Biosafety and Biosecurity in Health Laboratories

Report of a Regional Workshop

Pune, India, 8-11 July 2008

World Health Organization
Regional Office for South-East Asia

SEA-HLM-398
Distribution: General

Regional Workshop on Biosafety and Biosecurity in Health Laboratories

Report of the Regional Workshop
Pune, India 8–11 July 2008

World Health Organization
Regional Office for South-East Asia

Printed in India

Contents

1. Background

Biosafety is defined as the application of a combination of laboratory practices and procedures, laboratory facilities, and safety equipment when working with potentially infectious micro-organisms to protect the laboratory staff and, through them, the general public.

Biosecurity is the application of a combination of measures that are addressed through the coordination of administrative, regulatory and physical security procedures and practices implemented in a working environment for reducing the risks of biological material loss, theft or misuse caused by poor management or poor accountability and protection.

Microbiology laboratories are special, often unique, work environments that may pose identifiable infectious disease risks to persons working in these laboratories or to those in the vicinity. Infections are known to have been contracted in the laboratory throughout the history of microbiology. Reports around the turn of the century described laboratory-associated cases of typhoid, cholera, glanders, brucellosis, and tetanus. A number of cases were attributed to carelessness or poor technique in the handling of infectious materials. A published series of surveys of laboratory-associated infections summarized 222 viral infections in laboratory staff of which 21 were fatal. In at least a third of the cases the probable source of infection was considered to be associated with the handling of infected animals and tissues.

Advances in technology and knowledge have resulted in the establishment of high-containment laboratories which are highly sophisticated facilities, and which require specialized expertise to design, construct, operate, and maintain. Because these facilities are intended to contain dangerous micro-organisms, usually in liquid or aerosol form, even minor structural defects – such as cracks in the wall, leaky pipes, or improper sealing around doors – could have serious consequences. Supporting infrastructure, such as drainage and waste treatment systems,

must also be secure. High-containment laboratories are expensive to build and expensive to maintain and a small breach of security can result into a serious public health crisis.

The economic consequences and scientific concerns resulting from the laboratory-acquired SARS-CoV infections of 2003-2004 in Singapore, Taipei and Beijing raised biosafety awareness in the affected facilities. Most importantly, it promoted a review of biosafety practices in laboratories by the concerned scientific community and national regulatory bodies, demonstrating high political commitment to this issue.

A need has also been felt for emphasizing the practices and procedures used by trained laboratory staff for bio-risk management. The World Health Organization's *Laboratory Biosafety Manual* states that "no biosafety cabinet or other facility or procedure alone guarantees safety unless the users operate safe techniques based on informed understanding." It is the responsibility of everyone, including managers and laboratory workers, to perform their work in a safe and secure manner.

Despite a greater awareness of biosafety and biocontainment practices, handling infectious micro-organisms remains a source of infection, and even mortality, among laboratory workers. Incidents of secondary transmission of disease to the public at large, which may be due to possible contamination of the environment or personnel, are also being reported. Infection caused by SARS virus in laboratories in Singapore and China exemplify the possible threat to the general public.

Keeping the above scenario in mind, the WHO Regional Office for South-East Asia organized a Regional Workshop on Biosafety and Biosecurity at Pune, India from 8-11 July 2008. The workshop was attended by 11 participants from seven countries (Bangladesh, Bhutan, India, Indonesia, Maldives, Sri Lanka and Thailand) of the Region. The facilitators were from WHO (Headquarters, Lyon Office, and SEARO) as well as from several leading international institutions. The programme of work and the list of participants are attached as Annex 1 and 2 respectively. Dr AC Mishra, Director, National Institute of Virology, Pune chaired the meeting.

The workshop was aimed to advocate for and introduce the concept and approach to minimize or prevent the occurrence and consequences of

human error within the laboratory environment, as well as the bio-risk management approach, composed of biosafety, laboratory biosecurity and ethical responsibility by:

(1) Reducing the risk of unintentional exposure to pathogens and toxins or their accidental release (biosafety), and reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of micro-organisms (laboratory biosecurity);

(2) Providing assurance, internally and externally (facility, local area, government, global community, etc.), that suitable measures have been adopted and effectively implemented; and

(3) Providing a framework for continuous awareness-raising for biosafety, laboratory biosecurity and ethical code of conduct, and training within the facility.

2. Objectives

The following were the objectives of the workshop:

(1) To review the status of biosafety and biosecurity in laboratories in the Region;

(2) To orient participants on the principles, objectives and practices of laboratory biosafety and required infrastructure;

(3) To familiarize participants with international shipment of hazardous organisms; and

(4) To identify gaps and draft follow-up action points for strengthening biosafety in laboratories in the Member countries.

3. Inaugural session

Dr AC Mishra, Director, National Institute of Virology, Indian Council of Medical Research, Pune, India, welcomed the participants and highlighted the need for biosafety and biosecurity in the changing dynamics of microbiological practices and their impact on public health. He provided an introduction to various definitions of risk groups of micro-organisms and salient features of biosafety levels 1 to 4 in laboratories. He also provided a

brief on the status of high containment laboratories in India and some of the major constraints in proper designing, construction and maintenance of these facilities.

The message from Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia was read out by Dr Rajesh Bhatia, Regional Adviser, Blood Safety & Clinical Technology, WHO/ SEARO. Dr Samlee said that health laboratories are high risk environments where laboratory workers are at occupational risk of exposure to micro-organisms that cause a wide variety of diseases, from unapparent to life-threatening ones. The risk of acquiring infection has increased manifold in the recent past with the emergence of several highly pathogenic organisms notably the SARS virus, influenza H5N1 virus, Nipah virus and drug-resistant mycobacteria. Given the growing importance of emerging infectious diseases, the handling of pathogens in an imperfect environment or by improper techniques can be a threat to international health security.

The health laboratories are intended to contain dangerous micro-organisms, usually in liquid or aerosol form. Even minor structural defects could have severe consequences. High-containment laboratories are cost-intensive to build and expensive to maintain. A small breach of security can trigger or result in a major crisis.

WHO has recently witnessed a worldwide increase in the demand for biosafety guidance and support that culminated with the 2005 adoption by the World Health Assembly of resolution WHA58.29 on *Enhancement of Laboratory Biosafety*. The need to minimize the risk of laboratory-acquired infections to obviate the spread of emerging diseases has also been articulated in the Asia- Pacific Strategy on Emerging Diseases.

In accordance with the World Health Assembly resolution, WHO has initiated activities to strengthen national efforts in biosafety and biosecurity in health laboratories. This workshop was aimed to introduce the concept and approach on structural and functional aspects of health laboratories to minimize or prevent the occurrence and consequences of human error within the laboratory environment using the bio-risk management approach, Dr Samlee added.

Biosafety activities by WHO

The background of global biosafety activities by WHO was provided by Dr Nicoletta Previsani, Scientist, WHO/HQ, Geneva. The importance of biosafety grew with the recognition of emerging infectious diseases as significant public health problems.

Three resolutions (Box 1) have been adopted by the World Health Assembly that are either directly or indirectly related to biosafety in laboratories.

WHO has designated five Collaborating Centres on Biosafety in the recent past. Of these, two are in the USA and one each in Canada, Australia and Sweden. Recognizing the importance of the subject and the need for platforms for professionals to share views and to advise national authorities, several regional bodies of professionals have been established. These include the American Biosafety Association, the Asia-Pacific Biosafety Association and the European Biosafety Association.

Box 1: World Health Assembly Resolutions related to Laboratory Biosafety

- **World Health Assembly resolution 55.16 (2002)**
  - "Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health"
- **World Health Assembly resolution 58.3 (2005)**
  - "Prevention and control of the international spread of disease and public health risks"
- **World Health Assembly resolution 58.29 (2005)**
  - **"**Enhancement of laboratory biosafety**"**

Subsequent to the World Health Assembly meeting in 2005, several countries are reviewing and revising legislation in this area. New BSL 3 labs are being established in several countries, requiring greater advocacy and acceptance of biosafety in laboratories by policy makers, increasing the role

of management in laboratory biosafety and the need for training support using standard methodology.

WHO proposes to undertake training of trainers using a standardized course curriculum. The first course is likely to take place in late 2009. The training course and regional advocacy workshops being conducted by WHO are directed to increase knowledge, awareness and expertise in developing countries.

WHO is also planning to undertake collaboration with the vertical programmes to highlight biosafety, continue advocacy for biosafety in national policies with bio-risk assessment and introduce it as scientific disciplines in university teaching courses.

4. Proceedings of the workshop

The workshop included presentations of country reports to review the existing capacity of the countries; presentations and discussions to disseminate new information; field visit to BSL3 laboratory of the National Institute of Virology, Pune and a training course on compliance with the new international regulations for shipment of infectious material.

4.1 Current status

Status of biosafety in the South-East Asia Region

Dr Rajesh Bhatia provided an overview of the status of biosafety in laboratories in the South-East Asia Region of WHO. The Region carries 28% of the global burden of communicable diseases and is home to almost all emerging infectious diseases. The laboratories are in varying stages of development. In health services, these get low priority and within laboratory services, biosafety concepts are minimal. The countries with laboratory policies, national focal points and status of regulations are shown in Table 1.

With the growing importance of emerging infectious diseases some attention is being paid to establishment of laboratories with different biosafety levels. Table 2 shows the status of countries with one or more BSL2 labs, and the number of BSL3 and BSL4 laboratories in the Region.

Table 1: ***Status of regulations and laboratory policy in the South-East Asia Region***

Country	Bio-safety regulations	Lab policy and standards	Focal point for labs in MoH
Bangladesh	–	–	+
Bhutan	–	–	+
DPR Korea	–	–	–
India	Biowaste regulations	–	–
Indonesia	1994 (being revised)	–	+
Maldives	–	–	–
Myanmar	–	–	–
Nepal	–	–	–
Sri Lanka	–	+	+
Thailand	Institute specific	–/+	–
Timor-Leste	–	–	–

The major challenges include lack of awareness at the highest level of issues pertaining to biosafety policy, standards and regulations; inadequate human resources and infrastructure; lack of sufficient technical expertise and resources for risk assessment, biosafety practices, construction, operation and maintenance of facilities, validation and documentation; and limited emphasis in training courses or exclusive training courses/institutional facilities and the concepts of biosecurity as a critical issue yet to be recognized in the Region.

Table 2: ***Biosafety laboratories in South-East Asia Region***

Country	BSL-2 (>1 lab)	BSL-3 (Planned)	BSL-4
Bangladesh	+	1* (1)	–
Bhutan	+	– (1)	–
DPR Korea	+	–	–
India	+	14 (6)	1 (2)
Indonesia	+	6	–
Myanmar	+	–	–
Maldives	+	–	–
Nepal	+	– (1)	–
Sri Lanka	+	1*	–
Thailand	+ (+mobile)	5	–
Timor-Leste	–	–	–

*Non-functional

A summary of the biosafety programme in Member countries of the Region is shown in Box 2 below:

Box 2: Laboratory biosafety programme in the South-East Asia Region

- Virtually non-existent biosafety programmes
- Safety awareness and biosafety practices worsen from central to peripheral labs
- Specific training programme by countries/WHO inadequate
- Designated biosafety officers almost rare
- Biosafety guidelines not available or fully implemented
- Few institutes have SOP for spill-management and post-exposure management
- Documentation on safety errors and laboratory acquired infections minimal
- Mandatory immunization of lab personnel absent
- Availability of PPE inadequate
- Expertise and facilities available to plan and construct BSL 3 and BSL 4 facilities but coordination between various stakeholders and ownership limited
- National or regional professional associations yet to be formed.

Country reports

Bangladesh

Bangladesh has laboratories attached to hospitals/institutes up to the sub-district level. A set of criteria has been developed to obtain permission to operate a laboratory but it does not highlight the biosafety issues. One BSL3 facility was established in BSSM University to undertake work on anthrax. However, this facility is nonfunctional because of lack of proper maintenance. The Institute for Epidemiology, Disease Control and Research has a BSL2 laboratory where, with BSL3 practices, organisms such as Nipah and H5N1 are handled. This institute is in the process of establishing a prefabricated BSL3 facility by the end of 2008 with financial support from the World Bank. There are no national regulations on biosafety.

No special training programme is undertaken on laboratory biosafety but it is integrated into other training programmes.

Bhutan

Bhutan has 29 hospital-based laboratories. A BSL2 laboratory is in operation in the TB unit. There is no legislation on biosafety. Basic biosafety equipment has been made available for waste segregation at all facilities. Training on biosafety practices is part of overall laboratory training programmes. An infection control committee is functional only in the national hospital. Standard operating procedures (SOP) for cleanliness are available. Monitoring of staff health is being conceptualized. Two training modules have been drafted for infection control and for health waste management. Resource constraints are experienced to buy and maintain biosafety cabinets and other equipment.

India

Several BSL3 laboratories are functional and many more are being established. Primary funding is from the Government. Six BSL3 laboratories exist in the health sector and three more are coming up. Five of these are prefabricated. One BSL4 facility exists under the Ministry of Agriculture and deals primarily with large animals. Another BSL4 laboratory is being built at NIV, Pune.

National biosafety and biowaste activities are governed by legislation through State Pollution Control Boards.

Under the Integrated Disease Surveillance Programme a network of laboratories with biosafety practices and infrastructure is being set up. Rapid response team training also has a biosafety component under avian influenza and IHR training. A field manual has also been developed for biosafety.

All major hospitals have biosafety committees which meet monthly.

Indonesia

Indonesia has 12 BSL2 laboratories spread all over the country. Six BSL 3 laboratories are functional. The BSL3 laboratory at the National Institute for Health Research & Development, Jakarta (NIHRD), is likely to be operational by the end of 2008. One prefabricated BSL3 laboratory is providing molecular biological support from Eijkman Institute.

In 1994, national guidelines on biosafety in microbiology facilities were developed. These are being revised. However, there is no national body for maintaining standards. There is no professional association on biosafety.

NIHRD is developing a biosafety training programme comprising 32 modules adopted from a recently held training of trainers workshop held at Singapore in 2007.

Maldives

Maldives has eight BSL2 laboratories and some more are being upgraded to this level. The remaining 59 laboratories belong to BSL1 category. There is no legislation and regulations for biosafety. Maldives faces the challenge of a shortage of trained human resource.

Sri Lanka

The Medical Research Institute, Colombo (MRI) had established a BSL3 laboratory a few years ago which is not operational because of lack of maintenance. Several BSL2 laboratories are located in medical colleges and universities. There are no national biosafety regulations. However, it finds mention in the National Health Laboratory Policy (2006). Though the

country has 15 microbiologists, 5 virologists, 34 pathologists and about 900 medical technologists, there is hardly any one who is an expert in biosafety.

Infection control practices are followed in the hospitals and biosafety is part of special training for nurses. The laboratory staff are immunized against hepatitis B. Manuals on infection control and hospital-associated infections include a biosafety component.

Sri Lanka has consulted an expert to suggest measures to make the BSL3 laboratory at MRI functional. Resources to implement the recommendations are being mobilized.

Thailand

Thailand has five BSL3 laboratories in Bangkok of which two are located in the National Institute of Health (NIH). All 14 Regional Medical Sciences Centres have BSL2 facilities. National regulations have been framed for the import and export of pathogens. No national biosafty regulations exist but each institute has developed its own standards. Lack of safety equipment in some provincial institutions has been observed. A national biosecurity plan is being drafted by NIH. Biosafety training to new staff members is provided through a course being run every month. Non-availability of adequate number of trained staff in biosafety is experienced by Thailand.

4.2 Plenary sessions

Laboratory-acquired infections

Dr Ai Ee Ling, Chief of Biosecurity, Health Science Agency, Singapore, discussed the magnitude of the problem of laboratory-acquired infections. All categories of infections can be acquired in the laboratory. However, the most common are those by the respiratory route. SARS was acquired in the laboratory in Singapore and Taiwan in 2003 and in China in 2004. These occurred in a BSL3 laboratory in Singapore, a BSL4 in Taiwan and a BSL2 in China.

Only 20% of laboratory-acquired infections can be traced to recognized accidents and the source of 80% remain unknown and not related to recognized accidents. Of the known sources, 27% are following

spills, 25% after injuries (sharps, needles) and 14% occur because of aspiration through mouth.

Accidents in the laboratory can cause disease in large number of humans. Documented reports show the occurrence of 94 cases of brucellosis, 13 of coccidiodomycosis and 20 of tularaemia, each with a single source.

Important ways to prevent laboratory-acquired infections include good laboratory practices, engineering controls for containment, directional flow of air, use of high efficiency particulate air (HEPA) filters; administrative controls including training, use of SOP, proper waste management, good supervision, awareness about the hazards and availability and use of laboratory-specific manuals by all the staff members.

Following the diagnosis of SARS in a student in Singapore, several actions were taken to strengthen biosafety which included designation of exclusive staff in the Ministry of Health, development and implementation of national regulations, certification of laboratories by a third party and training of staff.

With increased awareness, Singapore also took the lead in establishing the Asia-Pacific Association of Biosafety which has already met thrice and provided a platform to experts to share their views and advise the national authorities on biosafety and biosecurity.

Implementation of biosafety

Professor Sean Kaufman, Rollins School of Public Health, Atlanta, USA, emphasized the need for a change in behaviour of staff working in laboratories towards their understanding of the risk, providing them with skills, resources and confidence to handle biosafety issues in a professional way.

Biosafety is ensured through implementation of four controls (figure 1).

(1) Engineering (physical facilities)

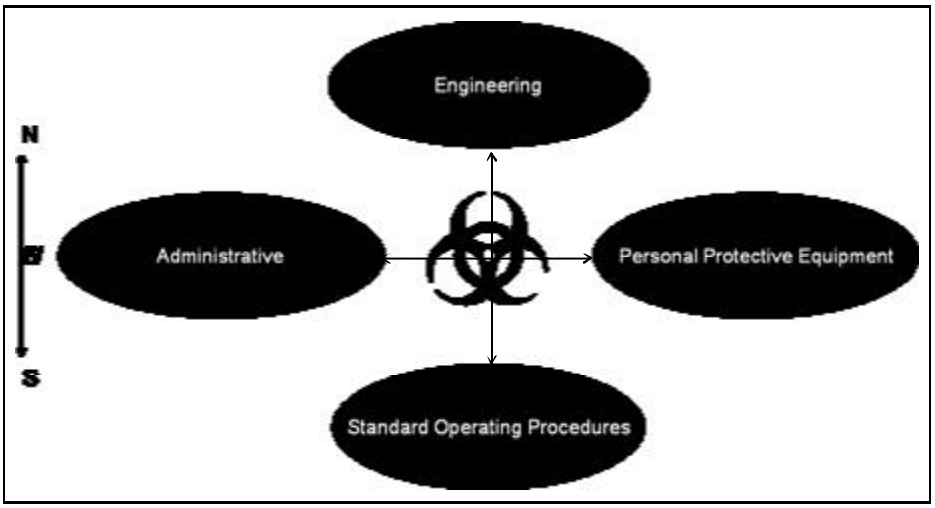
(2) Standard operating procedures (SOP)

(3) Administrative (including training, vaccines, medical surveillance system, compliance with SOP)

(4) Personal Protective Equipment (resources to protect staff).

All controls should carry equal importance or compensate for inadequacies of each other.

Figure 1: *Essential controls for biosafety*



Minimization of risk with regard to biosafety includes its assessment, management and communication. Risk communications is a psychological science and there is a need to train people on how to communicate. Establishment of any BSL3 or BSL4 laboratory may require communicating with the local population regarding any possible risk and the way it has been taken care of by the laboratory management to obviate their fear that high containment laboratories mean high risk for communities. Often the risk perception factors are different for different sets of people and hence risk communication should be packaged in such a way that the perceived risks are taken care of.

International Health Regulations (2005) and Biosafety in Laboratories

Dr Phillip Duboise, Scientist, WHO/Lyon office briefed the participants about the International Health Regulations (2005) and emphasized the role of quality laboratory services with appropriate biosafety in effective implementation of these Regulations.

The International Health Regulations (2005) herald a new era to keep pace with the changing health scenario of global health security. Endless

efforts have resulted in the formulation and updating of IHR (2005) towards making them a contemporary code of practice, and overcoming the narrow scope of the previous International Health Regulations (1969) which focused on the reporting of only three diseases. Based on recent experiences with SARS and avian influenza, the focus of IHR (2005) is on all events constituting a public health emergency of international concern, irrespective of whether they are biological, chemical or nuclear: thus they afford the maximum security against the international spread of diseases and public health events while ensuring minimum interference with international travel and trade.

It is clear that the implementation of IHR (2005) requires a basic core capacity in the health delivery system and the road ahead is full of opportunities and challenges. Quality laboratory services and efficient biosafety measures are integral part of core capacity to implement IHR (2005).

In order to implement IHR (2005), Member countries would need to identify and develop core capacities to recognize and report new diseases or events at the primary care level. In doing so, they will require basic capacity to confirm the diagnosis and institute appropriate control measures at various levels. They will also need to have in place a functional early warning system combined with diagnostic, prevention and control facilities especially in hospitals and at points of entry.

In today's age of globalization, no single country has the capacity to prevent international spread of diseases single-handedly. Undoubtedly, a global network decreases the vulnerabilities of individual countries and a collective effort ensures global public health security.

To fulfill the requirements of IHR 2005, Member countries and WHO have shared responsibilities and obligations. Member countries should designate a national IHR focal point; strengthen core capacity to detect, report and respond rapidly to public health events; assess events occurring in their territory and to notify WHO within 24 hours of assessment of all events that may constitute a public health emergency of international concern (PHEIC); provide routine inspection and control activities at international airports, ports and some ground-crossings and, build a legal and administrative framework in line with IHR (2005) requirements.

Use of biosecurity in life sciences research

Dr Emmanuelle Tuerlings, Scientist, WHO/HQ discussed the role of biosafety and biosecurity in laboratories undertaking research on life sciences. The possible dual use of research as exemplified by inadvertently increasing the virulence of mousepox and reconstruction of 1918 avian influenza virus gives additional responsibility to the scientists and highlights the governance for biosecurity.

Biosecurity can be ensured only through effective use of ethical review committees, research oversight mechanisms, publication policies by peer reviewed scientific journals, and enforcement of regulations. All these can have an impact on research in public health which should not be discouraged because of these factors. There is a need to enhance public confidence in science, increase awareness, and provide guidance and capacity building.

This risk management should promote responsible research through different risk management options.

International Laboratory Bio-risk Management Standard

Dr Nicoletta Previsani briefed about the European standard on biosafety. Standards are mandatory for management of laboratory bio-risks. European standard (CEN) provides valuable information and guidance as well as a check list for management of bio-risks. This standard has been based on the WHO Manual on Biosafety (2004) as well as WHO's Guidance on Biosecurity. These standards primarily focus on biological agents and are based on internationally acceptable best practices. This has been used by WHO for certification of two smallpox labs in the USA and Russia.

The CEN standards have a life of three years after which these are reviewed and revised. The standard costs around USD 80.

CEN is establishing certification and accreditation guidelines. Training and workshops on these issues may also take place.

Laboratory construction and design

Mr Ken Ugwu, Chief Biocontainment Engineer, Public Health Agency of Canada discussed the essential issues for planning, designing and construction of BSL3 and BSL4 laboratories. He stressed that good laboratory designs are possible only when the architect, engineers, commissioning agency and scientists work together right from the initial phase of the development of laboratories.

The following issues need to be considered while planning and constructing high containment laboratories.

- Containment barriers
- Architectural design
- Mechanical design
- Laboratory equipment
- Electrical design
- Commissioning

Factors that will influence the choice of laboratory include the kind of work to be performed, new/existing structure, location of mechanical room/services, availability of resources (initial/capital and maintenance) and that of experienced and qualified personnel.

All BSL3 laboratories are designed for work with Risk Group (RG) 3 micro-organisms and for large volume and high concentrations of RG 2 organisms which may be transmitted by the airborne route, have a low infectious dose to produce effects and can cause life-threatening disease. Accordingly, these laboratories require additional primary and secondary barriers to minimize the release of infectious organisms as well as features to prevent transmission of RG3 organisms through appropriate respiratory protection, HEPA filtration of exhausted laboratory air and strictly controlled laboratory access.

Similarly, BSL4 laboratories are designed to work with Risk Group 4 micro-organisms. These organisms may be transmitted by the airborne route and can cause high risk of life-threatening disease. In BSL4 laboratories all work is done in a class III cabinet or positive pressure personnel suit. This facility is separated from other work areas and the

access is strictly controlled. Currently, two Types/Models of BSL4 are possible: (a) Cabinet laboratory in which all agents are handled in Class III Biological Safety Cabinets and (b) Suit Laboratory in which the health worker must wear the positive pressure suit.

Regular scheduled maintenance is key to operating a functional laboratory facility. To carry out maintenance only on breakdown is costly financially and on down time. Most high containment laboratories have built-in redundancy for ease of maintenance.

4.3 Field visit

A field visit was organized for all the participants and faculty to the BSL3 laboratory in the National Institute of Virology, Pune. The head of the laboratory made a detailed presentation followed by a walk-through of the laboratory and its mechanical services especially the air handling units. A BSL4 facility is under construction in the same campus.

4.4 Training on International shipment of infectious material

The international regulations for the transport of infectious substances by any mode of transport are based upon the recommendations made by the Committee of Experts on the Transport of Dangerous Goods (UNCETDG), a committee of the United Nations Economic and Social Council. These regulations address the concerns of public health officials as well as the postal, airline and other transport industry authorities about the possibility of spreading infection as the result of exposure to infectious micro-organisms that may escape from broken, leaking or improperly packaged material. The packaging of infectious substances for transport must therefore be designed to minimize the potential for damage during transport. In addition, the packaging must ensure the integrity of the materials and, in turn, timely and accurate processing of specimens.

These guidelines provide practical guidance to facilitate compliance with current international regulations for the transport of infectious substances and patient specimens by all modes of transport, both nationally and internationally, and include the changes that apply from 1 January 2007. They replace the guidelines issued by WHO in 2005. This

publication, however, does not replace national and international transport regulations.

The latest regulations are based on a completely new system and are no longer related to the Risk Group concept used until the end of 2004. The rationale for the new system is set out in document WHO/CDS/CSRL/LYO/2004.9 entitled, Background to the Amendments Adopted in the 13th Revision of the United Nations Model Regulations guiding the transport of infectious substances (http://www.who.int/csr/resources/publications/WHO_CDS_CSR_LYO_2004_9/EN).

According to the new guidelines, an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals, belongs to Category A. A complete list of such organisms is available in the international guidelines. These infectious substances of category A, with potential to cause disease in humans and animals have been designated with a number (UN 2814); while category A agents that cause disease only in animals are referred to as UN 2900.

An infectious substance which does not meet the criteria for inclusion in Category A is called an Infectious Substance, Category B and the number assigned to it is UN 3373. The human clinical material with least risk of transmission of disease (serum sample for drug concentration etc.) is termed as "exempt" substance.

The shipment of all these substances require a triple packaging comprising of

(1) a leak-proof primary receptacle(s);

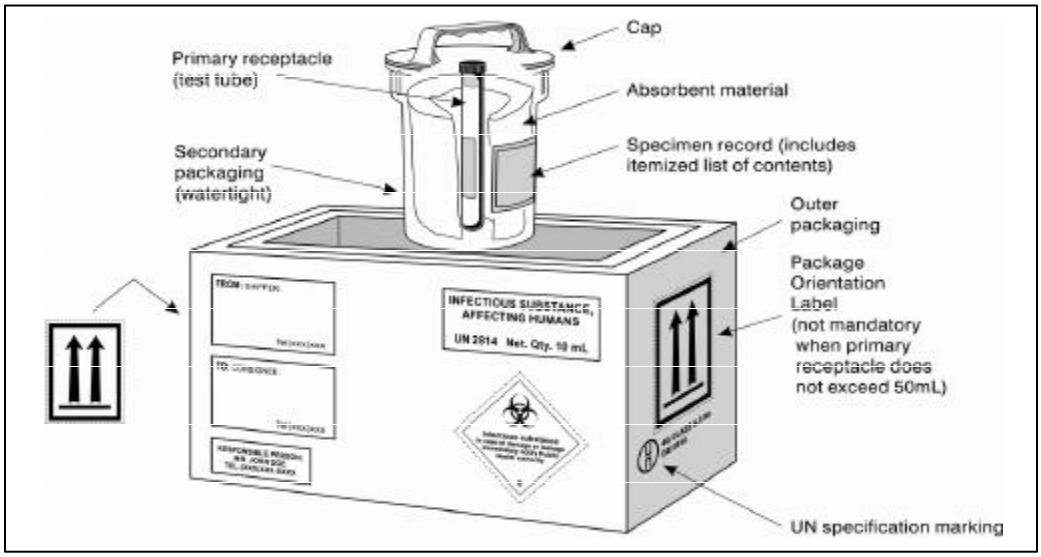
(2) a leak-proof secondary packaging; and

(3) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm.

Because of differences in the hazards posed by Category A infectious substances (UN 2814 and UN 2900) and Category B infectious substances (UN 3373), there are variations in the packaging, labeling and documentation requirements for the two categories. The packaging requirements are determined by UNCETDG and are set out as Packing

Instructions PI602 and P650. The requirements are subject to change and regular upgrade by the organizations mentioned.

Figure 2: *Example of triple packaging system for the packaging and labelling of Category A infectious substances (Figure kindly provided by IATA, Montreal, Canada)*



The hand carriage of Category A and Category B infectious substances and transport of these materials in diplomatic pouches are strictly prohibited by international air carriers.

5. Recommendations and conclusions

5.1 To Countries/participants

(1) All participants should advocate with the respective national authorities to develop and implement the national policy and strong legislation on laboratory biosafety. The lead should be taken by the MoH utilizing its own financial resources;

(2) Member countries should establish a National Biosafety Committee as an apex national technical and advisory body;

(3) Member countries should develop national biosafety guidelines on the basis of the WHO Manual on Biosafety;

(4) Specific biosafety training courses should be developed and conducted through leading public health laboratory or a university which may gradually lead to the development of a specialty of laboratory biosafety; and

(5) A national association of professionals with interest in biosafety should be forged and may be affiliated to other international professional bodies.

5.2 To WHO

(1) WHO should designate a Regional Training Institute/WHO Collaborating Centre in South-East Asia Region with Terms of Reference for training and providing technical support in strengthening biosafety in Member countries;

(2) WHO should develop and disseminate a manual on operations and maintenance of equipment required for implementing biosafety and support translation of the manual into different languages;

(3) WHO should support operational research on biosafety in labs to resolve some of the common problems being faced by laboratories in the South-East Asia Region

Annex 1

Programme

Day 1	Tuesday, 8 July 2007	Speaker
08:30-09:00	Registration	
09:00-09:15	Opening ceremony	
09:15-09:25	Objective of the meeting	N. Previsani
09:25-09:55	Biosafety and laboratory biosecurity in India	A.C. Mishra
09:55-10:45	WHO Global Biosafety and Laboratory Biosecurity programme	N. Previsani
11:15-12:15	Biosafety in SEAR countries	Countries' representatives
13:30-15:30	Biosafety in SEAR countries, cont'd	Countries' representatives
16:00-16:30	Laboratory acquired infections (LAI). Where are we today?	A.E. Ling
16:30-17:00	The SARS LAI in Singapore in 2003 and its consequences on the country's biosafety and laboratory biosecurity programmes	A.E. Ling
17:00-17:45	Experiences from other Regions: Central and South America	R. Fernandez
Day 2	**Wednesday, 9 July 2007**	**Speaker**
	1. Biosafety programme, training and human resources:	
08:30-09:15	Risk assessment, risk management, risk communication	S. Kaufman
09:15-10:00	Training and human resources	S. Kaufman
10:30-11:15	Disinfection, decontamination and emergency response	S. Kaufman
	2. Bio-risk reduction management:	
11:15-11:45	International Health Regulations	P. Dubois
11:45-12:15	Introduction to laboratory biosecurity	N. Previsani
12:15-12:45	Life science research: opportunities and risks for public health	E. Tuerlings

	3. Laboratory management and legislative framework:	
13:45-14:30	Biosafety programme management	S. Kaufman
14:30-15:15	The new CEN Biorisk Management standard CWA15793	S. Kaufman
	4. Physical environment in containment laboratories:	
15:45-16:30	Laboratory construction, design and equipment	K. Ugwu
16:30-17:15	Facility operation and maintenance	K. Ugwu
17:15-18:00	Biosafety networking: the Asian Pacific Biosafety Association	A.E. Ling
Day 3	**Thursday, 10 July 2007**	**Speaker**
	Scenarios-exercises-discussions	
08:30-10:00	Case study: a laboratory accident	S. Kaufman
10:30-12:00	BSL 3 design and construction: what if…..	K. Ugwu
13:00-13:30	Overview of biosafety and laboratory biosecurity in the South East Asian Region	R. Bhatia
13:30-15:30	Working group 1: Biosafety programme, training and human resources • Identification of gaps and needs • Country resolutions	A.E. Ling S. Kaufman
	Working group 2: Bio-risk reduction management • Identification of gaps and needs • Country resolutions	R. Fernandez N. Previsani
	Working group 3: Laboratory management and legislative framework • Identification of gaps and needs • Country resolutions	P. Dubois R. Bhatia
	Working group 4: Physical environment in containment laboratories • Identification of gaps and needs • Country resolutions	K. Ugwu A.E. Ling
16:00-16:30	Working group discussions, cont'd • Preparation of group reports	Group chairs
16:30-17:10	Presentation of reports by chairs of the groups	Group chairs
17:10-18:00	Discussion: Regional biosafety and laboratory biosecurity plans. Future activities and challenges	R. Bhatia N. Previsani

Day 4	Friday, 11 July 2007	Speaker
08:30-08:50	Infectious substances shipping training	Previsani, Kaufman, Fernandez
08:50-09:20	Pre-test	Previsani, Kaufman, Fernandez
09:20-10:00	Definitions	Previsani, Kaufman, Fernandez
10:30-11:00	Classification	Previsani, Kaufman, Fernandez
11:00-11:30	Packaging	Previsani, Kaufman, Fernandez
11:30-12:00	Labelling	Previsani, Kaufman, Fernandez
12:00-12:30	Documentation	Previsani, Kaufman, Fernandez
13:30-15:30	Practical session	Previsani, Kaufman, Fernandez
16:00-17:00	Post-test	Previsani, Kaufman, Fernandez
17:00-17:30	Grading and certificate delivery	Previsani, Kaufman, Fernandez
17:30-17:45	Closing of the workshop	R. Bhatia N. Previsani

Annex 2

List of participants

Bangladesh

Dr Chaman Afroz
Director
Institute of Public Health
Mohakhali
Dhaka

Dr Khondoker Mahbuba Jamil
Senior Scientific Officer
Institute of Epidemiology, Disease Control Research (IEDCR)
Mohakhali
Dhaka

Bhutan

Mr Jamphel Dorji
Assistant Engineer
Health Infrastructure Development Project
Ministry of Health
Thimphu

India

Dr Shashi Khare
Consultant
National Institute of Communicable Diseases
22 Sham Nath Marg
New Delhi

Indonesia

Dr Farida Soetiarto, DDS
National Institute of Health Research and Development
Badan Penelitian Dan
Pengembangan Kesehatan
Percetakan Negara No. 29
Jakarta 10560

Mr Holy Arif Wibowo, Bsc.
National Institute of Health Research and Development
Badan Penelitian Dan
Pengembangan Kesehatan
Percetakan Negara No. 29
Jakarta 10560

Maldives

Ms Shareefa Manike
Director-General
Department of Medical Services (DMS)
Ministry of Health
Male

Sri Lanka

Dr Geethani Galagoda
Consultant Virologist
Medical Research Institute
Colombo 8

Dr Sagarika Samarasinghe
Microbiologist
Medical Research Institute
Colombo

Thailand

Ms Punnarai Veeraseatakul
Medical Technologist
Regional Medical Science Centre
Chiang Mai

Mr Rungchai Loket
Medical Scientist
National Institute of Health
Bangkok

Facilitators

Dr Ai Ee Ling
Director Asian Pacific Biosafety Association (APBA)
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

Professor Sean Kaufman
Rollins School of Public Health

1518 Clifton Road, NE Room 417
Atlanta, GA 30322 USA

Dr Ken Ugwu
Chief, Biocontainment Engineering Division
Office of Laboratory Security
Centre for Emergency Preparedness and Response
Public Health Agency of Canada
100 Colonnade Rd., Loc. 6201A
Ottawa, ON K1A 0K9

Dr A.C. Mishra
Director, National Institute of Virology
20-A, Dr Ambedkar Road
Pune 411001

WHO Secretariat

Dr Nicoletta Previsani
Department of Epidemic and Pandemic Alert
and Response (EPR)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland

Dr Emmanuelle Tuerlings
Scientist
Department of Epidemic and Pandemic Alert
Response (EPR)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27,Switzerland

Dr Roberto Fernandez
Scientist
Department of Epidemic and Pandemic Alert and Response (EPR)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland

Mr Philippe Dubois
Scientist
National Systems Strengthening for IHR
International Health Regulations Coordination Programme
WHO Lyon Office for National Epidemic Preparedness and Response
58 Avenue Debourg, 69007, Lyon, France

Dr Rajesh Bhatia
Regional Adviser
Blood Safety & Clinical Technology &
Regional Focal Point for Zoonotic Infections
WHO House
Indraprastha Estate
Ring Road
New Delhi 110002

Handling infectious micro-organisms remains a source of infection, and even mortality, among laboratory workers. Incidents of secondary transmission of disease to the public at large, which may be due to possible contamination of the environment or personnel, are also possible. This report describes in brief proceedings of a Regional Workshop on Biosafety and Biosecurity in Health Laboratories which was held in Pune, India in July 2008.

The workshop was aimed to advocate for and introduce the concept and approach to minimize or prevent the occurrence and consequences of human error within the laboratory environment, as well as the bio-risk management approach, composed of biosafety, laboratory biosecurity and ethical responsibility by:

(1) Reducing the risk of unintentional exposure to pathogens and toxins or their accidental release (biosafety), and reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of micro-organisms (laboratory biosecurity);

(2) Providing assurance, internally and externally (facility, local area, government, global community, etc.), that suitable measures have been adopted and effectively implemented; and

(3) Providing a framework for continuous awareness-raising for biosafety, laboratory biosecurity an ethical code of conduct, and training within the facility.

World Health Organization
Regional Office for South-East Asia

World Health House,
Indraprastha Estate
Mahatma Gandhi Marg,
New Delhi-110002, India

SEA-HLM-398