A risk-based approach to biocontainment facilities: Practical, Sustainable, and Cost-Effective Solutions

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International Federation of Biosafety Associations

Engineering | Architecture | Design-Build | Surveying | GeoSpatial Solutions

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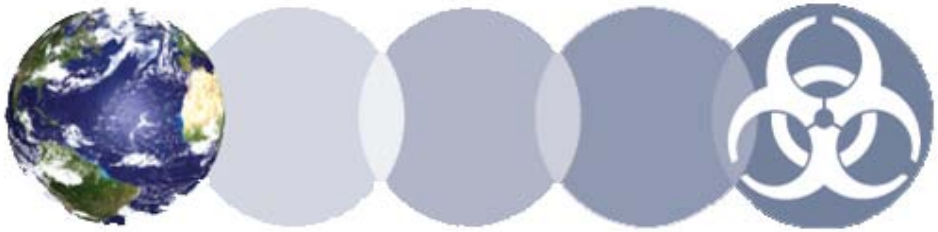
IFBA 5-Year Strategic Plan (2011)

- IFBA is an international organization (NGO) with the mission of safe, secure, and responsible work with biological materials

- IFBA's vision is to become the global resources for biorisk management by:
  - Building, empowering, and advocating for biosafety communities,
  - Establishing a platform for linking and leveraging expertise and support, and
  - Delivering relevant resources and tools in response to emerging needs.

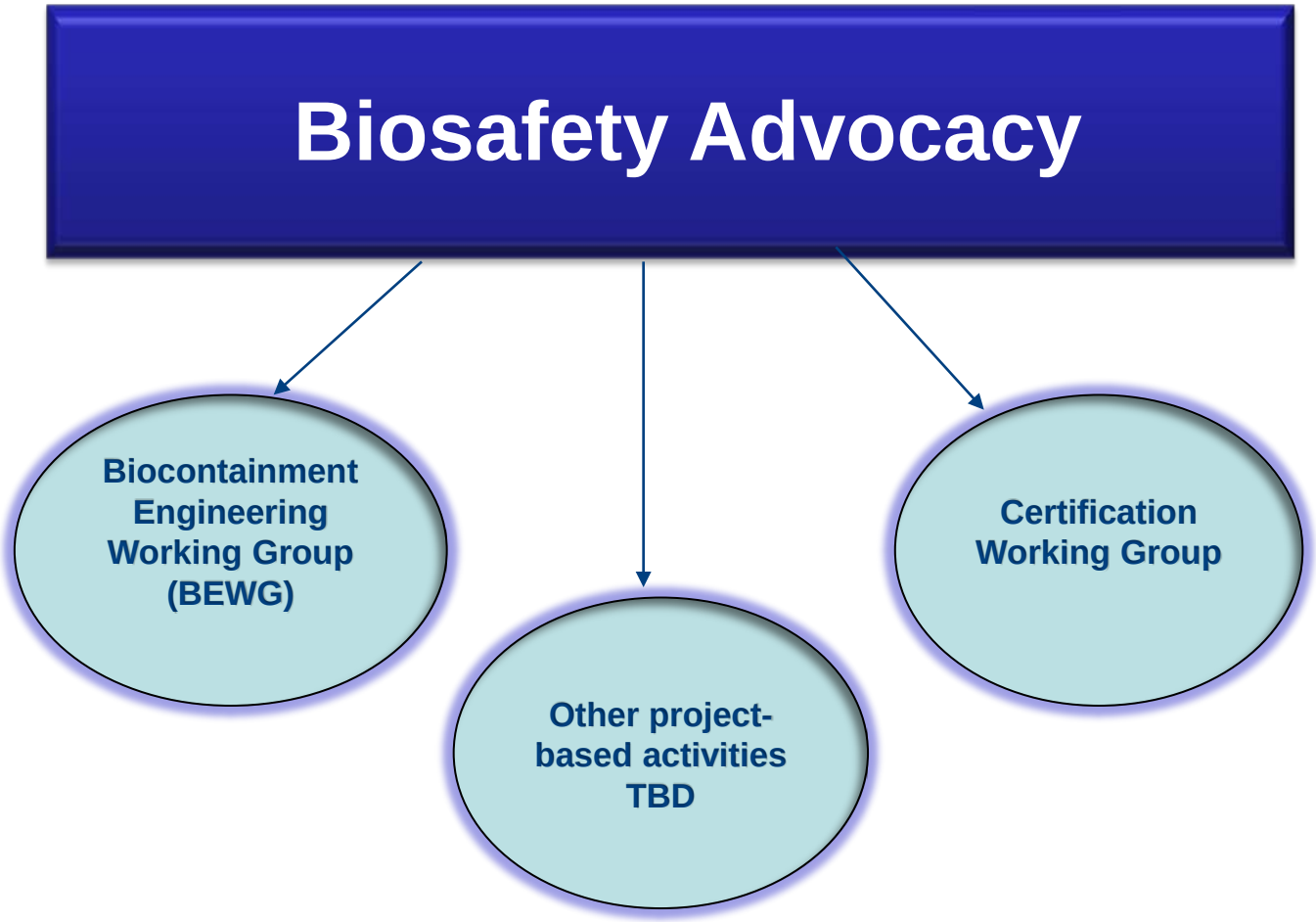


An Association of Associations

- American Biological Safety Association(ABSA)
- Association of Biosafety for Australia and New Zealand(ABSANZ)
- Azerbaijan Biological Safety Association(ABTA)
- African Biosafety Association(AfBSA)
- Association Marocaine de Biosécurité(AMBS)
- Mexican Biosafety Association(AMEXBIO)
- Associacao Nacional de Biossegurance, Brasil (ANBio)
- Asia-Pacific Biosafety Association(APBA)
- Biosafety Association for the Central Asia and Caucasus(BACAC)
- Biorisk Association of Singapore(BAS)
- Biosafety and Biosecurity Network, Thailand (BSNT)

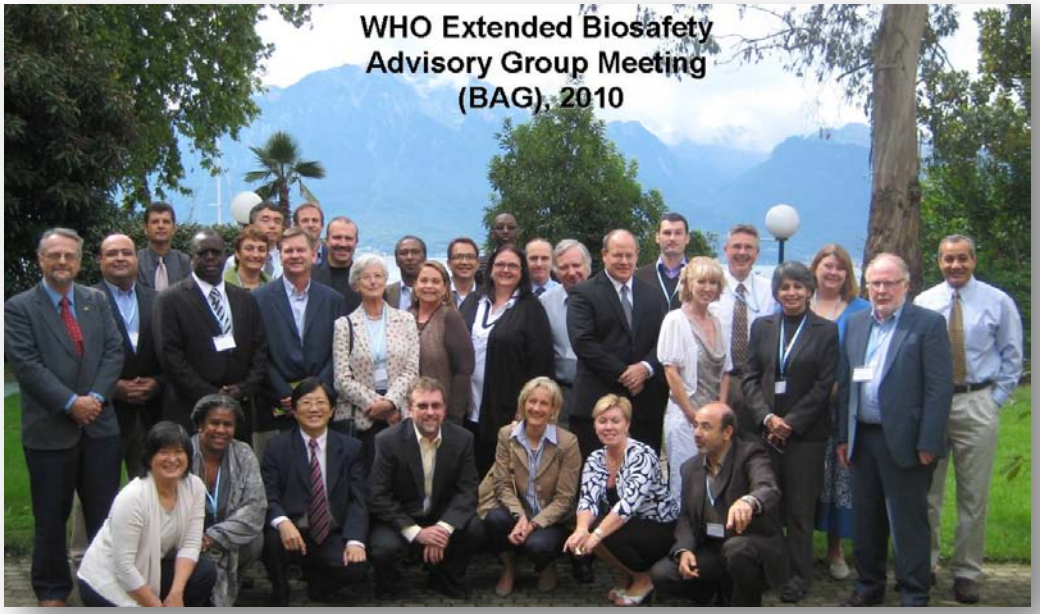
IFBA's strategic plan is implemented for and with its 31 member Biosafety Associations and 30 observer organizations worldwide.

The Focus of IFBA's Current Activities



Development of BEWG

- WHO Strategic Planning Meeting, Sept 2010
  - recognized lack of capacity in biocontainment engineering worldwide
  - recommended IFBA to develop a network from among their member biosafety associations to mentor those new to the field and build capacity in the field



BEWG Members

- scientists, biosafety professionals, architects, engineers, facility maintenance staff, equipment manufacturers from around the world
  - Malaysia, Indonesia, India, Uganda, South Africa, Tanzania, Kyrgyz Republic, Switzerland, UK, Canada, US, ….
- familiar with working in, maintaining, designing, building, certifying BSL2/3/4 laboratories for both human & animal health
- understand local, practical issues in building and maintaining cost-effective facilities that are sustainable in resource limited countries over the longer term

Co-chaired:

Paul Langevin, Canada
Siraj Kaahwa, Uganda

BEWG Priority Action Plan

- Reviewing the BEWG membership & engaging key individuals from all regions to participate;
- Implementing a BEWG project management framework with updated goals, objectives, priority projects and resources required;
- Utilizing a BEWG web portal for network communications and resource sharing;
- Developing tools and approaches for scalable risk-based biocontainment design (e.g. local risk-assessment model, engineering decision-tree model, commissioning & verification model);
- Collaborating with WHO, OIE and other stakeholders for incorporation of risk-based solutions into international best practices and guidelines;
- Exploring innovative ventilation solutions for biocontainment laboratories including natural ventilation as appropriate;
- Promoting the BEWG mentoring and twinning program.
- Recognition of local sustainable solutions

2nd International Conference

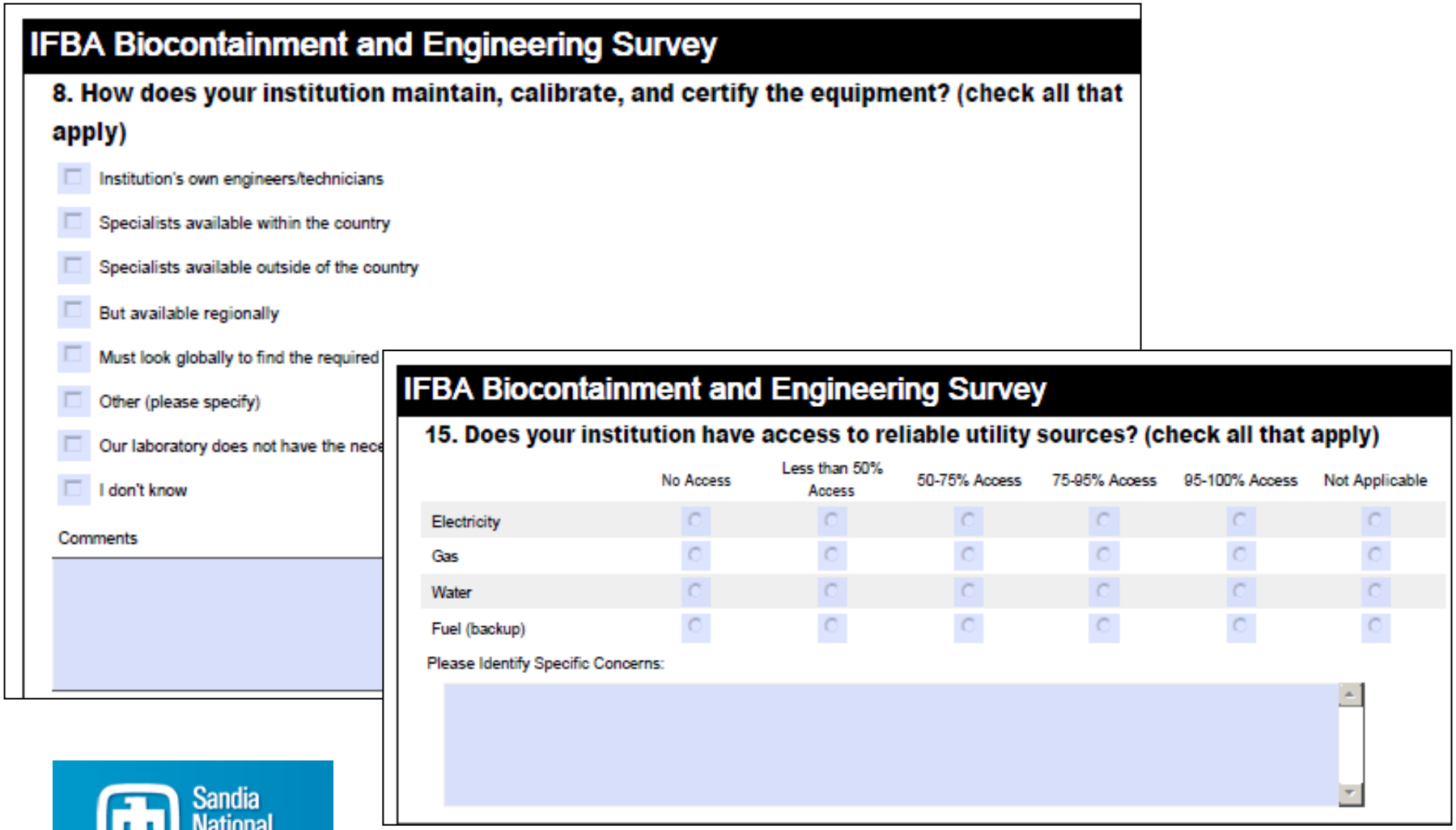
- June 28-29, 2012, Johannesburg, South Africa
  - 130 delegates from 47 countries
- BEWG Working Session

Biosafety and Biosecurity: Building Sustainable Capacity, June 28-29, 2012 South Africa
Working Group 2 "Practical and Sustainable Risk-based Biocontainment for Safely Diagnosing Pathogens"

- Building relevant facilities appropriate for their intended purpose
- Ensuring biocontainment guidelines are risk-based and evidence-based
- Identifying practical, cost-effective solutions that are locally sustainable
- Gathering available data and identifying/filling in gaps in knowledge
- Strengthening biocontainment networks to share knowledge and resources

Presentations: Biocontainment Survey (Jennifer Gaudioso); Chatham House meeting report on *"Safe and Secure Materials: Matching Resources to Reality" (Heather Sheeley)*
Facilitators: Paul Langevin, Siraj Kaahwa, Jonathan Richmond

Biocontainment Survey



IFBA Biocontainment and Engineering Survey

8. How does your institution maintain, calibrate, and certify the equipment? (check all that apply)

- Institution's own engineers/technicians
- Specialists available within the country
- Specialists available outside of the country
- But available regionally
- Must look globally to find the required
- Other (please specify)
- Our laboratory does not have the nece
- I don't know

Comments

IFBA Biocontainment and Engineering Survey

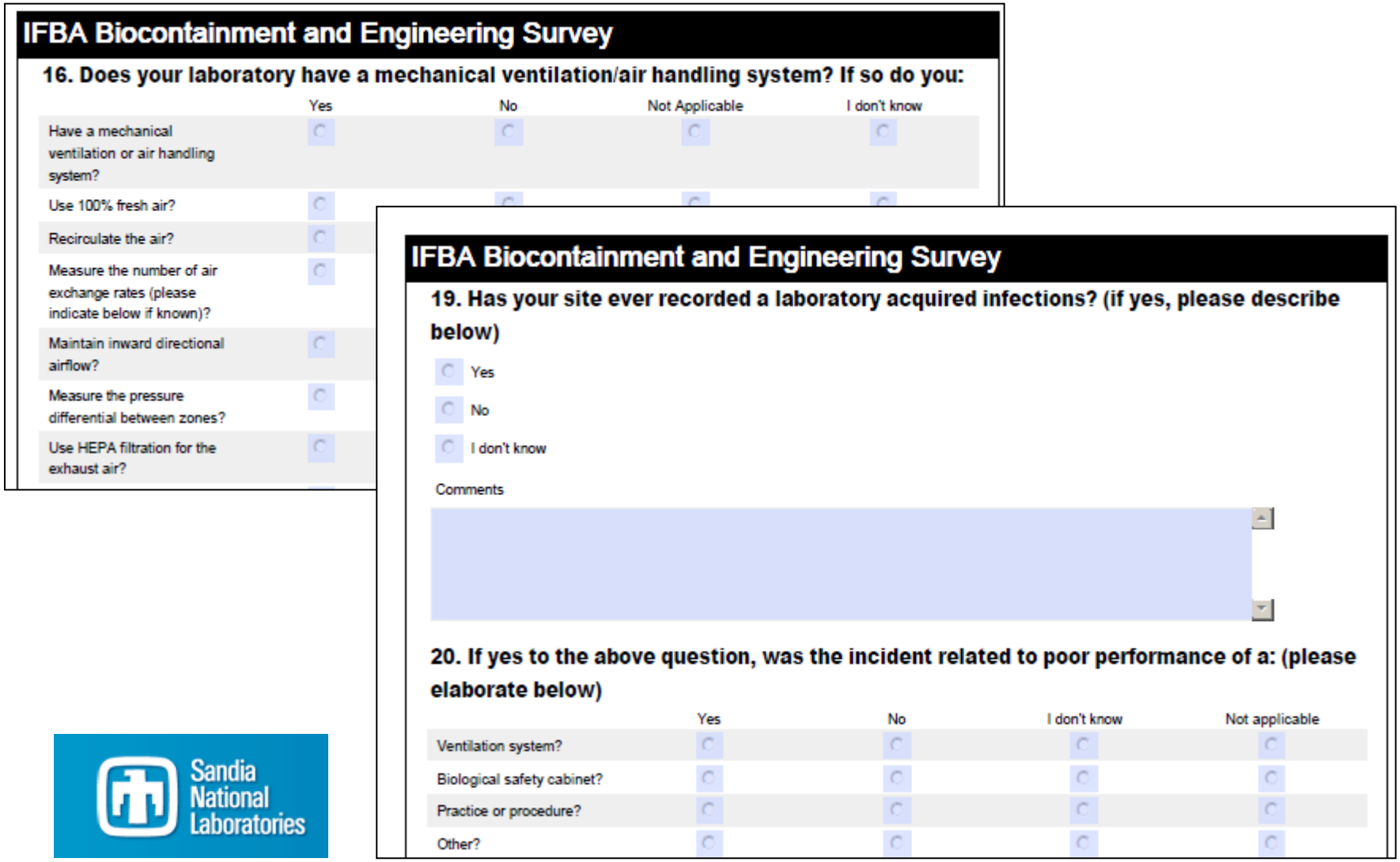
15. Does your institution have access to reliable utility sources? (check all that apply)

	No Access	Less than 50% Access	50-75% Access	75-95% Access	95-100% Access	Not Applicable
Electricity						
Gas						
Water						
Fuel (backup)						

Please Identify Specific Concerns:

Sandia National Laboratories

Biocontainment Survey



IFBA Biocontainment and Engineering Survey

16. Does your laboratory have a mechanical ventilation/air handling system? If so do you:

	Yes	No	Not Applicable	I don't know
Have a mechanical ventilation or air handling system?	○	○	○	○
Use 100% fresh air?	○	○	○	○
Recirculate the air?	○			
Measure the number of air exchange rates (please indicate below if known)?	○			
Maintain inward directional airflow?	○			
Measure the pressure differential between zones?	○			
Use HEPA filtration for the exhaust air?	○			

IFBA Biocontainment and Engineering Survey

19. Has your site ever recorded a laboratory acquired infections? (if yes, please describe below)

- ○ Yes
- ○ No
- ○ I don't know

Comments

20. If yes to the above question, was the incident related to poor performance of a: (please elaborate below)

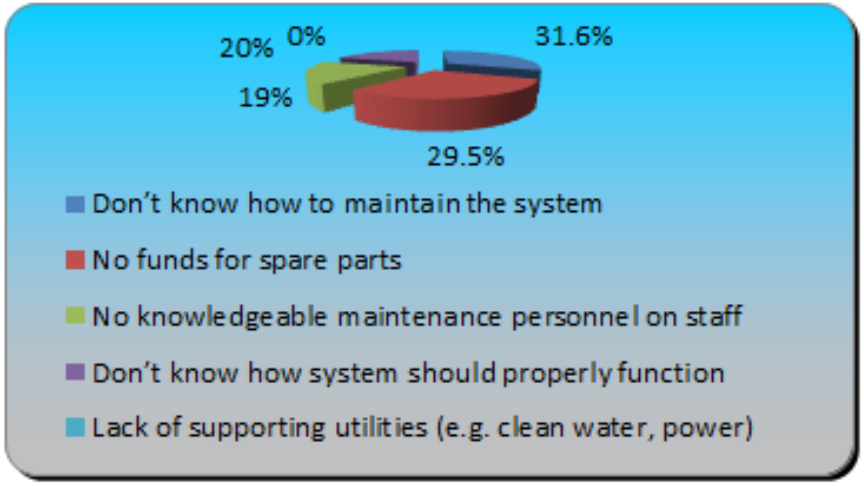
	Yes	No	I don't know	Not applicable
Ventilation system?	○	○	○	○
Biological safety cabinet?	○	○	○	○
Practice or procedure?	○	○	○	○
Other?	○	○	○	○

Sandia National Laboratories

WG 2 – Biocontainment Engineering

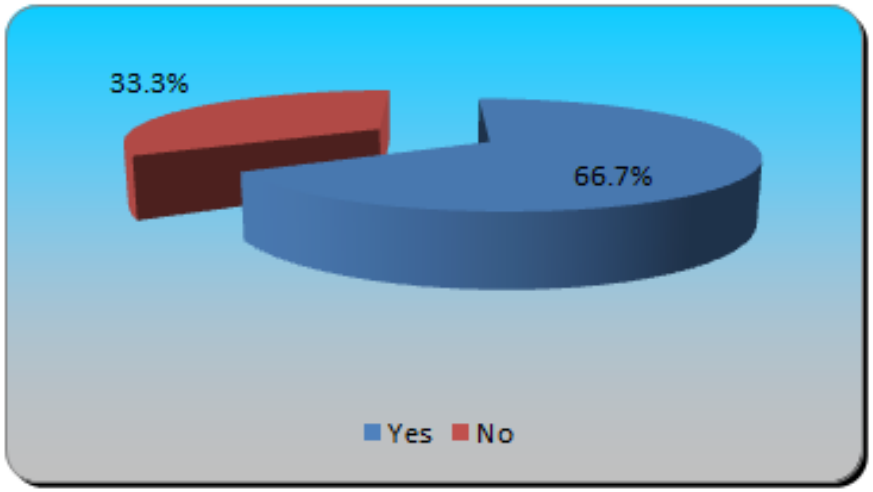
24.) My ventilation system is not maintained because: (pick top 3 choices) (priority ranking)

	Responses	
Don't know how to maintain the system	30	31.58%
No funds for spare parts	28	29.47%
No knowledgeable maintenance personnel on staff	18	18.95%
Don't know how system should properly function	19	20%
Lack of supporting utilities (e.g. clean water, power)	0	0%
Totals	**95**	**100%**



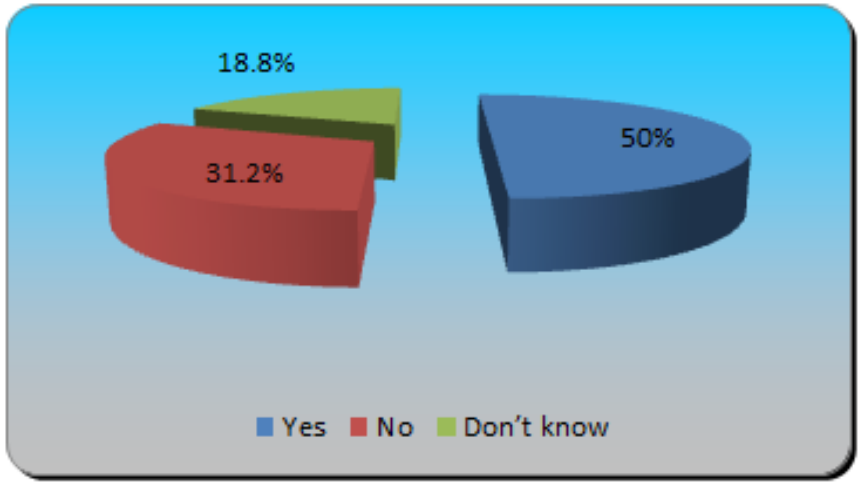
WG 2 – Biocontainment Engineering

15.) Our maintenance personnel have received training on BSL3 and containment principles (multiple choice)	Responses	
Yes	12	66.67%
No	6	33.33%
Totals	**18**	**100%**



WG 2 – Biocontainment Engineering

16.) My BSL3 facility meets the requirements of the WHO Laboratory Biosafety Guidelines (multiple choice)	Responses	
Yes	8	50%
No	5	31.25%
Don't know	3	18.75%
Totals	**16**	**100%**

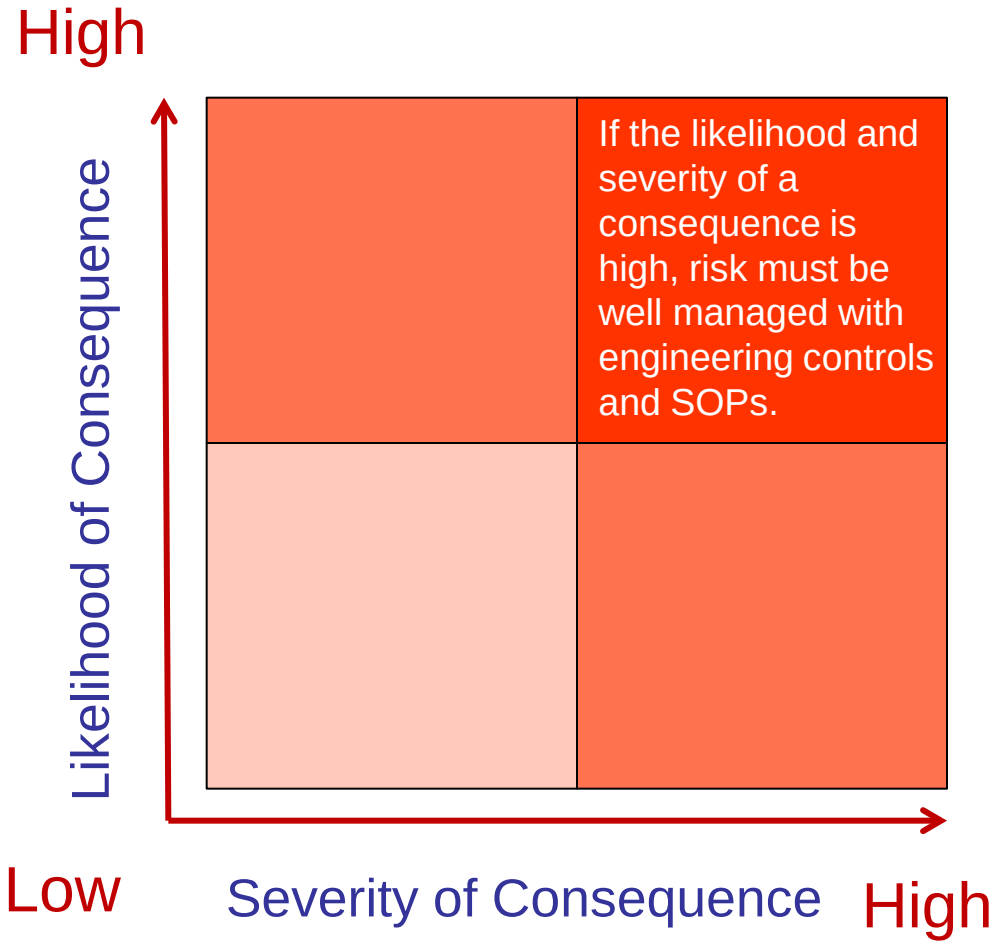


Tools and Methodology - Decision Trees

- Decision trees are road-maps and are not always the same
- Decision trees are project specific, however models that are presented today demonstrate some common assessments
- BEWG review and comments June 28/29, 2012 will assist to refine the decision tree for future applications
- Decision trees can be used to define a project need or a project system and should include RISK ASSESSMENTS
- Decision trees are not meant to be all-inclusive; additional decision making criteria can be provided

Risk Assessment

- Risk Decision making process & who is involved in risk assessment
- Role and application of CWA 15793
- Process to achieve end goals & desired performance
- SOPs vs. engineering solutions
- In-country technical operational support implications



Risk Classification Method- Sample 1

Likelihood	Consequences				
	Severe (1)	Major (2)	Medium (3)	Minor (4)	Negligible (5)
Almost certain (A)	E	H	H	M	M
Likely (B)	H	H	M	M	L
Possible (C)	H	M	M	L	L
Unlikely (D)	M	M	L	L	T
Rare (E)	M	L	L	T	T

E	Extreme risk — Immediate action required; this level of risk needs detailed research and planning by senior management.
H	High risk — Action plan is required as soon as practicable by senior management.
M	Moderate risk — Action plan is required by Area/Department Manager.
L	Low risk — Managed by routine procedures and employees under supervision.
T	Trivial risk — Unlikely to need specific application of resources.

Risk Classification Method: Sample 2

SEVERITY	How likely is it to be that bad? (PROBABILITY)			
How severely could it hurt someone or how ill could it make someone?	++ Very likely could happen anytime	+ Likely could happen at some time	= Unlikely could happen but very rarely	-– Very unlikely may happen but probably wont
Kill or cause permanent disability or ill health	1	1	2	3
Long term illness or serious injury	1	2	3	4
Medical attention and several days off work	2	3	4	5
First aid needed	3	4	5	6

1 and 2	**The hazard has a high risk of creating an incident. It requires immediate executive management attention to rectify the hazard. Control action must be immediately implemented before working in the area or carrying out the work process.**
3 and 4	**The hazard has a moderate risk of creating an incident. It requires management attention in a reasonable timeframe to prevent or reduce the likelihood and severity of an incident. Control action of a short term nature would need to be taken immediately so that work could still be carried out with further long term action taken to ensure that the hazard was fully controlled.**
5 and 6	**The hazard has a low risk of creating an incident. It requires supervisor and employee attention in a reasonable timeframe to prevent or reduce the likelihood and severity of an incident.**

Risk Classification Method: Sample 3

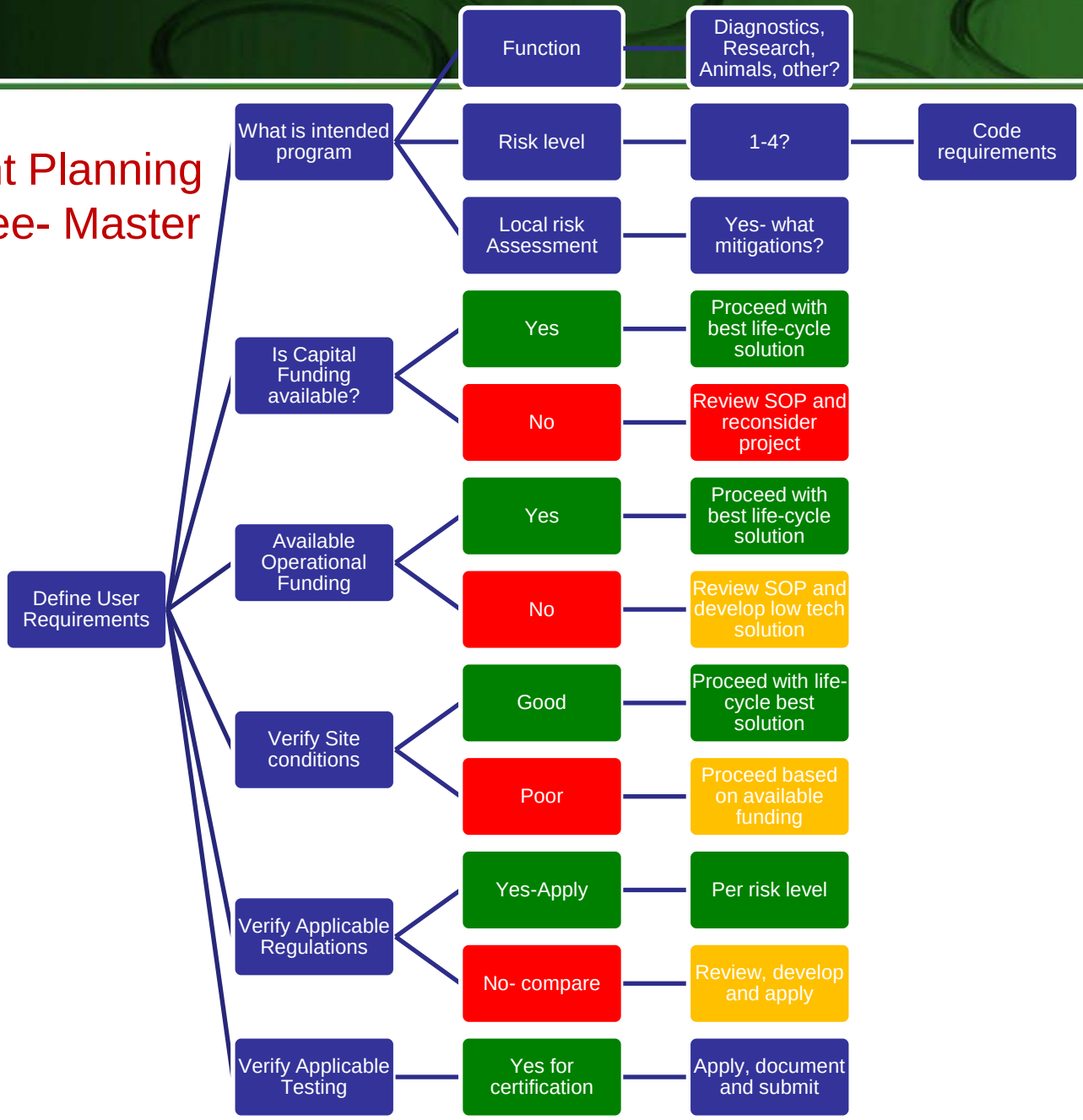
FINANCIAL RISK	Available Costs to build		
Available Costs to Operate	LOW	MODERATE	HIGH
LOW	1	2	2
MODERATE	2	2	3
HIGH	2	3	4

1	Need to rely on simple technical solutions and SOP; use of primary containment systems such as non-connect Class IIA cabinets; SOP training and monitoring of staff is high
2 and 3	Need to ensure capital investment is supported with increased costs of operations costs. If high operational costs are available, 3rd Party capital financing may be available (ESCO). Reliance on SOP are necessary. Look for energy recovery or power supply replacement opportunities.
4	Plan projects for need, redundancy and operational efficiencies in accordance with functional needs and safety requirements ; Reliance on biosafety is a combination of SOP and good engineering controls

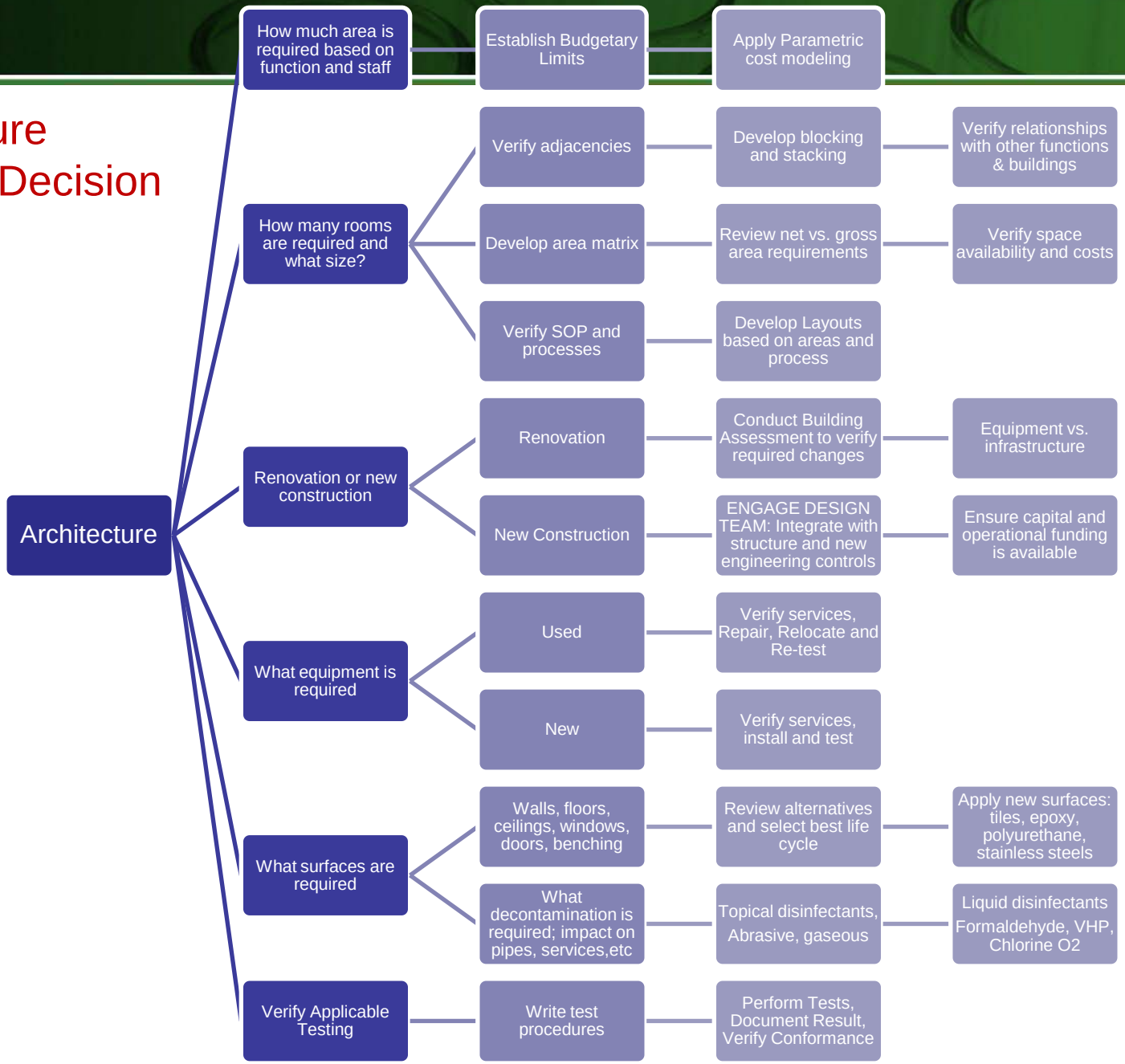
Planning & Design Decision Trees

- A Decision Tree is provided to assist verifying issues associated with deciding what design “solution” is required to resolve a requirement
- Decision trees require reflection and consideration of
  - Local Risk Assessments
  - Local Site Conditions
  - Funding conditions
  - Cost to build
  - Cost to operate
  - Technical capacity to maintain
  - Life-cycle cost to repair and replace
  - Local Codes and Regulations
  - Technical Options
  - Size of the requirement
  - Intended SOP

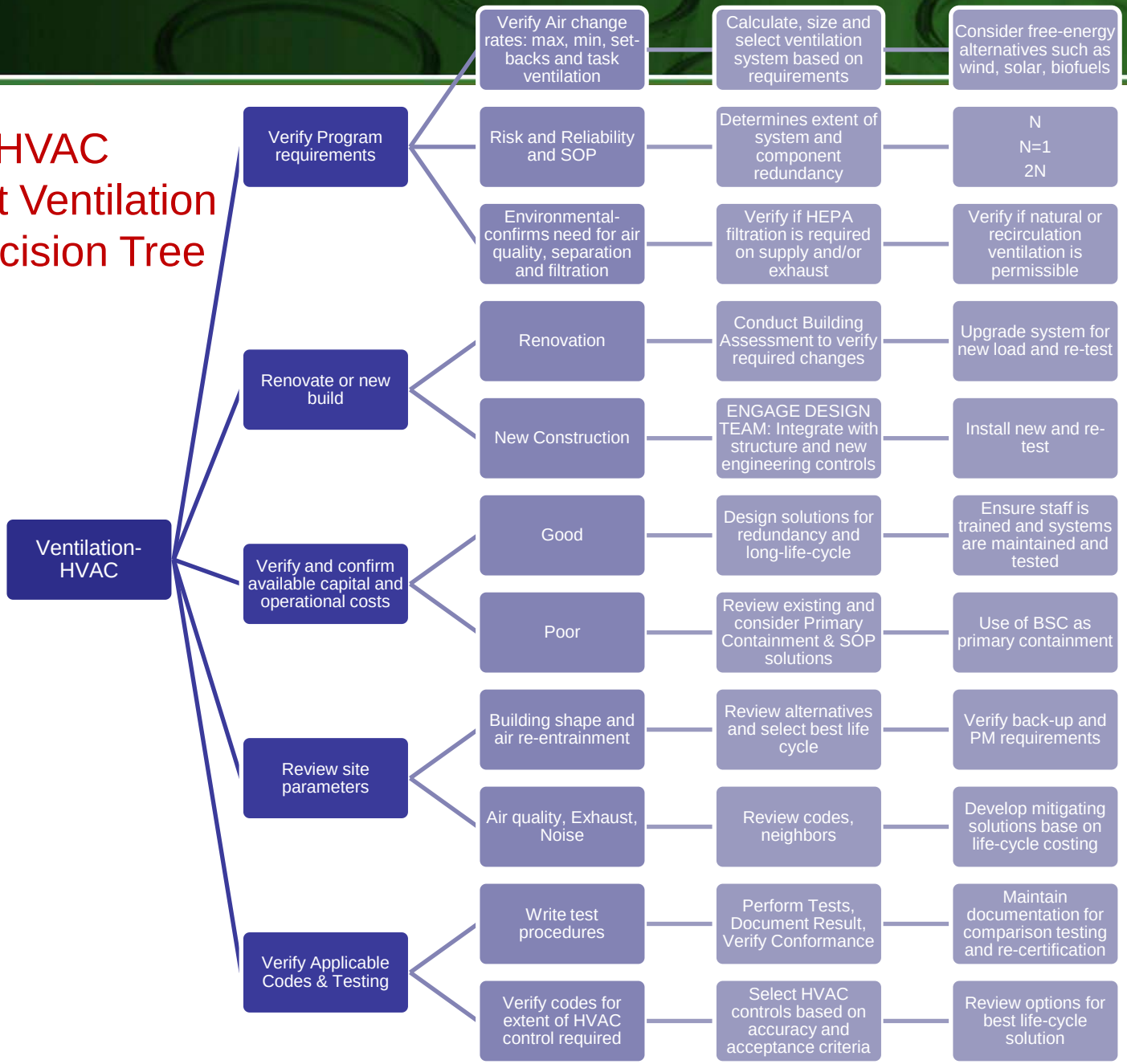
Containment Planning Decision Tree- Master



Architecture Planning Decision Tree



Mechanical HVAC Containment Ventilation Planning Decision Tree



O&M Cost Study

These facilities are located in the United States (2), United Kingdom (2), Central Europe (2), Canada (1) and Australia (1) and of the eight only one was academic based

Cost Study Findings, but Don't Use These Numbers

It is very difficult to put hard operating cost numbers in place because for a particular high-containment facility as there are a multitude of variables that can make up an operational budget. Below is a summary of some operational cost information from facilities that have provided cost data for this study. (Note that the information has been adjusted to US dollars and square feet.)

- Facility square footage ranged from 35,000 sf to 300,000 sf with BSL-3 space utilization within the overall space ranging from 10 percent to 60 percent.
- Overall annual operating costs ranged from $1 million to $16 million.
- When all facility metrics of the study are averaged and normalized the general numbers came out to be an average of $8 million annual operating costs for an average square footage of 150,000 sf of which 30 percent represents BSL-3 containment. This yields an average operating cost of $53/sf/year ($8 million/150,000 sf).

These costs are representative of current (active) facilities in the study and should be used with a critical eye and not be used in lieu of a detailed cost study for a specific facility. A cost study for a specific facility is needed to determine specific costs for specific functions with specific equipment and space configurations that factors in the understanding of why unit costs differ between like facilities.

IFBA/ERGRF
Sustainable Engineering Award

International Federation of Biosafety Associations

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IFBA/ERGRF
Sustainable Engineering Award

The Foundation has partnered with IFBA to encourage regional development of engineering solutions and strategies that are local, practical and sustainable.

The projects should be applicable to improving laboratory safety, be able to be constructed of locally available materials, require little or no alternations to existing infrastructure, and should have minimum environmental impact.

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IFBA/ERGRF
Sustainable Engineering Award

Regional awards will be presented at:
participating regional biosafety associations

Awards can include:

- Paid travel to the regional meeting.
- Monetary award
- Certificate and plaque
- Global recognition

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