Framework Guideline for Establishment of Private Selective Diagnostic Services

Ministry of Health

Background

The Constitution of Kingdom of Bhutan states that "The State shall provide free access to basic public health services in both modern and traditional medicines." Accordingly the RGoB shall continue to pursue and sustain the universal health care coverage by providing all the Bhutanese citizens with free access to equitable and quality basic health services. The Royal Government of Bhutan (RGoB) has been the sole provider of health care in Bhutan till date. With the increasing demand for faster and better services and with the increasing capacity of certain segments of the population to pay for availing healthcare services, engagement of participation of other stakeholders, in the delivery of health care services is felt appropriate. In particular, RGoB feels that the private sector could be involved in the provision of selective services which will reduce pressure on the government facilities thereby improving the service delivery to the general population.

Private sector participation in the delivery of health services however must not affect the free access to public health services to the general population through the government facilities. Therefore, the type of services provided by the private sector may be limited initially and gradually expanded so as not to affect the services to be provided by the government to the general population. The Ministry of Health (MOH) shall announce the selective services the private sector may engage and provide from time to time depending on impact on the capacity of the government health structure to meet its obligation as per the Constitution.

Accordingly, and as per the Health Policy 2011, the participation of other stakeholders, particularly private sectors shall be permitted in the provision of selective diagnostic services such as Laboratory Services, Radiology Services, Endoscopic Services and other supportive diagnostic services for those tests and examinations recommended by the government health professionals.

The establishment of the diagnostic services shall follow guidelines and be subject to supervision and monitoring as follows:

Procedure for Application

1 ***External***

a. Applicants to submit the proposal in the format annexed (*Annex I*) to Ministry of Health for technical assessment and approval.
b. Applicants to submit the proposal to Ministry of Economic Affairs for Licensing and other Administrative clearance, after the approval of National Selection Committee (NSC)-MoH

2 ***Within MoH***

a. The Policy and Legal Unit of Policy and Planning Division (PPD), MoH, shall be the focal agency to receive the proposals and review the policy implications;
b. PPD shall then forward the proposal to the Essential Medicine and Technology Division (EMTD) who is responsible to call for a Technical Review Committee TRC *(ToR Annex II)* meeting;
c. The proposals shall be reviewed by TRC on quarterly basis, as per the schedule annexed (Annex III).
d. TRC shall recommend the applicants to re-submit the proposals, within one week, if the proposals are not in line with this framework guideline.
e. The recommendation of the TRC shall then be put up to the National Steering Committees (NSC) *(ToR Annex IV)*by the EMTD, which is chaired by the Secretary, Ministry of Health;
f. NSC shall be conducted by PPD within 14 days of TRC meeting; and,
g. The decisions of the NSC shall be conveyed to the applicants by PPD, within one week after the NSC meeting.

Any diagnostic centers should be fully established in compliance with the standards and norms within a probation period of one year. If the technical requirement is not fulfilled within the given period, MoH shall withdraw its approval and advise MOEA to cancel the license for their service.

II Technical Component

Part A– Laboratory Services

3. Laboratory services established in the country shall:

a. ensure bio-safety level II (*minimum*) or above depending on the test parameters;
b. have patient and disable-friendly environment, adequate waiting space and friendly patient flow process; and,
c. also fulfill the following minimum criteria;

Parameter	**Details**
HR Requirement	**Working Level *** i. Laboratory Technician holding Certificate/Diploma in

&Qualifications	MLT fromRUB or equivalent institute recognized by BMHC; ii. Medical Technologist holding BSc./MSc. in MLT from institute recognized by BMHC ; iii. MD Pathologist or any other relevant MD specialist in Laboratory Medicine; iv. Process and result validation shall be done by MD Pathologist or any other relevant specialists with MD in Laboratory Medicine. v. All health and medical professionals should be registered with BMHC. vi. *The detailed requirements of HR will depend on the test parameters proposed.*
Test Parameters	Existing tests as provided at JDWNRH and additional test which are not available in the country and/or tests which are referred outside the country
Reporting/Interpretation of Results	Results shall be read, interpreted and reported by registered specialists in the concerned field but not limited to MD Specialist in Laboratory Medicine.
Equipments	Standard equipments required for the concerned test. *The detailed requirements of the equipments will depend on the test parameters proposed.*
Infrastructure	Rooms with standard dimensions and design with designated rooms for waste segregation, sterilization and disposal facility. Identified site for waste dumping*(details of the schedule of room/space requirement is as per Annex V)*
Quality Control	Exhibit standard protocols for quality control both Internal Quality Control (IQC) and External Quality Control (EQAS)

medical and health professionals routinely involved in conducting the tests

Part B- Radiology Services

4. The Radiology services in the country shall:

a. comply with Radiation safety norms
b. have patient and disable-friendly environment, adequate waiting space and friendly patient flow process;
c. also fulfill the following minimum criteria :

Parameter	Details
HR Requirement &Qualifications	**Working Level** i. Technicians with Certificate/Diploma in Radiology from RUB or equivalent institute recognized by BMHC; ii. Radio-Technologist with BSc/MSc. in Radio Technology from institutes recognized by the BMHC iii. Radiologist with MD/MPhil in Radio- Diagnosis from institutes recognized by the BMHC iv. Process should be monitored and controlled by a Radiologist v. All health and medical professionals should be registered with BMHC.
Test Parameters	Existing test provided at JDWNRH and additional test which are not available in the country and/or tests referred outside the country
Reporting/Interpretation of the Results	i. Results shall be read, interpreted and reported by registered specialists in the concerned field. ii. Contrast Examinations which are done after IV contrast injection shall be done by a Radiologist or under the supervision of Medical Officer or Radiologist
Equipment	Standard equipments required for concerned test. *Detailed requirements is as annexed (Annex VI)*
Rooms & Specifications	Standard rooms and specifications required for each test. *Detailed requirements is as annexed (Annex VII)*
Shielding Requirement	Structural shielding required as per the standard

Part C– Diagnostic Endoscopic Services

5. The Endoscopy services in the country shall:

a. comply with the standard safety norms
b. have patient and disable-friendly environment, adequate waiting space and friendly patient flow process;
c. also fulfill the following minimum criteria :

Parameter	Details
HR Requirement & Qualifications	**Working Level** Gastroenterologist/ Hepatologist/ Gastrointestinal Surgeon and trained Doctors with certificate/diploma in endoscopy or equivalent from institutes recognized by BMHC; **i.** Other degrees in endoscopy from institutes recognized by the BMHC **ii.** Process should be monitored and controlled by a surgeon/doctor trained in endoscopy **iii.** All health and medical professionals should be registered with BMHC.
Test Parameters	Existing test provided at JDWNRH and additional test which are not available in the country and/or tests referred outside the country
Reporting/Interpretation of the Results	Results shall be read, interpreted and reported by registered specialists in the concerned field.
Equipment	Standard equipments required for concerned service.
Rooms & Specifications	Standard rooms and specifications required for each test.

Part D– Supportive Diagnostics Services

6. The supportive diagnostic services in the country shall:

a. consist of services such as ECG(Electrocardiogram),EST (Exercise stress test),PFT (Pulmonary function test) and other tests that supports diagnosis of

diseases as required by prescribing physician and for health checkup packages

b. comply with the standard safety norms
c. have patient and disable-friendly environment, adequate waiting space and friendly patient flow process;
d. also fulfill the following minimum criteria :

Parameter	Details
HR Requirement & Qualifications	**Working Level** i. Doctors/Technicians with relevant Certificate/Diploma or equivalent from institutes recognized by BMHC; ii. Other relevant degrees from institutes recognized by the BMHC iii. Process should be monitored and controlled by a qualified person iv. The detailed requirements of HR will depend on the test parameters proposed. v. All health and medical professionals should be registered with BMHC.
Test Parameters	Existing test provided at JDWNRH and additional test which are not available in the country and/or tests referred outside the country and for the health check up packages
Reporting/Interpretation of the Results	Results shall be read, interpreted and reported by registered specialists in the concerned field.
Equipment	Standard equipments required for concerned service.
Rooms & Specifications	Standard rooms and specifications required for each test.

III- General Requirements

i. Infection Control and Waste Management

Diagnostic services shall comply with the Waste Prevention and Management Act of Bhutan, 2009 and Regulation, and any Guideline which may be developed in line with the aforementioned Regulation.

ii. Quality Assurance and Supervision

Diagnostic services shall comply with the respective national service standards and quality control as the minimum standards or may comply with the international standards.

The quality assurance and supervision of the diagnostic centers shall conduct on bi-annual basis by the Quality Assurance and Standardization Division (QASD) of MoH.

QASD shall be responsible to form a Committee comprising of members from relevant agencies/stakeholders to:

- Develop a M&S framework
- Conduct bi-annual monitoring and supervision

iii. Data Sharing

All diagnostic services shall submit records and data on bi- annual basis to the Bhutan health management and information system (BHMIS) in the prescribed format and time line, Ministry of Health.

Laboratory

a. The clinical Laboratory shall have a provision for reporting all the notifiable diseases as per guideline of the ministry;
b. The clinical laboratory shall report any untoward incidents to the responsible authority *(Public Health Laboratory, Department of Public Health- Ministry of Health), immediately; and,*
c. The clinical laboratory shall comply with the VCT protocol in detecting Human Immuno-deficiency virus (HIV) cases and report the HIV positive cases immediately to the Public Health Laboratory, Department of Public Health-Ministry of Health.

Radiology

a. Submit all records and data on bi- annual basis to the BHMIS, Ministry of Health; and

b. Report any untoward incidents to the Department of Radiology, JDWNRH.

Endoscopic Services

a. Submit all records and data on bi- annual basis to the BHMIS, Ministry of Health; and
b. Report any untoward incidents to the Department of Surgery, JDWNRH.

Supportive Diagnostic Services

a. Submit all records and data on bi- annual basis to the BHMIS, Ministry of Health; and
b. Report any untoward incidents to the relevant departments of JDWNRH

iv. Drug Regulatory Authority/Drugs and Vaccines

All the medicinal products imported into the country or purchased by any of the diagnostic services shall be registered with DRA and shall also comply with the Medicines Act and Regulations of the Kingdom of Bhutan.

v. Registration with the Bhutan Medical and Health Council

All health and technical personnel and standard of service shall be subject to the requirements of the BHMC Act, 2002.

vi. Confidentiality of the Reports

All documents and reports of the patients must be kept confidential and shared only with the MOH as part of the regular data sharing process.

vii. Service fees

Pricing or fees for the services shall be submitted to Ministry of Health along with the proposals and shall display the price list prominently in the waiting room of the center.

Annex I

PROPOSAL FORMAT

For the establishment of Diagnostic Services

1. Executive Summary
2. Background
3. Scope and Objective
4. Proposed Services and Name of Applicant
5. Project Location- *Specific District and specific address within the District*
6. Technical Component a. HR b. Equipment and Drugs c. Infrastructure- detailed specifications of the room (*size and structure*) d. Environmental Impact- Infection Control and Waste Management e. Data Sharing f. Quality Assurance
7. Schedule of fee

**Applicants are also required to submit the soft copy of the proposals to ppd@health.gov.bt*

Annex II- Terms of Reference and Screening Tool for Technical Review Committee

a. The Terms of Reference (ToR) are as follows:
   - Receive proposals from the PPD, Ministry of Health for establishing selective diagnostic services;
   - To review the proposals in line with the framework guideline, checklist and screening tools;
   - Evaluation of the submitted proposal based on the checklist, screening tools and respective regulations for each diagnostic service;
   - The committee will meet every quarter, as per the Annex III to review the proposals received;
   - This committee will recommend the proposal to the NSC.

b. Screening tools for the proposals

Title of the proposal:
Applicant:

Sl. No	Criteria	Score (on 10)	Acceptable (5 & above)	Not acceptable	Remarks
1	Proposed services (Kind, Type, Priority)				
2	Location (rural, urban, population density)				
3	Infrastructure (feasibility, safety plans)				
4	Human Resources (strength, qualification)				
5	Equipments (adequacy as per services, IS/ISO/CE/FDA/BS certified)				
6	Drugs (as per DRA regulations), Supplies and consumables				
7	Safety and security (Occupational safety, environmental safety, Infection control and waste management)				
8	Linkages with the relevant national health services (Surveillance, Data sharing and reporting)				
9	Quality assurance and proficiency protocol				
10	Price range				

Date of review:
Additional Comments:

Below 5: the particular criterion is not acceptable
5 and above: the particular criterion is acceptable

Scoring is done on the completeness of the information for each criterion.

_____

Signature, Name and Designation of the Reviewing Personnel

Annex III- Schedule of Proposal Submission and Review

Quarter	Submission Date	Review Date
1 Quarter	Within 15 August	15 September
2 Quarter	Within 15 November	15 December
3 Quarter	Within 15 February	15 March
4 Quarter	Within 15 May	15 June

**in case the proposals needs to be re-submitted, the review meeting shall be convened one week after the submission date indicated for the proposals that requires re-submission.*

Annex IV- Terms of Reference and Proposal Review Format for National Selection Committee

a. The Terms of Reference (ToR) are as follows:

- To see that proposals are in line with health policy and FDI policy;
- To ensure that the quality of private facilities are adequate in terms of quality and standards to provide cost-effective services to the public;
- To keep the Minister of Health informed on the services provision of such private driven health care services in the country;
- In case of not having consensus on the selection, external expertise from WHO or other relevant UN agencies will be sought; and,
- The approval of the Selection committee will be final and binding after obtaining the endorsement of the Minister of Health.

b. Format for Proposal Review for NSC

Date of Review: _____

1. **Title of the Proposal:**
2. **Applicant**
3. **Checklist:**
   a. In-line with the Health Policy Yes☐ No ☐
   b. In-line with DRA Regulations Yes ☐ No ☐
   c. In-line with BMHC Regulations Yes ☐ No ☐
   d. In-line with Quality Assurance and Standards Guideline Yes ☐ No ☐
   e. Recommended by the TRC Yes☐ No ☐
4. **Action:**
   a. Accepted ☐ (if all of the above criteria are marked as YES)
   b. Rejected ☐ (if all of the above criteria are marked as NO)
   c. Resubmit ☐ (if some of the above criteria are marked as YES and some NO)

Reasons for the proposals to be rejected or to be redone:

Members of the National Selection Committee:

1. Director General, DOPH (Vice Chairman) ……..
2. Director, DMS (Member)……..
3. Specialists JDWNRH (Member)……..
4. Chief Planning officer PPD (Member) ……...
5. Chief Program Officer QASD (Member) ……..
6. Registrar, BMHC (Member) ……...
7. Drug Controller, DRA (Member) ……
8. Chief Program Officer EMTD (Member Secretary)……..

Chairman of the National Selection Committee
Ministry of Health

Annex V- Schedule of Accommodation for Laboratory Services (Minimum Standard Required)

Room/Area	**Recommended Area in meter 2**
Reception	7
Specimen Collection	10
Specimen reception/sorting	5
Stores *	10
General Laboratory	15
Clean up/sterilization	06
Staff Change room	05
Toilet- patient	03
Staff (common)	05
Waiting (based on patient load)	10
Office	10
Circulation	30%
Division of Pathology, Histology and Cytology	
Office	5
Histopathology lab	15
Cytology lab	15
Reagent store	5
Histopathology Gross Specimen store	10
Specimen stores	15
Division of Microbiology	
Office	5
Bacteriology laboratory	15
Mycology Laboratory	15
Tuberculosis laboratory may include specimen collecting room, specimen processing room, ABST room (antibiotic sensitivity testing), incubator room, wash room	15
Incubator room	03
Cold Storage	03
Media rooms to include media kitchen, media storage and sterilizing room	12
Reagent/Specimen store	5
Division of Clinical Biochemistry	
Office	5
Bio-chemistry laboratory	15
Photometry, chromatography and electrophoresis	15

Reagent/Specimen store	5
Division of Hematology	
Office	5
Hematology Laboratory	15
Stool, virus examination with specimen cubicle	15
Reagent/Specimen store	5
Stool, virus examination with specimen cubicle (not required)	15

Annex VI- Technical Details for setting Radiology Services (Minimum Standard required)

Human Resources	The requirement will depend on the proposed test
Equipment	X-ray Machine (IS/ISO/CE/FDA/BS certified) Ultrasound Machine(IS/ISO/CE/FDA/BS certified) Film Processing -Film auto processor **Protective Devices** Safety Panel – 2 mm lead lining with viewing lead glass Lead Aprons, Thyriod Shield, Gonad Shield Thermo Luminescent Dosimetry (TLD) badges for the Radiographers
Room Specifications	X-ray room – not less than 15X15 feet Ultrasound room- not less than 10X10 feet with attached toilet Darkroom- not less than 10X10 feet with safe light trap and ventilation Documentation/Radiographers room- should be located separately from x-ray room
Shielding Requirement	**Structural shielding required to be provided for walls, door, ceiling and floor of x-ray room:** Primary wall should be 35 cm thick bricks or equivalent Secondary wall should be 23 cm thick bricks or equivalent OR 6 inches concrete Door should contain 2 mm lead line door or 2 mm lead equivalent Viewing glass should contain 2 mm lead glass or 2 mm lead equivalent

Annex VII- Schedule of Accommodation for Radiological Services (minimum standard required)

Room/Space	Area in feet	Equipments/
General X-ray room/Fluoroscopy viewing and Imaging	15'X15'	X-ray table, fluoroscopy monitor, X-ray control with safety panel, Table and Chair, cupboard to keep necessary things like compression belt, contrast media items, lead apron, abdominal shields, thyroid shield
Dark room/Film processing room attached with X-ray room connecting by cassette pass box	10'X10'	Film auto processor with table for loading and unloading of different sizes of films and film hangers
Reception and waiting area equipped with computer to be located near the X-ray room. Space allocated for the X-ray technician to record the patient data	15'X15'	Routine patient registration and file racks to document the patient data and reports. The waiting area for the patients should be equipped with chairs.
Toilet for X-ray room		To be attached with the X-ray room. Should have facility to wash hand.
Reception equipped with computer to be located near the Ultrasound room. Space allocated for the ultrasound technician to record the patient data	10'X10'	Routine patient registration and file racks to document the patient data and reports
Radiologist room	10'X10'	Should be located away from the X-ray room (safe from radiation). Should be equipped with X-ray viewing box with table for reporting the X-ray films. Computer with printer for issuing X-ray and

		Ultrasound reports
Changing room for Patients	5'X5'	Should be attached with the X-ray room. Should have the facility to hang cloths and shoe rack
Ultrasound room with attached toilet	12'X12'	One bed for patient scanning. Equipped with machine and printer.
Utility room for X-ray and Ultrasound room	5'X5'	To be attached with X-ray room and Ultra-sound room. Required to store the gowns, pillow covers and towels of patients
Staff room with attached toilet	10'X10'	For all the staffs of Radiology Department.
Store room	10'X10'	To be equipped with racks to keep X-ray and ultrasound articles such as X-ray films, cassettes, hangers, chemicals, thermal papers, ultrasound gel etc