We know there's no biosafety pipeline, but can we make one?

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15 JUNE 2022

Is there a problem?

- According to US Census Bureau, by 2030, all "Baby Boomers" (born between 1945-1963) will be >65…
- Even if nobody retired, informally it's an open secret that biosafety offices are significantly understaffed and don't grow proportionally to increases in research staff.
  - However, we also need to recognize there is no one single "golden ratio" of research staff to biosafety personnel. Like most of biosafety, the right answer is, "It depends".

ABSA?

- Session on March 2 was a major disappointment.
  - Lots of complaints, but no movement towards a solution, or even identifying the right questions, such as:
  - 1. What is the age distribution of current biosafety professionals?
  - 2. How long do they expect to stay in the field (either as biosafety professionals, or management)?
  - 3. How many institutions have actual OTJ training programs with available training/mentoring staff vs "on the fly" learning?
  - 4. (Less useful) Plans to increase (not replace) staffing? By how many people?
- There are additional sessions upcoming. (Mention more later)

Do we know we have enough now?

- No consensus on the optimal staffing ratio.
  - Too many variables (presence of Select Agents, number of labs, presence of BSL3 labs, prior regulatory issues, use of animals, use of large scale, use of plants).
  - Have been attempts
    - Bob Emery (UT Health) has developed a benchmark formula, using data from 102 US colleges and universities.
      - Key variables: presence of Med or Vet school, presence of BSL3 lab, lab net square footage, and non-lab net square footage.
    - This gives a figure for general EHS, but not specifically biosafety.
    - He did identify biosafety drivers (most noted above), but no specific relationship…yet.
  - Even what has been done relies on benchmarking, not direct examination of need.

So, assuming there is a pipeline need, how do we fill it?

- We can train incoming staff at our own institutions, using existing staff as trainers/mentors.
  - Low value, except for identifying site-specific details. Too few new staff enter for most institutions to spend resources on a trainer/mentor.
- We can develop an external training program/certification for biosafety professionals.
  - Not a novel concept. ABSA worked with two NIH NBBTP fellows (Brandon Hatcher and Chad Austin) to develop a biosafety course for students.
  - NBBTP (NIH) and LLS (CDC) prepare small numbers using a two year curriculum, , but neither can supply the need (3/yr w/NBBTP, usually 6-10 in LLS).
  - There are academic institutions looking as well…and have been for years.

How to develop a program?

- Any institution could do so independently- if they saw the value
  - But, we could have little, if any input.
- OR…we, as a professional society could generate a model program.
  - That takes money and effort and even as a volunteer association, it would get expensive and time consuming.
    - Not to mention trying to get consensus…
- Is there an alternative? Yes. Talk about later…
- So…what would you put into it?

What would we be looking for?

- In general, it would be either a certificate, or a MS degree.
  - A Masters would generally take 30 semester hours of credit (approximately 10 courses)
  - A certificate is generally less (on the order of 10 semester hours)
- Could we build a certificate and then extend to a MS?
  - Yes, but what do you want them to do? We could easily fall into the RBP/CBSP debate with a certificate and MS and a claim they're equal…
- Build a certificate for "intro" and a MS for "expert"?
  - More reasonable. Especially if the certificate is accepted as part of the MS.

CBSP Domains- could they work as curriculum base?

- Disinfection, decontamination, sterilization
- Work practices and procedures
- Risk assessment and hazard identification — Infectious agents and recombinant DNA
- Regulatory aspects, standards, and guidelines
- Program management and development
- Equipment operation and certification
- Facility design

Program Management and Development

- Understand the role and function of an institutional biosafety committee.
- Prepare and maintain a biosafety manual.
- Review project proposals and advise on biosafety issues.
- Advise on occupational health programs for persons working with biological materials.
- Provide and interpret biosafety resource and reference information.
- Organize and implement institutional biosafety compliance programs and audit their effectiveness.
- Institute, evaluate, and document biosafety training.
- Identify biological agents and materials in your institution.
- Develop and implement an infectious and medical waste management program.
- Provide technical information and advice on products impacting biological safety.
- Develop and recommend biosafety policies.

"Program Management" doesn't really describe management

- Not really an Exam Board criticism- difficult to do in current format. It checks on technical knowledge and can't really ask for multi-step processes or essay questions.
- Could end up with question like this:
  - During a lab inspection, you discuss your findings with the lab director. She tells you that you're wasting her time and the lab is running fine without your interference. What is your next step?
    - A. Put the findings in your database to provide "breadcrumbs" for OSHA when something goes wrong in the lab.
    - B. Acknowledge that she's right and she effectively pays your salary.
    - C. Provide feedback to her management and have them correct the behavior.
    - D. Get in her face and let her know you're the law around here.

CWA 16335 as model?

- Designed in 2011 to provide a model for the certification of biosafety professionals, both at a base level and advanced certification.
  - Short document (17 pages, plus five annexes, including a model training specification).


CEN
WORKSHOP
AGREEMENT
CWA 16335

What competencies are in the CWA?

- General principles of microbiology, biochemistry and cell biology
- General principles of molecular biology and genetic engineering
- Biological and other hazards in the work area
- Occupational health and biosafety
- Human factors
- Containment principles
- Biorisk assessment and management
- Environmental safety
- Facility (re)design, construction, commissioning, decommissioning, validation, operation and maintenance
- Selection, validation, certification and maintenance of equipment
- Good microbiological techniques (GMT)
- Personal protective equipment (PPE)
- Infection control, disinfection, decontamination and sterilization
- Biological waste management
- Emergency preparedness and response
- Incident and accident investigation
- Biorisk management programme
- Inventory monitoring and control
- Physical security
- Training
- Communication skills and information / knowledge systems
- Audits and inspections
- Packaging, shipping, transport, import and export of biological material
- International and national regulatory framework, standards, guidelines and conventions
- Bioethics

Possible certificate curriculum

- Certificate would be limited to 3-4 courses.
  - Prerequisites: a course in micro and a course in molecular biology.
  - Course 1: Risk assessment, including risk mitigation
    - Hierarchy of controls, description of controls, including engineering (incl BSCs), administrative and PPE controls. Occ health implications of risk.
  - Course 2: Program management, including regulatory aspects of biosafety.
    - Review of relevant regulations, including OSHA, EPA, DOT, USDA, CITES, BIS. Discussion of management programs, including ISO 35001. Inspection, audits, and discussion of interpersonal interactions (aka, how to deal with people as a biosafety professional).
  - Course 3: Facilities design, operations.
    - Facility siting, airflow, traffic considerations, security, waste handling/disposal, incident and emergency response.
  - Course 4: On site training (may not be practical for on line certificate).
  - Completion would certify person as "basic biosafety professional".

MS curriculum

- Builds on certificate. Those going straight to MS take the certificate courses first.
- Course 4 now becomes required (on site training).
  - Curriculum would require lab walk-throughs, assisting in audit(s), risk assessment evaluation, incident investigation reporting, and, where possible, discussions regarding staffing and budgeting.
- Course 5: Intersection with other EHS professionals.
  - Overview of Health Physics, Chemical Safety, Ergonomics, General Safety requirements as applied to research/production facilities.
- Course 6: Quality considerations and program management
  - Understanding validation and verification, including Select Agent requirements. Program management, including management theories and strategies for successful communication with senior leadership.
- Course 7: Elective. May be additional course in molecular genetics, microbiology, engineering (e.g., facility or HVAC design), occupational health, toxicology as approved by institution.
- Course 8: Elective. See above.
- Course 9 and 10: Capstone project (6 hrs). Preferably an applied biosafety project that could be published.
- Successful completion would certify person as "biosafety professional".

Do they replace RBP and CBSP?

- No. But there needs to be a realignment of the ABSA credentials.
- CBSP is too US-centric and too many people see the RBP as inferior.
- An ABSA taskforce has proposed the creation of an international CBSP credential to complement the current one.
  - A related taskforce recommended a holistic approach- have the two CBSP credentials be the "Senior Biosafety Professional" certificate, while the RPB gets retired. A new "Biosafety Professional" credential would be created, based on attaining a restricted set of competencies.

What is ABSA doing?

- LouAnn has talked to members of the taskforce about having a unified competency structure, and there is general agreement about the idea…but we haven't started on what those competencies are or how to describe them using something like Bloom's Taxonomy.

	Level 1	Level 2	Level 3	Level 4	Level 5
Labels	Basic Knowledge Beginner	Limited Experience Developing	Practical Application Competent Skilled	Applied Theory Proficient Coach	Recognized Authority Expert
Focuses on	Learning	On-the-job experience	Actively putting knowledge and experience to use towards competency	Applying and improving processes; responding to nonconformities	Application and improvement of competency with deep understanding and ability to explain to others; performs root cause analyses
Characteristics	• Has common knowledge of basic techniques and concepts	• Has limited experiential knowledge, based only on classroom or trainee experience • Understands and can discuss terminology, concepts, principles related to this competency	• Successfully completes tasks by applying and enhancing knowledge and experience • Actions taken are within the context of the unit's long-range goals and plans	• Understands situations as a whole; analyses and provides practical/relevant ideas and perspectives on process or practice improvements which may easily be implemented • Able to cope with and/or address contingencies and nonconformities	• Demonstrates consistent excellence in applying this competency across multiple projects and/or organizations • Possesses an intuitive grasp of situations and focuses on the root of the problem • Applies innovations in the competency to problem-solving and task completion and can synthesize, critique or teach the competency
Help needed from others	• Expected to require additional training and trainee on-the-job experience	• Expected to need supervision, or mentorship and/or coaching to succeed in this competency	• Expected to require help from supervisor, mentor, or coach occasionally, but can usually work independently		

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- OR…we, as a professional society could generate a model program.
  - That takes money and effort and even as a volunteer association, it would get expensive and time consuming.
    - Not to mention trying to get consensus…
- Is there an alternative? Yes.
  - Anyone remember X-prizes (https://www.xprize.org/)?

ABSA as seed provider

- Multiple options on a basic theme: organizations and groups will compete, even if the amount in the prize is a fraction of the real cost. ABSA provides the seed cost and hosts the judges.
  - Option 1. Generate RFP for the development of the certificate curriculum. Have a panel of experts review the RFP and award the winning team a prize (say, $25,000), to be delivered once the courses have been developed. This would provide ABSA an opportunity to provide multiple institutions the ability to implement a certificate program as a "canned program".
  - Option 2. Announce the competition for the development of the courses, with the winner receiving a similar prize. This would allow multiple teams to submit entries and the judges would review each program for their content prior to declaring a "winner". The risk is higher for each team, but lower for ABSA. There could also be a first and second place prize, in case there are elements that could be blended to make a superior product.

Could this work?

- Yes, if the certificate is done on line, it would provide a one-year means to becoming a base-level biosafety professional and would free up existing staff from training.
  - There would still be some training required on local policies and procedures.
- The program would still allow for individuals who have already started to become a professional to obtain their certifications.
- The MS program would allow those already established as biosafety professionals obtain the skill sets needed to become leaders in the field and for their organization.

Thank you for your time. Questions?