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A Biological Safety Cabinet Certification Program: Experiences in Southeast Asia

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Abstract

Biological safety cabinets (BSCs) are the primary means of containment used in laboratories worldwide for the safe handling of infectious microorganisms. They provide protection to the laboratory worker and the surrounding environment from pathogens. To ensure the correct functioning of BSCs, they need to be properly maintained beyond the daily care routines of the laboratory. This involves annual maintenance and certification by a qualified technician in accordance to the NSF/American National Standards Institute 49-2014 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. Service programs can be direct from the manufacturer or through third-party service companies, but in many instances, technicians are not accredited by international bodies, and these services are expensive. This means that a large number of BSCs may not be operating in a safe manner. In this article, we discuss our approach to addressing the lack of trained and qualified personnel in Thailand who can install, maintain, and certify BSCs in a cost-effective and practical manner. We initiated a program to create both local and regional capacity for repair, maintenance, and certification of BSCs and share our experiences with the reader.

Keywords

biosafety cabinet; training; fumigation; high-efficiency particulate filter; primary containment

Issues of biosafety and biosecurity have taken on an increased role in the international dialogue. Recent incidents of emerging infectious diseases[1] and at biocontainment laboratories[2] have contributed to a heightened awareness in the lay world of safety issues in clinical and diagnostic laboratories and infectious disease research facilities. To reduce and

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prevent such incidents and allay fears, laboratories must adopt and implement effective biosafety programs. This requires proper containment facility design, consistent use of primary containment equipment, and good laboratory practices. The biological safety cabinet (BSC) is considered primary containment equipment for working safely with microorganisms[3] as it mitigates possible exposure to aerosols from infectious biologicals to laboratory personnel and the environment. The BSC also protects the material being worked on from possible contamination. However, BSCs are probably one of the least understood pieces of laboratory equipment. Laboratorians need to recognize that an active BSC is a primary containment system that must be routinely tested by trained personnel to verify it is working correctly. The BSC should be certified prior to initial use, and ideally this should be performed annually. In many low-resource regions, a number of practical problems prevent this from happening, most notably lack of awareness of this requirement and an absence local competent, qualified certifiers. In a survey of biosafety level (BSL) 2 and 3 laboratories in 7 countries in the Asia-Pacific region, 30% of Class II BSCs tested were poorly designed, incorrectly installed, not certified, or being operated improperly.[4] In Thailand, an estimated 600 BSCs need annual certification, and in 2013, only 1 accredited certifier was registered with the NSF International for BSC field certifications, and only 1 local company was known to perform these services to NSF standards. Information from other countries such as Vietnam, Cambodia, and Laos is not readily available, but we assume a similar situation.

In an attempt to address a lack of trained and qualified personnel in Thailand who can install, maintain, and certify BSCs in a cost-effective and practical manner, the Strengthening Laboratory Capacity Program (SLCP) of the US Centers for Disease Control and Prevention—Thai Ministry of Public Health Collaboration (TUC) initiated a program to create both local and regional capacity for repair, maintenance, and certification of BSCs. Funding came through the Defense Threat Reduction Agency's (DTRA's) Cooperative Biological Engagement Program (CBEP). Implementing partners included the US Army Medical Component of the Armed Forces Research (USAMC-AFRIMS) Thailand, the Mahidol-Oxford Tropical Medicine Research Unit (MORU), the Thai National Institute of Health (NIH), and the National Institute of Animal Health (NIAH). Three Thai staff from the NIH, NIAH, and SLCP were selected to participate in the initial training program with mentoring by an accredited NSF 49 certifier with approximately 5 years of experience. All were fully accredited within 18 months of their initial selection.

This training model has now been extended to Cambodia, where a further 2 locally employed staff are going through the program, with mentoring support coming from the newly accredited Thai certifiers. In this report, we describe our experiences in BSC certification training and hope our experience will assist others in implementing similar programs in low-resource countries.

Methods

Candidate Selection

It is critical to have the correct candidate with the right aptitude for BSC certification. Our experience has shown that candidates with math and some basic mechanical skills fare well in the training process. English proficiency should be considered as it allows for understanding and comprehension of training materials and BSC manuals, and it helps in the written and oral examinations. As a high school diploma (or equivalent) is a requirement for NSF 49 BSC field certifier accreditation, this too is essential. Having several candidates train at the same time allows them to support one another and work through problems together.

Ongoing responsibilities need to be considered when selecting candidates. Both laboratory scientists and biomedical engineers have participated in our program. For the engineers, this was an extension of their current work responsibilities, and there have been no issues. For laboratorians, consideration was not given to career path, and problems have arisen as to how the time away from laboratory duties will affect long-term advancement.

Trainee Mentoring

Our program mandates that BSCs be certified by accredited individuals to verify the required personnel, product, and environmental protection requirements. The accompaniment of all trainees by an accredited certifier allows students to develop and validate their skills through one-on-one instruction. This approach also provides immediate troubleshooting, repair, and problem-solving assistance through the greater experience of the mentor.

In Thailand, we were fortunate to have the cooperation of the one in-country NSF-accredited certifier from our collaborating partner at USAMC-AFRIMS. For the Cambodian program, we used our newly qualified NSF-accredited certifiers from Thailand as mentors, traveling with the trainees quarterly to certify BSCs for 2-week stints. These mentors do not have a broad range of experience, so ongoing advice and training were supported by an ABSA International registered biosafety professional (S.B.) from MORU, Thailand.

Training

The model we use divides the training program into 2 formal courses (basic and advanced), with a minimum of 12 months in between, during which students practice their newly acquired skills from the basic training. To date, the Eagleson Institute (Sanford, Maine; affiliated with The Baker Company) has been our primary training provider (http://www.eagleson.org/complete-schedule), as all instructors are NSF 49-accredited engineers with many years of hands-on design, manufacturing, testing, and troubleshooting experience. In addition, they provide an individual mentoring service for the students immediately after both weeklong classes; these are offered twice a year.

Other companies do offer BSC training services in the United States, including Agape Instrument Services, Labconco Corporation, Thermo Fisher Scientific, and NuAire (http://www.nuaire.com/products/training.html). More regionally, training courses are conducted at ESCO’s headquarters in Singapore at their Demonstration and Training Facility (http://www.escoglobal.com/support/training-courses-and-seminars/78/). However, Singapore is not our primary training facility as they do not offer mentoring classes. We do use this facility for our repeat NSF practical examinations.

The first training is basic and offers an introduction to certification and the use of BSCs. Students learn to triage BSCs for problems and perform the primary certification tests. Instruction is a combination of lectures, discussion, problem-solving activities, and hands-on certification laboratories. The course focuses on Class II Type A2 BSCs, the most common BSC type in Southeast Asia.

After the completion of the basic training, students return to their facilities and practice their new certification skills, completing a certification report for each BSC tested. One year of practical experience from the date of the basic course is required to meet NSF BSC accreditation criteria.

Subsequently, students return to the United States for the 5-day advanced course at Eagleson Institute, followed by another week-long mentored practical application workshop. During this time, trainees gain in-depth information and refine their practical BSC certification skills. This course includes certification of Class II Type B BSCs. Additional content is added depending on the problems the students confronted while certifying BSCs in-country.

NSF Accreditation

Because of the specialized knowledge required for proper and safe BSC certification, NSF International administers an accreditation program for field certifiers. To become accredited, 3 obligations must be met: (1) a passing score of ≥80% on the written examination; (2) ≥90% score on primary and at least 70%on secondary practical tests; and (3) candidates must sign an ethics statement. Continuing education and periodic reexamination are required to maintain accreditation.[5]

The NSF accreditation examination is not mandatory for individuals taking the advanced class, but Eagleson does coordinate the written and practical examinations at the end of the advanced class for qualified individuals. To be eligible, the person must have proof of a high school diploma (or equivalent) and either completed a training course on BSC certification with evidence of active field certification through the submission of 20 test reports, 5 of which must be for Type B BSCs, or at least 3 years of field experience shown through submission of 10 reports per annum, with 2 being from B1 or B2 BSCs.

The written examination is 3½ hours long and covers field certification, instrumentation, testing procedures, troubleshooting, and NSF standards/policies. It comprises 120 multiple-choice questions, each with only 1 correct answer. During the examination, the applicant may access NSF/American National Standards Institute (ANSI) standard 49 and program policies.

The practical examination entails the evaluation of Type A and B BSCs, covering both the primary tests (downflow velocity, inflow velocity, high-efficiency particulate air [HEPA] filter leak, cabinet leak, airflow smoke patterns, and site installation) and secondary tests (vibration, noise level, and lighting intensity).[6] Instrument calibration and operation are also evaluated. Each test has a time limit, with a maximum of 9 hours for the full examination. Test equipment with current calibration documentation is provided by Eagleson so trainees need not travel with 70 kg of excess baggage.

Fumigation of BSCs

We have recently added fumigation training to our program to expedite repairs, minimize costs, and provide sustainable practices. Typically, fumigation is required when a nonfunctioning component (such as a HEPA filter), located in a potentially contaminated plenum area, requires replacement. Primary methods for BSC decontamination are formaldehyde gas, vapor phase hydrogen peroxide, and chlorine dioxide gas.[7] The decision was made to use the formaldehyde system as it was inexpensive with regard to equipment and consumables, and purchase is not restricted in Southeast Asia despite the fact that it is an Occupational Safety and Health Administration (OSHA)-classified carcinogen. This required that appropriate respiratory protection be purchased for all trainees (Table 1) and that they be fit-tested and given respiratory protection training. This was provided by an ABSA International registered biosafety professional (S.B.) with many years of experience and included monitoring of formaldehyde levels, validation of the decontamination process, and correct use of personal protective equipment.

Equipment

The essential equipment used to determine the performance of the BSC in the 6 primary tests necessary for certification is detailed in Table 1. The total investment was approximately US $34 000 for each set of equipment purchased. Additional equipment for secondary, optional testing (measuring noise, vibration, and lighting levels in the BSC) ensures a comfortable work environment. If certifiers are involved in BSC relocations, then it is recommended that appropriate lifting devices such as flat woven wire slings and scissor lifts be purchased. These allow for easy positioning of the BSC between their stand and floor level. Secondary and additional equipment costs are about US $6500.

Mobile applications and web-based subscriptions are available that provide invaluable information for BSC certification. The Controlled Environment Testing Association (CETA) Spec Guide (http://www.cetainternational.org/content/ceta-products) includes airflow specifications, HEPA filter, motor, and bulb sizes for all major international manufacturers of BSCs, information that is required for certification. The guide is updated regularly, adding new models and changes in specifications. A subscription is currently $119.99/annum. The information in this guide is generally available in the BSC manual provided by the manufacturer, but this is often not available in the laboratory at the time of certification.

Software products such as Cert-Pro (http://www.cert-pro.com/) support field testing of BSCs, fume hoods, and clean-rooms, allowing for automation of the process by facilitating direct collection of data from instruments and automatic production of a certification report upon completion. Software costs around US$4500.

Budget and Financial Obligations

Expenses incurred for the basic and advanced workshops are detailed in Table 2 and are accurate as of January 2016.

Highly specialized, expensive equipment is needed to perform certifications (Table 1). As part of our sustainability plans, equipment was purchased and donated to the respective institutes for their use. Discussions on implementing a certification program were needed regarding the ongoing expenses in maintaining this service. The budgets developed included the cost of replacement parts and HEPA filters. Until institutional information is available, we have budgeted for a filter failure rate of 10% of BSCs certified annually.

To ensure equipment performance (and maintain accreditation), annual calibration and general maintenance are required. This may not be available in-country, so expenses (along with shipping charges) need to be considered (Table 1). Further consideration should include travel and per diem of staff if a regional program is implemented. For air travel, excess baggage for approximately 70 kg of equipment is needed.

Certifiers should also have access to petty cash for purchasing small items and consumables for service requirements during certifications. Without this, another layer of difficulty is added to achieving a timely outcome.

Activities Performed in Association with Each Certification

Our certifiers have developed materials outlining the certification process that are shared with the laboratory manager several weeks prior to their arrival. This document details why BSCs need to be certified, when this should happen, and what preparation is needed prior to the certifier's arrival. The documents clarify the process for management and emphasize that certification does not include the repair of the cabinet, clean bench, or fume hood. All materials have been translated into the local language to ensure the information is understood.

During visits to different laboratories, it was clear that many staff had not been trained in the correct use of BSCs. While it is important that the BSCs operate safely, the individuals using them also need to be trained. As a routine part of each certification, the certifiers provide training in which they briefly describe the operating characteristics of BSCs, show how to correctly use them, and demonstrate the main maintenance operations. Training materials have been developed that include videos, presentations, job aids, standard operating procedures, and hands-on instruction.

Results

The first BSC certification training program commenced in Thailand in 2013 with 3 candidates, 1 each from the animal and human health ministries and a locally employed staff person from TUC, selected by February 2013. A total of 64 Class II Type A BSCs were certified by the trainees, and 3 Class II Type B BSCs were recertified several times for each candidate to meet the NSF qualification criteria of 5 Type B certifications. For NSF accreditation, 1 candidate qualified after passing both the written and practical examinations on the first try; a second needed to repeat the written examination and passed on the second attempt; our final candidate passed on the second attempt of both the practical and written examination. By July 2014, we had 3 additional fully accredited NSF BSC certifiers in Thailand. The total cost of training and equipment was US $60 000 per candidate. In Thailand, the accredited certifiers continue to work within their respective ministries; qualifying certifications are no longer tracked.

In September 2013, we extended the training program to Cambodia, and that November, our 2 trainees completed the basic course at Eagleson Institute. BSC certifications were performed quarterly with an NSF-accredited mentor traveling from Thailand to support activities. A total of 132 certifications have been performed in-country, and candidates traveled to Thailand just before completing the advanced class to train on certifying Type B BSCs, as no such BSCs were available in Cambodia. The advanced training with NSF examination was completed in September 2015; neither candidate passed the written or practical examinations, and they are currently preparing to repeat these.

Between April 2013 and December 2015, a total of 210 Class II BSC certifications have been performed in Thailand (47), Cambodia (117), Laos (33), and Vietnam (13), not including fume hoods, clean benches, and polymerase chain reaction (PCR) hoods. This represents 163 individual BSCs. Certification failure rates were between 50% and 70% at the start of our training programs (Figure 1), and we are slowly seeing a reduction in the number of failures. Annual certification is an issue at this time primarily because there are still many BSCs in the region that have not yet had an initial certification. Significantly, we do see a reduction in failure rates on BSCs that have been certified regularly. The most often reported reason for certification failure was HEPA filter damage or leak, with the exhaust filter being the most commonly affected (Table 3). Of all problems mentioned in the final certification report, these accounted for 76% of BSC failures.

Replacement of HEPA filters (or any repairs requiring access to the sealed plenum area) of a BSC requires that it be fumigated. Our technicians have performed 16 fumigations themselves and provided oversight for several performed by local BSC distributors.

Fifteen different cabinet manufacturers (Figure 2) represented by 49 models were certified in the 4 Southeast Asian countries covered by this program. The top 3 manufacturers covered 78.5% of BSCs tested. These were from ESCO (52/163; 31.9%), NuAire (42/163; 25.8%), and Thermo Scientific (34/163; 20.9%).

Discussion

BSCs are one of the most important pieces of laboratory safety equipment used in the detection, isolation, and diagnosis of infectious agents. They are in government, medical, academic, and private industry laboratories. The importance of ensuring all these BSCs are functioning correctly is essential, as the consequences of poorly functioning equipment range from contaminated product and wasted time to serious illness and/or death of laboratory personnel. In many middle- and lower-income countries, it is one of the few aspects of laboratory safety not being addressed, probably because of the complexity of issues and the enormous financial investment required. Many of our partner institutions cited expense as the main reason for not having BSCs certified annually. They found the use of external certifiers prohibitively expensive. In Southeast Asia, certification services, provided by local distributors, range in price from US $300 to US $500 per BSC. Competitive bidding for the certification of all BSCs within an institute can bring the price down. However, other considerations, such as qualifications and experience of certifiers, standard to which certifications are performed, and experience with a broad range of manufacturers all should be considered in making this important decision. Our program cost approximately US $60 000/candidate, the cost of certifying 200 BSCs using a commercial vendor. Every country needs to have access to experienced, qualified BSC certifiers who are able to perform all required tests to international standards. We hope that sharing our experience on implementation of a BSC certification training program will assist others in the quest to provide practical, sustainable solutions for effective biocontainment in countries with limited resources.

In this program, we have encountered a number of practical issues that need to be addressed. The great number of BSC manufacturers and models has proved to be a concern. International guidelines specify BSCs are to be field tested and certified in accordance with NSF/ANSI 49 (or equivalent European standards) and manufacturer specifications.[6] In several instances, our certifiers encountered BSCs not manufactured to international standards, or the manufacturer specifications were not easily available, or the manuals and installation certification test reports were not obtainable, all factors making adjustments needed for a passing certification difficult. For many of the common international BSC manufacturers, the CETA Spec Guide application obviates the need for the BSC-specific manual, but data for BSCs manufactured in Asia are not available. Another issue arising from the many different models of BSCs in use is the availability of parts and HEPA filters for repair. Distributors do not keep stocks, and delays in repair can be 3 months while orders are placed. It would be in the best interests of all parties for ministries and institutes to adopt a standard specification for all BSC purchases and include preferred manufacturers, allowing for certification consistency, availability of spare parts, and warehousing of a few standard-size HEPA filters, thus greatly expediting repairs. Institutional policies should also insist on the purchase of an appropriate uninterruptible power supply (UPS) for each BSC. This would provide protection from the power surges often experienced and reduce the number of electronic repairs that currently need to be made. The UPS also provides battery support when the primary power source is lost, giving laboratory staff sufficient time to shut down the BSC safely.

One of the largest financial commitments is the specialized equipment needed for certification. In several cases, the highly specialized equipment was not available in-country, so our external purchases resulted in increased pricing because of customs and duty charges. Other problems were differences in electrical supply, plugs, and availability of consumables required for operation. Certain pieces of equipment need annual calibration to international standards, often a service not available in many countries.

We wish to expand our activities in several areas in the near future. First, it is important to develop an accreditation program suitable for Southeast Asia. There is a desperate need for more individuals who could support BSC certifications within the region. The NSF accreditation program has a specific focus on North America and does not currently accommodate international needs. For example, Type B BSCs tend to be used infrequently outside of North America, and it has been a challenge to meet the accreditation registration requirement of 5 Type B test reports. This, together with the high costs of travel, plus the language barrier for the written examination, makes this an unattractive only option. In collaboration with the NSF and Eagleson Institute, we hope to engage regional partners from the private sector such as BSC and HEPA filter manufacturers and distributors in the workshop certification program development. The option of having the written multiple-choice examination presented in the candidate's native tongue should be explored along with having an independent translator present to accurately explain the questions for the practical examination, both of which would be beneficial. Currently, ESCO holds BSC training courses at its Demonstration and Training Facility in Singapore (http://www.escoglobal.com/support/training-courses-and-seminars/78/). The program could initially provide a certificate of proficiency until accreditation requirements for the region are established. Further capacity development is needed to ensure that local equipment distributors can supply, service, calibrate, and maintain the equipment used in certifications.

In addition, regional stakeholders from the ministries of public and animal health, the Asia Pacific Biosafety Association (http://www.a-pba.org/), World Health Organization, and Food and Agriculture Organization need to be brought together to strategize on best practices for the management and sustainability of cabinet certification programs. A standard certification model for biosafety and biocontainment in public health and veterinary laboratories in Southeast Asia is needed. Local testing standards need to be developed that take into account local constraints. A list of minimum specifications should be developed to aid countries when purchasing BSCs. Simple tests to detect reduced cabinet function should be devised, as annual certifications may not be implementable until this capacity is more fully developed.

The certification training program as implemented here requires an enormous time commitment from both trainees and mentors, especially when being run from a distance. When our mentors traveled to Cambodia, certifications were scheduled over a 2-week period every quarter with 15 to 20 BSCs being certified each time (certifications take a minimum of half a day per cabinet). Each certification was also used as an opportunity to train laboratory personnel on best practices for working in a BSC and BSC maintenance. Time was also needed for report writing. This program used a mentor paradigm, but our experience indicates trainees are capable of certifying BSCs on their own after the basic training. We would propose that mentors are available to provide technical support via telephone or email to cover the unexpected.

To gain local buy-in and support for activities ensuring sustainability once training was completed, ministry or institute partners were encouraged to participate in all activities. This included keeping updated lists of BSCs that fell under their jurisdiction, coordination and scheduling of laboratory visits, obtaining the appropriate permissions from hospital directors and laboratory managers, monitoring and recording all certifications, and assisting with report distribution.

BSC certification is part of a sensible bio-risk management program and allows for the safe handling of pathogens. Certifications are essential for the implementation of the International Health Regulations (2005) and affect several of the action packages detailed in the Global Health Security Agenda (http://www.cdc.gov/globalhealth/security/actionpackages/). We hope this report will facilitate the implementation of similar training programs in countries/regions where such activities are not routinely implemented.

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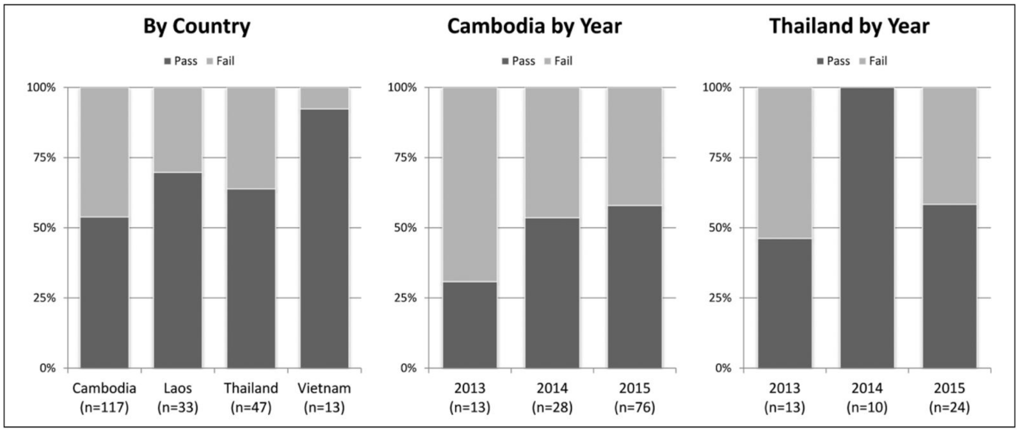

Figure 1.

Biological safety cabinet (BSC) certification failure rates by country (a) and years 2013–2015 for Cambodia (b) and Thailand (c).

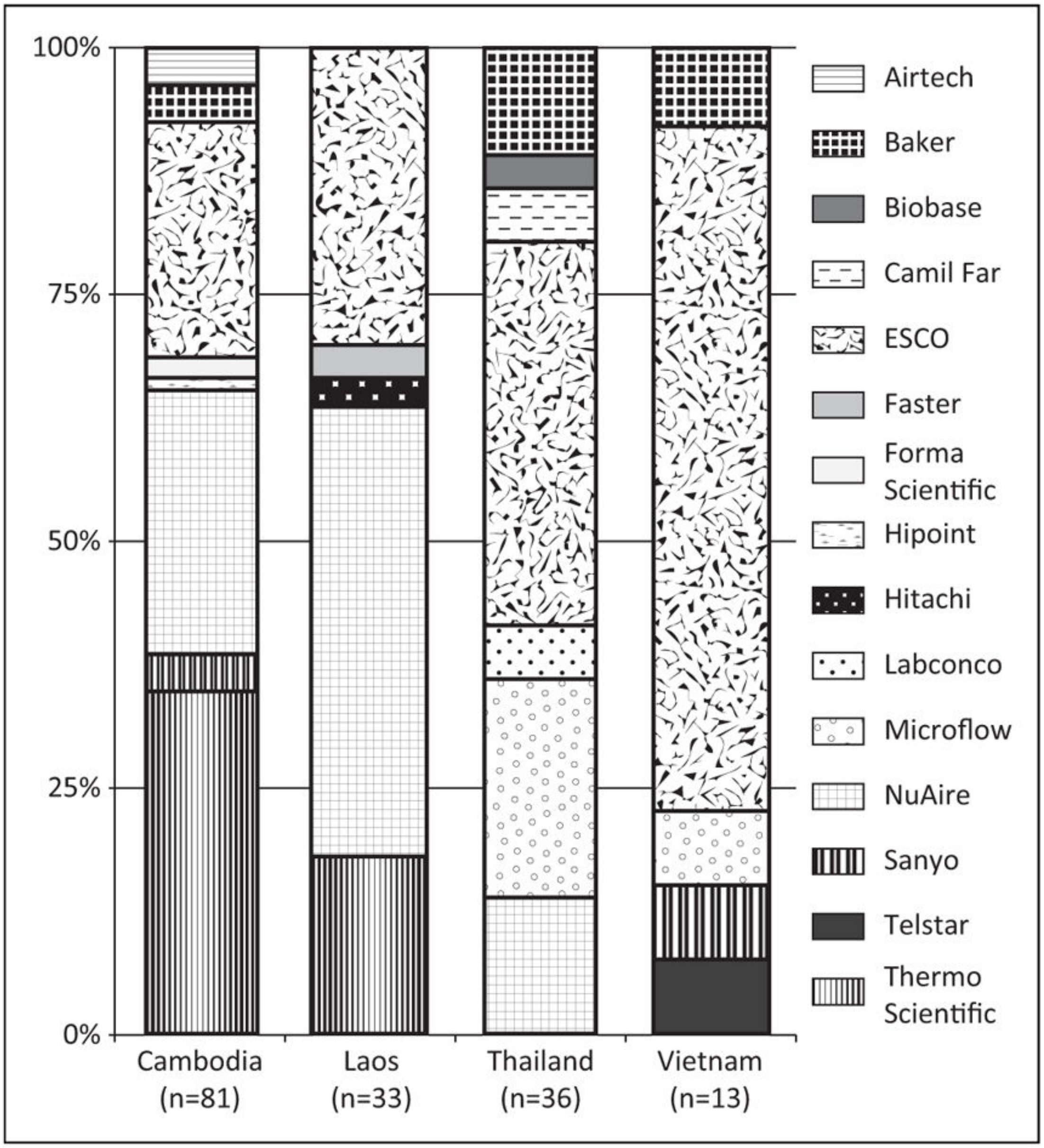

Figure 2.
Stacked graph showing manufacturers of biological safety cabinets (BSCs) certified by program trainees from 2013–2015 by country. BSCs manufactured by Kendro, Jouan, and Holten were recorded as Thermo Scientific and recorded as separate models.

Table 1

List of Equipment and Pricing Necessary to Certify Biological Safety Cabinets.[a]

Test Measurement	Equipment	Make and Model	Country of Purchase	Initial Cost (US $)[b]	Annual Calibration	Cost (US $)
Essential certification						
Airflow rate	Air capture hood	Accubalance 8380	Thailand	5000	United States	330
Downflow velocity	Air velocity meter	Velocicalc 9535-A	Thailand	1300	United States	195
Downflow velocity	Equipment stand		Thailand	120		
HEPA filter leak test	Aerosol generator	ATI6 6D	Thailand	6600	United States	130
HEPA filter leak test	Aerosol photometer	Laskin-Nozzle 2i	Thailand	13 500	United States	630
Air smoke pattern test	Smoke machine	Tiny FX	United Kingdom	2400		
Transportation	Equipment cases		United States	700		
General	Hand tools		Thailand	300		
Supplies	Poly alpha olefin liquid	ATI PAO-4	Thailand	700		
Supplies	Adaptors/connectors		Thailand	25		
Essential fumigation						
Base fumigator	Vaporizer	VAP3/T	United Kingdom	2300		
Monitoring	Formaldehyde meter	htV	Thailand	120		
Monitoring	Formaldehyde calibration standard[c]		Thailand	300		
Monitoring	Biological indicators	Releasat	Thailand	320		
PPE	Full-face respirator	6900	United States	150		
PPE	Multi-gas vapor filters	6006	United States	190		
Supplies	Formaldehyde		Thailand	75		
Supplies	Ammonia		Thailand	90		
Secondary certification						
Comfort and safety	Noise meter	SD-200	Thailand	650		
Comfort and safety	Noise calibrator	AC-300	Thailand	1600	United States	170
Comfort and safety	Light meter	47026-NIST	Thailand	600		
Comfort and safety	Vibration meter	407860-NIST	Thailand	1000	United States	350
Comfort and safety	Electrical leak detector	ESA609	Thailand	1900	Thailand	100
Miscellaneous						
Lifting assistance	Woven wire slings (3)			50		

Test Measurement	Equipment	Make and Model	Country of Purchase	Initial Cost (US $)[b]	Annual Calibration	Cost (US $)
Lifting assistance	Scissor lift			350		
Access	120-cm double-sided ladder			100		

HEPA, high-efficiency particulate air; PPE, personal protective equipment.

[a]Similar lists can be obtained from either Eagleson Institute or NSF.

[b]The pricing noted is from 2014 and is subject to change.

[c]Calibration needed every 6 months. Done by fumigation technician.

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Table 2

Expenses for Each Candidate Incurred for US Training Activities.

Activity[a]	Cost (US $)
Airline tickets to (Bangkok, Thailand, to United States)	2500
Lodging (minimum 15 days with per diem $124/day)	1860
Meals and incidental expenses ($56/day; 15 days + 2 travel days)	952
Ground transportation (to and from airports)	300
Transport from hotel to training ($75/day—shared by all participants)	750
Incidental fees (passport, visas)	500
Internet fees, telephone calls	50
Class registration fees	3000
Week 2—mentored applied practice workshop	2500
NSF Accreditation Program's written and practical examinations	1200
Total	13 612

[a]These are estimates for the advanced classes, which include the NSF examination and materials. The basic course will be slightly less (around US $11 500) as this does not include additional examination fees and charges.

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Table 3

Reasons for Biological Safety Cabinets Failing Certifications, 2013–2015.

Failure	Report Comments	Reason Failed	% Failed Certifications[a]
Exhaust HEPA leak		32	44.4
Supply HEPA leak		23	31.9
HEPA gaskets damaged		4	5.6
Exhaust HEPA filter damaged[b]		6	8.3
Supply HEPA filter damaged[b]		1	1.4
Low inflow or downflow velocity[c]	1	7	9.7
Smoke pattern test		4	5.6
Incorrect installation (ducting)	4[d]	6	8.3
No reference ranges/manuals	1	3	4.2
Main electronic board damaged		1	1.4
Power supply issue	2		
Total number reasons reported		87	
No. of BSCs that failed certification		72	

HEPA, high-efficiency particulate air.

[a]Total percent >100% as failure can result from several reasons.

[b]If HEPA filter is damaged, it will leak. For this table, we only recorded the event as damaged.

[c]Mainly caused by HEPA filter loading.

[d]Most were ducting issues, so damper could not be adjusted.