in Regulatory Science
- Conducting a Risk Assessment
- Current Issues and Problems

Course Objectives

After completing this course, students will possess a practical knowledge of how to apply risk analysis to hazards in regulated products. The course is intended to equip students with the breadth of knowledge needed to participate in policy development and manage risk at a corporate and government level, as well as utilize standards to evaluate conformance based on regulatory science principles.

Instructor Information

Dr. Tim Herrman
Professor, Department of Soil and Crop Sciences
State Chemist and Director, Office of the Texas State Chemist

Email Address: tjh@otsc.tamu.edu
Phone Number: (979) 845-1121
Fax: (979) 845-1389
Program Website: http://regsci.tamu.edu/
**Course Tools**

All course materials and activities will be presented using the eCampus Learning Management system, powered by Blackboard. Log into eCampus at [http://ecampus.tamu.edu](http://ecampus.tamu.edu) to gain access. Before you access course materials, please perform a Vista Browser Check by clicking on the Check Browser Support link to ensure compatibility.

**Resource Materials**

There are no required text books. Readings will be taken from reference materials including government publications and standards. Most readings will be available in eCampus in .pdf format. Other readings will be available online, with a hyperlink provided in eCampus. Online slide presentations with audio for each module can be accessed from eCampus. The slides for each presentation will be provided as a .pdf file that can be downloaded and printed if needed.

**Technical Requirements**

To ensure successful participation, students must have access to:

- A computer that is less than 4 years old
- Microphone and speakers
- High-speed Internet connection (cable/DSL or better) and an updated browser
- Microsoft Word, PowerPoint, and Excel (2003-2013) or equivalent
- Plug-ins for course materials (e.g. Adobe Reader, Adobe Flash player, etc.)

Software is available to students at a discounted price through the Texas A&M Software Center, available at [http://software.tamu.edu](http://software.tamu.edu)

**Graded Assessments**

**Discussions (4)**

There will be four graded discussions held on the discussion forum in eCampus. Your responses to the questions posted to the discussion board will be evaluated and included in your final grade. Ungraded discussions are also available and are a good way to communicate with other students to share ideas and insights or ask a question. However, if you need an immediate answer to a question, please send an email directly to Dr.Herrman at tjh@otsc.tamu.edu

**Homework Assignments (5)**

Homework will involve applying a model for risk assessment using DecisionTools Suite.

**Quizzes (4)**

There will be four quizzes on information in the course readings and presentations. All quizzes will be administered through eCampus.

**Projects (2)**

Project #1 will be to perform a Qualitative Risk Assessment. Project #2 will be to perform a Quantitative Risk Assessment.
Exams
There are no exams for this course.

Grading Policies

Discussions, homework, quizzes, and projects must be completed by the due date unless prior approval has been granted by the instructor. Your grades will be determined as follows:

- Quizzes (4) = 20 points
- Homework assignments (5) = 25 points
- Discussions (4) = 20 points
- Project (#1) = 20 points
- Project (#2) = 20 points

A = 90+ points
B = 80 - 89 points
C = 70 – 79 points
D = 60 – 69 points
F = < 60 points
## Course Topics, Calendar of Activities, Major Assignment Dates

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<th>Week</th>
<th>Topic</th>
<th>Assignments</th>
<th>Due Date</th>
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<tr>
<td><strong>Unit 1 – Emerging Field of Regulatory Science</strong></td>
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<tr>
<td>1</td>
<td>What is Regulatory Science; Origins and Rationale behind US FDC Act;</td>
<td>Self-intro. Quiz</td>
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<td>2</td>
<td>Other US food safety agencies, laws, and regulations</td>
<td>Quiz</td>
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<td><strong>Unit 2 – Regulatory Policy</strong></td>
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<td>3</td>
<td>US Food Policy</td>
<td>Discussion</td>
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<td>4</td>
<td>Integrated Food Safety System; Globalization and Trade</td>
<td>Quiz</td>
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<td><strong>Unit 3 – Risk Analysis and Food Protection System</strong></td>
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<td>5</td>
<td>Risk and Uncertainty; Risk Analysis – FAO/WHO Model</td>
<td>Discussion</td>
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<td>6</td>
<td>Risk Analysis – OIE Model, NAS-NRC Model Risk Assessment - OIE</td>
<td>Quiz</td>
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<td><strong>Unit 4 – Probability Distribution and Risk Assessment</strong></td>
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<td>Introduction to @ Risk Probability Principles Review Binomial Process</td>
<td>Homework</td>
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<td>Poisson and Hypergeometric Processes Normal Distribution, Central Limit Theorem</td>
<td>Homework</td>
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<td><strong>Unit 5 – Risk Assessment Modeling</strong></td>
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<td>9</td>
<td>Risk Assessment Modeling; Probabilistic Scenario Modeling; Introduction to Precision Tree</td>
<td>Homework</td>
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<td>Infectious Disease Modeling</td>
<td>Homework, Class Project</td>
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<td>Dose Response</td>
<td>Homework</td>
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<td>Bootstrap and Bayesian Modeling</td>
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<td><strong>Unit 6 – Current Issues and Problems</strong></td>
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<td>13</td>
<td>Whose science should we use?</td>
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<td>14</td>
<td>Social and Economic Implications of Compliance</td>
<td>Discussion</td>
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<td>Class Project</td>
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**Instructor/Student Communication**

Please send all emails to tjh@otsc.tamu.edu. I will not be using the eCampus Mail Tool. If you have a question about the material, please post it in the discussion board so that other students have the chance to respond to it and/or benefit from the answer. I will read the discussion board and will reply to messages when necessary. All student communication will be sent via TAMU email accounts (http://gateway.tamu.edu) unless you provide a preferred alternate email address.

**Attendance and Make-up Policies**

Due to the participatory nature of this online class, regular log-in to the eCampus is expected. Excused absences are subject to Texas A&M rules and guidelines. For more information, visit http://student-rules.tamu.edu/rule07. If an absence is excused, the instructor will either provide the student an opportunity to make up any quiz, exam, or other work that contributes to the final grade or provide a satisfactory alternative by a date agreed upon by the student and the instructor. The make-up work must be completed in a timeframe not to exceed 30 calendar days from the last day of the initial absence.

**University Policies**

The Americans with Disabilities Act (ADA) is a federal anti-discrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this legislation requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation for their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services at Student Services at the White Creek Complex on west campus, or call (979) 845-1637. For additional information, visit http://disability.tamu.edu

Information regarding Texas A&M’s Accessibility Services can be found at http://itaccessibility.tamu.edu

**Copyright**

Course materials and all other materials generated and/or used during this course are copyrighted. As a result, you do not have the right to copy the course packets unless given explicit permission by the instructor.

**Academic Integrity**

“An aggie does not lie, cheat, or steal or tolerate those who do.”

For more information about the Aggie Honor code, please visit http://aggiehonor.tamu.edu