

Assessor Technical Training: Microbiology Course Agenda

Day 1 (ALL TIMES ARE EASTERN TIME)

11:00 AM Introductions & Logistics – Present logistics for Webinar

Submittal of Exam must be before start of class on Day 2

11:15 AM Chapter 1: TNI Standards, PTs, Theory

- Review standard (2009/2016) requirements, V1M1, V1M2, V1M5
- Review theory for microbiology analysis

12:30 PM Break (15 minutes)

12:45 PM Chapter 2: Basic Principles

- Review technology including instrumentation and support equipment
- Review techniques and representative methods - microbiology
- SOP review and assessment

2:00 PM Break (30 minutes)

2:30 PM Chapter 3: Assessment Process

- Professional conducts and ethics refresher
- Gather objective evidence, Interview and Observation

3:45 PM Break (15 minutes)

4:00 PM Chapter 3; Assessment Process (continued)

- Review Exercises/Exam to be completed and returned
- Questions – Did we miss anything

05:00 PM Course Ends for Day

Approximately 60 minutes to complete exercise/exam

(Class time for day = 4 hours, plus 1 hour exam)

Day 2 (ALL TIMES ARE EASTERN TIME)

11:00 AM Review and Questions from Day 1

Return Day 1 Exam before start of class

Points deducted for late submittal

(Zero if not returned before the start of class)

11:15 AM Chapter 4: Quality Control and Criteria

- Essential QC V1M2 5.9 and V1M5
- Writing non-conformances

12:30 PM Break (15 minutes)

12:45 PM Measurement Uncertainty - Microbiology

- Major sources of error, and how to assess them

1:30 PM Chapter 6: Assessment Process and Data Review

- Managing the assessment - Sampling and thoroughness of site visit
- Record keeping review
- Assessment report writing
- Corrective Action/root cause review and evaluation of corrective actions

2:00 PM Break (30 minutes)

2:30 PM Chapter 7: Summary and Questions

- Answer questions related to technologies and assessment process
- Data Exercise/Exam including ways to detect improper practices
- Complete exercise/exam and return before the start of class tomorrow

04:00 PM Course Ends for Day

Approximately 60 minutes to complete exercise/exam

(Class time for day = 3.25 hours, plus 1 hour exam)

Day 3 (ALL TIMES ARE EASTERN TIME)

11:00 AM Review Day 1 and Day 2. Questions addressed

Return Day 2 Exam before start of class

Points deducted for late submittal

(Zero if not returned before the start of class)

11:15 AM Chapter 8: Exercise/Exam review

Review answers to Day 1 Exercise/Exam

Review answers to Day 2 Exercises/Exam

12:30 PM Break (15 minutes)

12:45 PM Chapter 9: Final Examination

Prepare for Final Exam

Scoring:

Submit Exams for grading via email (mmoore@advancedsys.com and TNI)

Send via email when completed and before 3:00 PM eastern

01:00 PM Start Exam

Return test by 3 PM (eastern)

03:00 PM Break (15 minutes)

03:15 PM Review Exam

03:55 PM Chapter 10: Wrap-up

Evaluation Forms

04:00 PM Course Ends for Day

(Class time for day = 2.25 hours, plus 2 hours exam)