JEFFERSON COLLEGE
COURSE SYLLABUS

BET205
Regulations and Public Safety in the Healthcare System
2 Credit Hours

Prepared by: Melissa Kanzelberger-Coolich, PhD
Date: 2/12/2013

Dr. Mary Beth Ottinger, Division Chair
Dr. Dena McCaffrey, Interim Dean, Career & Technical Education
BET205 Regulations and Public Safety in the Healthcare System

I. CATALOGUE DESCRIPTION

A. Pre-requisite: ENG101 English Composition I with a “C” or better, and reading proficiency.

B. Credit Hour Award: 2 semester hours

C. Regulations and Public Safety in the Healthcare System provides a broad survey of the major standard and regulatory bodies impacting healthcare (FDA, OSHA, NEC, FCC, ANSI) and the correlation to safety precautions, best practices and standard operating procedures. Medical device data systems, application of risk management for IT, HIPPA, Digital Millennium Copyright Act, and biomedical equipment certification are also discussed. Writing and video presentation assignments will demonstrate comprehension and medical communication skills. (S)

II. EXPECTED LEARNING OUTCOMES/CORRESPONDING ASSESSMENT MEASURES

<table>
<thead>
<tr>
<th>Expected Learning Outcomes</th>
<th>Assessment Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understand the legal rhetoric, scope, and impact of the Food and Drug Association on medical equipment decisions, device approvals and reporting</td>
<td>FDA web search Video presentation on FDA regulated device and how regulation affects design characteristics Written Examinations</td>
</tr>
<tr>
<td>Learn and apply occupational health and safety standards, precautions, engineering controls, work practices and enforcement</td>
<td>Class Discussion/Activity Written Assignment Written Examinations</td>
</tr>
<tr>
<td>Learn the fundamentals of the National Electric Code along with procedure evaluation, and practices for safe installation and inspection</td>
<td>Class Discussion/Activity Assessment to identify examples of unsafe practices. Written Examinations</td>
</tr>
<tr>
<td>Identify Federal Communications Commission-proposed solutions to reduce healthcare costs</td>
<td>Report on how FCC proposes to reduce medical costs. Identify ways to improve proposal and submit idea to FCC representative. Written Assignment Written Examinations</td>
</tr>
</tbody>
</table>
| Understand the role and impact of the American National Standards Institute- Healthcare Information Technology Standards Panel with specific focus on electronic health records reporting, biosurveillance, public healthcare reporting, patient security and remote monitoring | Class Discussion/Activity | Written Assignment
Written Examinations |
| Mitigate legal risks through the understanding of the Health Insurance Portability and Accountability Act, digital millennium copyright act, biomedical systems precautions | Class Discussion/Activity | Written Assignment
Written Examinations |
| Execute standard working-practices including material safety data sheet implementation, and the handling of chemicals, radiation, fire, biologics and other hazards | Written Assignment
Written Examinations | AAMI website familiarization
Written Assignment
Written Examinations |
| Learn about the Advancing Safety in Medical Technology (AAMI) association, CBET certification, and association membership | | |

### III. OUTLINE OF TOPICS

**A. Food & Drug Association (FDA)**
1. Influence
2. FDA database navigation
3. Identifying approved devices
4. Human device exemption
5. Center for Devices and Radiological Health
   i. Identifying device recalls
   ii. Medical device reporting/Safe Medical Device Act
6. Federal safety commission

**B. Occupational Safety and Health (OSHA)**
1. Bloodborne pathogens
2. Engineering controls
3. Sharps/needlesticks
4. Work practices
5. Enforcement procedures
6. Equipment hazards
7. Fire extinguishers
8. Lock out/tag out

**C. National Electric Code (NEC)**
1. NFPA 70
2. Benchmark for safe evaluation
3. Installation
4. Inspection

**D. Federal Communications Commission (FCC)**
1. Broadband enabled solutions
2. Implementation of new systems
3. Initiatives to reduce healthcare costs led by technologists
E. Advanced Transfusion and Cellular Therapies Worldwide (AABB)
   1. Blood transfusion medicine
   2. Patient blood management

F. American National Standards Institute (ANSI) Healthcare Information Technology Standards Panel
   1. Electronic health record laboratory results reporting
   2. Biosurveillance
   3. Consumer empowerment
   4. Emergency responder electronic health record
   5. Quality
   6. Public healthcare reporting
   7. Patient-secure messaging
   8. Remote monitoring

G. Risk Management for Electronics Professionals
   1. HIPPA
   2. Digital Millennium Copyright Act
   3. Precautions

H. Standard Practices
   1. Material Safety Data Sheet
   2. Chemical handling
   3. Fire
      i. Class
      ii. Fire extinguishers
   4. Radiation hazards
      i. Light spectrum
      ii. Types of rays
   5. Biological safety
      i. Sharps handling
      ii. Equipment decontamination
      iii. Bloodborne pathogens
   6. Compressed gas safety

I. Association for the Advancement of Medical Instrumentation (AAMI)
   1. Certified biomedical electronics technician (CBET)
   2. Exam requirements
   3. Exam preparation
   4. Membership

IV. METHOD(S) OF INSTRUCTION

Traditional lecture, individual research with writing assignment, and final project featuring video presentations.
V. REQUIRED TEXTBOOK(S)


VI. REQUIRED MATERIALS

A. Textbook
B. Binder
C. Flash Drive
D. Computer with Internet Access (Available through Jefferson College Computer Lab)
E. Access to Recording Software or Video Camera

VII. SUPPLEMENTAL REFERENCES

A. Library Resources
B. Course Handouts
C. Online Media/Reference Materials

VIII. METHOD OF EVALUATION

A. Attendance/Participation 10%
B. Midterm 20%
C. Quizzes 5%
D. Assignments 15%
E. Final Project 15%
F. Final Examination 35%
G. Grading Scale:

- A= 90-100%
- B= 80-89.9%
- C= 70-79.9%
- D= 60-69.9%
- F= 0-69.9

All written/oral assignments and test questions will be judged by content as well as quality of writing and presentation skills.

IX. ADA AA STATEMENT

Any student requiring special accommodations should inform the instructor and the Coordinator of Disability Support Services (Library; phone 636-481-3169).

X. ACADEMIC HONESTY STATEMENT

All students are responsible for complying with campus policies as stated in the Student Handbook (see College Website, http://www.jeffco.edu).

XI. ATTENDANCE STATEMENT

Regular and punctual attendance is expected of all students. Any one of these four options may result in the student being removed from the class and an administrative withdrawal being processed: (1) Student fails to begin class; (2) Student ceases participation for at least two consecutive weeks; (3) Student misses 15 percent or more of the coursework; and/or (4) Student misses 15 percent or more of the course as defined by the instructor. Students earn their financial aid by regularly attending and actively participating in their coursework. If a student does not actively participate, he/she may have to return financial aid funds. Consult the College Catalog or a Student Financial Services representative for more details.

XII. OUTSIDE OF CLASS ACADEMICALLY RELATED ACTIVITIES

The U.S. Department of Education mandates that students be made aware of expectations regarding coursework to be completed outside the classroom. Students are expected to spend substantial time outside of class meetings engaging in academically related activities such as reading, studying, and completing assignments. Specifically, time spent on academically related activities outside of class combined with time spent in class meetings is expected to be a minimum of 37.5 hours over the duration of the term for each credit hour.