

Austin Community College, Biotechnology Department

Quality Manual

Version 1.4

Reviewed and Approved by:

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QUALITY MANUAL

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Section 1 Austin Community College, Biotechnology Department

1.1 Profile

The Biotechnology Program at Austin Community College works with the local bioscience industry to educate students in basic laboratory skills, math skills, genetic engineering, protein purification, cell culture, quality assurance and quality control principles, regulations, trouble shooting skills, bioinformatics, computer skills, ethics, documentation, and teamwork. Students are educated and trained to work in a variety of positions that span various different fields including Pharmaceutical, Molecular Diagnostics, Manufacturing, Research and Cancer Research, Fisheries and Wildlife and Cell Culture. The State of Texas has adopted the Washington Skill Standards for Biotechnology. The Austin Community College Biotechnology Program has formally adopted these standards and has received program recognition from the Texas Skill Standards Board.

The ACC Biotechnology Program provides a 1-year Certificate, a 2-year Associates of Applied Science (AAS) degree and an Advanced Technical Certificate for students with a 4-year degree, in addition to a series of short continuing education courses. The Certificate provides students the basic skills for an entry-level job. The AAS degree provides students the more advanced skills necessary to be a biotechnician as well as to complete the courses for transfer to a university such as Texas A&M University, or Texas State University-San Marcos. The Advanced Technical Certificate educates post-baccalaureate students to work at the bench and is composed solely of biotechnology courses. Students can also take the biotechnology courses through the Continuing Education Program. In addition, we offer a series of short continuing education courses to satisfy workforce professional development requirements.

At the end of the program, all of the biotechnology students are required to participate in an internship. Ninety-five percent of these students are hired during their internship with starting annual salaries ranging from \$30,000 to \$40,000.

The Biotechnology Program shares facilities with the Medical Technology Program at the Eastview campus (1,610 sq. feet) and at the new facilities at the Round Rock Campus (3,600 sq. feet). The Biotechnology Program has a separate preparation room, cell culture, and storage room at both facilities and a shared lecture and instrumentation room. Students are instructed on state-of-the-art equipment such as a real-time PCR machine, HPLC, FPLC, GC, fluorescent microscope, microplate reader fluorometer, microsample quantitation (NanoDrop), and the Agilent 2100 Bioanalyzer.

Our full-time faculty have doctorate degrees with extensive experience in both academic research and industry. Many of the adjunct faculty work in industry with specializations in molecular biology, biochemistry, proteomics and cell culture.

1.2 Program Philosophy

We are committed to serving our students and the biotechnology community through excellent academic instruction and professional training utilizing traditional and innovative techniques. The faculty and staff of the biotechnology program are committed to assist the student toward the greatest academic, personal, and professional potential through quality courses and instruction.

We understand the cultural diversity of individuals, and the importance of maintaining a student-centered philosophy while striving to make wise use of community and educational resources and materials.

We are committed to continue an ongoing process of self-evaluation and self-renewal, and to maintain an outstanding accreditation rating. The Biotechnology Program, with the assistance of its Advisory Board, is committed to provide quality instruction in current techniques in industry.

The program is committed to meet the employment needs of biotechnology laboratories and to provide quality continuing education to laboratory professionals in our service area.

1.3 Mission Statement

Recognizing that the educator is the vital link between the ever-evolving biotechnology industry and a dynamic workforce, it is the mission of the Biotechnology Program to provide exceptional quality education while delivering a technologically-relevant workforce to our community-based industry partners.

Section 2 Quality Policy

2.1 Definitions

From the FDA's Code of Federal Regulations, title 21, Section 820.3, subsection s, u and v:

- **Quality** means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
- **Quality policy** means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
- **Quality system** means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

2.2 Quality Statement

The Biotechnology Department is committed to maintain and monitor a quality system to ensure we meet the educational needs of our community. The Biotechnology Department is committed to disseminating quality throughout the department in a systematic and conscientious program of *Leading by Example*.

2.3 Quality Policy

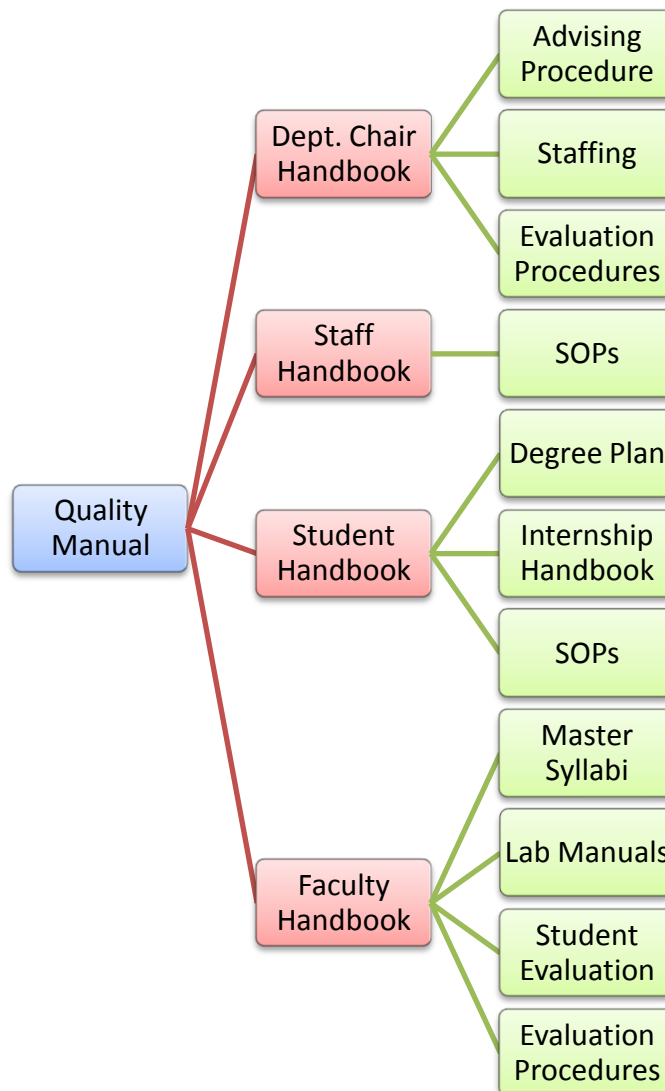
The Austin Community College Biotechnology department will accomplish the goals outlined in the mission statement by:

- Committing to a department wide Quality System detailed in the Quality Manual
- Engaging the local biotechnology industry in the development of our academic program through student internships, faculty training, and adjunct faculty and guest lecturer participation
- Committing to a program that is designed and implemented to meet customer requirements; the ACC biotechnology student, the Austin biotechnology industry and the Austin and surrounding communities as a whole
- Ensuring Biotechnology Department staff and faculty are highly qualified by meeting educational and work experience standards, annual professional development requirements, consistent policy training and continual recruitment of adjunct faculty from the local biotechnology industry
- Establishing departmental policy guidelines for students, staff and faculty ensuring communication through development of departmental handbooks and training
- Emphasizing competency-based education principles using TSSB recognized Skill Standards as guidelines in program development and classroom training
- Setting up an active monitoring system which consists of measurable quality objectives to ensure standards are maintained, evaluated, reviewed and revised as needed
- Presenting life-long learning opportunities to our community by offering an Associate's degree, certificate programs, distance learning classes, continuing education classes, short courses, work-force professional development and on-the-job training through internships within our community
- Educating students with a solid foundation in problem solving, communication, quality processes and team work, with current and emerging Biotechnology skills
- Working in partnership with our advisory board and the Texas Skills Standard Board to keep our educational program relevant

Section 3 Quality System & Documentation

Documentation is the written record of activities and is a critical part of a quality system. *Every employee of the department is responsible for quality documentation.*

3.1 Quality System Organizational Chart



3.2 Quality Manual

The quality system consists of a three-tier documentation system, beginning with the *Quality Manual*. The Quality Manual is the top-tier document that outlines the quality policy and procedures that ensure the quality system.

3.3 Handbooks

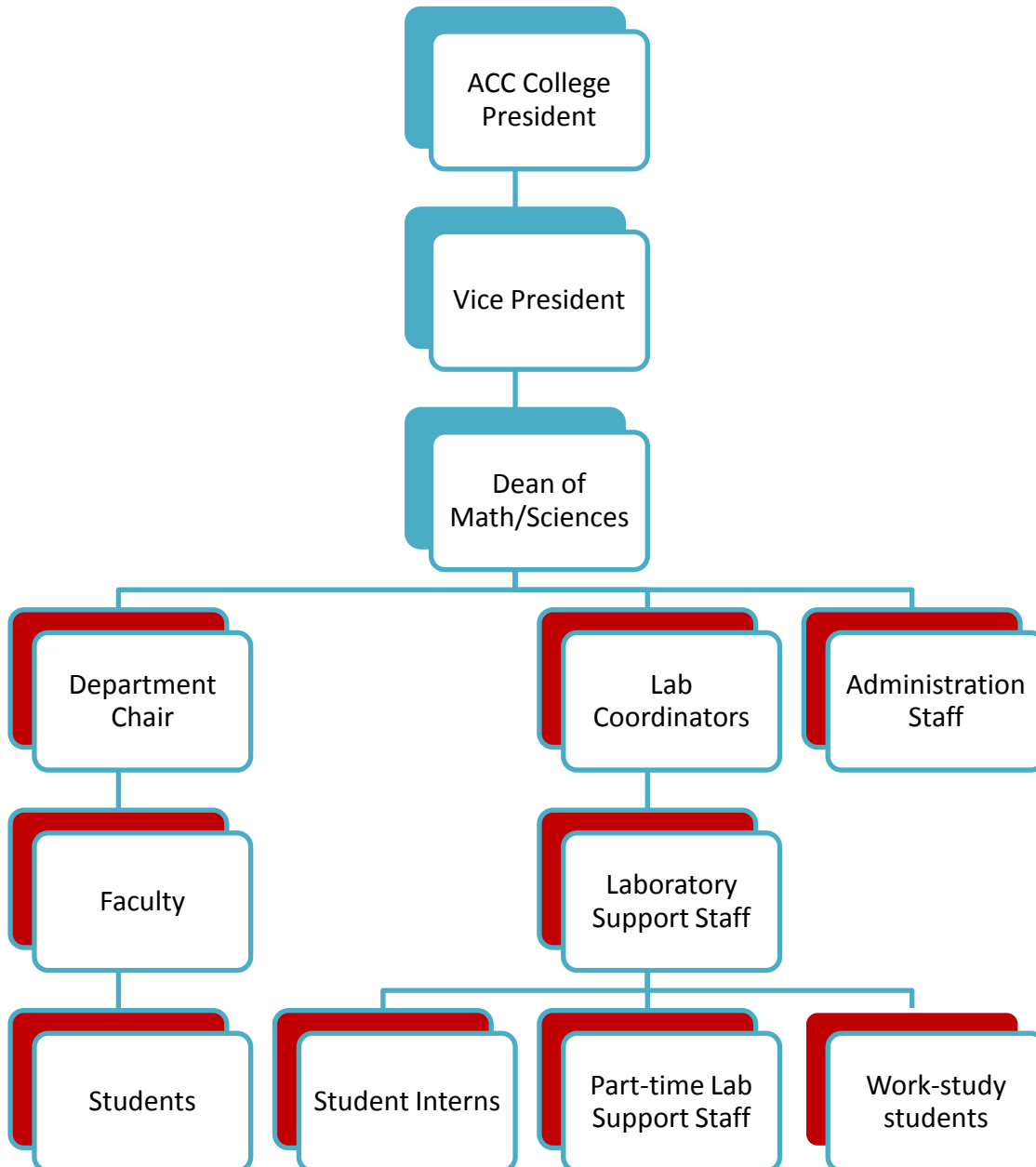
The second tier documentation consists of the instruction manuals (*handbooks*) for each of the participant subsets. The handbooks will outline the Biotechnology departmental policies and procedures.

3.4 Associated Documents

The handbooks will all have associated documents with them, such as standard operating procedures (SOPs), laboratory manuals, master syllabi, etc.

Section 4 Organization

4.1 Departmental Organization Chart



4.2 BIOTECHNOLOGY DEPARTMENT-SPECIFIC JOB DESCRIPTIONS

4.2.1 Department Chair Job Description

Job Purpose: To provide leadership and coordinate efforts of departmental personnel in accordance with Austin Community College policies.

Essential duties and responsibilities include the following.

1. Maintains compliance of the department policies, procedures, and operation to the Biotechnology Department Quality System & the ACC requirements.
2. Evaluates faculty credentials
3. Plans, develops, and evaluates curriculum
4. Oversees departmental internship/practicum program
5. Supervises & evaluates full-time and adjunct faculty and monitors performance improvement (as required by evaluation process)
6. Maintains departmental administrative requirements such as hiring recommendations, equipment acquisition, assigning classes, etc.

Required Education: In accordance with SACS accreditation requirements: Master's degree Biotechnology, Biology, Biological Sciences, Molecular Biology, Microbiology or Biochemistry or a Master's degree in Chemistry with a Biochemistry thesis topic or a Master's degree plus 18 graduate hours in Biotechnology, Biology, Biological Sciences, Molecular Biology, Microbiology or Biochemistry.

4.2.2 Full-time Faculty & Adjunct Faculty Job Description

Job Purpose: To instruct students in Biotechnology courses in accordance with College policies and procedures.

Essential duties and responsibilities include the following. Other duties may be assigned.

1. Instructs students in the biotechnology discipline. Provides learning activities that stimulate student involvement and encourage critical thinking.
2. Utilizes innovative teaching strategies to meet the learning needs of a diverse student population, including interactive video technology; online format and other uses of technology.
3. Maintains regular office hours to assist students; responds to students' emails and voice mails in a timely fashion, responds to assignments and students' concerns in a timely manner, accurate assessment of student performance and timely filing of grades.
4. Maintains professional competencies in the subject area and currency in instructional methodologies through professional associations and professional development.

5. Plans and organizes syllabi, course work, study guides and other support material for the classroom setting as well as online learning. Participates in curriculum development, implementation, and review in accordance with college concerns.

Required Education: In accordance with SACS accreditation requirements: Master's degree Biotechnology, Biology, Biological Sciences, Molecular Biology, Microbiology or Biochemistry or a Master's degree in Chemistry with a Biochemistry thesis topic or a Master's degree plus 18 graduate hours in Biotechnology, Biology, Biological Sciences, Molecular Biology, Microbiology or Biochemistry.

4.2.3 Laboratory Support Staff

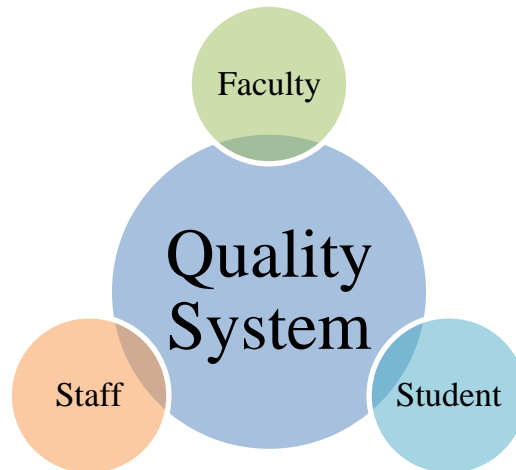
Essential duties and responsibilities include:

1. Maintains area facilities, prepares and organizes lab materials including supplies, equipment, and media.
2. Performs clerical duties in support of the department. For example, writing SOPs for new equipment purchases, and proof reading lab manuals.
3. Assists instructors and/or students in a lab/classroom setting.
4. Ensures the lab/classroom is clean and safe.
5. Complies with all applicable health and safety regulations, policies, and established work practices.
6. Lab techs at higher levels may also handle orders including the bidding process, troubleshoot problems with existing labs, repair or coordinate repair of lab equipment, supervise the work of lab personnel. They may also research, evaluate, and recommend new lab experiments, materials and equipment.

4.2.4 Administration Support Staff

Each campus has a Math & Science Administrative Assistant (admins). The admins are a resource for all biotechnology and biology faculty and students on that campus. They are responsible for obtaining textbooks and other teaching material for faculty, or office supplies like chalk, paper and pens. In addition to administrative assistance, they provide logistical support to staff, students and faculty of the Biotechnology Department. The admin assigned to work with the Biotechnology Department Chair is also responsible for record keeping and documentation storage and oversight. The current Administrator that works with the Department Chair is Steven Spurlock on the Eastview Campus. The admins are obligated to communicate with students, ACC faculty and staff by email and telephone in a timely manner.

Section 5 Authority and Responsibility



Quality is the responsibility of each and every student, faculty and staff in the Biotechnology Department

- The ***Biotechnology Department Chair*** is to create an environment where people are valued and treated with respect, dignity, fairness and equality
- The ***Biotechnology Department Chair*** is responsible for communicating the quality system to the staff and faculty and to ensure the full understanding and commitment to this policy by creating a positive atmosphere where commitment to this policy is the highest priority.
- The ***faculty*** and ***staff*** are responsible for overseeing the implementation and maintenance of the quality system in the classroom.
- ***Faculty*** will monitor, document and report on classroom quality systems to the Department Chair.
- Each ***staff*** member is responsible for assuring the quality system is established, implemented and maintained in their area.
- Each ***student*** is responsible for implementing quality processes as instructed and responsible for the quality of their work.

Section 6 Compliance

6.1 Texas State Skills Standards

The State of Texas has adopted the Washington Skill Standards for Biotechnology. The Austin Community College Biotechnology Program has formally adopted and applied these standards to its program and is recognized by the Texas Skill Standards Board (www.tssb.org). Each course in the Biotechnology Program fulfills a specific set of skill standards. Those can be found here: <http://www.austincc.edu/biotech/skillstandards.php>

It is the responsibility of each faculty member to document compliance to the skills standards in the following ways:

1. Align course curriculum for each course with the assigned skill standards.
2. Demonstrate compliance. This is done in two ways. First, the faculty member must insert the skills standards key into the course syllabus along with the lab and lecture schedule to demonstrate they have aligned their curriculum with the standards. The faculty member must also provide sample assessments in their portfolio which demonstrate evaluation of students' mastery of the key activities and related criteria, skills, and knowledge.

6.2 Commission on Colleges, Southern Association of Colleges and Schools (SACS)

Austin Community College District is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (SACS) to award the associate degree.

The U.S. Department of Education recognizes the Commission on Colleges as the authority for accrediting institutions of higher education that award associate, baccalaureate, masters or doctoral degrees throughout the Southeast. Accreditation is based on compliance with the policies and procedures of the Commission and the Principles of Accreditation: Foundations for Quality Enhancement, a set of core, comprehensive, and federal regulation standards predicated on a commitment to integrity and quality enhancement that are designed to ensure educational quality throughout the southern region. Accreditation provides assurance to the public that the College meets these standards that address faculty credentials, curriculum, institutional mission, governance and effectiveness, student learning outcomes, student services, libraries and financial stability.

Accreditation:

- Allows ACC continued access to federal funding for student financial aid
- Allows students to transfer credits to other accredited schools
- Is an important element of public stewardship

Section 7 Training

Training does more than provide a document of management's expectations, it creates a positive work climate by easing employee anxiety with new policies, prevents confusion and potential legal problems and saves time by providing the employees with a valuable quick reference they can use to reference basic questions.

7.1 Quality Policy Training

Dissemination of the quality policy is just as crucial as its creation. Each person responsible for the Quality Policies must have a clear understanding as to what their responsibilities are. All new students, staff and faculty are required to participate in a ***Departmental Quality Policy training class***. If there have been substantial changes in the Quality Policy, all current students, staff and faculty will be required to participate in this training as well. The Biotechnology Department Chair, or their appointee, will organize this training class.

The training will contain five elements:

1. Watch a video on the importance of quality.
2. Review a self-directed Power Point lecture.
3. Read the entire Quality Manual.
4. Pass with an 80% a short ten-question quiz.
5. Sign a document stating they have performed the above tasks and will abide by the Biotechnology Department policies and procedures outlined in Quality Manual.

7.2 Student, Faculty & Staff Training of ACC & Biotechnology Department Policies

7.2.1 Students

Biotechnology student receives two handbooks: The ACC Student Handbook (<http://www.austincc.edu/handbook/>) and the Biotechnology Department Student Handbook (<http://www.austincc.edu/biotech/>). The Biotechnology student is responsible for complying with policies and procedures as outlined in each of these handbooks.

7.2.2 Faculty

Biotechnology Department faculty members receive two handbooks: The ACC Faculty Handbook (<http://www.austincc.edu/hr/FacultyHandbook/index.php>) and the Biotechnology Department Faculty Handbook (<http://www.austincc.edu/biotech/>). All faculty members are responsible for complying with policies and procedures as outlined in each of these handbooks.

7.2.3 Staff

All staff members are responsible for complying with policies and procedures as outlined in the ACC Employee Handbook (<http://www.austincc.edu/hr/employeehandbook/leavebenefits.php>).

Section 8 Change Control

To meet the goals outlined in Mission Statement, it is important that the quality system be open to change. However, controlling this change is an essential part of the quality system. All changes to the quality system should be carefully researched, investigated, reviewed, and evaluated thoroughly. A seemingly small change can at times have unexpected outcomes.

8.1 Change Control Responsibilities

Changes can be initiated by the person(s) that originated the documents or the Biotechnology Department Chair. Other students, faculty and staff can recommend changes by presenting them to the Biotechnology Department Chair for consideration. The Department Chair will have final approval of any changes *prior* to dissemination. Once the change has been approved, change must be disseminated through the Administrator in charge of documents and records.

After a change has been implemented, it is important to monitor the change to ensure the quality system is still effective and has not resulted in unintended consequences. The person initiating the change must monitor the change for one year and report their analysis to the Department Chair.

8.2 Change Control Procedure

- 8.2.1 The originator of the change recommends the change to the Biotechnology Department Chair.
- 8.2.2 The Department Chair reviews the change. If approved the change is disseminated through the admin in charge of documents and records. They will assign the new document a control number, and they will ensure all essential parties will receive a copy of the new document.
- 8.2.3 If a change is made it must go through a probationary period before the change will be finalized. This probationary period is to allow a thorough evaluation of the effect of the change. The Department Chair will determine the parameters of the probationary period.
- 8.2.4 After the probationary period, the originator will write a report that outlines the change and their evaluation of the change with any recommendations.
- 8.2.5 The Department Chair will review the report and determine if the change will be made permanent or if further analysis or change must occur.
- 8.2.6 After implementation of the final change, the originator will continue to monitor the change for one year after its approval. They will report any adverse effects of the change to the Department Chair.

8.3 Reasons for Change

Changes may be made in response to the following:

- An audit revealed a need for a process/document change
- Advisory Board recommendation
- Industry standard change – industry has adopted a new policy or procedure
- To reflect regulatory requirement, such as TSSB standards
- New equipment
- Curriculum enhancement

8.4 Documents that are controlled

The following documents are controlled and cannot be changed without Departmental approval:

Control Number	Document	Control Number	Document
LM_BITC1414	Lab Manual for BITC1414	PE_BITC	Placement Exam
LM_BITC1402	Lab Manual for BITC1402	SPE_BITC	Student Work Performance Evaluation
LM_BITC2441	Lab Manual for BITC2441	IE_BITC	Internship Evaluation Form
LM_BITC2411	Lab Manual for BITC2411	STU_H_BITC	Student Handbook
LM_BITC2431	Lab Manual for BITC2431	IH_BITC	Student Internship Handbook
CC_BIOL1414	Course Content BIOL1414	STA_H_BITC	Staff Handbook
CC_BITC1240	Course Content BITC1240	FAC_H_BITC	Faculty Handbook
CC_BITC2441	Course Content BITC 2441	LS_BITC	Lab Safety Training Form
CC_BITC2431	Course Content BITC 2431	MS_BITC	Master Syllabi
SOP_BITC	SOP Booklet		

Section 9 Quality Records

The Biotechnology Department will retain records to document compliance to regulations and compliance with its own quality policy. As appropriate, documents will be maintained electronically and/or in paper form by the Administrator of the Department Chair.

9.1 Control of Quality Records

- 9.1.1 The Human Resources Department will retain employment-specific records such as transcripts and employment application.
- 9.1.2 Under the direct supervision of the Department Chair, the Biotechnology Department Administrator will control electronic and paper documentation for the department.
- 9.1.3 The Biotechnology Department Administrator will ensure that Quality records will be made readily available for audit purposes to the following: Biotechnology Department Chair, the Biotechnology Department Advisory Board, SACS, TSSB
- 9.1.4 Only the Biotechnology Department Chair can determine if the documents are obsolete and to be destroyed.
- 9.1.5 Distribution of the records will be at the discretion of the Biotechnology Department Chair.

Section 10 Quality Monitoring, Analysis & Response

10.1 Student

This is a competency-based program. Each student is expected to successfully demonstrate competency in classroom work and in laboratory skills.

10.1.1 Skills Standards

The State of Texas has adopted the Washington Skill Standards for Biotechnology. The Austin Community College Biotechnology Program has formally adopted and applied these standards to its program and is recognized by the Texas Skill Standards Board (www.tssb.org). Each course in the Biotechnology Program fulfills a specific set of skill standards:

<http://www.austincc.edu/biotech/skillstandards.php>

10.1.2 Placement (competency) Exams

Students must pass a competency exam in order to take all second year advanced Biotechnology courses. A study guide for preparing for the competency exams will be given to the student when they request admission in the advanced Biotechnology course, and ***the competency exam must be passed prior to registration***. Grade requirements are as follows:

1. 70-79% eligible to register for one semester
2. 80-89% eligible to register for two consecutive semesters (including summer)
3. >90% eligible to register for three consecutive semesters (including summer)

10.1.3 Class grades & GPA

Biotechnology courses require a minimum of 70% in **both** the lecture and the laboratory components, even though the average of the two components may be 70% or greater. The courses use the following scale for determination of final grades: A = 90-100%, B = 80-89%, C = 70-79%, D = 60-69%, F = 59% and below. ***The student must achieve a minimum grade of "C" in all academic course work of the degree plan.***

10.1.4 Student Work Performance Evaluations

Part of being a good technician is being able to work effectively in a team and this evaluation is designed to help the student achieve that goal. This evaluation will cover areas such as technical skills, initiation and follow through, independence and dependability, prioritization and organization, problem solving, quality of work and leadership.

For every Biotechnology class with lab, the student will obtain a final performance evaluation from the instructor. The instructor will meet with the student individually to review the evaluation, give the student a copy and the department will retain a copy.

10.1.5 Student Portfolio

Throughout their tenure in the program, the students will build a portfolio that will be presented to the Department Chair in their final semester. This portfolio will be graded pass or fail and be part of their final internship grade. The portfolio will include their resume which outlines their newly acquired educational background, technical experience (in the classroom) and work experience (internship) in addition to all the SOPs of each equipment they have trained on, their class presentations and papers and classroom performance evaluations.

10.1.6 Internship evaluations

Students will be evaluated by their internship supervisor based on their technical performance, their professionalism, safe behavior and compliance to company policies and procedures.

10.1.7 Non-compliance

Student non-compliance to the quality policy and not meeting minimal departmental competency standards follows the Progressive Discipline Policy as outlined in the Student Manual. The *Progressive Discipline Policy is designed to guide the students to a successful reintegration into compliance in the program.*

10.2 Faculty

All faculty monitoring processes apply to both full-time faculty and adjunct faculty. Any differences are noted in the specific area.

10.2.1 Academic and Experience standards

ACC human resources department will verify academic standards and will maintain employee records which may include their application, transcripts and work experience.

10.2.2 Classroom Syllabi with schedule

Classroom syllabi and detailed schedule must be posted on-line in compliance with the Texas House Bill 2504. During the first day of class faculty will supply a copy of the syllabus (with lecture and lab schedule) and review the classroom policies and procedures, including grading policy, with the students. A copy of all first day handouts is given to the Biotechnology Department Admin and is also presented in the faculty Portfolio. *The syllabi and schedule will be used to demonstrate quality compliance to classroom skill standards and teaching evaluation.*

10.2.3 In-classroom Evaluations by Supervisor

New faculty will have at least one classroom observation performed by the Department Chair or their appointee (full-time faculty member).

10.2.4 Student Evaluations

- 10.2.4.1** New faculty will have a student evaluation performed in their first teaching class(s) for the Biotechnology Department.
- 10.2.4.2** Each fall semester every faculty teaching will have an automatic student evaluation performed for each class taught.
- 10.2.4.3** Student evaluations will also be initiated for faculty who did not meet the previous year evaluation standards. This is at the discretion of the Biotechnology Department Chair.

10.2.5 Teaching Portfolio

Teaching materials for each class are to be made available in a Faculty Teaching Portfolio. This will include a paper portfolio which will be used for evaluation and regulation compliance documentation purposes in addition to an electronic copy which will be used to disseminate teaching materials throughout the department. Policies and procedures for the portfolio are outlined in the ACC Faculty Handbook and the Biotechnology Department Faculty Handbook. *The Portfolio will be used to demonstrate quality compliance to classroom skill standards and teaching evaluation.*

10.2.6 Non-compliance

Faculty not meeting compliance as outlined above (by either not submitting or meeting compliance standards) will follow the Progressive Discipline Policy outlined in the ACC Faculty Handbook.

10.3 Community Accountability

10.3.1 Advisory Board

The biotechnology department is responsive to an *Advisory Board* whose members are selected from the local biotechnology industry. After the Advisory Board meeting, the minutes are posted on the Biotechnology Department website: <http://www.austincc.edu/biotech/boardmin.php>

The Biotechnology Department works to address Advisory Board concerns and/or suggestions on program improvement.

Section 11 Quality Audit

11.1 Internal Audits

Internal audits will be performed by the Department Chair and/or the designated person(s) by the Department Chair. The internal audits will specifically target the following compliances. Other areas part of the quality policy may also be audited.

- Faculty credentials
- Faculty teaching portfolio compliance
- Student portfolio compliance
- Records maintenance compliance
- Student performance evaluations
- Document control

11.2 External Audits

11.2.1 SACS

All institutions accredited by the Commission on Colleges are required to undergo a review for reaffirmation of accreditation every ten years. The review includes compiling and submitting a Compliance Certification documenting compliance with the Principles of Accreditation and (as of 2004) submitting a Quality Enhancement Plan for review by peer review committees. In addition, it requires a 5th year interim report to ensure that institutions having access to federal funds continue to meet accreditation standards.

11.2.2 Advisory Board

The Biotechnology Department is responsive to an Advisory Board whose members are selected from the local biotechnology industry. The Advisory Board is permitted to request site visits to audit program.

11.2.3 Skill Standards Board

The State of Texas has adopted the Washington Skill Standards for Biotechnology. The Austin Community College Biotechnology Program has formally adopted these standards and is recognized by the Texas Skill Standards Board. Every three years this recognition must be renewed. The Biotechnology Department is due for renewal 2010.

The renewal process requires an audit of the Biotechnology Program. The department is required to demonstrate that the students' mastery of the skill standards content in the program is being assessed. The renewal process provides a quality assurance check that the college program is truly teaching to, and preparing students to perform, the industry-defined standards.

Section 12 Teaching Quality: Quality in the Classroom

It is the mission of the Biotechnology Department to disseminate quality processes throughout the department in a systematic and conscientious program of *Leading by Example*. The Quality Manual is one of many quality components that are implemented into the classroom.

12.1 BITC 1240: Quality Assurance for the Biosciences.

The Biotechnology Department offers a 12-week distance-learning course covering quality assurance principles and applications which is required of all Biotechnology Department degree plans. In addition, this class can be taken as a Continuing Education class. *The learning objectives in this class include:*

- Defining quality
- Regulations, Rules and Agencies as They Pertain to Biotechnology
- Approval and Regulation of Pharmaceutical Products
- Quality documentation and Quality Systems in the Laboratory
- International Organization for Standardization (ISO9000) system of quality
- Federal Drug Administration (FDA) regulations to the biotechnology, biopharmaceutical, and biomedical device industries

12.2 Quality built-in: Laboratory Exercises

We have built into our program quality teaching principles to each course with laboratory exercises. These include both Quality Assurance and Quality Control processes.

12.2.1 Standard Operating Procedures (SOPs)

The department supplies the students with SOPs booklet which contains SOPs for each piece of equipment they will be using throughout the semester. In addition to learning how to read and follow SOPs, the students will be instructed on how to write SOPs for laboratory exercises.

12.2.2 Forms

Students will learn how to correctly fill out forms associated with SOPs. Examples of these forms include Media Preparation forms, gel documentation system forms and 96-well plate forms. Students will be instructed on generating typical Biotechnology forms.

12.2.3 Equipment Validation

The student will learn how to validate standard laboratory equipment following established procedures. They will understand the importance of using properly validated laboratory equipment, analyze and troubleshoot results to determine if the equipment meets specifications, learn how to properly follow protocols, and accurately fill out equipment validation forms and determine if equipment meet specification.