



National Laboratory Biosafety & Biosecurity Policy

Islamic Republic of Pakistan

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National Laboratory Working Group Ministry of National Health Services Regulations & Coordination Government of Pakistan

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Message

Federal Minister

The Government of Pakistan considers implementation of International Health Regulations (IHR) (2005) as priority agenda as it pertains to national and international health security. Pakistan is fully committed for strengthening the core capacities to meet obligations under the IHR 2005 and Global Health Security Agenda.

The development of a National Biosafety and Biosecurity Policy has been part of this process. The policy comprehensively covers all biomedical laboratories under the One Health concept; a fundamental step in ensuring that laboratory practices are carried out in a safe and secure manner as ordained by the Cartagena protocol. It is now vital that the strategic policy is endorsed for implementation followed by operational planning for enforcement in the all biomedical laboratories.

I believe that this important framework document will lay the foundation for building a safe and secure laboratory system in the country. The Ministry of National Health Services, Regulation & Coordination remains committed to implementation of Global Health Security Agenda, advocacy and resource mobilization for the building IHR 2005 core capacities in the country.

> Saira Afzal Tarar Federal Minister National Health Services Regulations & Coordination Government of Pakistan

Message

Federal Secretary

The Ministry of National Health Services, Regulations & Coordination regards IHR 2005 as priority technical areas for Global Health Security. One of the key core capacity for IHR implementation is the strengthening of the laboratory services which are considered as a vital component of health care delivery system of the country. Among the key essential elements of laboratory quality management system, biosafety and biosecurity are important components. Both are required to ensure that the laboratory personnel and environments are not affected by potential hazards associated with the laboratory work. Thus an effective biosafety and biosecurity system is required to be in place across the laboratories operational in different sectors.

The policy framework for biosafety and biosecurity was a long awaited need of the country and will serve as a starting point for establishing a biosafety and biosecurity system in Pakistan. This technical document outlines the key element of biosafety and biosecurity management system such as legislation, capacity building, infrastructure, human resource, administration as well as operational requirements to mitigate the threats associated with unsafe practices.

The Ministry will extend guidance to all the stakeholders in establishing a system of safe and secure laboratories in the country. We also look forward for providing assistance in translating this policy framework to strategic and operational plans both at national and provincial levels.

Naveed Kamran Baloch

Rederal Secretary National Health Services Regulations & Coordination Government of Pakistan

Preface

Pakistan being signatory to the International Health Regulations (IHR) (2005) is fully cognizant of the fact to strengthen the IHR core capacities to meet its obligations. Strengthening of laboratory services is a core public health capacity under the IHR 2005 framework, One Health and Global Health Security Agenda. In order to meet the demand for diagnostics and research in relevant sectors, all countries need to have reliable and safe laboratory capacity in place.

The development of a National Biosafety & Biosecurity Policy covering all laboratories from health, non-health, research and development is a fundamental step in ensuring that laboratory practices are carried out in a safe and secure manner.

Through a effectual consultative process ensuring national ownership and commitment, the National Laboratory Working Group with experts and stakeholders from different sectors and provincial authorities have provided valuable input for the finalization of National Laboratory Biosafety & Biosecurity Policy for Pakistan. This framework document describes fundamental elements that are required for implementing a comprehensive, sustainable and legally embedded national biosafety and biosecurity program while ensuring effective use of governmental resources and donor investments to strengthen public health laboratories.

Prof Brigadier Aamer Ikram, SI(M)

Executive Director National Institute of Health

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The insight and expertise extended by all the members of the National Laboratory Working Group greatly assisted in the development of this policy, strategic plan and action plan.

We would also like to recognize efforts by the National Institute of Health for organizing series of workshop and meetings of all the stakeholders; and some personalized efforts by Dr Muhammad Salman (NIH), Dr Uzma Bashir Aamir and Dr Yahya Gulzar (WHO Country Office), and Dr Humayun Asghar.

This policy was partially supported by Department of State (US); much appreciated. We are also indebted to our collaborating partners: Centres for Disease Prevention and Control (CDC); World Organisation for Animal Health (OIE); German Technical Cooperation Agency (GTZ); German Development Bank (GFK); and American Society of Microbiology (ASM).



Contents

Content	
Introduction	1
Process followed	2
Situational Analysis (Summary)	4
Aim of the document	6
Policy statements	7
Topic 1: Legislation	7
Topic 2: National biosafety and biosecurity representatives	8
Topic 3: Human resource	9
Topic 4: Funding	10
Topic 5: Infrastructure	11
Topic 6: Equipment	11
Topic 7: Waste management	12
Topic 8: Sample Transport, Handling and Storage	13
Topic 9: Occupational health	13
Topic 10: IT and Data Security	14
Annex 1: Members of the National Laboratory Working	
endorsed by the MNHSRC	15
Annex 2: SWOT analysis	16
Topic 1: Legislation	16
Topic 2: National biosafety and biosecurity representatives	17
Topic 3: Human resources	17
Topic 4: Funding	18
Topic 5: Infrastructure	18

Contents

Topic 6: Equipment	19
Topic 7: Waste management	19
Topic 8: Transport, handling and storage	20
Topic 9: Occupational health	20
Topic 10: IT and Data security	21
Annex 3: List of evidence used to verify the SWOT	22
anarysis	22
Annex 4: Situational analysis summary table	23



Acronyms

BSL	Biosafety level	
BSC	Biosafety Cabinet	
CDC	Centre for Disease Control & Prevention	
EPA	Environmental Protection Agency	
FELTP	Field Epidemiology & Laboratory Training Program	
HIMS	Hospital Information Management System	
IHR	International Health Regulations	
IATA	International Air Transport Association	
IT	Information Technology	
LIMS	Laboratory Information Management System	
MNHSR&C	Ministry of National Health Services Regulation and Coordination	
NIH	National Institute of Health, Pakistan	
NLWG	National Laboratory Working Group	
OIE	World Organisation for Animal Health	
PBSA	Pakistan Biological Safety Association	
PNAC	Pakistan National Accreditation Council	
PPE	Personnel Protective Equipment	
SOP	Standard Operating Procedure	
SWOT	Strengths, Weaknesses, Opportunities, Threats (Analysis)	
ТВ	Tuberculosis	
WHO	World Health Organization	
WHO/EMRO	WHO Regional Office for the Easter Mediterranean	
WHO HQ	WHO Head Quarters	

Introduction

The infectious disease panorama is changing with emerging and re-emerging infectious agents. To meet the demand for diagnostics and research for human, animal health, food and environmental safety, countries need reliable and safe laboratory capacity. The laboratories handle potentially hazardous biological materials and therefore, a dire need for guidance is essential to ensure safe and secure operations. It is critical that all countries endorse biosafety and laboratory biosecurity policy with establishment of strategic planning for enforcement in the biomedical laboratories.



Process Followed

This National Laboratory Biosafety and Biosecurity Policy for Pakistan was developed with the National Laboratory Working Group (NLWG) notified by the Ministry of National Health Services Regulations and Coordination (NHSR&C), Government of Pakistan, during two interactive workshops facilitated by the WHO HQ, WHO Regional Office for the Eastern Mediterranean (WHO EMRO) and the WHO Country Office Pakistan. The first workshop was organized on the 6th July 2015 and the second from 7th to 9th September 2015 in Islamabad.

The policy development has been led through a consensusbuilding process involving a diverse group of national, provincial and international technical experts from public and private sectors, including, microbiologists, laboratory scientists, public health specialists, biosafety biosecurity experts and academia. The list of these experts is appended as Annex 1.

Ten policy areas were identified on the basis of the situational analysis, and detailed SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis was performed for each policy topic. During the second workshop, SWOT analysis statements were discussed, key elements were identified per policy topic and verification of SWOT statements was initiated. Desired outcomes were formulated for each key element and policy statements were developed. The key elements and policy statements form together the nucleus of this policy document. The policy is relevant to all laboratory sectors.

The SWOT¹ analysis is a structured planning method used to evaluate internal and external factors affecting a particular organization, system or project. The analysis guides the identification of the positive (Strengths) and negative (Weaknesses) characteristics of the organization, system or project and the positive (Opportunities) and negative (Threats) elements outside the organization, system or

Source: the community toolbox http://ctb.ku.edu/en/tablecontents/sub_section_main_1049.aspx

Process Followed

project, in the environment. The purpose of performing a SWOT analysis is to reveal positive forces that work together and potential problems that need to be addressed or at least recognized in order to build on strengths, minimize weaknesses, seize opportunities and counteract threats.

The SWOT analysis results for the Pakistan laboratory biosafety and biosecurity can be found in Annex 2, where Strengths, Weaknesses, Opportunities and Threats are presented in a table for each policy topic. The list of evidence used to verify the SWOT analysis is provided in Annex 3.



Situational Analysis (Summary)

In order to form an overview of the current state of the national laboratory biosafety and biosecurity management, the NLWG utilized assessments of public and private sector laboratories carried out with the support of WHO/EMRO and the WHO country office. The laboratory analysis included clinical diagnostics, National TB Program, veterinary services and academia at both national and provincial levels. Building on these findings, the NLWG performed the SWOT analysis.

The following are the key issues identified through these assessments and associated discussions:

- Some biosafety awareness and practices are in place, showing the laboratories' concern in the domain, but there is no centralized, structured Biosafety and Biosecurity Management System in place.
- 2. Profound attention is required in the area of qualified human resource with relevant education and training. Some training programs are being elaborated to train biosafety experts but still the basic trainings in biosafety are lacking for staff and no competency assessments are being performed to ensure acknowledgement of these practices by the staff. Pakistan Biosafety Association (PBSA) is elaborating awareness and trainings, which remains insufficient at larger scale.
- 3. Maintenance of critical protective equipment is not up to requisite standards, exposing the staff handling the hazardous material to risks.
- 4. Waste disposal management is also weak, with no national legislation in place for the infectious material disposal, putting at risk not only the staff but the environment and the communities too.

Situational Analysis (Summary)

- 5. There is no occupational health for the staff, in order to protect and cure them from potential laboratory acquired infections.
- 6. In general, there are weak fire prevention measures in place, putting at risk all personnel working in the institutions.
- 7. Legislations:
 - a. The Ministry of Environment has written national biosafety guidelines (Notification No. F.2(7)95-Bio) concerning Genetically Modified Organisms (GMOs) and products thereof.
 - b. A national legislation exists in biosafety but falls under the Ministry of Environment and does not address human and animal health laboratories as such.
 - c. Certain aspects of biosafety have been covered under Punjab PHCC/EPA Act 2010 which is being partially enforced.

Therefore, there is still a need for national biosafety guidelines to help human and animal health laboratories implement their biosafety and biosecurity practices.



Aim of the Document

Ensure safety and security of laboratory workers and environment in Pakistan by adopting the national biosafety and biosecurity policy under 'One Health'² concept.

² http://www.onehealthinitiative.com/ (accessible the 28-09-2017)

Topic 1: Legislation

Outcome: To ensure biological safety and security in the field of life sciences at all levels including academia, diagnostic, public health and research laboratories dealing with human, animal, food and plant specimens and any other specimen expected to contain biological materials, products and waste.

- 1.1 Establish regulatory and legal frameworks to ensure requisite biosafety and biosecurity requirements are prescribed and implemented for the field of life sciences.
- 1.2 There shall be certain imperative components for considerations while formulating the legislation, but not limited to the following:
 - a. Infrastructure.
 - b. Equipment & PPE.
 - c. Storage, Handling & Transport of Specimens.
 - d. Infectious Waste Management.
 - e. Training of Personnel.
 - f. Occupational Health.
 - g. Biosecurity.
- 1.3 There shall be a National Biosafety Committee responsible for overall guidance and implementation of legislation.
- 1.4 There shall be an Oversight Committee responsible for ensuring effective monitoring and implementation of the policies.

Topic 2: National Biosafety and Biosecurity Representatives

Outcome: The biosafety and biosecurity legislations will be implemented and monitored in Pakistan.

- 2.1 There shall be a body of national representatives of experts in laboratory biosafety and biosecurity endorsed at federal and provincial levels (National Biosafety Committee; clause 1.3).
- 2.2 The body shall be formed of representatives from each of the following public and private sectors:
 - 2.2.1 Human
 - 2.2.2 Animal
 - 2.2.3 Agriculture
 - 2.2.4 Environment
 - 2.2.5 Academia
 - 2.2.6 Civil society
 - 2.2.7 Representatives of Professional organizations/societies [Pakistan Association of Pathologists (PAP); Pakistan Biological Safety Association (PBSA); Medical Microbiology & Infectious Diseases Society of Pakistan (MMIDSP)]
 - 2.2.8 Other relevant not addressed above.
- 2.3 Such a body shall be represented at Federal and Provincial levels.

- 2.4 All institutions dealing with biological material shall have an institutional biosafety committee (IBC).
- 2.5 All laboratories dealing with biological material shall have dedicated/designated laboratory biosafety officer (BSO).
- 2.6 Biosafety and biosecurity programs of institutions shall be overseen by the National Biosafety Committee.

Topic 3: Human Resource

Outcome: Competent human resources in biosafety and biosecurity (wherever applicable) in laboratories of Pakistan.

- 3.1 Standard biosafety training modules shall be developed.
- 3.2 All employees shall undergo pre-service (on induction) and on job training periodically to update their knowledge and skills on biosafety.
- 3.3 Competency assessment programs covering biosafety/biosecurity shall be conducted periodically.
- 3.4 The personnel job descriptions should include biosafety responsibilities.
- 3.5 Background checks shall be performed before hiring staff for specific (like BSL 3) laboratories.

Topic 4: Funding

Outcome: Ensure implementation of institutional biosafety and biosecurity programs.

- 4.1 Institutes dealing with biological material shall have dedicated annual funds to implement the biosafety and biosecurity program.
- 4.2 Funds shall be befitting to the scope of the biosafety program in the institute.



Topic 5: Infrastructure

Outcome: Ensure safe and secure infrastructure for laboratories in Pakistan.

Policy Statements

- 5.1 Infrastructure should be designed and maintained according to the assessed risks of biological hazard and threat.
- 5.2 Laboratory shall be designed or modified in the light of recommendations set by the NBC.
- 5.3 Laboratory design shall address the basic requirement of laboratory work, personnel safety, security access, proper workspace, material storage, workflow of samples, personal, animals and waste disposal and information technology (IT) flow.
- 5.4 There shall be contingency plan addressing electricity cuts, water shortage, fire prevention, natural disasters, and safe exits.

Topic 6: Equipment

Outcome: Requisite biosafety related equipment is available and maintained.

- 6.1 There shall be availability of biosafety related equipment in respective facilities along with assurance of technical guidance and spares.
- 6.2 There shall be a well-defined procedure for procurement at institutional level for equipment as per requisite specifications and standards involving the concerned technical personnel/end-user.

- 6.3 There shall be regular maintenance of all the equipment along with traceability.
- 6.4 There shall be a Governmental body to certify and/or license other agencies to certify biosafety cabinets in accordance with accepted international standards.
- 6.5 There shall be a decontamination policy for each institute, which should be strictly implemented.
- 6.6 PPE availability to staff should be ensured.

Topic 7: Waste Management

Outcome: Safe and reliable handling and disposal of biological waste in Pakistan.

- 7.1 All institutions dealing with biological material shall have an effective waste management program that incorporates:
 - 7.1.1 Waste segregation at site and time of waste generation.
 - 7.1.2 Waste minimization.
 - 7.1.3 Waste disposal and traceability of the disposed material.
- 7.2 Institutes/ labs shall ensure proper training of the staff handling the waste.
- 7.3 Institutes/labs shall ensure provision of appropriate PPE for the handling of waste.
- 7.4 In case of third party involvement for waste disposal, institutes shall ensure the vendor credibility and validity through appropriate authorities.

Topic 8: Sample Transport, Handling and Storage

Outcome: Safe and secure handling, packaging, storage and transport of specimens within the facility, across the country and abroad.

Policy Statements

- 8.1 There shall be legislation for safe transport/shipment of specimens within the country.
- 8.2 Institutes shall implement and familiarize the staff for safe handling storage, packaging and transport including accidents such as leakage and spills of biological materials.
- 8.3 There shall be proper documentation of specimen along with traceability.
- 8.4 Local courier services should be authorized by National Biosafety Committee and guided for proper and safe transport of such specimens.
- 8.5 IATA rules should be adhered for international shipments.

Topic 9: Occupational Health

Outcome: Laboratory staff is well protected from occupational health hazards

Policy Statements

9.1 There shall be plans of annual medical check-up for all employees.

- 9.2 Proper vaccination policy shall be established with the accessibility to requisite vaccines ensured.
- 9.3 There shall be a system in place for incident reporting, corrective measures adopted and documentation.
- 9.4 Identified personnel shall be trained in providing first aid /emergency care; and first aid kits made available.
- 9.5 There shall be clear guidance and accordingly specific measures in place to address risk based biosafety issues related to gender (such as pregnancy), personal with immune compromised status or disability.
- 9.6 Due consideration shall be given to ergonomics conducive to biosafety practices.

Topic 10: IT and Data Security

Outcome: Secure accessibility of data to authorized persons only.

- 10.1 It shall be obligatory to secure data and develop policy at the institute level.
- 10.2 Institutes having a centralized IT system shall make sure the confidentiality of data and its protection.
- 10.3 It shall be obligatory to have backup data under appropriate security conditions.

Members of the National Laboratory Working Group working on the biosafety and biosecurity policy endorsed by the MNHSRC

Name	DESIGNATION	ORGANIZATION
Aamer Ikram	Professor & Consultant	Armed Forces Institute of Pathology
Aamir Ali Khan	Head of Pathology Department	Nishtar Medical College, Multan
Arshad Mumtaz	Chief Public Health Lab Division	National Institute of Health
Ashok Kumar Tanwani	Professor & Pathologist	PIMS Hospital Islamabad
Attiya Bhatti	Associate Professor ASAB	National University of Science & Technology, Islamabad
Erum Khan	Associate Professor	Aga Khan University Hospital, Karachi
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Ghulam Fatima	Senior Pathologist	Civil Hospital, Karachi
Ghulam Sarwar Pirkani	Professor Microbiology	Bolan Medical College, Quetta
Imran Ahmad	Chief Pathologist	Shifa International Hospital, Islamabad
Khalid Naeem Khawaja	Chief Scientific Officer Animal Science Institute	National Agriculture Research Center Islamabad
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Muhammad Athar Abbas	Senior Scientific Officer NRLPD	National Agriculture Research Center, Islamabad
Muhammad Kaleem Khan	Pathologist	Ayub Medical College Abbottabad
Muhammad Salman	Microbiologist	National Institute of Health
Muhammad Usman	Pathologist	Shifa International Hospital Islamabad
Mumtaz Ahmad Khan	Head Pathology Department	Abass Institute of Medical Science, Muzaffarabad
Musa Rahim	National Professional Officer	WHO Country Office, Islamabad
Naila Siddique	Program Leader	National Agriculture Research Center Islamabad
Obaidullah Qazi	Microbiologist	Institute of Public Health, Lahore
Rani Faryal	Associate Professor	Quaid-e-Azam University
Rumina Hassan	Professor of Pathology & Microbiology	Aga Khan University Hospital, Karachi
Sabira Tahseen	National Advisor TB	National TB Program
Shahtaj Khan	Head of Pathology Department	Hyattabad Medical Complex, Peshawar
Uzma Bashir Amir	Senior Scientific Officer	National Institute of Health

SWOT Analysis

Topic 1:Legislation

STRENGTHS	WEAKNESSES
 Existing rules/regulations External input/resources available Expertise available within the country 	 Stand alone documents Consolidation and consistency of efforts are lacking Laws need strict enforcement at all levels Lack of legislation for transport of biological material within country Attention on implementation of infectious waste laws More attention on human and animal health communication
OPPORTUNITIES	THREATS
 Consolidation of the available material and guidelines into an authentic document acceptable and implementable to all NLWG 	Decentralised health system

Topic 2: National biosafety and biosecurity representatives

STRENGTHS	WEAKNESSES
 Different societies and councils available: PNAC, PBSA, HEC exist 	 Inadequate coordination between various platforms Assessment by health regulations or biosafety authority Need for advocacy at Government level
OPPORTUNITIES	THREATS
National platform NLWG	Sustainability

International projects

Topic 3: Human Resources

STRENGTHS	WEAKNESSES
 Manpower is available Curricula being established 	 Precise training is required including knowledge in good practices, different technical needs Job descriptions are not well defined Lack of competency assessments Insufficient pre-service biosafety trainings Scarcity of designated biosafety officers
OPPORTUNITIES	THREATS
• IHR	 Staff recruitment under lab prerogative at places

Topic 4: Funding

STRENGTHS	WEAKNESSES
 International treaties and concerns Availability of scientists dedicated to the cause 	 Dependence on international agencies Lack of funds Donor coordination Need for running costs/ high maintenance costs Insufficient finance for occupational health/security conditions
OPPORTUNITIES	THREATS
 Global agenda 	 Utilization of funds/resources for other projects

Topic 5: Infrastructure

STRENGTHS	WEAKNESSES
 Awareness of needs Good laboratories in some public and private sectors (accredited ISO labs) Register of labs in Punjab 	 Electricity cuts Lab designs Fire prevention Water shortages Security access No central register of labs
OPPORTUNITIES	THREATS
 Donor funding for new buildings in vertical programs 	• Sustainability

Topic 6: Equipment

STRENGTHS	WEAKNESSES
 Availability of biosafety related equipment in some institutions International companies which can supply good equipment 	 Unavailability of requisite equipment in many laboratories Lack of international certified facility to monitor and calibrate critical equipment (BSC, autoclaves, etc) End-user opinion in the procurement processes (like incinerators) Supply lag (between supply order and installation)
OPPORTUNITIES	THREATS
 Different training workshops 	 Inappropriate equipment supplied

Topic 7: Waste management

STRENGTHS	WEAKNESSES
 Law for disposal of general waste Equipment available in some agencies 	 Law enforcement Lack of PPEs Lack of awareness Outsourcing the waste disposal but no traceability
OPPORTUNITIES	THREATS
 Community awareness programs 	Risk for environmental, healthcare system contaminations

Topic 8: Transport, handling and storage

STRENGTHS	WEAKNESSES
 Different courier services exist Personnel trained in transport, handling and stor 	 No clear identification of the trained persons No national guidelines rage
OPPORTUNITIES	THREATS
• Collaboration with WHO, CDC	 Risk for environmental, occupational contamination

Topic 9: Occupational health

STRENGTHS	WEAKNESSES
 Public hospitals Most of the Government organizations have annual check up plans Awareness for certain labs about the occupational hazards Availability and qualified staff 	 Inadequate occupational health implemented in labs
OPPORTUNITIES	THREATS
National interestDemands from different stakeholders	• Personnel ill health/family dependency

Topic 10: IT and Data security

STRENGTHS	WEAKNESSES			
 LIMS available at places 	 National surveillance data 			
Telephone networks are	is fragmented and not			
operational	integrated, partially			
	computerized			

Insecure THREATS

Breakdown

OPPORTUNITIES

- FELTP
- Availability of models



List of evidence used to verify the SWOT analysis

Laws and Regulations of Pakistan, Orders of the Ministries and Agencies

Federal documents

Year	Title	Relates to			
2005	National Biosafety Guidelines	Ministry of			
		Environment			
2005	National Biosafety Rules	Ministry of			
		Environment			
2010	National Guidelines for Code	Ministry of Foreign			
	of Conduct for Life Scientists	Affairs			
1997	Pakistan EPA	Ministry of			
		Environment			
Provincial documents					
Year	Title	Relates to			
2010	The Punjab Healthcare	Punjab			
	Commission Act				
Ordinance	Baluchistan Clinical Laboratory	Baluchistan			
2001	Regulating Authority				
2012	Punjab EPA	Punjab			
2014	KP EPA	КР			
1997	Safe Blood Transfusion Act	Sind			

Situational analysis summary table

Summary of the laboratory results using the Biosecurity LAT.

	National Public Health	National Ref Lb	National Vet Lb	Provincial hospital and academia Lab	Provincial research university lab	Provincial Public Health lab	Provincial Public hospital lab	Provincial lab national network
Average indicator	52%	50 %	77%	39 %	37%	34%	81%	42%
Organization	57%	36 %	93 %	33 %	38 %	42 %	73%	32 %
Documents	63 %	68%	98%	37%	32 %	25 %	93 %	41%
Specimen handling and transport	86%	86 %	98%	55%	32 %	32 %	82 %	61 %
Data security	55%	45 %	77%	50%	44%	38%	100%	27%
Equipment	58%	62 %	97%	39 %	30 %	23 %	90%	61 %
Facilities	72%	72 %	96%	67 %	76 %	75%	93%	70%
Human resources	47%	68 %	93 %	42 %	59 %	51%	83%	45%
Good practices	52%	50 %	80%	38%	29 %	33%	63 %	50%
Security conditions	45%	46 %	67%	51%	53%	46 %	96 %	57%
Risk assessment and plans	0%	0%	13%	0%	0%	0%	52%	0%
Monitoring and Improvement	40%	17%	41%	15%	15%	15%	68 %	17%





Pubic Health Laboratories Division, National Institute of Health, Islamabad