4.5.2 - There are established systems and processes for maintaining physical and academic support facilities: (laboratory, library, sports facilities, computers, classrooms, etc.

Any other relevant information:

Standard Operating Procedures (SOP) are designed to develop action plans and procedures for the maintenance repair and replacement of all equipment physical academic, and support infrastructure to sustain the delivery of quality teaching and learning in the institution.

REGISTRAR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

BLDE (DEEMED TO BE UNIVERSITY)

STANDARD OPERATING PROCEDURES

BLDE (Deemed to Be University) Shri B. M. Patil Medical College & Research Centre Vijayapur-586103 Karnataka

Contact: +91-9448131879, +91-9845272720+91-984592623
Email: bmpmc.principal@bldedu.ac.in

Version History

Sl. No.	Details	Date	Status
1	Draft prepared by IQAC		

Sign and Seal of Dean
PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

TABLE OF CONTENT

FOREWORD

The IQAC team of BLDE (DEEMED TO BE UNIVERSITY) Shri B M Patil Medical College & Research Centre has prepared the Standard Operating Procedure according to the Institution policy for Quality Monitoring and Quality Improvement. The feedback was taken from all stakeholders for the preparation of the Standard Operating Procedures (SOP). The SOP was reviewed and approved by the Principal.

INTRODUCTION

BLDE (Deemed to be University) is one of the reputed universities in Karnataka providing education in various medical courses. Housed in a sprawling campus at Bijapur (now Vijayapura) in Karnataka, it was declared a University under Section 3 of the UGC Act 1956 and approved by the Ministry of Human Resource Development. It has been established under the BLDE Association, a renowned educational society, running number of institutions in the state. Shri B. M. Patil Medical College has been offering UG Programme-MBBS (with an intake of 150 students), PG Programme in 21 disciplines, PG Super Specialty Programme in Urology (M.Ch.), PhD Programme in 17 disciplines and Innovative courses like Fellowship, Diploma and Certificate Courses in Medical, Allied Sciences and value added courses.

MISSION

Shri B M Patil Medical College & Research Centre (BLDE DU) aims to be a top-ranking Centre of Excellence in Medical Education and Research. Students graduating from the institute will have the required skills to deliver quality health care to all sections of the society with compassion and benevolence, without prejudice or discrimination, at an affordable cost. As a research center, it will focus on finding better, safer and affordable ways of diagnosing, treating and preventing diseases. In doing so, it will maintain highest ethical standards.

VISION

To improve the quality of life, both at individual and community level, by imparting quality medical education to tomorrow's doctors and medical scientists and by advancing knowledge in all fields of health sciences through meaningful and ethical research. The institute in pursuit of its vision provides outstanding educational experience in all the disciplines of Medicine and allied Health Sciences in a supportive environment of scholarship, research, integrity, critical thinking and self-directed learning. It provides comprehensive, culturally sensitive, community-oriented health care to individuals and families. The Vision and mission of the institute is accomplished by using the values of congeniality, openness, inclusiveness and community involvement at a local and global level. The hard work and dedication put in by the management and the devotion of staff and faculty members combined with passion and zeal of the students have allowed the institute to scale new heights.

1. SCOPE

This document describes the SOP for maintenance of all facilities located in the campus of BLDE (Deemed to be University)

2 SOP FOR CLASSROOMS

The cleaning of classrooms on daily basis is done by the sweepers & cleaning staff are appointed by the BLDE(DU) University. The Administrator and the Cleaning and maintenance committee of the institution supervise and review the status of the cleanliness. Any breakage of the restroom fitting is reported to the administrator for the replacement. Appropriate boards are displayed for proper usage of the restroom facilities and to maintain cleanliness

3. MAINTENANCE OF IT FACILITIES

The Dept of Information Technology Services provides high-quality information technology and communications resources and services through shared resources, common infrastructure and functions in support of the academic and administrative activities of the BLDE (DU) medical college, Hospital. The IT dept provides centralized services in the areas of academic computing; server administration; administrative computing; application development; training and faculty development; technology consulting; information and network security; data, voice, and video networks; computer installation, upgrades, service, and support; helpdesk support for faculty, staff, and students on and off campus; computer hardware, software, and accessory configuration and acquisition; cable TV; telephone technical services; multifunction convenience copiers, printers, and scanners installation, configuration, and repair; digital printing services; and discounted prices for students on computer hardware, software, and supplies. These services are in place to provide a flexible infrastructure to meet the rapidly changing needs for instruction, all types of learning, research, and administrative functions.

4 SOP FOR MAINTAINANCE OF LIBRARY FACILITIES

The library provides access to an extensive range of informative resources like books, e-books, journals, e-journals, newspapers, and access to a wide range of resources to improve the academic fraternity and students' knowledge and thought process.

5 SOP FOR SPORTS

Sports make a vital contribution to educational standards and health it helps students to work in teams develops as individual and help in quick decision making. It promotes self-discipline and raises the standard of fitness and endurance. Physical activity has been shown to have a strong and positive influence on mental wellbeing and some mental illnesses brings the positive impact on depression, anxiety,

6 SOP FOR MAINTENANCE OF MEDICAL RECORDS

Medical record is a scientific, clinical, administrative and legal document relating to patient care, in which is recorded sufficient data written in a sequence of events to justify the diagnosis, treatment and results. Medical Record department is an important area of the hospital, which directly assist in the delivery of quality medical care.

7 SOP FOR MAINTENANCE OF LABORATORY

Safe and secure execution of experiments will minimize health and safety risks to laboratory personnel and those in the surrounding area. When institutional laboratory standards are not sufficient to mitigate the risks, laboratory personnel may use the Moderate Risk Standard Operating Procedure (SOP) or the High-Risk SOP for the specific process.

8 SOP FOR MAINTAINANCE OF BLOOD BANK

Blood Transfusion Service is a vital part of the National Health Service and there is no substitute for Human Blood and its components. Increasing advancement in the field of Transfusion Technology has necessitated to enforce stricter control over the quality of Blood and its products. In most of the developed countries, the blood banking system has advanced in all facets of donor management, storage of blood, grouping and cross matching, testing of transmissible diseases, rationale use of blood and distribution. And it is important to consider policy decisions enforcing appropriate regulations or necessary functions of health service to ensure high quality service and safe blood.

9 BIOMEDICAL WASTE MANAGEMENT

Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps. Improper biomedical waste management (BMWM) is a major public health problem. Inefficient disposal of BMW can lead to infectious diseases, malignancies, fetal malformations, chronic cardio-pulmonary diseases, antimicrobial resistance, endocrinal disturbances, air, landand water pollution for generations to come. Efficient and eco-friendly methods for handling BMW are crucial.

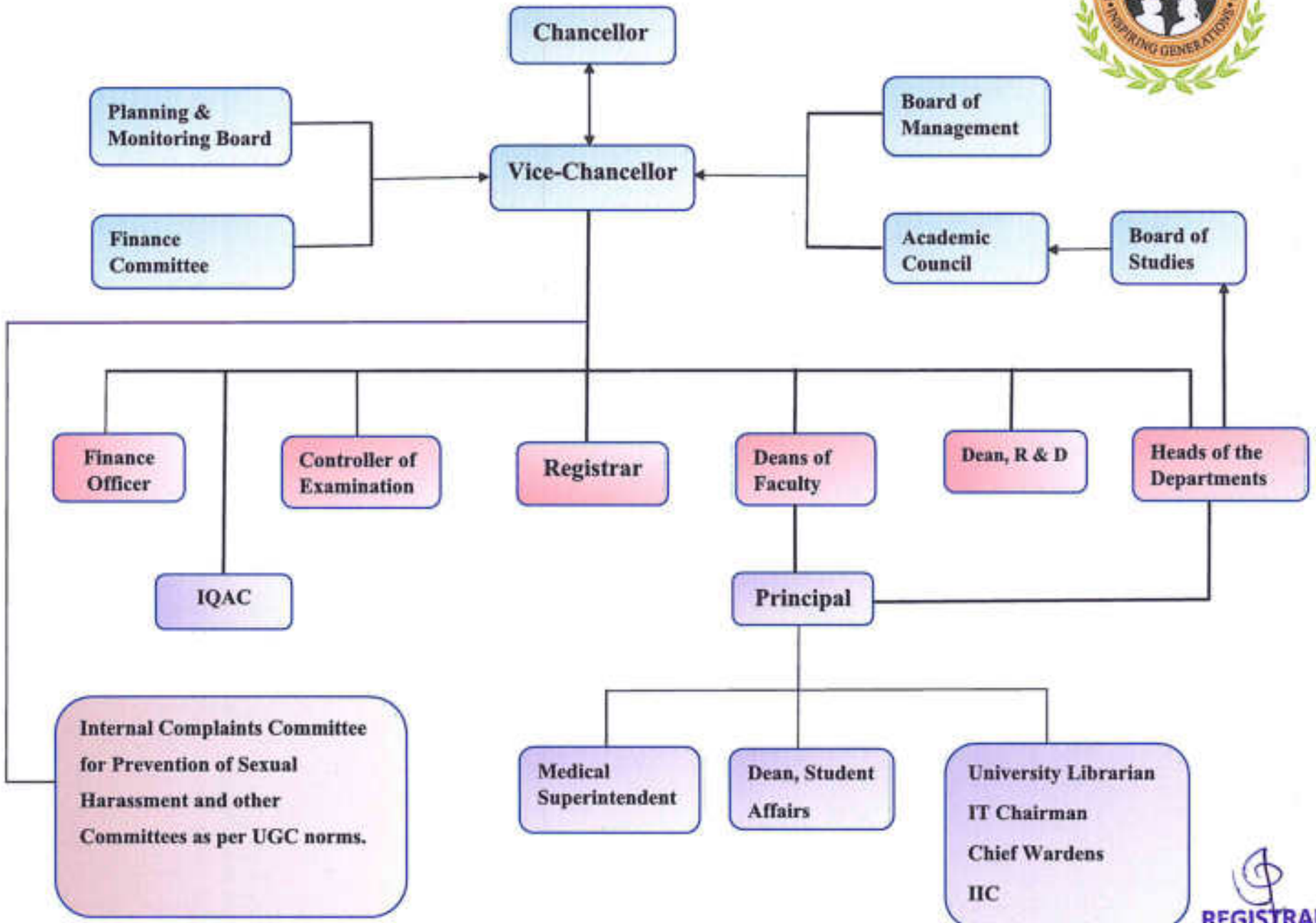
10 MAINTENANCE OF FIRE EXTINGUISHING EQUIPMENT'S

The purpose of this Standard Operating Procedure (SOP) shall be to establish a program for structural firefighting protective ensembles and the individual ensemble elements to reduce the safety risks and potential health risks associated with poorly maintained, contaminated, or damaged protective ensembles and ensemble elements.

The purpose of this procedure shall also be to establish basic criteria for selection, inspection, cleaning, decontamination, repair, storage, and retirement of structural firefighting protective ensembles and ensemble elements.

11. SOP ON SPILLAGE MANAGEMENT OF BLOOD AND BODY FLUIDS

This standard operating procedure (SOP) should be implemented to safely and properly respond to all incidents requiring cleaning and disinfecting of body fluid spills. Body fluids – including vomit, diarrhea, and blood – are considered potentially infectious. Employees should always wear personal protective equipment when cleaning and disinfecting body fluid spills.



REGISTRAR
BLDE (Deemed to be University
Vijayapura-586103. Karnataka

BLDE
(DEEMED TO BE UNIVERSITY)
Declared as Deemed to be University u/s 3 of UGC Act, 1956
The Constituent College
SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

SOP FOR CLASS ROOMS

PRINCIPAL
BLDE (Deemed to be University)
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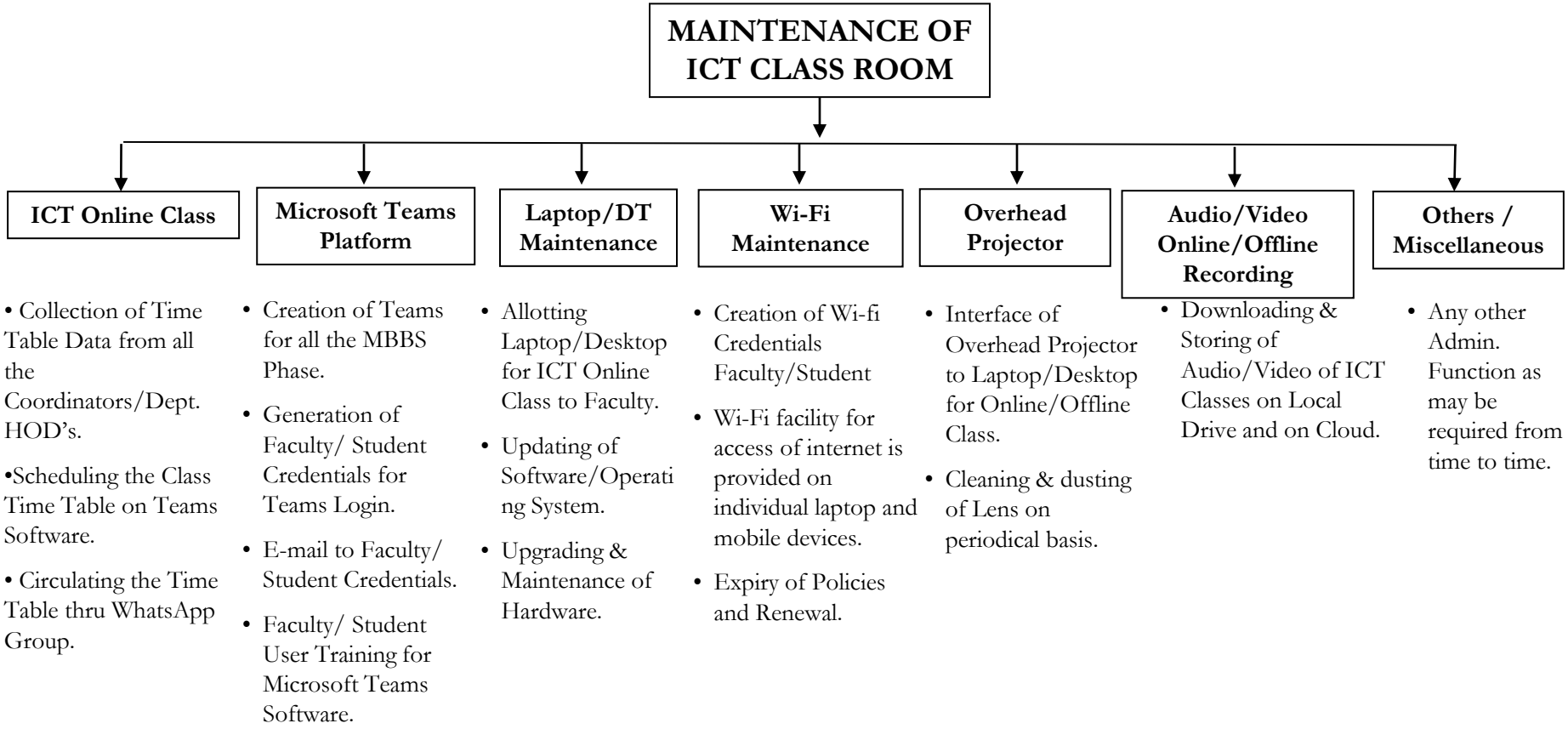
VIJAYAPURA-586 103

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in, E-mail:office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

SOP FLOW CHART FOR THE ICT CLASSROOM.



BLDE
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The Constituent College
SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

INFORMATION TECHNOLOGY (IT) STANDARD OPERATING PROCEDURES

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in, E-mail: office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

SOP FLOW CHART FOR THE LIBRARY

MAINTENANCE OF ICT LIBRARY

Computer Desktop

- 40 Nos. Total number of Computers for student access connected thru LAN N/w.
- 1 No. of Reprographic Multifunctional Machine, 1 no. of Standalone Printer for the Student access.
- Internet leased line

PROHIBITED USES

- Attempting to bypass the security of the computers or local area network at the Library.
- Attempting to harm or destroy the data of another user, the network, any technology resource or other computer network services that are connected to the Internet.

Surveillance CCTV Camera

- Smart IP cameras for surveillance installed, Audio/Video Capturing of footages.
- Auto Alert to the warden for monitoring
- Receive complaint
- Fill in complaint record and pass on to Chief Warden
- Fill Complaint Register, assign serial number and issue acknowledgement to the student.
- Forward Complaint Record to the Dean.
- Dean scrutinizes the complaint, actions taken, verifies resolution and corrective action taken, calls for Parents/ Guardian and closes the complaint

RFID Card Reader

- Creation of RFID Card for all the Students.
- Issue of RFID Card after Activation & Printing of the Details.
- RFID Card Reader is installed at entrance of the Library .
- RFID Card Reader captures the IN & OUT time log data along with snap shot of the student, in the console system
- Maintained & Supported by IT Dept., Technician
- Hardware support Onsite site within 30-60min non repairable standby Card Reader will be provided by IT Technician.

Wi-Fi Maintenance

- Creation of Wi-fi Credentials Faculty/Student
- Wi-Fi facility for access of internet is provided on individual laptop and mobile devices within the Library
- Expiry of Policies and Renewal.
- Reset of User Credentials by IT Admin.
- Maintained & Supported by IT Dept., Technician
- Hardware support Onsite site within 30-60min non repairable Switch/Router standby will be provided by IT Technician.

Biometric

- Scanning of Face & thumb impression for creating user Credentials for all the Students.
- Biometric device is installed at entrance of the Library.
- Students IN & OUT time log data is captured thru Biometric device
- Maintained & Supported by IT Dept., Technician
- Hardware support Onsite site within 30-60min non repairable standby machine will be provided by IT Technician.

Library Software

- OPAC
- KOHA: Open Source Integrated Library Management System
- Federated searching tools to search articles in multiple databases with remote
- Library Website
- In-house/remote access to e-publications
- Library automation
- Institutional Repository
- Participation in Resource sharing networks/consortia (like delnet)

.

•This includes, but is not limited to, the uploading or creation of computer viruses.

• Attempting to alter or damage any hardware, software, operating systems, or configuration files on Library equipment.

• Attempting to use unauthorized computer accounts, access codes, or network numbers

• Maintained & Supported by IT Dept., Technician

• Hardware support Onsite site within 30-60min non repairable Desktop standby will be provided by IT Technician.

• Maintained & Supported by IT Dept., Technician

•Hardware support Onsite site within 30-60min non repairable standby Camera will be provided by IT Technician.

- The institution facilitates extensive use of ICT resources including development and use of computer-aided teaching/ learning material
- NewGenLib Software is implemented with has all functional modules: Technical Processing (or cataloging), Circulation, Acquisitions, Serials Management, MIS Reports, Web Online Public Access Catalog, Administration
- Software Annual AMC are renewed.

SOP FLOW CHART FOR THE CAMPUS HOSTEL

MAINTENANCE OF ICT CAMPUS HOSTEL

Surveillance CCTV Camera

•Smart IP cameras for surveillance installed, Audio/Video Capturing of footages.

• Auto Alert to the warden for monitoring

•Receive complaint

•Fill in complaint record and pass on to Chief Warden

•Fill Complaint Register, assign serial number and issue acknowledgement to the student.

•Forward Complaint Record to the Dean.

•Dean scrutinizes the complaint, actions taken, verifies resolution and corrective action taken, calls for Parents/ Guardian and closes the complaint

RFID Card Reader

- Creation of RFID Card for all the Students.
- Issue of RFID Card after Activation & Printing of the Details.
- RFID Card Reader is installed at entrance of the Hostel Gate.
- RFID Card Reader captures the IN & OUT time log data along with snap shot of the student, in the console system
- Hardware support Onsite site within 30-60min non repairable standby machine will be provided by IT Technician.

Biometric

- Scanning of Face & thumb impression for creating user Credentials for all the Students.
- Biometric device is installed at entrance of the Hostel Gate.
- Students IN & OUT time log data is captured thru Biometric device
- Hardware support Onsite site within 30-60min non repairable standby machine will be provided by IT Technician.

Wi-Fi Maintenance

- Creation of Wi-fi Credentials Faculty/Student
- Wi-Fi facility for access of internet is provided on individual laptop and mobile devices within the College Campus.
- Expiry of Policies and Renewal.
- Reset of User Credentials by IT Admin.
- Hardware support Onsite site within 30-60min non repairable Switch/Router standby will be provided by IT Technician.

Others / Miscellaneous

- Any other Admin. Function as may be required from time to time.

BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

SOP FOR LIBRARY

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in, E-mail: office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

BLDE
(Deemed to be University)

Library Manual

Published by

BLDE (Deemed to be University)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

Smt. Bangaramma Sajjan Campus, B. M. Patil Road(Sholapur Road), Vijayapura- 586103, Karnataka, India

Phone: +918352-262770, Fax: +918352-263303, Website: www.bldedu.ac.in

THE FOUNDERS & VISIONARIES


H.H. Shri. Banthanal Swamiji


Dr. Fa.Gu. Halakatti


Dr.B. M. Patil

FOUNDER OF THE UNIVERSITY

Dr. M. B. Patil B.E.
President

BIJAPUR LIBERAL DISTRICT EDUCATIONAL ASSOCIATION (BLDEA)

BLDE Association was established in 1910. It is committed to the cause of imparting quality education from primary to university in the backward region of North Karnataka. The Association was nurtured and shaped by great visionaries- Dr.P.G.Halakatti, known as 'Vachana Pitamah' in Kannada Literature, Shri Shri Sanganabasaveshwar Maha Shivayogigalu of Banthanal, a great religious leader, and Dr. B. M. Patil, a great statesman. Presently, the Association is guided by Dr.M.B.Patil, a young and dynamic leader.

BLDE (Deemed to be University)

BLDE (Deemed to be University) came into existence on 29/2/2008 with the sole objective of providing quality Medical Education and meeting the health care needs of the people in this backward region of North Karnataka. Shri B. M. Patil Medical College, Hospital & Research Centre is the only constituent college of the university, was established in 1986. It has unitary campus of 45 acres with 24 departments and a teaching hospital with 1125 beds.

The Institute has been offering: UG Programme-MBBS (with an intake of 150 students), B.Sc. (MIT), PG Programmes in 18 disciplines, M.Sc. (Medical), PG Super Specialty Programme in Urology (M.Ch.), Ph.D. Programme in 14 disciplines and Innovative courses like Fellowship, Diploma and Certificate Courses in Medical and Allied sciences.

Research has received major thrust after being conferred with the Deemed to be University status. This has resulted in enhanced MoUs and Collaborations with reputed Universities and research institutes. The University Journal with international academics on Editorial Board is being published by Wolters-Kluwer. (BJHS).

University has been concentrating on enhancing ICT facilities, strengthening and upgrading training (Skills Lab.), research facilities (Central Research Lab, Vascular Lab, Molecular Biology Lab, Genetics Lab and Cadaver Lab). Digital Integrated Campus Networking on Optical Fiber.

This year, a Swimming Pool has added to the existing sports facilities and Indoor Sports facilities are coming up.

BLDE (Deemed to be University) has a deep concern for health care facilities provided to socially disadvantaged sections of the society both in rural and urban areas. It is worth mentioning that University has established a very well equipped Rural Health Centre in the nearby village, Ukkali. Recently, the Institute has been assessed by NAAC and accredited with CGPA of 2.90.

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre, Vijayapura
LIBRARY MANUAL

BLDE (Deemed to be University), Shri B M Patil Medical College Hospital & Research Centre, Vijayapura LIBRARY MANUAL

APPROVAL OF LIBRARY MANUAL

The Library Advisory Committee comprising of the following members hereby state that the 'Library Manual-2020' of BLDE (Deemed to be University), Shri B M Patil Medical College Hospital & Research Centre, Vijayapura is a whole document comprising the necessary procedures, rules and regulations that are to be followed in the functioning of the Central Library.

We hereby recommend to the patron of the Institute that the 'Library Manual-2020' is to be practiced in actual functioning of the Central Library, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital & Research Centre, Vijayapura from 25-02-2020 onwards.

Library Committee Members

Sl No	Name	Designation	Role in Committee
1	Dr. M. S. Biradar	Vice-Chancellor	Chairman
2	Dr. Aravind V Patil	Dean, FOM & Principal	Member
3	Dr. Tejswini Vallabha	Dean. Faculty of AHS	Member
4	Dr. S P Choukimath	Prof. & HOD of Psychiatry	Member
5	Dr. A C Inamdar	Prof.& HOD of DVL	Member
6	Dr. J G Ambekar	Registrar	Member
7	Dr. Kusal K Das	Prof. of Physiology	Member
8	Dr. Nethra Reddy	PG Student (Medicine)	Member
9	Miss. Sharanya	UG Student	Member
10	Mrs. S S Hiremath	Senior Librarian	Member
11	Dr. Prasanna Kumar B.M.	I/c Chief Librarian	Member Secretary

Dr.Prasanna Kumara B.M
Member Secretary and Librarian

Prof. M.S Biradar
Chairman LAC

DECLARATION

I am happy to learn that the staffs of Central Library of BLDE (Deemed to be University), Shri B M Patil Medical College Hospital & Research Centre, Vijayapura have clearly spelt out the functional procedure in the form of 'Library Manual. I do appreciate the staff headed by librarian in this regard.

I, Prof. MS Biradar, Vice Chancellor hereby state that, by the approval of library Advisory Committee, I declare that the Library Manual is right in all aspects and deem fit for actual practice in the functioning of the Central Library.

Prof. MS Biradar
Vice Chancellor & Chairman LAC

PREFACE

The Central Library of BLDE (Deemed to be University), Shri B M Patil Medical College Hospital & Research Centre, Vijayapura was established as an integral part of the education that the Institute offers. The Library intends to facilitate the aspiring graduates with relevant and reliable learning materials in the form of Print and E-resources. The centre strives to update and upgrade with the core objective of meeting the rising expectations of its stakeholders.

The staffs of Central Library professionally carry out the functions that are relevant within the scope of the centre by continuously contributing towards upholding the vision of the centre and in doing so draws the interest of its users.

The Central Library is always at the User's disposal for service, good number of print and E-resources in the field of science and Engineering management. However, there has been a long felt need to bring clarity and uniformity in procedures and practices of the library so as to further improve its efficiency, utility, and services. Therefore a 'Library Manual' is warranted where all the rules, regulations and procedures are clearly spelt out. The Librarian and the library committee members have prepared a draft of the library manual.

The said library manual touches upon all important functional modes of the library as and delineates clear policy as to how the activities of library like acquisition, technical processing, arrangement of resources, transactions, library services and facilities etc., should be carried out,

To be able to give direction in organizing and in managing the library, this manual will serve as a guide to the library staffs and users alike.

To make this manual relevant, it is recommended that this work be reviewed and be revised periodically as the need arises.

Prof. Aravind V Patil

Dean Faculty of Medicine and Principal

VISION & MISSION

Vision

To link health professionals, reliable health sciences knowledge, and technology in support of effective learning, quality health care, vital research, and engaging community service.

Mission

To enhance access to the knowledge base of the health sciences, instruct users in information retrieval and management techniques acquire and organize a specialized collection of electronic, print and other resources for the achievement of the University's objectives in teaching, learning, research, creativity, and community service.

1. Introduction

Central Library of BLDE (Deemed to be University) Shri B.M. Patil Medical College, Hospital & Research Centre has always been striving hard to meet its users' expectations. Four qualified professionals run the Library assisted by other support staff. However, a long-felt need to bring clarity and uniformity in procedures and practices of the Library and resource centre to improve its efficiency, utility and services further.

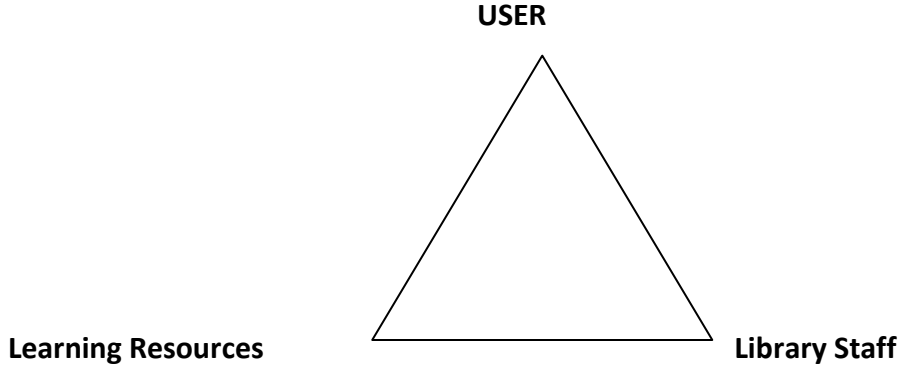
This manual touches upon all important functional modules of the Library and delineates a clear policy as to how the Library's activities like collection development, provision of information services, and management of other academic support facilities should be offered.

Library Manual

Library manual is a source of information, a constitution that lists all departments, sections, and functions, procedures, and policies within the Library. It is a source that library staff will consult whenever there is any confusion about any function or procedure. A lot of efforts go into the preparation of the manual. It goes through a series of meetings with all stakeholders where the procedures and functions and policies are deliberated in detail over and again, to draft the final policy. Hence, a Library Manual goes through a validation process before being finally accepted as a policy document.

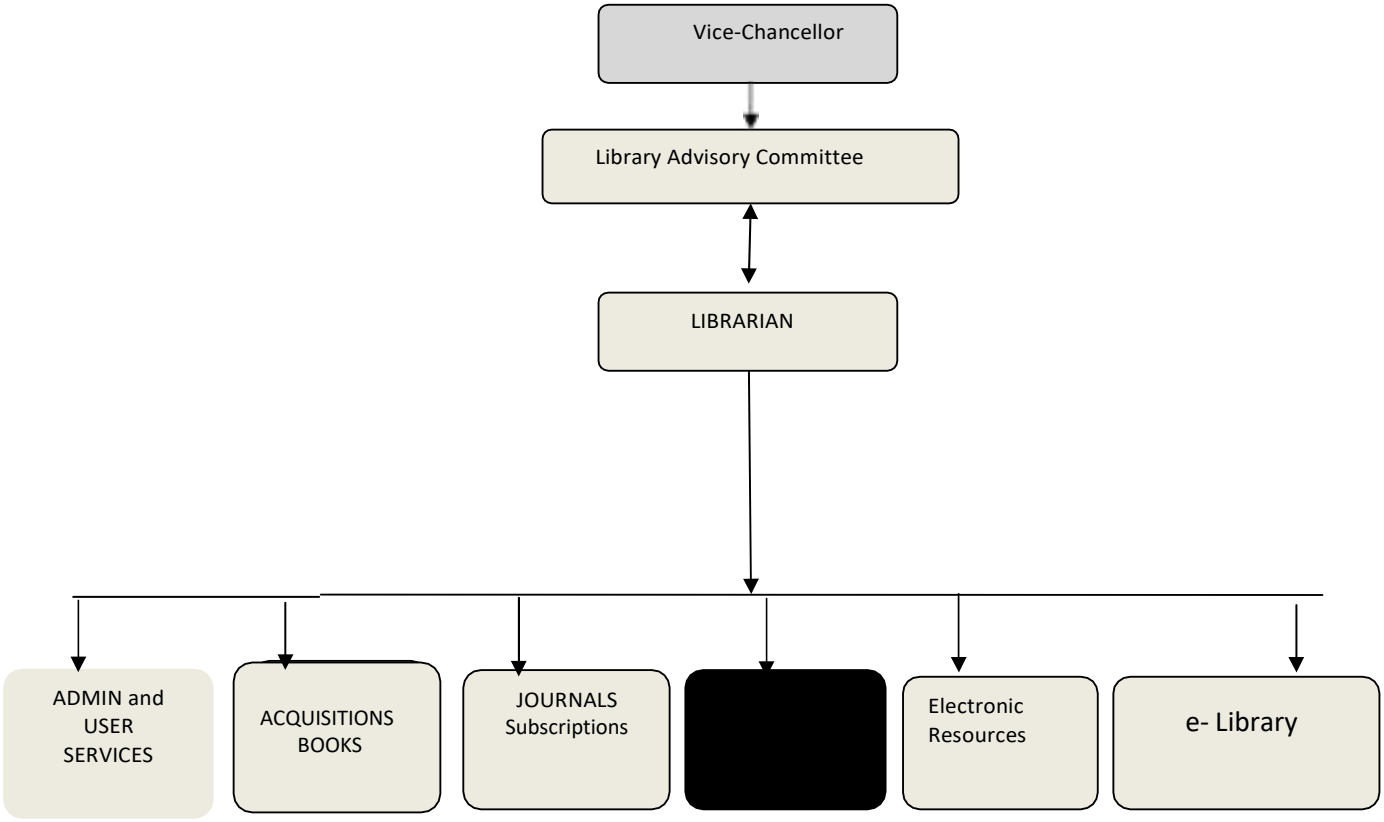
Role of Library

The library plays a very critical role in supporting the academic programmes of the Institute. It identifies, evaluates, procures, processes and then makes these learning resources available to the Faculty and students for their teaching, learning and research assignments. That is why, Dr.S.R.Ranganathan, father of library Science development in India has famously said that the Library is the trinity of Learning resources, Faculty/Students and the Library Staff.



Organization Chart

CENTRAL LIBRARY



1.0 LIBRARY ADVISORY COMMITTEE

The function of the Library Advisory Committee is to support the functioning of the library so that it can facilitate the library development plans by advocating the library development activities with the management. The committee acts as a channel of communication and dialogue between the Library System and its users. The Committee's main objective is to aid in the establishment of a bridge between the Library and the academic fraternity and the institute management. The Library Advisory Committee (LAC) is to be appointed by the Head of the Institute.

2.0 Composition

The Principal will constitute the Library Advisory Committee.

Sl No	Name	Designation	Role in Committee
1	Dr. M. S. Biradar	Vice-Chancellor	Chairman
2	Dr. Aravind V Patil	Dean, FOM & Principal	Member
3	Dr. Tejswini Vallabha	Dean. Faculty of AHS	Member
4	Dr. S P Choukimath	Prof. & HOD of Psychiatry	Member
5	Dr. A C Inamdar	Prof.& HOD of DVL	Member
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8	Dr. Nethra Reddy	PG Student (Medicine)	Member
9	Miss. Sharanya	UG Student	Member
10	Mrs. S S Hiremath	Senior Librarian	Member
11	Dr. Prasanna Kumar B.M.	I/c Chief Librarian	Member Secretary

All library professionals shall participate in the meeting as invitees to provide required inputs

2.1 Function of Library Advisory Committee

2.1.1 To provide general direction to the Library

2.1.2 To review, rewrite and approve library procurement policy

2.1.3 To negotiate and approve subscriptions to online databases (e-journals, eBooks and data sets)

2.1.4 To formulate the policy for library use and procedure to be framed

2.1.5 To review the functioning of the library with regard to its support to the academic programmes of the institute.

2.1.6 To outline the library collection development policy as and when required, for its implementation.

2.1.7 To monitor and evaluate, from time to time, trends and developments in information technologies, networking, library automation, library cooperation etc., and to direct the library in their adoption.

2.1.8 To formulate action plan for the development of library human resource, infrastructure, facilities, products and services.

2.1.9 Any other function as assigned by the higher authorities

2.1.10 The LAC would meet at least once in six months to review the library

affairs

2.1.11 The committee shall be reconstituted once in three years

2.1.12 Minutes of the meeting shall be recorded and circulated to all members for consideration and approval

1.3 **Meeting Frequency:**

TheLAC shall meet at least once in six months to review the library affairs and if necessary, more often.

1.4 **Minutes of the Meeting:**

minutes of the meeting shall be recorded by the Librarian, as Member Secretary and circulated to all members for consideration and approval.

Chairman of the LAC is empowered to nominate the members to the committee as and when required. In case of any member is discontinued from his/her service, due to various reasons, the principal can nominate other suitable members to the committee.

1.**5 Library Advisory Committee and the librarian**

The Librarian is the member secretary in the committee. The library advisory committee is responsible for policymaking.

3.0 Library Budget

Library budget means the financial allocation to procure documents and provide access to the information resources.

BLDE (Deemed to be University) Shri B.M. Patil Medical College, Hospital & Research Centre is an unaided and self-financing institute run by BLDE Association, Vijayapur.

BLDE DU central finance department will take care of the allocation of budget to the Institute.

The annual budget of Library may have the following components.

1. The main source of income for the Institute is from fees collected by the student.
2. The librarian has to prepare the estimated budget copy for the financial year and same copy should be submitted to the Principal for further processing.
3. Allocation of budget for the books, Journals and E-Resources etc.,
4. Allocate the budget for upgradation of ICT infrastructure, furniture etc.,

Budget must have contingency funds for Binding and other stationery needed to process and maintain the Books/Journals etc.,

The Institute has to call for quotations/tenders to procure the books/Journals /E-Resources from the competent vendors approved by GOC and the comparative statement has to be prepared. Subsequent negotiations have to be made before finalizing the order. The same list has to be placed in the institute level purchase committee. The final negotiations or decisions to place order/ reject will be taken care of by the central purchase committee of BLDE Association. The BLDE Association will send the approved list of vendors to the college to place the purchase order.

The tenders/quotations need not be called for procuring every single title/journal. Instead, quotations may be called from empanelled suppliers to fix discount rates and terms of supply, which will be valid for a period of two years.

4.0 Procurement of Learning Resources

Procurement of learning resource constitutes the primary responsibility of Library. Library makes a systematic effort in building up the collection development by identifying, evaluating, selecting, processing and making it available to the users. Whether it's a book, journal or an online database, any learning resource that gets added goes through a rigorous selection process. And since this collection building requires huge sums of money and has long-lasting repercussions, it is very much essential that libraries have a well thought out collection development policy.

Procurement of Books: Process and Approvals

a) Recommendation: Faculty can recommend the books to be procured for their courses and research. Students/Research Scholars can also recommend the books for procurement provided their recommendation is endorsed by a faculty member

b) Indent Approval: All faculty indents will be routed through HoDs and Principal.

c) Ordering: The ordering can be done by print, online, e-mail, etc., depending upon the convenience of the library with standard terms and conditions. Purchase Orders will be Issued by the Principal

d) Supplier Panel: Appoint a Panel of Vendors based on their performance like response to the queries, speed of supply, adherence to the terms and conditions, etc. This panel will be reviewed every two years based on the supplier performance. A panel should have at least 6-8 Vendors

e) Discount: While empanelling a supplier panel, library advisory committee will negotiate and fix a flat discount structure to be followed. This discount rate will be followed for the next two years.

f) Other Suppliers/ Low Discount: There are cases where the books carry low discount, or can be obtained only from specific sources, standard agencies – which are not on the panel. Such cases will be processed after taking due approval.

g) Supply Deadline: Maximum time limit for supplying ordered titles will be 60 days. However, after checking the supply status with suppliers, based on genuineness, additional TWO weeks time may be given. Books which arrive after this will be accepted only after taking approval from the authorities

Foreign Currency: For foreign exchange conversion, Good Offices Committee (GOC) Rates will be followed

h) Price Proof: Accepted Price Proof are:(Signed & Stamped by supplier)

- Distributor's invoice to supplier,
- Print out from the publishers catalogue
- Photocopy from Publisher Catalogue
- For some Indian publications, price mentioned on the title
- Alternatively, Library also cross verifies the prices from publisher's website. Such printouts verified and signed by library

staff will be accepted as price proof

i) Exhibitions: Library may arrange for books exhibition through publishers or their representatives or the empanelled suppliers. Institute will facilitate the exhibitions by providing the space, basic furniture, indent forms, etc for obtaining book recommendations

Terms and conditions for Vendors :

a. All books carry a discount as per the agreed terms
b. The order should be acknowledged within 7 days from this date
c. If a book is ordered from abroad, we should be informed accordingly before sourcing it.
d. Please supply latest editions. Always supply paperback editions unless otherwise mentioned. Indian reprints/editions, if available should be supplied. Consult us beforehand if you intend to supply hardback editions, if the ordered paperback edition is not available.
e. The maximum time limit for supplying such books is 60 days.
f. The order would be treated as cancelled, if the books are not supplied or no report as to availability or otherwise is received within this period.
g. You should certify on the invoice that the prices quoted there in are the publisher's current prices. And, enclose the stamped price proof along with the invoice
h. Payment will be made within 45days from date of receipt of the invoice.

Book Procurement Process Workflow:

I. Initiation of Acquisition:

- Receiving Recommendations by Indent Forms, Emails, Noting Sheets, Publisher Catalogues marked and signed
- Find out the exact details of the Title recommended
- Duplicate Checking
- Correspond with Suppliers/vendors for checking Availability Status
- Put up for Approval
- Prepare and Issue Purchase Orders after approval

II. Accessioning

- Accessioning : Enter the details of the Invoice and Books in Accession Register
- Assign Accession Numbers to Titles in Database
- Pass entries in Bill Register and forward bills
- Maintain Bill File
- Maintain Bill Register Data in EXCEL Sheet for reporting

III. Invoice Processing:

- Receive Books from Suppliers/Vendors
- Crosschecking with Purchase Orders
- Foreign Exchange Rate Verification as per Good Offices Committee Report
- Price Proof Verification
- Prepare Book Received Report and Purchase Bill (BRR) in Database

IV. Classifying

- Classify Books/Thesis/Dissertations as per the Dewey Decimal Classification (DDC) Schedule
- Write the Class No, and Collation on the back of Title page

V. Cataloguing:

- Bibliographic Details of each book is entered into Cataloguing Module database according to AACR2 Standards
- Assigning Keywords : Minimum three keywords are assigned to each title
- Data validation: Regular editing of various access points in the database like Author, Title, Class No, etc.
- Making Analytical Entries, wherever needed.

VI. Processing Books:

- Stamping – Library Stamp to be put on the back of Title page, on Secret page and on the Last page.
- Paste Spine labels, Bar Codes on the Front Page and on the Title page and laminate it with Cello tape
- Prepare Book cards using System
- Send the completely ready to use new arrivals to New Additions Rack, Reference Section or Reserve Shelf, as the case may be.

VII. Institute Material like Dissertation/Thesis/Reports and the Books received as Gift

- These items to be treated like books for processing, etc.
- If the book/Report is already available in Main Library, then it may be sent to other campuses

VIII. Financial Planning/Budgeting:

- Monthly Utilization Report: Grants/Account wise
- Inform Faculty about the arrival of books every month
- Initiate utilization of funds in advance so that funds are utilized before the deadlines set in.
- Prepare proposals/ requests for mobilizing funds for the acquisition

IX. Maintain Reports (Bi-Monthly)

- No. of Requests Received from Faculty
- No. of Titles Recommended
- Status of the recommended titles(Already Library has, Out of Print, Untraced)
- No. of Titles Ordered
- No. of Titles received(Success rate)
- No. of Titles received as Gifts/Donations
- "New Additions Bulletin" (Monthly)
- Book Received information to recommending faculty (Monthly)

X. Vendor Follow Up:

- Titles Not Supplied
- Reminders to Suppliers fortnightly

Non Supply of Books: Process to be followed

- Fortnightly follow up with the vendors

- Evaluate the supply status
- Change supplier and re-order books
- Prepare a performance report of the supplier every six months

Maintenance of Files and Records

Following records/files will be maintained properly

- Accession Register
- Bill Register
- Purchase Orders
- Invoices
- Approvals
- Reminders
- Budget/Finance

3.1 Subscriptions of Journals:

Subscription Process and Approvals

a. Budgetary provision: Ensure that adequate recurring/annual funds are available for the approved Journals Subscription/renewals etc. as required.

b. Beginning of Renewal Process: The process of renewals should begin at least four months in advance (in September) so that by December end/early January all the renewals are done and the subscriptions are continued without any discontinuation in issues

c. Indian Journals will be subscribed directly from the publishers who are usually institutions, govt. agencies, societies, etc. Approval will be taken for these direct subscriptions, but other conditions that govern foreign journal renewals are not applicable to Indian journals.

d. Panel of Subscription Agents: Library Advisory Committee will form a panel of Subscription Agents through whom library will place orders of all its foreign journal subscriptions. All terms and conditions will be decided by the Library Advisory Committee.

e. Procedure for preparing a panel of Subscription Agents: LAC will formulate a panel of vendors/subscription agents for supplying foreign journals with following criteria:

    - Registration number obtained under shop act, age of the organization
    - Performance: Response to the correspondence, speed of supply, adherence to the terms and conditions
    - Experience by the peers
    - PAN/TAN, Sales / VAT tax number
    - Publishers that a vendor supports
    - Vendors turnover having at least 10 times of the value of the order (for the journals subscriptions)
    - Based on the performance, the panel should have least 3 members

f. Foreign Currency: For subscription agents, the foreign currency conversion rate will be as per the payment made by the agents to the respective publisher. Agent will have to produce the proof of payment made to the publisher, along with conversion rates. The difference in pro forma invoice

conversion rates and actual payments to the publisher will be adjusted through additional payment to the agent or through refunds to the institute.

Bank Guarantee for Advance payment:

Since for journal subscriptions, advance payment is required, it is essential that institute has certain mechanism to safeguard the advance being paid to the subscription agent.

The supplier will have to produce a Bank Guarantee of the invoice value to the institute. The duration of this would be for three months, within which the supplier must produce the proof of remittance to the publisher and the subscription should commence.

- After direct confirmation from publishers/vendors that the journals are subscribed in the name of the Institute
- Proof for remittance: (i) Invoice/Bill in duplicate should be provided by the publisher/vendor
- Publishers' Renewal Letter/Notice mentioning the subscription price/cost (e.g. Indian journals)
- Even print out of the from the Publishers'/journal's official website can also be considered wherein the proper invoice/bill etc. not received by the publisher/s.
- a copy of the letter sent to the publisher giving details of the journals for which remittance has been made and
- copy of demand draft issued by bank attested by the bank or a letter from the bank giving details of remittance (if the payment is made by foreign currency draft obtained from the bank)
- Publisher's acknowledgement of receipt of payment or letter from bank as a proof regarding the final remittance to the publisher (if the payment is made from vendor's foreign currency account)

Agreement: Institute must enter into an agreement with the subscription agent/supplier, that all terms and conditions as laid out by the institute will be binding on the supplier.

Subscription Process Work Flow:

a) Recommendation: The list of journals to be renewed is put on faculty circulation through email and recommendations received. Faculty can also recommend new titles.

b) Approval:
   - The list will be processed for exact details like price/publisher
   - Duplication checking with BLDE DU subscriptions
   - Put up for Dean/Chairpersons approval.
   - Put for approval by Library Advisory Committee.
   - If there is no response from faculty or any difficulty or lack of time in obtaining the approval of respective HoDs then the list must be approved by Principal.

c) Proforma Invoices: Invoices must carry a certification that the price has been charged in accordance with the publisher's price list.

d) Ordering : Journals Renewal and Subscription Orders will be issued to empanelled agents by Librarian

e) Maintain proper Bill Register and invoices passed for payment

f) Binding of Journals: All journals procured through "to be capitalized grant" will be bound and kept on shelves.

Receipt of and access to journals

a) Ensure that the items received are as per the order/ access is enabled to the desired resource
b) Manual (Kardex) and computerized record of receipts of the journal issues
c) Processing of Journal Issues: Physical verification, Stamping, RFID tag insertion
d) Timely display of the Loose Issues of the periodicals on the respective display racks.
e) Linking to the online content wherever applicable
f) Accessioning the virtual resources should not be done since they do not exist in physical form.
g) Accompanying materials such as CDs/DVDs etc are being preserved. Other than CDs/DVDs are kept with the Periodicals Section.

Gratis and Exchange Periodicals:

a) The documents relevant to the scope of the Institute's study and research areas be added to the gift collection and displayed.
b) Try to get the free/discounted subscription/s to the periodical/s wherever possible.
c) Gratis may be accepted from the Institute's faculty, scholars, or outside institutes and organizations of similar interest.
d) Avoid duplication unless essential
e) There should be a proper record of gratis items and can be acknowledged appropriately. Maintain a separate MIS file of Gift/ Exchange periodicals
f) Journals under Exchange mode are being handled by the Manager, Publications Unit, and the Library is at the receiving end only.
g) Journals under 'Exchange and Free Subscription' can be treated as regular subscriptions and the completed volumes will be bound and accessioned and archived.

Non Supply of Journal Issues:

a) Reminders: Missing issue reminders can be sent with the following frequency:
    - For weekly and bimonthly journals: Once every month
    - For Quarterly/Biannual journals: Once every two months

b) Replacement of missing issues: Supplier must be asked to replace missing issues by way of
    - replacement copy, or
    - publisher certified and reproduced copy or
    - refund either in the form of credit note or Demand Draft/Cheque or
    - extend the subscription period equivalent to corresponding period

Archiving and Weeding Out

In order to provide better access to the frequently consulted literature, back volumes

are archived in a less active storage area. Though the library gets access to the back volumes online from the publisher's websites, etc., the print volumes of these journals also be considered for archiving in less active storage area. Adequate space should be provided for archival storage to Library if not available.

The following categories of materials can be considered for weeding out:

- Ephemeral material (e.g. newsletters, progress reports, pamphlets) including those materials that lose value after a certain period of time such as: annual reports, directories, yearbooks, etc. These are weeded out annually.
- Duplicate issues of the journals may be weeded out after checking that no other department library wants to have them in their collection.
- Material (Books, journals, reports) that library received as gifts/complementary by individuals/institutions and organizations which have no relevance to BLDE DU users.
- Books/Journals that have become unserviceable/mutilated due to heavy use, wear and tear, obsolete/white ant old infected material

Other Resources Managed:

A variety of other information resources are received and displayed for use in the Periodicals Section which are being received free of charge, viz:

- Complimentary Loose issues of Journals
- Annual Reports
- Working Papers
- Occasional Papers
- Discussion Papers
- Technical/Trend Reports
- Brochures
- Prospectus etc.

Non-Book Materials

A small collection of Non-Book Materials such as Audio Cassettes, Video Cassettes/VHSs, Microfilms, Microfiche, 35mm films, Psychological Tests, Booklets, Posters etc is being maintained at the Periodicals Section and enlisted in a computer file (MS-Excel). These materials are open to all our Library users.

Maintenance of Records:

The transactions of all the activities/procedures/etc. in the Periodicals Section should be carefully and properly recorded for the relevant information and documentation. In this regard apart from the automated system, the section maintains the following documents for keeping the records:

- Journal Subscription Registers
- Bills Register
- Kardex (Journal Loose Issue Entry)
- Subscription Orders
- Approvals

3.2 Procurement of e-Resources

Electronic Resources include electronic journals, online databases, data sets, bibliographic databases, indexing/abstracting services, software tools for research, eBooks, or any information resource that is available in electronic form.

Pricing Models

There exist many pricing models. BLDE DU can adopt the model depending on various factors like suitability for different programmes, research area, relevance to different campuses and a usage analysis, if it is a renewal.

- Annual Subscription: Access to content is available for only one calendar year
- Perpetual Access: Access to content is available for the year that we are subscribing. After expiry of subscription, we will still have access to the content of the year we subscribed for future but not the subsequent new years.

Negotiation

Negotiation plays a vital role in deciding the pricing factors. One can enforce terms to the publishers/vendors in form of the pricing, access to the back volumes, locking period, perpetual access, archival rights, governing laws, training and awareness programmes, immunity, access to the walk-in-users, usage statistics, simultaneous access, etc.

There are no standard/ uniformly acceptable terms that are yet to be established in this area, as this is almost virgin and challenging field. Large opportunities exist in this area for negotiation with the publishers/ resource providers and arrive at win-win situation.

Process and Approvals

Online databases are expensive resources which need to be evaluated properly before subscribing. Hence, the following procedure be followed for subscribing to Online Databases (not for single and individual eJournals or eBooks)

- Identify the need
- Ask for a Trial Access
- Publicize the availability of resource on Trial
- Analyze the Usage statistics
- Make a cost benefit analysis by considering all relevant facts
- Put up for approval
- Convene a Library Advisory Committee for negotiation and conclude the deal

Electronic Journals:

When subscribing to individual titles, same procedure as that of print journals will be followed with regards to preparing the list of journals, duplication checking, finding out price and finally putting up for the approval of Library Advisory Committee.

If e-Journals are being subscribed as subject collections, bundles, or databases then library will prepare a proposal by making a cost benefit analysis by considering the relevance of the resource to BLDE DU academic and research interests, usage analysis and availability of funds. This proposal needs to be approved by the Library Advisory Committee

eBooks:

When purchasing/subscribing to individual eBook titles, same procedure as that of print books will be followed with regards to preparing the list of titles, duplication checking, finding out price and finally putting up for the approval of Principal.

If ebooks are being purchased or subscribed as subject collections, bundles, or databases then library will prepare a proposal by making a cost benefit analysis by considering the relevance of the resource to BLDE DU academic and research interests, usage analysis and availability of funds.

5.0 Circulation Section:

Circulation Section handles the Front Desk operations of the library and is very important because it is the first contact point for faculty and users to the library. Efficiently functioning Circulation Desk leaves a lasting impression on the user and hence it is very important section of the library. Major Activities of the Section are:

a) Issue and returns of Learning Resources(Primarily Books)
b) Attending the Users' query for effective interpretation of library rules and regulations
c) Registration of new members
d) Inter Library Loan Service
e) Maintenance of "Circulation Module" of Library Management Software Maintenance and updatation of all data related to library users
f) Sending Reminders to overdue documents users
g) Correspondence & No Due issuing
h) Library Orientations/Information and Digital Literacy
i) Assisting the users for accessing OPAC and Reference
j) Managing Counter Operations during Weekends/Holidays

5.1Issue/Return procedure

Issue/Return of library materials is the routine operation of any library. Proper sequence of activities to be followed to issue and receive the library books is defined as followed:

While Issuing Book:

- Quickly glance the book for any damage
- Ensure that the User writes signs on the Book card
- Enter details into Issue Database
- Checkout the books to the patrons using barcode labeled on the document
- Handover the books to the user

While receiving the books:

- Quickly glance the book for any damage
- Check Due dates for necessary action
- Cancel the entries from user Account in NGL/library automation database
- Cancel the entry in Book Card
- Send them to Stack for Shelving

5.2Borrowing entitlements for faculty/Students/Admin

Clearly define the number of items that and user is eligible to borrow:

Category	Issue Books	
	No of Books	Issue Period (days)
Academic Staff: faculty	10	15
Research Scholars	02	15
PG Students	02	15
UG Students	01	07

Documents that Can and Cannot be borrowed

Documents/Books that can be borrowed:

- Books from the general shelf
- Reserve Shelf Books can be borrowed only for two days
- CD ROMS, DVDs and audio video cassettes can be borrowed for a period of one week.

Documents/Books that cannot be borrowed:

- Journals Bound Volumes, Loose issues of journals and the latest available issue of the magazines are to be referred within library premises and are not available for issuing out.
- Dissertations/Project Works submitted by BLDE DU Students are not issuable.

5.3Library Fine, Renewals and Reservations

- There will be a overdue charge Re.5/- per day per book from Issue Section
- Fines will be kept pending as "due from borrower" in the system
- "No dues" certification will be cleared from library only after the library dues are fully paid up upon completion of programme
- Faculty and Staff will not be levied any library overdue fine
- Books can be renewed for another term of 15 days, if no demand is there.
- The renewal must be made on or before the due date
- User may borrow it again, if there is no reservation placed on that.
- Students are advised to pay overdue fine if any to the college account section and obtain proper receipt.

5.4Loss or Mutilation of documents and Policy of Compensating Library

- Library materials are to be handled with care.
- If a borrowed book is lost or mutilated beyond usable condition, then the user will inform the library using the prescribed form.
- Library will follow the below mentioned steps, in the same order of preference to settle the dues
  - 5.4.1 Book has to be replaced with the same or latest edition OR
  - 5.4.2 The user has to pay the 1.5 times of the actual cost of the book as per library records/Accession Register
  - 5.4.3 Overdue charges will not be levied in such cases from the date of report until the same is replaced(must be resolved within a month)
  - 4) Students/faculty members are advised to pay loss of books charges if any to the college account section and obtain proper receipt.

5.5Library Access by Visitors: Day Membership and Charges

All external users who want to utilize library facilities and services for their academic

purposes to be allowed after following verification.

- User must produce a valid identify proof like their university/college of study, work place id, Driving License, Aadhar, PANCARD, Voter ID.
- Fill up Day Membership form by furnishing the details
- Pay the library Usage Fees as below:

Category of User	Library Usage Fees	Entitlements
Students / Research Scholars/ Teachers except BLDE DU	Rs 5000.00	Access to print collection and e-Resources as guest login

5.6 Internet and e-Resources access by Visitors and Charges

- The bona fide students, research scholars, faculty, staff (including project staff) are eligible to access internet and e-Resources in library
- Those holding memberships like Alumni, day membership can access internet at no cost using the terminals with Guest Login facility .
- The Guest Login computers are made available subject to the availability.
- Remote Login facility is to be provided for bona fide students, staff and research scholars of the institute. No external user will
- be provided remote login facility.

5.7 Photocopying Services:

- Library has one photocopiers and operates from 9.00am to 5.00pm
- Photocopying charges
- Students, Faculty, Staff, Alumni, Individual/day membership holders/Participants of BLDE DU Conference/Workshops: Rs.1.00 per exposure.
- Copyright rules are applicable for photocopying process. At any given point, only up to 20% document can be photocopied. Photocopying of any document cover to cover is prohibited.
- Photocopies can be taken from Books, Journals, Project Reports, Thesis/Dissertations, etc.

5.8 Theft/Misuse of Library resources:

- The theft or abuse of Library resources like books, journal issues, reports, and dissertations will be viewed very seriously.
- Each case will be examined to ascertain its genuineness and the matter will be reported to the Principal for further action.

5.9 Issue of Library Use Certificates

Librarian/Asst Librarian (User Services) shall issue Library use/Attendance certificate to research scholars who request for it. The procedure to obtain a Attendance Certificate is as below:

- Obtain Day membership for library usage
- Apply for the certificate using prescribed form
- BLDE DU students visiting other libraries can request introduction for library use letter directly

6.0 Collection Development

All academic and research libraries have a common objective to provide its users the information they want. The effectiveness of this function is directly related to collection

development and organization information services. Collection development being the most important of these primary functions, a written acquisition policy outlining the various procedures and methods necessary for collection development is prepared.

6.1 **Study the Strength and weakness of the existing collection**.

Every four years syllabus will be revising for under-graduate and two years for post-graduate by the affiliating body. Encourage the stake holders to make use the E-resources effectively.

7.0 Stack Room /Display Area Management

Collection Organization plays a very important role in ensuring the optimum utilization of the books, journals kept in the library. Presently, the learning resources are stacked/displayed in the following categories:

7. Stock Verification and Procedure to Write off Books

8.0 Stock Verification Periodicity

Physical verification of the library stocks has to be carried out to identify the losses, identifying misplaced and/or mutilated documents that need repair, or to weed out from the library collection. Depending upon the size of the library following periodicity is fixed:

Size of library	Periodicity
Up to 20,000 volumes including journal back volumes	100% physical verification at 3 year intervals
Above 20,000 and up to 50,000 volumes including the journal back volumes.	100% physical verification at 5 year intervals
Above 50,000 volumes and up to 1,00,000 volumes including the journal back volumes	Sample (20% of the total stock) physical verification at intervals of not more than 5 years. If such a sample verification reveals losses up to 10% of the sample chosen, complete verification is required to be done
Above 1,00,000 volumes including the journal back volumes	Sample (10% of the total stock) physical verification at intervals of not more than 5 years. If such a sample verification reveals losses up to 10% of the sample chosen, complete verification is required to be done

The sample can be of random generation of numbers. The verification has to be carried out by a team of members appointed by the principal and the library staff will assist the verification team.

8.1 Loss of Publications

8.1.1 Books are vulnerable to physical handling and environmental

conditions. Hence, mutilation, wear and tear of books by heavy use is a common occurrence in libraries.

8.1.2 Some loss of publications is inevitable especially in the context of open access practice in libraries. The librarian and library staff has a role as information manager and facilitator and not just a custodian. Library operates for long hours during all working days and including weekends and also Sundays and it's the responsibility of entire library team and the security guards employed in the library. Therefore librarian alone should not be held responsible for the losses, unless it is attributed to dishonesty and gross negligence.

8.1.3 Loss of 5 volumes per 1000 volumes issued and/or consulted in a year may be taken as reasonable.

8.1.4 Loss of a book of the value exceeding Rs.2000.00 for books published in India and Rs.10,000.00 for books published abroad and books of special nature and rarity shall invariably be investigated and consequential action taken. The Principal will write off all such losses. The base values suggested for Indian and foreign books shall be reviewed every five years.

8.1.5 A publication may be considered as lost only when it is found missing in two successive stock verifications and thereafter only action be taken to write off the publications by competent authority.

8.1.6 If the loss of book is more than the permissible extent, the causes of such loss may be investigated by the competent authority and the remedial measures be strengthened.

8.1.7 Occasional loss/damage of issues of periodicals is inevitable during postal transit. If the payment is made directly to the publisher, then sometimes it is not possible to get the replacement. In such cases, the non- receipts/damages be considered as loss for write-off.

8.1.8 There may be no objection to the Librarian, after due approval, in disposing of mutilated/ damaged/ obsolete volumes to the best interest of the library. However, the disposal of such volumes should be made on the recommendations of a Library Advisory Committee to be appointed by the competent authority which shall decide whether the books mutilated/damaged/obsolete are not fit for further use.*

Appendix- 1 General Financial Rules 2017 / Ministry of Finance /Department of Expenditure

Appendix-2 (* Extract from Ministry of Finance O.M. No. 23(7) E II(A)/83 dated 7.2.1984 and CAG's U G No. 1964-TA.II/21-83 dated 23.12.83)

8.2 Procedure for write-off

8.2.1 List the documents not found during stock verification

2) Library staff to make all possible efforts to locate the document not found during stock verification (the process can go up to six months but not as an exclusive task)

3) Prepare pre-final list of the documents not found and publicize

4) Compile a final list of documents not found

5)Compare with the list of earlier stock verification to identify common entries

6) Compare losses with borrowing/ consulting / photocopying statistics

7)Put up the list of common entries to the Library Advisory Committee along with justification for the losses (open access, limited staff, inadequate security system, large number of students visiting library, losses within permissible limits, etc.)

8) Obtain approval from the Library Advisory Committee

9) Obtain approval from the Principal / Competent Authority

10) Make necessary entries in the accession register, write-off register

11) Remove records from databases

12) Close file.

13) Improve the system with additional precautionary measures

8.3 Preventive measures:

Some preventive measures are listed below.

8.3.1 Follow closed access to the rare books and specialized collections

8.3.2 The exit/entry to the library be monitored

3) Sealing of windows with wire mesh, installation of wicket gate, adequate vigilance in the stack room(s), provision of adequate lighting, use of electronic or magnetic gadgets for detection of the theft, closed-circuit television monitoring system, introduction of identity/membership cards for identification of users, etc., can be adopted.

8.3.3 Employ adequate number of staff in the library for monitoring.

8. User Services

The Library is open from 8.00am to 10.00pm on all 365 days .

Following sections are kept open as below:

Reading Halls	24/7 365 Days
Digital Library	08.00am to 10.00pm (All days)

During Examination time working hours of library timings will be extended

Compensatory off for staff who work on Sunday and holidays

- The library counter has to be kept open on Sunday and weekends.
- Staff will be called for doing these holiday duties at counter on rotation basis.
- Staff will be eligible to avail compensatory off.
- Such compensatory off cannot be accumulated and must be taken during vacations

Reference Service

Library houses all important reference sources like Encyclopedias, Dictionaries, handbooks and Manuals, Statistics, Yearbooks. The collection ranges from general to subject specific sources. All the reference sources are housed in the Ground floor Reference section. Users can also contact staff on duty for any assistance.

Library also has access to online reference sources which may be accessed from the library website/publishers website

Information and Digital Literacy/Library Orientation

Library will conduct Information Literacy/User Education/Orientation programmes to all in the beginning of the academic year. Besides this, these awareness programmes should be conducted when requested by users from time to time.

Inter Library Loan

Library maintains an inter library loan arrangement with DELNET. Hence, all possible efforts must be made to make available the learning resources needed for the faculty and students.

9. ICT Services Division

Document Delivery Services:

Library is also part of DELNET where the books are borrowed from other universities/colleges through DELNET network. Similarly, library also provides document delivery loans to other universities through DELNET.

Digital Library Services: A State-of-art Digital Library provides seamless access to various online Databases, Electronic Theses & Dissertations, In-house Bibliographic and full text Databases, Institutional Repository, etc.

- Digitization of library materials including Rare and Out of Print books but in demand
- Digitization of Theses and Dissertations submitted to the institute
- External Digitization projects
- Scanning and printing facility for the students

Digital Library

The Library has set up digital Library with over 50 computers working in a networked environment through connectivity through leased line of 20 mbps bandwidth. The Online databases like Proquest Health Research Premium Collection , Proquest Central Ebooks, and Scopus database will provide access to full text journals. In addition Grammarly Digital writing assistant tools and Similarity Index tool Urkund anti-plagiarism software is available in the library.

Digital Library-Acceptable Use and Code of Conduct:

1. Do Not Connect Your Mobile or any external device to Computers.
2. Do Not Install Any Software Without Prior Permission Of IT Team.
3. Do Not Download Movies OR Songs.

4. Do Not Remove LAN Card, Keyboard And Mouse From The Computers.
5. Do Not Save Any Document On The Desktop.
6. Kindly Scan Your storage devices like Pen Drive Before Use.
7. Keep Your Mobile On Silent Mode.
8. Eatables are not allowed inside the Library.
9. Take Care Of Your Own Belongings.
10. Turn Off The Computer After Your Work Is Completed.
11. All Drives Will Be Formatted After Every 15 Days by IT team Without Any Intimation.
12. IT Team Will Not be Responsible For Any Data Loss
13. Kindly Co-operate With IT Team For Minimum Downtime of the Computers.
14. Please Inform To IT Team In Case Of Any Computers Problem.
15. Please Keep The digital Library Clean.
16. Keep Silence In digital Library.

Licenses and Fair Use of e-Resources:

The BLDE DU subscribes to thousands of electronic journals including full-text electronic resources and bibliographic databases for its member institutions. All electronic resources available through the library are governed by license agreements. The terms and conditions for using these resources are spelled out in license agreements that are signed with each publisher by the library on behalf of its member institutions.

The licenses for electronic resources impose two types of restrictions on its usage, namely i) who can use these resources; and ii) how the resources can be used. The first restriction defines authorized users for e-resources, which generally includes students, faculty, staff and onsite visitors of a subscribing institution. The second restriction deals with how these resources can be used. It is the responsibility of individual users to ensure that e-resources are used in a fair and just manner and for personal, educational and research purposes only.

Computer Access-Acceptable Use and Code of Conduct:

Only registered members of the Library are authorized to use the Computers, Internet facility or to access e-Resources. Prior to such authorization, the students must sign and return the Library Registration Form acknowledging their responsibilities and the consequences of violation.

Students are expected to observe network etiquette by being polite. Students are prohibited from pretending to be someone else; transmitting obscene messages or pictures; revealing personal addresses or telephone numbers-either their own or another person's; or using the network in a way that would disrupt use by others.

The following policy for acceptable use of computers, networks, and system resources, including the Internet and e-resources, shall apply to all BLDE DU , faculty, staff, and students. All technology equipment shall be used under the supervision of the instructor. Any user who violates any condition of this policy is subject to disciplinary action or administrative sanctions. In addition to any other disciplinary action taken, the library Department reserves the right to terminate access to system resources for any user who violates these guidelines.

1. Every user in whose name a system account is issued will be responsible at all times

for its proper use.

2. Users shall not let other persons use their name, logon, password, or files for any reason
3. Users shall not use others' system accounts or try to discover another user's password.
4. Users shall not erase, rename, or make unusable anyone else's computer files, programs or disks.
5. Users shall not use Computers for any non-instructional or non-administrative purpose, including, instant messaging, online shopping, or personal use of streaming media such as online radio stations or video broadcasts.
6. Users may not install, download, copy, or distribute copyrighted materials such as software, audio or video, files, graphics, and text without the written permission of the administrator.
7. Users shall not use the Computers for illegal purposes, in support of illegal activities, or for any other activity prohibited.
8. Users shall not write, produce, generate, copy, propagate, or attempt to introduce any computer code designed to self-replicate, damage, or otherwise hinder the performance of any computer's memory, file system, or software. Such software is often called a bug, virus, worm, Trojan Horse, or other name.
9. Users shall not use Computers to purposefully distribute, create, or copy messages or materials that are abusive, obscene, sexually oriented, threatening, harassing, damaging to another's reputation, or illegal.
10. Users shall not use Computers to purposefully access materials that are abusive, obscene, sexually oriented, threatening, harassing, damaging to another's reputation, or illegal. In the event that accidental access to prohibited materials occurs, users are expected to immediately discontinue such access and report the incident either to Library staff or to the administrator.
11. Users shall not intentionally damage the system, damage information belonging to others, misuse system resources, or allow others to misuse system resources.
12. Users shall not alter or vandalize computers, networks, printers, or other associated equipment and system resources. Alteration or vandalism includes, but is not limited to: removal of parts, intentional destruction of equipment, altering system settings or software, installing unauthorized or unlicensed software or programs, attempting to degrade or disrupt system performance, or attempting to make system resources unusable.
13. Users shall not use Computers for the forgery or attempted forgery of email messages. Attempts to read, delete, copy, or modify the email of other system users, deliberate interference with the ability of other users to send/receive email, or the use of another person's email account is prohibited.
14. Users should not use library network for sending and receiving a large number of personal messages, including using group email distribution lists to send non-administrative or non-instructional messages to other users.

10 Library Security System

Library employs a security system to safeguard the library resources. The following security systems are employed in the library

a) Closed Circuit Camera System (CCTV)
   - Library has installed 30 cameras across different floors, stack rooms and study areas for monitoring.
   - Librarian's Office also has a LED monitor where the CCTV feed is provided
   - System administrator has access to recording of the footage

b) Library Attendants:

- Library attendants have been allotted different sections of the stack rooms and they will provide monitoring at stack rooms and study places.

C) RFID Systems.

Library is having rich collections of more than 21500 printed documents, it is advisable to install RFID solution to control theft, easy tracking the documents, inventory and accuracy of issue/return of books.

11 Physical Ambiences:

Cleanliness:

Library is a central resource department that is the backbone of all academic programmes of the institute. Students and faculty would be spending their considerable time in library premises pursuing their research and studies. Hence it is very much essential that library has a checking system in place to monitor the cleanliness and hygiene of the library premises like regular sweeping, cleaning and mopping of all floors, and washrooms.

Electricity and Water and Ventilation

Library will ensure that these essential things are working at all times and users would not be put to any inconvenience.

Floor Plan and Direction/Guideposts

Library shall have floor plans designed and proper directions/guideposts for people to move around the library looking for resources/services.

12. Managing the Performance of Library team

The library is managed by a professionally qualified and competent team. It is suggested that the performance of the team can be optimized by taking the following measures.

Clearly defined Job Descriptions at all levels

Each member of the library team shall have a clearly defined, unambiguous job description that facilitates and gels with the library's and then Institute's Mission and Vision Statements. The organization chart with a clear reporting structure be developed for having effective span of control within the library.

Quarterly Work Plan and Predefined, agreed Targets for achievement

Each section in the library shall have a Quarterly Work Plan. Here, the works to be carried in the next quarter and the predetermined, agreed targets for achievements will be decided. There will be a review process after every quarterly assessment.

General Conduct

Every member of library team shall exhibit the highest level of professional conduct in discharging their duties. Staffs are expected to be in their sections unless otherwise their work takes them away from the desk. Providing polite and efficient service shall be the motto of the library.

Department Performance Audit by yearly user feedback surveys

Library will initiate a annual department performance audit wherein the performance

of each section of library will be evaluated based on the feedback surveys, user satisfaction surveys. This feedback and evaluation will certainly help library to overcome any lacunae in the facilities and services being provided.

Bimonthly Reports about Library Functioning

Library shall compile, analyze and submit a performance report every two months. In this, the performance and productivity of each section of the library shall be reported with descriptions as to how many targets were achieved, difficulties faced and how they were overcome.

13. General Rules and Regulations:

1. All the students/scholars and outsiders entering the Library shall deposit their bags and other belongings at the entrance. Only notebooks and the Library books to be returned will be allowed inside. Do not to leave any valuables at the Check Point. Library is not responsible for any loss of personal belongings. All files, books and notebooks must be presented to the security guard at the checkpoint for inspection while leaving the Library. Library does not permit any exception in the observance of this rule.
2. Library Identity Card is compulsory for getting access to the library.
3. Books removed from the shelves by students, if not required for reference, should be kept on the book trolley or on table nearest to them. Please do not try to shelve them yourself*. Please remember that a book misplaced is a book lost.*
4. The newspaper(s) should be folded properly after reading and kept back in the designated place.
5. Readers should not deface, mark, cut, mutilate or damage library resources in any way. If anyone is found doing so, he will be charged the full replacement cost of the resource. Books Borrowed should be protected from RAIN, DUST, INSECT, etc.
6. All the students/scholars are required to bring one of their recent photograph (Passport Size) while applying for Library membership.
7. *All the students who want to return the books issued on their names are advised to wait until the books are shown as cancelled against their names.*
8. There will be a fine of Rs. 5.00 per Issue book
9. Students are advised not to issue Books to others on their names.
10. Conversation and discussion disturbs library ambience. Therefore, all are requested to maintain silence. If discussion is necessary, the common room should be utilized for the same.
11. Smoking/chewing tobacco is not permitted in the Library.
12. All users are requested to keep their mobiles switched off or in silent mode in the Library.
13. Beverages and Eatables are not allowed inside the library.
14. No visitor or guest is permitted to use the Library without obtaining a visitor/day membership.
15. No photograph of the Library shall be taken without proper authorization.
16. Library reserves the right to call back any issued book/item at any time.
17. All research scholars are advised not to keep Library books/journals (loose & bound) inside their lockers without getting them issued.
18. Library reserves the right to inspect these lockers, whenever necessary.
19. All students are advised to come to the Library in decent dress as they are in the

classrooms.

20. Demand and suggestion slips are available at the circulation desk for your use.

14. BEST PRACTICES

- Visitors tracking system. The reports will be sent to the concerned HODs and Principal periodically
- Information Literacy Programme for users/Library Quiz/Book Talk
- Displaying New Arrivals and communicated to the users periodically
- Library Orientation Program for stakeholders.
- Newspaper Clipping service
- Library Website/library page in the college website/Promotion of E-Resources/ Digital Contents
- Research Support Services –Plagiarism Check using Urkund/Any other tool
- Maintaining Institutional Repository for in-house faculty publication using Dspace/E Prnt digital library software
- Best Library User Awards for students (Once in an Academic Year)
- CAS/SDI services /OPAC and Web OPAC facility
- Analysis of usage statistics of E-Resources
- Organize workshop/Training program/seminar/FDP for the benefit of stakeholders.
- Feedback from the stakeholders once in a year

15. Requisition Forms used in Library

a) Library Membership Form (Student/Research Scholar)

b) Membership form Faculty/others

c) Day Membership/Visitor Membership Form

d) Book Recommendation form/Indent

e) No Dues Certificate

References:

1. The College Library Manual, A guide for library Professionals, Department of Collegiate Education, Govt of Karnataka, 2015
2. The Library Manual-2013, TISS,Mumbai
3. Library Manual-2019 Maharaja Institute of Technology,Mysore

Library Membership: Students / Research Scholars

Photograph

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre
Vijayapur-586 103

Central Library

I, the undersigned would like to apply for Library Membership. I hereby undertake the responsibility to abide by rules of the library. In case of late return/loss or damage to any library resources borrowed by me, I am willing to pay the required amount.

Name in full: Mr./ Ms./ Dr.……

Roll No. :……..

Programme: ☐ MBBS/BSc ☐ MS/MD/MCH ☐ PhD ☐

Specialization:……

Present Address:……

……..

……Cell:……

Email:.....(Please write legibly)

Permanent Address:……..

:……..

……

……Tel:……..

Date: :…… Signature of Student:…….

****

Library Membership may please be granted.

Patron No……. Data Entry Done : ……

Professional Assistant (Circulation) :

Assistant Librarian (User Services) : :

Librarian :

Library Membership: Faculty / Staff/Others

PHOTOGRAPH

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre
Vijayapur-586 103

Central Library

I, the undersigned would like to apply for Library Membership. I hereby undertake the responsibility to abide by rules of the library. In case of late return/loss or damage to any library resources borrowed by me, I am willing to pay the required amount.

Membership as : ☐ Faculty ☐ Visiting faculty ☐ Staff ☐ Others

Name in full: Mr./ Ms./ Dr.……
Institute Name :……..
Department :

Present Address:…….

……

……Cell:……

Email:.....(Please write legibly)

Permanent Address:……..

:……..

……

……Tel:……..

Date: :…… Signature:…….

****

Library Membership may please be granted.

Patron No……. Data Entry Done : ……

Professional Assistant (Circulation) :

Assistant Librarian (User Services) : :

Librarian :

Library Membership: Day Member

PHOTO GRAPH

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre
Vijayapur-586 103

Central Library

I, the undersigned would like to apply for Library Membership. I hereby undertake the responsibility to abide by rules of the library. In case of late return/loss or damage to any library resources borrowed by me, I am willing to pay the required amount.

Membership as : ☐ Day Member Period of Validity :

Name in full: Mr./ Ms./ Dr.…….

Present Address:…….

…….

……Cell:……

Email:.....(Please write legibly)

Permanent Address:……..

:……..

……

……Tel:……..

Date: :…… User Signature:…….

****

Day Membership Fee : Rs 100 per month Receipt No: Date:

Library Membership may please be granted.

Patron No……. Data Entry Done : ……

Professional Assistant (Circulation) :

Assistant Librarian (User Services) : :

Librarian :

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre
Vijayapur-586 103

Central Library

BOOK RECOMMENDATION FORM/INDENT

To,
The Librarian
BLDE DU

Please procure the following titles which are useful for my teaching and research purpose.

Name of the Faculty:
Department :

Sl No	Title	Author	Year of Pub	Publisher & Ed	Price	No of Copies Required

----
Signature of the Faculty

Approximate cost of the Books Rs----------

Recommended by the Head of the Department: ----------

Date:

Librarian: ----------

BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre
Central Library

NO DUES CERTIFICATE

Patron ID No.----------

This is to certify that Shri/Smt---------- has returned

all the books and Journals to the library in perfect order. He/She owes no dues in the library.

Place: Vijayapur
Date :

Librarian
BLDE (Deemed to be University),
Shri B M Patil Medical College Hospital & Research Centre, Vijayapura

Appendix 1 (Part-1)

GENERAL FINANCIAL RULES 2017 / MINISTRY OF FINANCE/DEPARTMENT Of EXPENDITURE

Rule 215 Physical verification of Library books.

I. Complete physical verification of books should be done every year in case of libraries having not more than twenty thousand volumes. For libraries having more than twenty thousand volumes and up to fifty thousand volumes, such verification should be done at least once in three years. Sample physical verification at intervals of not more than three years should be done in case of libraries having more than fifty thousand volumes. In case such verification reveals unusual or unreasonable shortages, complete verification shall be done.

II. Loss of five volumes per one thousand volumes of books issued/consulted in a year may be taken as reasonable provided such losses are not attributable to dishonesty or negligence. However, loss of a book of a value exceeding Rs. 1,000/- (Rupees One thousand only) and rare books irrespective of value shall invariably be investigated and appropriate action taken

Rule 217 Disposals of Goods.

I. An item may be declared surplus or obsolete or unserviceable if the same is of no use to the Ministry or Department. The reasons for declaring the item surplus or obsolete or unserviceable should be recorded by the authority competent to purchase the item.

II. The competent authority may, at his discretion, constitute a committee at appropriate level to declare item(s) as surplus or obsolete or unserviceable.

III. The book value, guiding price and reserved price, which will be required while disposing of the surplus goods, should also be worked out. In case where it is not possible to work out the book value, the original purchase price of the goods in question may be utilized. A report of stores for disposal shall be prepared in Form GFR - 10.

IV. In case an item becomes unserviceable due to negligence, fraud or mischief on the part of government servant, responsibility for the same should be fixed.

V. **Sale of Hazardous waste/Scrap Batteries/Electronic waste:** Scrap lots comprising of hazardous waste, batteries etc. shall be sold keeping in view the extant guidelines of Ministry of Environment & Forest. Prospective bidders of such lots of hazardous waste/scrap batteries/ e-waste should be in possession of registration, valid on the date of e-Auction and on the date of delivery, as recycler/ pre- processor agency.

Rule 218 Modes of Disposal.

I. Surplus or obsolete or unserviceable goods of assessed residual value above Rupees Two Lakh should be disposed of by :

(a) obtaining bids through advertised tender or

(b) Public auction.

For surplus or obsolete or unserviceable goods with residual value less than rupees two lakh, the mode of disposal will be determined by the competent authority, keeping in view the necessity to avoid accumulation of

such goods and consequential blockage of space and, also, deterioration in value of goods to be disposed of Ministries / Departments should, as far as possible prepare a list of such goods.

I. Certain surplus or obsolete or unserviceable goods such as expired medicines,food grain, ammunition etc., which are hazardous or unfit for human consumption, should be disposed of or destroyed immediately by adopting suitable mode so as to avoid any health hazard and/or environmental pollution and also the possibility of misuse of such goods.

II. Surplus or obsolete or unserviceable goods, equipment and documents, which involve security concerns (e.g. currency, negotiable instruments, receipt books,stamps, security press etc.) should be disposed of/ destroyed in an appropriate manner to ensure compliance with rules relating to official secrets as well as financial prudence.

Rule 221 Disposal at scrap value or by other modes. If a Ministry or Department is unable to sell any surplus or obsolete or unserviceable item in spite of its attempts through advertised tender or auction, it may dispose of the same at its scrap value with the approval of the competent authority in consultation with Finance division. In case the Ministry or Department is unable to sell the item even at its scrap value, it may adopt any other mode of disposal including destruction of the item in an eco-friendly manner.

Rule 222 A sale accounts should be prepared for goods disposed of in Form GFR 11 duly signed by the officer who supervised the sale or auction.

Rule 223 (1) Powers to write off. All profits and losses due to revaluation, stocktaking or other causes shall be duly recorded and adjusted where necessary. Formal sanction of the competent authority shall be obtained in respect of losses, even though no formal correction or adjustment in government accounts is involved. Powers to write off of losses are available under the Delegation of Financial Powers Rules.

Rule 223 (2) Losses due to depreciation: Losses due to depreciation shall be analyzed, and recorded under following heads, as applicable:-

I. Normal fluctuation of market prices;

II. Normal wear and tear;

III. Lack of foresight in regulating purchases; and

IV. Negligence after purchase.

Rule 223 (3) Losses not due to depreciation: Losses not due to depreciation shall be grouped under the following heads:-

I. Losses due to theft or fraud;

II. Losses due to neglect;

III. Anticipated losses on account of obsolescence of stores or of purchases in excess of requirements;

IV. Losses due to damage, and

V. Losses due to extra ordinary situations under 'Force Majeure' conditions like

fire, flood, enemy action, etc.

Appendix 2 Part-II)

No. F.23(7)-E.II(A)/83

Government of India Ministry of Finance (Department of Expenditure)
New Delhi, Dated the 7-2-1984 18 Magha 1865 (Saka)

OFFICE MEMORANDUM

Subject: Amendment to Rules 99 and 116 of the General Financial Rules, 1963 (Third Edition)

Exclusion of books, publications and periodicals etc. from the definition of 'Stores'. Attention of all the Ministries/Departments of the Government of India is invited to Rules 99 and 116 contained in Chapter 8 dealing with the 'Stores' in the General Financial Rules, 1963. The President has been pleased to decide that hereafter the books, publications, periodicals etc. of a library will not be treated as an item of 'Stores' as defined in the 'Note' below Rule 99 of the General Financial Rules, 1963.

Accordingly the provisions of the said 'Note' and the Government of India's decision (1) below Rule 116 of the General Financial Rules, 1963 (Third Edition) have been amended as per amendment enclosed. This issues with the approval of the Comptroller and Auditor General of India and the Department of Supply.

2. Hindi version of this O.M. is enclosed.

Sd/-

(K.L. MEHTA)
UNDER SECRETARY TO THE GOVT. OF INDIA

AMENDMENT TO GENERAL FINANCIAL RULES, 1963 (3rd Ed.)

PAGE 38, CHAPTER 8, RULE 99

The following words shall be added to the last sentence in the 'Note' below Rule 99:- "but excluding books, publications, periodicals etc. in a library."

(Ministry of Finance (Dept.of Exp.) O.M.No. F.23(7)-E.II(A)/83 dated 7-2-1984 and Dept. of Supply U.O. No. I.D.No. PIII-3(5).82 dated 23.2.83 and C.A.G's U.O. No. 1964-TA.II/21-83 dated 23.12.83.

PAGE 40-41, CHAPTER 8, RULE 116

For the existing Government of India's decision (1) below rule 116, the following shall be substituted:

"Government of India' decision (1):- The position of library books, etc. is different from that of other stores. Accordingly, the following procedures shall be observed for purchase, write off, disposal of mutilated/damaged books and physical verification of books in the libraries attached to the various Departments/Offices:-

(i) Librarian (not below the rank of Deputy Secretary to the Govt. of India) subject to the powers delegated under Delegation of Financial Powers Rules, 1978, may purchase books etc. from the reputed and standard booksellers on the prevalent terms and conditions. Tenders need not be called for this purpose.

(ii) Loss of three volumes per one thousand volumes issued consulted in a year may be taken as reasonable provided such loss cannot be attributed to dishonesty or negligence on the part of Librarian. Loss of a book of the value exceeding Rs.200 (Rs. two hundred) and the books of special nature and rarity shall invariably be investigated and consequential action taken. All such losses will however be written off only by a competent authority.

(iii) Librarian who is of the rank not below Deputy Secretary to the Government of India or Head of the Department may write off the loss of volumes mentioned in the preceding paragraph provided the total value of all such books, etc. does not exceed the monetary limit prescribed in the Delegation in respect of deficiencies and depreciations in the value of stores (other than a motor vehicle or a motor cycle) included in the stock and other accounts. In the event of the total value exceeding the monetary limit specified above. The loss of books shall be written off by the competent authority as per Delegation of Financial Powers Rules 1978.

(iv) There may be no objection to the Librarian disposing of mutilated/damaged/obsolete volumes to the best interest of the Library. However, the disposal of such volumes should be made on the recommendations of a three member Committee to be appointed by the Administrative Ministry/ Department which shall decide whether the books mutilated/damaged/obsolete are not fit for further use.

(v) Complete annual physical verification of books should be done every year in the case of Libraries having not more than 20,000 volumes and not fewer than two library qualified staff. In case there is only one qualified staff the verification may be done as per sub-Para (vi).

(vi) Complete physical verification at intervals of not more than three years should be done in the case of libraries having more than 20,000 but not more than 50,000 volumes.

(vii) Sample physical verification at intervals of not more than five years may be done in the case of libraries having more than 50,000 volumes. If such a sample verification reveals unusual or unreasonable shortages, complete verification shall be done.

(viii) The verification should always be subject to surprise test check by some independent officers. The decision regarding the selection of the staff towhom this work may be entrusted, should be taken by the Administrative Ministries/Departments and Heads of Departments".

(Ministry of Finance O.M. No. 23(7)-E.II/83 dated 7-2-1984 and CAG's U.O.
No. 1964-TA.II/21-83 dated 23.12.83. Deptt. of Supplies U.O. No. I.D. No. PIII-3(5)/82 dated 17.1.83)

Reference: **The Federation of Publishers' & Booksellers' Associations in India,** *News Letter, Volume: 18 No. 18, April 2012 – June 2012.*

BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

SOP FOR SPORTS AND GYMNASIUM

PRINCIPAL

BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in, E-mail: office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

STANDARD OPERATING PROCEDURES FOR SPORTS & GYMNASIUM

Swimming Pool

Size of the Swimming Pool 50 Mtrs x 21mtrs (Standard Swimming Pool)

Swimming is the best form of exercise both voluntary and involuntary muscles are involved.

The plant operators ensure that the water level is maintained.

The plant operators ensure that the filtration plant is as per requirement.

Cleaning of water and suction of pool is done regularly.

Swimming coach and lifeguards supervise the swimmers.

Lifesaving equipment are kept ready.

There are dress changing room, toilets, bathrooms are available both for boys and girls.

Cleanliness is maintained in and around the pool.

Students attend the swimming pool in the Morning and evening,

Attender checks I.D. Card of the students.

GYMNASIUM

Gymnasium is derived from Greek 'Gymnasium' which means fitness centre, which is often an area for indoor recreation.

Purpose

- Better health.
- Better posture and balance.
- Improve heart function.
- Helps to lose weight.

- Gym facilities are separate for boys and girls.
- Gym trainer is appointed in the Gymnasium.
- Students attendance registers both for boys and girls are maintained.
- Gym timing 6 am to 8 am Morning and 5 pm to 8 pm Evening.
- The trainer ensures the hygiene and cleanliness is maintained in gym always.

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SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

List of Gym Materials available:

Boys Gymnasium Hall

1	5 kva servo stabilizer
2	5 kva servo voltage stabilizer wide range model 500 s
3	Co-ax preacher curl
4	Pec-deck 4x2 60 kg
5	Ab crunch hd 84
6	Seated rpw 4x2 60 kg
7	High lamp pully 4x2 (75 kg)
8	Adjustable simple bench
9	Stool dx
1	T bar machine
11	Dumbles bar threaded
12	Flat bench 4x2
13	Squat stand
14	Rowing handle (biceps & triceps
15	Treadmill hd 84
16	Hs weight plat stand
17	Bar bell 3'
18	Weight plat stand

19	Simple bench
20	Upright bike af 9.6
21	Multi stepper af 303
22	Treadmill dimmo nd 51 51 3 hp ac
23	Six station multi gym delu-x9+1
24	Upright bike
25	Medicine ball 3 kg
26	Multi bench 7107

Ladies Gymnasium Hall

1	5 station multi gym
2	Treadmill hd 84
3	Ab crunch hd 84
4	Fly bike hd
5	Heb dumbbells
6	Upright bike af 9.6
7	Multi stepper-af 303

Other Sports Facility

Outdoor activities for both Men and Women

1. Track and Field Events (Athletic events Men and Women)
   (100 M, 200M, 400M, 1500M, 5000M, Long Jump, High Jump, Shot put, 4x100M, 4x400M relay)
2. Throwball
3. Volleyball
4. Cricket
5. Football
6. Kho-Kho
7. Badminton
8. Basketball
9. Kabaddi

Indoor activities for both Men and Women

1. Chess
2. Table tennis
3. Carrom

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The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

SOP FOR MEDICAL RECORDS

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in, E-mail: office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

B.L.D.E

(Deemed to be University)

APEX MANUAL

DEPARTMENT OF MEDICAL RECORDS

SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARC CENTRE, (BLDEU, SBMPMC&RC)

VIJAYAPUR

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QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR DESTRUCTION OF MEDICAL RECORDS

Issue No – 01

Copy No- 01

Document No- 1		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College	
Prepared date:	01/01/2020	Amendment no :	00
Review date :	01/01/2021	Amendment Date :	–

AMENDMENT SHEET

Sl. No.	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority

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The authority over control of this manual is as follows:

Title	Preparation	Approval	Issuing authority
Sign			
Name	A.A.Kochi	Dr.Vijayakumar Kalyanappagol	A.A.Kochi
Designation	Medical Record Officer	Medical Superintendent	Medical Record Officer
Date	01/01/2020		01/01/2020

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10	Department of ENT	HOD Department of ENT
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12	Department of Chest & TB	HOD Department of Chest & TB
13	Department of Dermatology	HOD Department of Dermatology
14	Department of Psychiatric	HOD Department of Psychiatric
15	Department of Emergency Medicine	HOD Department of Emergency Medicine

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PROCEDURE FOR DESTRUCTION OF MEDICAL RECORDS

- Discussion with Medical Superintendent.
- Call for meeting of Medical records Department Committee.
- Discuss the destruction of documents for the specified period.
- Get the approval of committee members.
- Send the meeting proceeding to university for approval of destruction of documents.
- After approval from the university propagate to the public through print media specifying for any objection within the stipulated period.
- Destruction documents in the specified manner after the stipulated period expose.

Medical Superintendent

Document No- 01		Document Name – Quality Manual of Medical Record Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.	
Prepared date:	01/01/2020	Amendment no :	00
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APEX MANUAL

DEPARTMENT OF MEDICAL RECORDS

SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARC CENTRE, (BLDEU, SBMPMC&RC)

VIJAYAPUR

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QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR GIVING RECORD TO THE ELLIGIBLE PERSONS

Issue No – 02

Copy No- 01

Document No- 2		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : **Medical Record Officer** **Dept. of Medical Records** **BLDE (Deemed to be University)** **Shri B. M. Patil Medical College** **Hospital & R.C. VIJAYAPURA-586103.**		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared date:	01/01/2020	Amendment no :	00
Review date :	01/01/2021	Amendment Date :	–

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Designation	Medical Record Officer	Medical Superintendent	Medical Record Officer
Date	01/01/2020		01/01/2020

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5	Department of Surgery	HOD Department of Surgery 16/5/2020
6	Department of Orthopedic	HOD Department of Orthopedic 16/5/2020
7	Department of OBG	HOD Department of OBG 16/5/2020
8	Department of Paediatrics	HOD Department of Paediatrics 16/5/2020
9	Department of Ophthalmic	HOD Department of Ophthalmic 16/5/20
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13	Department of Dermatology	HOD Department of Dermatology 16/5/20
14	Department of Psychiatric	HOD Department of Psychiatric 16/5/2020
15	Department of Emergency Medicine	HOD Department of Emergency Medicine Vikas Patil 16/5/2020

THE MEDICAL RECORDS ARE GIVEN TO THE ELIGIBLE PERSON AND THE RULES THAT NEED TO BE FOLLOWED ARE.

Patient / Patient Relative

- For further patient treatment of patient.
- For Medical reimbursement.
- To avail Government facilities.
- Name of correction in Birth and Death registration.

Rules to follow to avail the above Documents

- Patient / Patient blood relative with Government identity card.
- Permission letter from medical superintendent.

Doctors / PG Students

- The previous medical documents required when the patient revisits the hospital for treatment.
- The Document is given if the patient requires it for the further treatment.
- On court order for witness the documents related for the patients should be given.
- The documents should be given to PG Students for thesis work.
- The documents should be given to the research work on diseases.
- The document taken by the above persons should return to Medical records Department in the specified period.

For the above request the documents are given only if the permission letter has be sign of related unit head and Medical Superintendent.

- Insurance / LIC.
- For Reimbursement if patient has life insurance.

Rules to be followed

- The Identify card belonging to the Insurance Company.
- Insurance policy bond.
- Patient / Patient Relative identify card.
- Medical Superintendent Permission letter.

Police / Judiciary Department

- Ifwound Certificate and X-Ray Reports are required for Police department, then the police officers should send application to the Medical Superintendent.
- If Judiciary department requires the documents related to patient then they need to send summons and get permission from Medical Superintendent.

Document No- 2		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : **Medical Record Officer** **Dept. of Medical Records** **BLDE (Deemed to be University)** **Shri B. M. Patil Medical College** **Hospital & R.C. VIJAYAPURA-586103.**		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
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APEX MANUAL

DEPARTMENT OF MEDICAL RECORDS

SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARC CENTRE, (BLDEU, SBMPMC&RC)

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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR MAINTAINING CONFIDENTIALITY, INTEGRITY, SECURITY OF RECORDS & DATA

Issue No – 03

Copy No- 01

Document No- 3		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : **Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.**		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared date:	01/01/2020	Amendment No :	00
Review date :	01/01/2021	Amendment Date :	:-

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Sl. No.	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority

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Title	Preparation	Approval	Issuing authority
Sign			
Name	A.A.Kochi	Dr.Vijayakumar Kalyanappagol	A.A.Kochi
Designation	Medical Record Officer	Medical Superintendent	Medical Record Officer
Date	01/01/2020		01/01/2020

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DOCUMENTED POLICIES AND PROCEDURES FOR MAINTAINING CONFIDENTIALITY, INTEGRITY AND SECURITY OF RECORDS, DATA AND INFORMATION

01) The confidential documents are kept in lockers under the custody of Medical Records Department Office.

02) All the confidential records viz.

A) MLC Case Papers. B) MLC Registers. C) PM Reports. D) Wound Certificates E) MTP Reports.

03) All the MLC case papers and MLC Register are kept in separate racks.

04) Any Document requested for will be issued only when requested duly signed by Medical Superintendent.

05) The issue of documents is entered in the issue register with the Name of doctor date and time.

06) The returned document is taken back and entered in the register duly verifying the documents and recording in the register.

07) The document is safely kept back in the lockers.

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Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijaykumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPURA-586103.	
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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR RETENSION OF MEDICAL RECORDS

Issue No – 04

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Document No- 4		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : **Medical Record Officer** **Dept. of Medical Records** **BLDE (Deemed to be University)** **Shri B. M. Patil Medical College** **Hospital & R.C. VIJAYAPURA-586103.**		Approved by Dr.Vijayakumar Kaiyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared date:	01/01/2020	Amendment no :	00
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BLDE (DEEMED TO BE UNIVERSITY) SHRI.B.M.PATIL MEDICAL,COLLEGE,HOSPITAL AND RESEARC CENTRE VIJAYAPUR-586103	DOC.NO 4	E/NABH/BLDE/14
	ISSUE NO.	01
	Rev. No.	00

POLICY AND PROCEDURE ON RETENTION OF MEDICAL RECORDS	Date	05/01/2020
	Page	Page /2

Document Name:	PROCEDURES FOR RETENTION TIME OF MEDICAL RECORDS,DATA AND INFORMATION
Document No :	E/NABH/BLDE (DU)/14
No of Pages :	07
Date Created :	05/01/2020
Date of Implementation :	04/01/2021
Prepared By :	Designation: Medical Record Officer Name: Shri.A.A.Kochi Signature:
Approved by :	Designation: Medical Superintendent Name: Dr.Vijayakumar.T.Kalyanappagol. Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103. Signature:
Responsibility of Updating	Designation: Medical Record Officer Name: Shri.A.A.Kochi
Date of Next Review and revision :	Signature 04/01/2021

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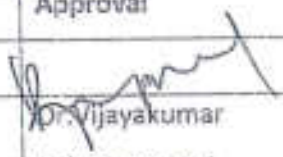
Sign			
Name	A.A.Kochi	Dr.Vijayakumar Kalyanappagol	A.A.Kochi
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	Rev. No.	00

POLICY AND PROCEDURE ON RETENTION OF MEDICAL RECORDS	Date	05/01/2020
	Page	Page /5

1. INTRODUCTION:

1.1. To meet the necessary guidelines and procedure as per the prevailing laws and Regulations on retention of medical records in hospital.

2. SCOPE:

2.1. Hospital Management
2.2. Health Care Providers
2.3. Patients
2.4. Government agencies

3. RESPONSIBILITY:

3.1. Director
3.2. Doctors
3.3. Medical records department

6. POLICY:

Procedure policy on **Retention time of records, data and information.**

Retention time of records, data and Information:

A Retention period of records (In hardcopy):

Retention period of medical records is done as per the requisite government policies

- Outpatient case sheets shall be maintained for a period of 5 years after the last visit
- Inpatient case sheets shall be maintained for a period of 7 years after the last visit
- MLC case sheets shall be retained lifelong or till the final judgment from the Supreme Court.
- Pediatric records till the time of child attains the age of 18 years
- Death records for a period of 10 years

- Hardcopy of Medical records which expires retention period are expected to be scanned and stored for future reference purpose.

6.1.1. B Retention period of records (In Electronic form):

- All medical records in electronic form are preserved permanently.
- If for any reason a electronic storage devise is been discarded which may have been used for any medical record storage, discarding will be done only after a mandated data deletion process, after which data cannot be recovered by a third party.

6.1.1. C Retention period of records as per specific Act or law:

- The provision of specific Acts like the pre –conception prenatal Diagnostic Test Act.1994 (PNDT), environmental Protection Act, etc.. Necessitate proper maintenance of record that have to be retained for periods as specified in the Act. Section 29th of the PNDT Act, 1994 requires that all the documents be maintained for a period of one year. The PNDT Rules, 1996 requires that when the records are maintained on a computer, a printed copy of the record should be preserved after authentication by the person responsible for such record.

The records which have crossed the retention period shall be selected and destroyed as per documented procedure.

A.A.Kochi
Medical Records Officer

Dr Vijayakumar Kalyanappagol
Medical Superintendent

Medical Superintendent
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & R.C., VIJAYAPUR-586103.

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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR RETENSION OF MEDICAL RECORDS

Issue No – 04

Copy No- 01

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Document Name :	PROCEDURES FOR RETENTION TIME OF MEDICAL RECORDS, DATA AND INFORMATION
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No. of Pages:	6
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Prepared By :	Designation: Quality Coordinator Name: Dr. Ashok S. Taradi Signature:
Approved By :	Designation: Medical Superintendent Name: Dr.Vijaykumar T.Kalaiyanappagol Signature:
Responsibility of Updating :	Designation: NABH Chief Coordinator Name: Dr. Ashok Taradi
Date of Next review & revision	Signature: 04/ 01/ 2021

Medical Superintendent
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
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Sr. No	Designation	Authority
1	Director	Approval
2	Nursing Head & Quality Coordinator	Preparation

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1. INTRODUCTION:

1.1

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2. SCOPE:

2.1 Hospital Management

2.2 Health Care Providers

2.3 Patients

2.4 Government agencies

3. RESPONSIBILITY:

3.1 Director

3.2 Doctors

3.3 Medical records department

4. ABBREVIATIONS:

NABH: National Accreditation Board for Hospitals and Healthcare Providers

IP: Indoor Patient

OP: Outdoor Patient

HMIS: Hospital Management Information System

5. REFERENCE:

NABH: Pre Accreditation Entry Level Standards for Hospitals —First Edition: April 2014

5.2 Office Memorandum — F.No.A.12034/3/2014-MH-II/MH-I, Directorate General of Health Services. Ministry of Health & Family Welfare, Govt. of India. Dated 28/10/2014

6. POLICY:

Procedure policy on **Retention time of records, data and information.**

Retention time of records, data and information:

A Retention period of records (In hardcopy):

Retention period of medical records is done as per the requisite government policies

- Outpatient case sheets shall be maintained for a period of 5 years after the last visit
- Inpatient case sheets shall be maintained for a period of 7 years after the last visit
- MLC case sheets shall be retained lifelong or till the final judgment from the Supreme Court.
- Pediatric records till the time of child attains the age of 18 years
- Death records for a period of 10 years

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	Issue No.	04
POLICY AT D PROCEDURES ON RETENTION oF MEDICAL RECORDS	Rev. No.	00
	nate	05/01/ 2020
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AMENDMENT SHEET

S.No.	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority

- Hard copy of medical records which are expires retention period are expected to be scanned and stored for future reference purpose.

6.1.1. B Retention period of records (In Electronic form):

- All medical records in electronic form are preserved permanently.
- If for any reason a electronic storage device is been discarded which may have been used for any medical record storage, discarding will be done only after a mandated data deletion process, after which data cannot be recovered by a 3rd party.

6.1.1. C Retention period of records as per specific Act or law:

- The provisions of specific Acts like the Pre-Conception Prenatal Diagnostic Test Act, 1994 (PNDT), Environmental Protection Act, etc. necessitate proper maintenance of records that have to be retained for periods as specified in the Act. Section 29 of the PNDT Act, 1994 requires that all the documents be maintained for a period of 1 year. The PNDT Rules, 1996 requires that when the records are maintained on a computer, a printed copy of the record should be preserved after authentication by the person responsible for such record.

The records which have crossed the retention period shall be selected and destroyed as per documented procedure.

A.Kochi
Medical Record Officer

Medical Record Officer
Dept. of Medical Records
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
spital & R.C. VIJAYAPURA-586103.

Dr.Vijayalaxmi Sidramappa Uppin
Medical Superintendent
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Hospital & R.C., VIJAYAPUR-586103.

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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR DESTRUCTION OF MEDICAL RECORDS

Issue No – 01

Copy No- 01

Document No- 1		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared date:	03/03/2020	Amendment no :	00
Review date :	01/01/2021	Amendment Date :	–

TABLE OF CONTENT

PROCEDURE FOR DESTRUCTION OF MEDICAL RECORDS

- Discussion with Medical Superintendent.
- Call for meeting of Medical records Department Committee.
- Discuss the destruction of documents for the specified period.
- Get the approval of committee members.
- Send the meeting proceeding to university for approval of destruction of documents.
- After approval from the university propagate to the public through print media specifying for any objection within the stipulated period.
- Destruction documents in the specified manner after the stipulated period expose.

Medical Superintendent.

Document No- 01		Document Name – Quality Manual of Medical Record Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical Colleg		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared date:	01/01/2020	Amendment no :	00
Review date :	01/01/2021	Amendment date :	–

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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR GIVING RECORD TO THE ELLIGIBLE PERSONS

Issue No – 02

Copy No- 01

Document No- 2		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPUR-586103.	
Prepared date :	01/01/2020	Amendment no :	00
Review date :	01/01/2021	Amendment Date :	–

TABLE OF CONTENT

THE MEDICAL RECORDS ARE GIVEN TO THE ELIGIBLE PERSON AND THE RULES THAT NEED TO BE FOLLOWED ARE.

Patient / Patient Relative

- For further patient treatment of patient.
- For Medical reimbursement.
- To avail Government facilities.
- Name of correction in Birth and Death registration.

Rules to follow to avail the above Documents

- Patient / Patient blood relative with Government identity card.
- Permission letter from medical superintendent.

Doctors / PG Students

- The previous medical documents required when the patient revisits the hospital for treatment.
- The Document is given if the patient requires it for the further treatment.
- On court order for witness the documents related for the patients should be given.
- The documents should be given to PG Students for thesis work.
- The documents should be given to the research work on diseases.
- The document taken by the above persons should return to Medical records Department in the specified period.

For the above request the documents are given only if the permission letter has be sign of related unit head and Medical Superintendent.

- Insurance / LIC.
- For Reimbursement if patient has life insurance.

Rules to be followed

- The Identify card belonging to the Insurance Company.
- Insurance policy bond.
- Patient / Patient Relative identify card.
- Medical Superintendent Permission letter.

Police / Judiciary Department

- If wound Certificate and X-Ray Reports are required for Police department, then the police officers should send application to the Medical Superintendent.
- If Judiciary department requires the documents related to patient then they need to send summons and get permission from Medical Superintendent.

Document No- 2		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
Prepared Date:	01/01/2020	Amendment no :	00
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HOSPITAL AND RESEARCH CENTRE VIJAYAPUR-586103

KARNATAKA- INDIA

QUALITY MANUAL

OF

DEPARTMENT OF MEDICAL RECORDS

SOP FOR MAINTAINING CONFIDENTIALITY, INTEGRITY, SECURITY OF RECORDS & DATA

Issue No – 03

Copy No- 01

Document No- 3		Document Name – Quality Manual of Medical Records Department	
Prepared and Revised by A.A.KOCHI Medical Record Officer SIGNATURE : Medical Record Officer Dept. of Medical Records BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C. VIJAYAPURA-586103.		Approved by Dr.Vijayakumar Kalyanappagol Medical Superintendent SIGNATURE : Medical Superintendent BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & R.C., VIJAYAPUR-586103.	
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SOP FOR LABORATORY

PRINCIPAL
BLDE (Deemed to be University)
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Standard Operating Procedures for Central Diagnostic Laboratory

1. **Purpose:**
   Describes the complete operation flow of the central laboratory of BLDE (DU) Hospital

2. **Scope**
   Scope of this procedure is limited Consultants, Residents Doctors, Interns, technicians,
   Laboratory Trainee other lab professionals.

3. **Procedure**

BLDE (DU) Medical College & Hospital's Central Laboratory is always on the wheel of continuous improvement. Efforts are seen in terms of quality, efficiency, reliability of patients on us, and the urge to satisfy our patient's needs.

3.1 24hrs emergency service

The lab provides 24 hrs. services to patients

3.1.2 Laboratory test services offered are:

BLDE (DU) Medical College & Hospital's Central Laboratory provides all types of routine and common specialized tests in

Haematology

Biochemistry & immunochemistry

Serology

Clinical pathology

Microbiology

Histopathology & cytology

3.1.3 Laboratory Test Guide (Directory of Services)

This Test Guide defines the essential procedures for the collection and transport of each specimen type. The information is specific for the analytical methods. It also provides brief information about our services, our facilities and quality programs.

BLDE (DU) Medical college and Hospital's Central Laboratory, Vijayapur, Karnataka			
QSP No: 01	**Laboratory operating procedure**		
Issue No: 02	Issue Date: 1.1.2017	Copy No:01	Page 1 of 11
Prepared by QM	Issued by QM	Approved by: Laboratory Director	

Specimen Collection and Handling provide general information on procedures necessary to obtain and submit proper samples and expanded collection information for selected tests.

Test Requisition Information provides instructions on the proper completion of a Quest.
Diagnostics test requisition.

General Test Listing includes specific specimen type and sample transport information for individual tests/profiles organized alphabetically.

Index By Test Name lists page numbers for tests organized alphabetically.

3.2 Quality Assurance: An Overview

As part of an extensive set of activities focused on quality, BLDE (DU) Laboratory has a formal Quality Assurance Program that monitors and evaluates the testing process's quality (pre-analytic, analytic, and post-

analytic). Quality test results and interpretation requires the engagement of the patient, the physician, the suppliers of test equipment and reagents, the information system, the laboratory, and everyone involved. To assure quality, standards are defined, work is conducted based on the standards, and performance measured and reported. The laboratory cannot deliver quality alone. You too are an integral part of this process that brings quality to every patient. Our goal is to give error-free performance by embracing quality standards.

3.3 Laboratory Team

BLDE (DU) Laboratory has a team of highly qualified and competent professionals headed by experienced management. We have high-quality human resources possessing vigour, expertise and skills. We conduct internal induction programs and training modules, which facilitate job- rotation and quick career growth.

Our dynamic, highly skilled and enthusiastic teamwork really hard to maintain excellence in the services we deliver. We are a highly motivated team, focused on ensuring that every engagement meets our patients' needs.

Our team promise is that individually, and together, we are -

- Accountable
- Committed
- A team Player
- Trustworthy
- Competent
- Customers Focused

3.4 Test Requisition Form

Completing the Request Form and Labelling the Specimen

For accurate identification of specimens and patients, specimens must be labelled properly, and that request forms are completed clearly and accurately. Upon receipt, in the laboratory, every specimen is checked to ensure it is suitable for processing. Discrepancies or omission of essential information may result in the

specimen not being analyzed. Up to date, Addressograph labels are acceptable on laboratory request forms.

To avoid processing delays or sample not being processed, please fill in samples and request forms with the following information.

Blood Science Request Form (Haem/Biochem) – Mandatory information highlighted
Patient's **FULL** name (First name and surname)
D.O.B. and/or hospital number
Patient's Gender
Patient's Address
Patient Consultant
Date of Specimen
Time of Specimen
Specimen Receiver's name and Sign
Tests Requested and Specific Clinical Information

3.5 Primary Sample Manual

This manual cover description and procedure of following

3.5.1 Specimen Collection – Phlebotomy Procedures:

- Guidelines for Phlebotomy:
- Instructions to patients
- Sample acceptance / Rejection criteria
- Sample processing
- **Reporting**

Specimens are processed upon receipt. Reporting times vary, depending upon the nature of the test, the analytical time required for the procedure and the method of reporting. Reports are delivered by facsimile, e-mail, or by the Postal Service. Critical priority (potentially imminently life-threatening) and STAT results are communicated by telephone as soon as they are available and are followed by written reports.

3.5.2 Biological Reference interval are available for the user to understand and compare results obtained for the specimen provided.

3.5.3 Confidentiality

BLDE (DU) laboratory is committed to protecting the confidentiality of individuals' private laboratory

test results and other personal information in compliance with all applicable laws and regulations

3.6 Quality Management System

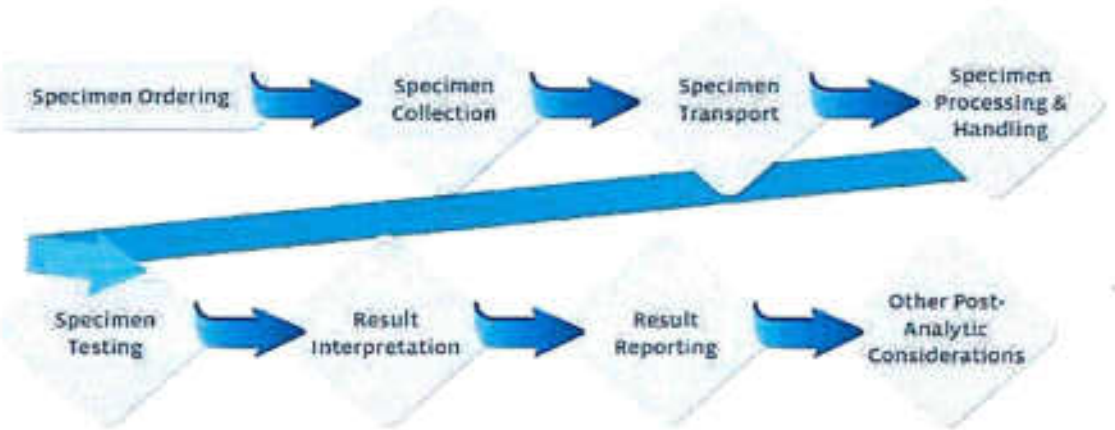
A quality management system is e defined as "coordinated activities to direct and control an organization concerning quality". This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI). Both groups are internationally recognized laboratory standards organizations. In a quality management
the system, all aspects of the laboratory operation, including the organizational structure, processes and procedures need to be addressed to assure quality.

There are many procedures and processes performed in the laboratory, and each of these
is carried out correctly to assure accuracy and reliability of testing. An error in any part of the cycle can produce a poor laboratory result. A method of detecting errors at each phase of testing is existing to assure the quality.

Work Phases of Laboratory

Laboratory processes are grouped into pre-examination, examination and post-examination categories. Comparable terms in current laboratory use include pre-analytic, analytic and post-analytic processes; or pre-test, test and post-test processes. The entire set of operations that occur in testing is called the path of workflow ow. The workflow path begins with the patient and ends in reporting and results in interpretation, as shown in the figure below. The concept of the workflow path is a key to the quality model or the quality management system and must be considered when developing quality practices.

The laboratory system's complexity requires that many factors must be addressed to assure quality in the laboratory. These factors include the laboratory environment quality control procedures communications record-keeping competent and knowledgeable staff, and good-quality reagents and equipment.



3.7 Laboratory SOP

Laboratories must have SOPs (written documents) that detail lab activities and procedures. The code allows a great deal of flexibility in the way the SOPs are designed, which leaves it up to the lab to decide. The SOPs may be in electronic form or hard copy.

The code requires that for each method being performed that the laboratory generates a specific analytical SOP. In addition to the analytical SOPs, the code requires that the lab document their procedures for at least 19 specific subjects. These 19 issues can be documented in separate SOPs, grouped in one SOP, or documented in the Quality Manual as long as they are all covered.

BLDE (DU) Medical Hospital's Central laboratory's requirements regarding laboratory SOPs is mainly broadly in two areas

General SOP (Quality System Procedures)

Technical Sops(SOPs for tests a parameters and equipment operation)

3.7.1 Quality System Procedures

Quality System Procedures are usually comprised of descriptions for the laboratory structure, responsibilities assigned to personnel, processes to follow so that workflows from one organization to another, step-by-step procedures used to conduct business in a consistent manner and resources to draw upon to do the best job possible. These procedures must be clearly documented so that all personnel can follow the steps.

3.7.2 Technical SOPS (Analytical)

Analytical SOPs are SOPs that describe exactly how the lab performs the method. There are generally three ways for the lab to create their own analytical SOPs.

Option 1: the analytical SOP may consist entirely of the referenced published analytical method. Keep in mind that this option will only work if the lab follows the method exactly (very unlikely).

Option 2: the lab may reference a published method and include an addendum that details exactly where the lab deviates from the published method. Note that when this option is used, the addendum must include a date of issue or revision date. Generally speaking, this option is considered the most practical approach for small wastewater laboratories.

Option 3: the lab may choose to create their own SOP from "scratch" . If this option is chosen the
code specifically requires that the SOP includes each of the following elements:

1. Identification of the test method

2. Applicable analytes

3. Applicable matrices

4. Method sensitivity

5. Potential interferences

6. Equipment and analytical instruments

7. Consumable supplies, reagents and standards

8. Sample preservation, storage and hold time

9. Quality control samples and frequency of their analysis

10. Calibration and standardization

11. Procedure for analysis

12. Data assessment and acceptance criteria for quality control measures

13. Corrective actions and contingencies for handling out of control or unacceptable data . Analytical SOPs created from "scratch" must include a date of issue or a date of revision These SOPs can be done in any format/style the lab chooses as long as all of the required elements are included and understandable.

Analytical SOPs can be kept in an "analytical methods manual" and can be included as part of the quality manual or kept as individual SOPs.

As with all other laboratory procedures, SOPs should be reviewed periodically to ensure that they remain current.

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STANDERD OPERATING PROCEDURE FOR BLOOD BANK

PRINCIPAL
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BLOOD BANK
STANDARD OPERATING PROCEDURE

Location	**SUBJECT**
Reception room	Duties of technician while entering Blood Bank **DISTRIBUTION** Reception room & master file

SCOPE & APPLICATION
This protocol guides the technicians regarding the work to be done before performing other Activities.

RESPONSIBILITY

It is the responsibility of the technicians.

PROCEDURE
1. Remove shoes and chapples and wear clean and dry slippers.
2. Check whether the floor is clean or not.
3. Signed in muster book.
4. Check the Digital temperature of Tested and Untested refrigerator as well as Thermograph.
5. Also check temperature of Reagent refrigerator and Incubators. Enter in respective registers.
6. Prepare pooled cells of A cells, B cells, and O cells.
7. Do the Quality control of reagents.
8. Then proceed for routine work e.g. grouping, cross matching, etc.
9. Daily blood Bag Stock should be checked and enter in Stock Register at 00.00 a.m.

END OF DOCUMENT

Number	**Effective Date**	**Pages**	**Prepared by**	**Authorized by**
	01/01/16	**1**	**Deepak Sawant**	
	Review Period	**No. of copies**		
SOP 01	5 Year	**2**	**Approved by** **Dr. Vijayalaxmi Patil**	**Dr. Prakash Patil**

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location	**Subject**
Registration and medical examination Room	Criteria for donor selection
Function	**Distribution**
Assessing suitability of donor for Blood donation	Medical officer in charge of donor area - Master File

1. SCOPE & APPLICATION

This SOP describes the criteria for a donor to be accepted for blood donation, for ensuring safety of donor as well as recipient. The purpose of donor selection is to identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently.

2. RESPONSIBILITY

The Medical Officer is responsible for determining the suitability of donor for blood donation. He/She should confirm that the criteria are fulfilled after evaluation of health history questionnaire and medical examination including the results of pre donation screening tests.

3. REFERENCES

(a) Transfusion Medicine Technical Manual Sponsored by WHO.
(b) Transfusion Medicine Technical Manual by R.K.Saran.

4. MATERIALS REQUIRED

- Donor Questionnaire
- Donor Card

5. PROCEDURE

1. CRITERIA FOR SELECTION OF BLOOD DONORS

A. Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled

The interval between blood donations should be no less than three months. The donor shall be in good health, mentally alert, and physically fit and shall not be a jail inmate, or a person having multiple sex partners or a drug addict.

The donors shall fulfill the following requirements, namely:-

(a) The donor should be in the age group of 18 to 60 years
(b) The donor's weight should not be less than 45 kg. for collection of 350 ml blood and 55 kg. for collection of 450 ml blood.
(c) Temperature and pulse of the donor should be normal
(d) The systolic and diastolic blood pressures should be within normal limits without medications.
(e) Hemoglobin should not be less than 12.5 g/dL
(f) The donor should be free from acute respiratory diseases.
(g) The donor should be free from any skin diseases at the site of phlebotomy
(h) The donor should be free from any disease transmissible by blood transfusion, in so far as can be determined by history and examination indicated above
(i) The arms and forearms of the donor should be free from skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics

B. Defer the donor for the period mentioned as indicated in the following table:

CONDITIONS	PERIOD OF DEFERMENT
(1)	(2)
(a) Abortion	6 Month
(b) History of blood transfusion	6 Month
(c) Surgery	12 Month
(d) Typhoid fever	12 Month after recovery
(e) History of Malaria duly treated	3 Months(endemic) 3 years (non endemic area)
(f) Tattoo	6 Months
(g) Breast feeding	12 Months after delivery
(h) Immunization (Cholera, Typhoid, Diphtheria, Tetanus, Plague ,Gamma globulin)	15 days
(i) Rabies Vaccination	1 year after vaccination
(j) Hepatitis in family or close contact	12 Months
(k) Hepatitis Immune globulin.	12 Months

C .**Defer the donor permanently if suffering from any of the following diseases:**

A) Cancer
B) Heart disease
C) Abnormal bleeding tendencies
D) Unexplained weight loss
E) Diabetes – controlled on insulin
F) Hepatitis B infection
G) Chronic nephritis
H) Signs and symptoms, suggestive of AIDS
I) it is important to ask donors if they have been engaged in any risk behavior.
J) Liver disease
K) Tuberculosis
L) Polycythemia Vera
M) Asthma
N) Epilepsy
O) Leprosy
P) Schizophrenia
Q) Endocrine disorders

D .Private interview:

A detailed sexual history should be taken

E. Informed consent:

Provide information regarding:

I) need for blood
II) Need for voluntary donation
III) Regarding transfusion transmissible infections
IV) Need for questionnaire & honest answers
V) Safety of blood donation
VI) How the donated blood is processed &used
VII) Tests carried out on donated blood

N.B. This gives the donor an opportunity to give his / her consent if they feel they are safe donors.

- Request the donors to sign on the donor card indicating that he is donating voluntarily.

6. DOCUMENTATION

Enter all details in the donor questionnaire form / card and computer.

7. END OF DOCUMENT

Number	Effective Date	Pages	Prepared by	Authorized by
	01/01/16	3	Deepak Sawant	
	Review Period	No. of copies	Approved by	Dr. Prakash Patil
SOP 02	5 Year	2	Dr. Vijayalaxmi Patil	

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BLOOD BANK

STANDARD OPERATING PROCEDURE

SCOPE & APPLICATION

Location Medical Examination Room **Function** Physical Examination of the Donor	**SUBJECT** Donors Screening **DISTRIBUTION** - Medical officer in charge of donor area - Master File

To perform a physical examination of the donor for confirming fulfillment of the criteria which ensure safety of the donor as well as the recipient?

1. RESPONSIBILITY

It is the responsibility of the medical officer to perform the physical examination of the donor.

2. REFERENCES

- Transfusion Medicine Technical Manual Sponsored by WHO.
- Transfusion Medicine Technical Manual by R.K.Saran.

3. MATERIALS REQUIRED

- Weighing scale
- Sphygmomanometer
- Clinical thermometer
- Calorimeter /Sahli's haemoglobinometer
- Lancet
- Donor card

PROCEDURE

Medical Examination:

- General Appearance : Defer a donor who appears ill, under the influence of Drugs/alcohol or do not appear to be providing reliable answers to medical history.
- Check and enter donor's WEIGHT. The weight should be >55kg. to collect 450 ml. And more than 45 kg's to collect 350 ml blood.
- Check if the BLOOD PRESSURE, PULSE AND TEMPERATURE are within The acceptable limits:
  - → Systolic blood pressure not > 180 mm of Hg.
  - → Diastolic pressure not > 100 mm of Hg.
  - → Pulse regular, between 60 and 100 beats / minute.
  - → Oral Temperature 37.5° C +/ - 0.2° C (98.6° F = / - 0.5° F).

- HAEMOGLOBIN ESTIMATION: Blood donation can be accepted only if the Hemoglobin is > 12.5 g/dl. Test for Hemoglobin by CuSO4 specific gravity Method.

DOCUMENTATION

Enter details in the donor card / computer.

6. END OF DOCUMENT

Number	**Effective Date** 01/01/16	**Pages** 1	**Prepared by**	**Authorized by**
SOP 03	**Review Period** 5Year	**No. of copies** 2	**Deepak Sawant** **Approved by** **Dr. Vijayalaxmi Patil**	**Dr. Prakash Patil**

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location Medical Examination Room **Function** Method of estimation of Donor's Hemoglobin by Drab kin's Method	**SUBJECT** Qualifying Test for Blood Donation **DISTRIBUTION** - Medical Examination room Master File

1. SCOPE & APPLICATION

To find a fit and healthy donor, assuring his or her safety.
This also helps in assuring the quality of the product.

2RESPONSIBILITY

It is the responsibility of the technician working in the donor area.

3REFERENCE

a. Transfusion Medicine Technical Manual Sponsored by WHO.
b. Transfusion Medicine Technical Manual by R.K.Saran.

4. MATERAIL REQUIRED

1. Colorimeter.
2. Sterile gauze/ cotton, spirit and sterile disposable lancets.
3. Containers with 1 % sodium hypochlorite solution for disposing sharp lancets. and biohazards MATERIALS.
4. Drabkins Solution.
5. Distilled water.
6. Cuvette
7. Micropipette (20Microlitre).
8. Tips.

PRINCIPLE:

This is based on conversion of Hemoglobin to Met hemoglobin & Met hemoglobin is converted in Cyanmethemoglobin .The absorbance of Cyanmethemoglobin is directly proportional to the hemoglobin concentration which is measured at 540 nm.

PROCEDURE

1. Take 5ml Drabkins Solution in a clean test tube.
2. Clean finger tip with antiseptic solution and puncture the skin with sterile disposable lancet.
3. Take 20µl of blood By Micro pipette.
4. Transfer it to Test tube containing Drabkins solution.
5. Mix well, wait for 5 min.
6. Take Drabkins solution in Cuvette & set zero on colorimeter at 540nm.
7. Take reading of donors sample on colorimeter.
8. Read the hemoglobin on the standard chart.
9. This is the value of Hb gm %

END OF DOCUMENT

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SOP 04	5Year	2		

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location	SUBJECT
Medical examination room **Function** Method of estimation of Donor's Hemoglobin by Copper Sulphate Method	Qualifying Test for Blood Donation **DISTRIBUTION** - Medical officer in charge of donor area for use by all Technicians in the area - Master File

SCOPE & APPLICATION

To find a fit and healthy donor, assuring his or her safety. This also helps in assuring the quality of the product.

RESPONSIBILITY

It is the responsibility of the technician working in the donor area.

REFERENCE

c. Transfusion Medicine Technical Manual Sponsored by WHO.
d. Transfusion Medicine Technical Manual by R.K.Saran.

MATERAIL REQUIRED

1. Copper Sulphate working solution with a specific gravity 1.053.
2. Sterile gauze/ cotton, spirit and sterile disposable lancets.
3. Containers with 1 % sodium hypochlorite solution for disposing sharp lancets and bio hazards MATERIALS.
4. Coupling jars with lid.

PROCEDURE

5.1 Principle:

This is qualitative test based on specific gravity. The drop of donor's blood Dropped in to Copper Sulphate solution becomes encased in a sac of copper Sulphate which prevents any change in the specific gravity for about 15 seconds if the hemoglobin is equal to or more than 12.5 gm /dl the drop will sink within 5 Seconds and the donor are accepted.

N.B: * Do not depend on Colour of tongue or conjunctiva.
* Accept a donor only if hemoglobin is > 12 .5g/dl

5.2 Method:

1. 30 ml copper Sulphate working solution (sp.gr.1.053) in a clean , dry coupling jar Is used for determining hemoglobin. The jar is kept covered with a lid when not In use .The working solution is changed after every 25 tests.
2. The fingertip is cleaned thoroughly with a spirit swab and allowed to dry.
3. The finger is punctured firmly near the tip with a sterile disposable lancet. A Good free flow of blood is ensured. The finger is not to be squeezed repeatedly Since it may dilute the drop of blood with excess tissue fluid and give false low Results.
4. Allow one drop of blood to fall gently from the Micropipette from a height of about 1 cm above the surface of the copper Sulphate solution, into the coupling jar.
5. The drop of blood is observed for 15 seconds.
6. The lancet and Micropipettes tips are disposed off in a container with 1% sodium Hypochlorite solution.

5.3 INTERPRETATION:

If the drop of blood sinks within 15 seconds (i.e. donors hemoglobin is more than 12.5gm/dl), the donor is accepted for blood donation.

1. However, if the blood drop sinks midway (i .e. hemoglobin level is less than 12.5gms / dl) and then comes up, the donor is deferred.
2. If the drop sinks slowly ,hesitates and then goes to the bottom of the jar Confirm the hemoglobin of this donor. By cell counter Machine.
3. If the donor fails the CuSO4 test repeat hemoglobin by Sahlis / Drabkins / Automated Cell Counter.

5.4 DOCUMENTATION

Enter the result on donor register.

END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Blood Collection room.	Blood collection
FUNCTION	**DISTRIBUTION**
Solution and method for preparing Phlebotomy site	- Medical Officer in charge of Donor Room for all phlebotomist - Master File

1. SCOPE AND APPLICATION

Cases of transmission of bacterial infection in blood are fortunately rare, but when they do occur can be fatal. Thus careful preparation of the skin of the phlebotomy site before venipuncture is very important.

2. RESPONSIBILITY

The phlebotomist collecting the blood unit from the donor is responsible for preparation of phlebotomy site.

3. REFERENCE

(i) Transfusion Medicine Technical Manual Sponsored by WHO.
(ii) Transfusion Medicine Technical Manual by R.K.Saran.

4. MATERIALS REQUIRED

. Sterilizing Tray
. Demethylated Spirit
. Povidone iodine.
.Tourniquet
. .Bandaid

4. PROCEDURE

After selection of the vein for venepuncture, apply spirit, povidone- iodine and finally spirit swab, in this order, to the skin at the phlebotomy site. Start disinfection of the skin of about an area of 5cm diameter from the centre to outwards in a circular motion. Scrub the povidone-iodine vigorously for at least 30 seconds or till forth forms. Do not touch the site prepared for venepuncture. Should it be necessary touch the skin away from the point of needle insertion. If the puncture site is touched repeat skin preparation procedure as detailed earlier.
Discreetly check the used swab. If it is physically soiled/ contaminated take a new swab and repeat skin preparation procedure as detailed earlier.
Dispose of used swab(s) into a waste bin meant for bio-hazardous MATERIALS. Allow the skin to air dry. Do not wipe the area with cotton wool, fan or blow on it.

6 .END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Blood Collection room	Blood collection
FUNCTION	**DISTRIBUTION**
Assessing suitability of donor for Blood donation	- Medical Officer in charge of Donor Room all phlebotomist - Master File

1. SCOPE AND APPLICATION

This describes a procedure for blood collection from the donor, using an aseptic method. Blood is collected in a sterile closed system bag with a single venepuncture. A correct performance of venepuncture is essential for the quality and safety of the blood donation. Successful venepuncture results not only in safe collection of a full unit of blood suitable for separation of components with good quality yields, but also contributes to the comfort and satisfaction of the donors thus encouraging re-attendance.

2. RESPONSIBILITY

The phlebotomist or doctor is responsible for blood collection from the donor after verifying the donor screening details. Checking the unit number, labels and preparing the phlebotomy site.

3. REFERENCE

(i) Transfusion Medicine Technical Manual Sponsored by WHO.
(ii) Transfusion Medicine Technical Manual by R.K.Saran.

5. MATERIALS REQUIRED

- Cotton/Gauze swabs
- Artery Forceps
- Pilot tubes: Plain
- Tourniquet
- Oxygen Cylinder with accessories
- Rubber Gloves
- First Aid Tray.(Emergency drugs.)
- Tubing Stripper
- Electronic Tube Sealer

- Needle Destroyer
- Blood collecting Bags
- Discard Jar with 10% Sodium Hypochlorite
- Artery Forceps, Scissors
- (adhesive) Tapes
- Comfortable donor couch or chair

6. PROCEDURE

(a) Make the donor lie down in a comfortable donor chair. Loosen tight garments.
(b) Identify the donor by name & bag No.
(c) Ask the donor if he/she is in a comfortable position. Give the donor a ball to hold.
(d) Select the venepuncture site
(e) Apply the tourniquet on donor arm.
(f) Start disinfection of the skin of about an area of 5cm diameter from the centre to outwards in a circular motion. Scrub the povidone-iodine vigorously for at least 30 seconds or till forth forms. Do not touch the site prepared for venepuncture. Should it be necessary touch the skin away from the point of needle insertion. If the puncture site is touched repeat skin preparation procedure as detailed earlier.
(g) Insert the blood bag needle into the vein for about 1 to 1.5 cms by a bold single prick to Ensure smooth flow of blood and secure on the arm with adhesive strips.
(h) Advise the donor to gently squeeze the boll to improve blood flow.
(i) Once 350 ml/450ml blood is collected clamp the bloodline at 2 sites and cut in the middle. Collect blood in the pilot tubes from the tubing so that blood flows directly into the tubes from the donor arm.
(J)Release the tourniquet and remove the needle gently from the donor's vein immediately keep swab and apply tight pressure on phlebotomy site.
(k)Seal the blood bag tubing with the tube sealer.
(l)Burn the needle of the bag in the needle incinerator. Discard the tubing with the burnt needle in a Container of sodium hypochlorite solution.

7. DOCUMENTATION

Make entries in the donor register

END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Blood Collection room **FUNCTION** Management of adverse reaction in a donor.	**SUBJECT** Blood collection **DISTRIBUTION** - Medical Officer in charge of Donor Room - for all phlebotomist - Master File

1. SCOPE AND APPLICATION

Any adverse reaction in the immediate post donation period needs to be attended to.

2. RESPONSIBILITY

The medical officer in attendance attendance is responsible for managing the adverse reaction in the donor.

3. REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R. K. Saran.

4. MATERIAL REQUIRED

Following material are required to attend to any emergency airing in the post Donation period.

I. Oral Medication

- Analgesic Tablets / Tab Ecosprin
- Calcium & Vitamin C tablets
- Electrolyte replacement fluid (Electoral)
- Glucocorticosteroid (Dextrose25%)
- Metoclopramide (Perinorm)

II Antiseptic.

- Benzoine
- Hydrogen Peroxide
- Sprit

III Injection.

- Epinephrine (Adrenaline)
- Atropine sulphate
- Pheniramine Maleate (Avil)

- Glucocorticosteroid (Dextrose 25%)
- Metoclopramie (perinorm)
- Prochlorperazine Maleate (Stemetil)
- Sodium Bicarbonate
- Glucose Saline (Sodium Chloride and Dextrose 500 ml)

IV Miscellaneous

- Bandages / Dressing
- Band-aids
- Anti Histamine (Anthisan) Cream
- Heparin and Benzyl Nicotniate (Hirudoid /Thrombophomb) ointment
- Tongue Depressor
- Disposable Syringes and needle 22G
- Clinical Thermometer
- Oxygen Cylinder
- Infusion Set
- Paper Bag.

MANAGEMENT OF ADVERSE REACTIONS

1. Giddiness / Syncope (vasovagal syndrome):

Raise feet and lower head end
Loosen tight clothing (belt, tie, etc)
Ensure adequate airway.
Check pulse and blood pressure
Apply cold compresses to forehead and back.
Administer inhalation of spirit of ammonia if needed. The donor should respond by coughing which will elevate the blood pressure.
If there is bradycardia and hypotension

- Administer inj. atropine 1 ml IM,

If bradycardia continues for more than 20 minutes.

- Administer IV normal saline or dextrose saline infusions if Hypotension is prolonged.

2. Convulsions:

Keep the head titled to the side; prevent the tongue bite, keep the airway by inserting a tongue blade or gauze between the teeth

3. Vomiting:

Usually this provides relief. If the donor feel nauseous or if vomiting is severe, inject stemetil. Usually subsides on its own.

4. Tatany / Muscular spasm/ Twitching:

These are usually due to hyperventilation in an apprehensive donor.
Ask the donor to breath in a Paper bag, which provides prompt relief. Do not give oxygen.

5. Haematoma:

Release the tourniquet / pressure cuff immediately.
Apply pressure on the venepuncture site and withdraw the needle from the vein. Raise the arm above the head for a few minutes. Apply Thrombophobe ointment around the phlebotomy site after about 5 minutes. Advise the donor to apply ice if there is pain and inform about the expected change in skin color.

6. Eczematous reactions of the skin around venipuncture site:

Apply steroid ointment.

7. Delayed syncope:

These may occur as late as 30 minutes to 1 hour after donation, usually after the donor has left the blood bank. Permanently defer any donor who gives history of such attacks more than twice.

8. END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Blood Collection room **FUNCTION** Post donation care	**SUBJECT** Blood collection **DISTRIBUTION** - Medical Officer in charge of Donor Room - for all phlebotomist - Master File

5. SCOPE AND APPLICATION

The donor needs to be observed after blood collection, in order to attend to any adverse reactions in the immediate post-donation period.

6. RESPONSIBILITY

The medical officer in attendance attends to the donor.

7. REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

8. MATERIAL REQUIRED

. Sterile Swabs
. Adhesive tape
. Thrombophobe ointment

5. PROCEDURE

a. To prevent adverse reaction like giddiness ask the donor not to get up from the chair/bed for 5 minutes if he feel perfectly all right.
b. Observe for another 10 minutes in the refreshment area whilst having coffee.
c. Inspect the venepuncture site before the donor leaves the donor room. Apply an adhesive tape only after oozing stops. If there is a persisting oozing at the site of venepuncture, apply pressure with a dry, sterile cotton swab. If there is haematoma apply Thrombophobe ointment gently over the area after 5 minutes. Inform the donor about the expected change in the skin Colour. If the pain persists ask him/her to apply ice.
d. Instruct the donor to drink adequate fluid in the days and avoid strenuous activities.

6. DOCUMENTATION

Record any adverse reaction on the donor card.

7. END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Blood Collection room **FUNCTION** Method of accurately relating product to Donor	Traceability of Blood Bags **DISTRIBUTION** - Medical Officer in charge of Donor area all phlebotomists - Master File

1. SCOPE & APPLICATION

To label the blood bags and pilot tubes after verification of donor details in order to accurately relate the blood product to the donor. The unit number label is the unique identifier for the donor and all the blood components separated from the unit collected from the donor.

2 RESPONSIBILITY

It is the responsibility of the phlebotomist collecting the blood units to ensure proper labeling and recording of the requisite details, even if the donor area attendant affixes the labels.

3. REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

4. PROCEDURE

- Give each donor a unique number and once his blood is collected, identify by that number only.
- Do not write donor's name on his / her blood bag or sample tube. This maintains the donor's confidentiality.
- Affix written number on the bag on both sides, the three pilot tubes (1 plain and One with CPD anticoagulant)
- Verify the donor's identity by tallying with the name on the master register.
- Cross check the numbers on the bag, pilot tubes and master register to ensure identify.
- Whilst issuing the unit, use the same number on issue card.

5. DOCUMENTATION

Make sure that the number is written clearly on all records and there is no transcription Errors, as this number will trace any product to the donor of the blood and vice versa in Case of requirement.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Red cell Serology lab. **FUNCTION** This is used for most of the blood banking procedure.	**SUBJECT** Preparation of 5% red cell suspension. **DISTRIBUTION** - Red cell Serology lab. - Master File

SCOPE & APPLICATION

To remove the unbound or atypical antibodies & for maintaining correct ratio of Antigen – Antibody reaction.

RESPONSIBILITY

It is the responsibility of technician.

REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

MATERIAL REQUIRED

1. Test tubes
2. Pasture pipettes
3. Ant coagulated fresh blood

PROCEDURE

1. Take the anticoagulated fresh blood in a clean test tube.
2. Add normal saline to cell suspension till the tube is ¾ th full. Mix & centrifuge at 1500 rpm for 2-3 min.
3. Discard the supernatant
4. Follow the wash procedure for three times.
5. Dilute the red cell concentrate with normal saline to a Tomato red color it will be your approximately 5% red cell suspension.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology lab.	Preparation of pooled red cell suspension.
FUNCTION	**DISTRIBUTION**
This is used for serum grouping.	- Red cell serology room. - Master File

SCOPE & APPLICATION

Pooled red cell suspension is used for serum grouping i.e. reverse grouping.

RESPONSIBILITY

It is the responsibility of technician.

REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

MATERIAL REQUIRED

1. Test tubes
2. Pasture pipettes
3. Fresh blood cells from 'A' 'B' & 'O' group at least 3 different individuals.

PROCEDURE

1. Take 3 test tubes & label as A, B, & O.
2. Add 1 ml of each three A, B, & O, blood samples to respective labeled test tubes
3. Mix these 3 samples of blood of A, B, & O, group separately.
4. Take 0.5 ml of cells from each tube (Group wise) & mix well.
5. Wash the cells with normal saline 3 times.
6. Dilute the red cell suspension with normal saline to get 5% 'TOMATO RED' suspension.
7. Test all these pooled cells with anti- A, anti-B, & anti-AB sera.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology lab **FUNCTION**	Blood Grouping **DISTRIBUTION**
Method of testing blood group by slide method.	- Red cell serology room. - Master File

SCOPE AND APPLICATION

This method is used for testing of blood group of donors and recipient.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of blood Group.

REFERENCE

Transfusion MedicineTechnical Manual Sponsored by WHO.
Transfusion MedicineTechnical Manual by R.K.Saran.

MATERIALS REQUIRED

1. Monoclonal anti-A, anti-B sera 2.Glass slides 3.Clean sticks

METHOD

1. The slide test may be performed on clean microscopic slide.
2. Put one drop anti-A serum and one drop of anti-B serum separately on the labeled slide.
3. Add one drop of whole blood of test sample to each drop of typing serum.
4. Mix the cells and reagent using a clean stick. Spread each mixture evenly on the slide over an area 15-mm-diameter.
5. Rock –rotate the slide and leave the test for 2 min at room temperature (20°-24 °C). Then rock again and look for agglutination.
6. Record the result.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Serology lab	Blood Grouping
FUNCTION	**DISTRIBUTION**
Method of testing blood group by tube method.	- Red cell serology room. - Master File

SCOPE AND APPLICATION

This method is used for testing of blood group of donors and recipient.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of blood Group.

REFERENCES

Transfusion MedicineTechnical Manual Sponsored by WHO.
Transfusion MedicineTechnical Manual by R.K.Saran.

MATERIALS REQUIRED

1. Monoclonal anti-A, anti-B sera, anti-AB sera
2. Glass test tubes
3. Centrifuge
4. Microscope

METHOD

Cell Grouping

1. Prepare an appropriate 5% cell suspension of test sample in normal saline.
2. Set up three rows of clean test tubes and label them. Add two volumes (2 drops) of anti-A in the tube labeled A, two volumes (2 drops) of Anti-B in tube labeled B and two volumes (2 drops) of anti-AB in tube Labeled AB.
3. Add one volume (1 drop) of 5% suspension of test sample in each Tube

4. Mix the contents of each tube by gently shaking and leave at room temperature (20°-24 °C) for 30-45 min. or spin after 5-10 min. (Spin method).

5. Observe the supernatant fluid for the presence of haemolysis against a well-lighted background.

6 Gently disperse the cell button and check for agglutination against a well-lighted background.

7. Where no agglutination is seen macroscopically, examine the Contents under the microscope.

8. Record the results immediately.

Reaction of test red cells with			group
Anti-A	Anti-B	Anti-AB	
+	+	+	AB
+	0	+	A
0	+	+	B
0	0	0	O

(+ = Agglutination. O= No Agglutination.)

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology lab **FUNCTION**	Blood Grouping **DISTRIBUTION**
Method of testing serum group by tube method.	-Red cell serology room. - Master File

SCOPE AND APPLICATION

This method is used for testing of blood group of donors and recipient.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of blood Group.

REFERENCES –

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED -

1. Monoclonal anti-A, anti-B sera, anti-AB serum
2. Glass test tube
3. Centrifuge
4. Microscope

METHOD

SERUM GROUPING

1. Use tube technique to test patients /donors serum against 5% saline Suspensions of pooled 2-3 samples of group A cells, B cells and O cells.
2. Label three tubes A cells, B cells and O cells.
3. Place two volumes (2 drops) of the test serum, in each tube.
4. Add one volume (1 drop) of A cells to tube labeled A, one volume(1 drop) of B cells to tube labeled
   Band one volume (1 drop) of O cells to tube labeled O.

5. Mix the contents of each tube by gentle shaking and leave at R.T. for 30 minutes.
6. Observe the supernatant fluid for the presence of haemolysis against well-lighted background.
7. Gently disperse the cell button and see for the agglutination.
8. All negative result must be examined under microscope.
9. Record the result immediately

SPIN TUBE METHOD

All steps are similar to the sedimentation technique except in step 4 of the above method, the serum and cell mixture is centrifuged after 5-10 mi Incubation at room temperature and see the results. It is very useful in urgent Cases.

TABLE: Record of the results (ABO grouping)

Reaction of serum with pooled cells			Interpretation (blood group of test cells)
A	B	O	
0	0	0	AB
0	+/H	0	A
+/H	0	0	B
+/H	+/H	0	O
+/H	+/H	+	Oh

+ = Agglutination; 0 = No agglutination; H = Haemolysis

GRADING OF AGGLUTINATION REACTION

+4 Single clump of agglutination with no free cells
+3 three or four individual clumps with few free cells
+2 Many fairly large clumps with many free cells
+1 Fine granular appearance visually, but definite small clumps (10-15 cells) per Low power field.
W 2 to 3 cells sticking together per low power field, uneven distribution.
O All cells are free.
+H Haemolysis (partial or total) must be interpreted as positive.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology lab	Blood Grouping
FUNCTION	**DISTRIBUTION**
Method of testing Rh typing by tube method.	-Red cell serology room - Master File

SCOPE AND APPLICATION

This method is used for testing of Rh typing of recipient and donor.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of Rh typing.

REFERENCES

Transfusion MedicineTechnical Manual Sponsor by WHO.
Transfusion MedicineTechnical Manual R.K.Saran.

MATERIALS REQUIRED

1. Test tubes
2. Centrifuge
3. Monoclonal Anti-D from two different manufacturer's labeled D1 &D2.
4. Rh (D) control cells.

METHOD

1. Place one drop of Anti-D serum in tubes labeled 'test' and in other two tube labeled 'controls'.
2. Place one drop of control D positive and D negative cells in tubes labeled controls.
3. Add one drop of 5% washed cell suspension in saline in each tube labeled test.
4. Mix well and incubate at 37°C, for 45 min (sedimentation method).
   In case of emergency incubate the tubes for 10 min at37 °C, and then centrifuge at 1000 rpm for 1 min (spin tube method).
5. Gently resuspend the cell button and observe for agglutination, all negative results must be confirmed under microscope.

INTERPRITATION

1. Agglutination in the tube test and in the tube positive control and the Smooth suspension of cells in the tubes negative control is interpreted as Test cells Rh (D) positive.
2. A smooth suspension of red cells in tubes of 'test' and negative 'controls' the test cells are Rh(D) negative. Agglutination in tube labeled positive Control.
3. Donors red cells found negative should be further tested by AHG test for Weak D (D^u).
4. If in any test 'negative control' gives agglutination, the results are invalid.

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
T.T.D.Room	Atypical Antibody Detection
FUNCTION	**DISTRIBUTION**
The Atypical Antibody Detection	- Serology lab - Technician - Master File

SCOPE AND APPLICATION

The Atypical Antibody Detection is done to determine the presence of Any unexpected antibodies in patient's serum / donor serum.

RESPONSIBILITY

It is the responsibility of technician.

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Test Tubes.
2. Normal saline
3. Recipient's cells.
4. Anti Human Globulin (AHG)
5. Centrifuge.
6. Microscope.
7. Glass slide.

PROCEDURE

1. Add two drops of test serum in a test tube labeled as T.
2. Add 1 drop of 5% suspension of the pooled O Rh positive red cells in the tube
3. Incubate the tube for 37°C at 30 min.
4. Centrifuge at 1000 rpm for 1 min.
5. Examine for haemolysis / agglutination. Agglutination at this stage indicates the Presence of saline (complete) antibodies.
6. If no agglutination is seen, wash cells 3-4 times in a large volume of saline. Decant the Supernatant in each wash as completely as possible.

7. Add 2 drop of AHG serum to the cells.
8. Mix and centrifuge at 1000 rpm for 1 min. immediately.
9. Gently shake the tubes to dislodge the button & examine for agglutination. Record the results.
10. Add 1 drop of IgG coated red cells to any test that is negative. Mix & centrifuge at 1000 RPM for 1min. look for agglutination. If there is no agglutination, the test is invalid & the Whole test is repeated. If agglutination is obtained the result is valid.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Serology lab	Major Cross Match
FUNCTION	**DISTRIBUTION**
Assessing the suitability of blood bag for transfusion to a particular recipient having same ABO group without any untoward effects.	- Technician - Master File

SCOPE AND APPLICATION

This method is used to ensure that particular unit of blood may be safely transfused to a patient.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of Cross match.

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Recipient's serum
2. Donor's red cells taken from the segment attached to the bag.
3. Test tubes
4. Saline.
5. Anti Human Globulin serum.
6. Microscope.

METHOD

Saline technique is designed to detect compatibility of Ig M antibodies in patient's serum against antigens on donor's red cells.

Saline technique

1. Label 1 tube for each donor sample to be tested.
2. Put 2 drops of patient's serum in labeled tube.
3. Add 1 drop of 5 % saline suspended red cells of donor.
4. Mix and incubate for 5-10 min. (spin method) at R.T.
5. Centrifuge at 1000rpm for 1min. in spin method (after 5-10 min. incubation)
6. Read the result, observe for haemolysis and agglutination.

7. Negative result should be confirmed under microscope.

INTERPRETATION

Agglutination or haemolysis indicates a positive result (incompatible)

COMPATIBILITY TEST for IgG Antibodies

Anti-Human Globulin Test (IAT)

Indirect antihuman globulin test (IAT) is the most important and widely used serological procedure in modern blood banking to test the IgG compatibility between recipient's serum and donor's cells. The Majority of incomplete antibodies is IgG and is detected by AHG test.

METHOD

1. Put 2 drops of patient's serum in a labeled tube.
2. Add 1 drop of 5% saline suspended red cells of donor.
3. Incubate for 30-45 min. at 37°C
4. Centrifuge at 1000 RPM for 1 min, check for haemolysis /agglutination.
5. If there is no haemolysis /agglutination, wash the cells three times with normal saline.
6. Perform IAT test.
   - Add 2 drops of polyspecific AHG serum to washed cells
   - Centrifuge at 1000 RPM for 1 minute
   - See for agglutination
7. Add IgG coated red cells to negative AHG test.
8. Centrifuge and check for agglutination – if there is no agglutination test is Invalid.

INTERPRETATION

Haemolysis or agglutination at any stage indicates incompatibility.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Serology lab **FUNCTION** Assessing the suitability of blood bag for transfusion to a particular recipient having same ABO group without any untoward effects.	**SUBJECT** Minor Cross Match **DISTRIBUTION** - Technician - Master File

SCOPE AND APPLICATION

This method is used to ensure that particular unit of blood may be safely transfused to a patient.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of Cross match.

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Recipient's cells
2. Donor's serum taken from the segment attached to the bag.
3. Test tubes
4. Saline.
5. Anti Human Globulin serum.
6. Microscope.

METHOD

Saline technique is designed to detect compatibility of Ig M antibodies in donor's serum against Antigens on patient's red cells.

Saline technique

1. Label 1 tube for each donor sample to be tested.
2. Put 2 drops of donor's serum in labeled tube.
3. Add 1 drop of 5 % saline suspended red cells of patient.

4. Mix and incubate for 5-10 min. (spin method) at R.T.
5. Centrifuge at 1000 RPM for 1min. in spin method (after 5-10 min. incubation).
6. Read the result, observes for haemolysis and agglutination.
7. Negative result should be confirmed under microscope.

INTERPRETATION

Agglutination or haemolysis indicates a positive result (incompatible)

COMPATIBILITY TEST for IgG Antibodies

Anti-Human Globulin Test (IAT)

Indirect antihuman globulin test (IAT) is the most important and widely used serological procedure in modern blood banking to test the IgG compatibility between donor's serum and patient's cells. The majorities of incomplete antibodies are IgG and are detected by AHG test.

METHOD

1. Put 2 drops of donor's serum in a labeled tube.
2. Add 1 drop of 5 % saline suspended red cells of patient.
3. Incubate for 30-45 min. at 37°C
4. Centrifuge at 1000 RPM for 1 min, check for haemolysis /agglutination.
5. If there is no haemolysis /agglutination, wash the cells three times with normal saline.
6. Perform IAT test.
   - Add 2 drops of polyspecific AHG serum to washed cells
   - Centrifuge at 1000 rpm for 1 minute
   - See for agglutination
7. Add IgG coated red cells to negative AHG test.
8. Centrifuge and check for agglutination – if there is no agglutination test is invalid.

INTERPRETATION

Haemolysis or agglutination at any stage indicates incompatibility.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red Cell Serology lab	Direct Coomb's Test
FUNCTION	**DISTRIBUTION**
The direct antiglobulin test (DAT) detects sensitized red cells with IgG	- Serology lab - Technician - Master File

SCOPE AND APPLICATION

The direct antiglobulin test (DAT) detect sensitized red cells with IgG

RESPONSIBILITY

It is the responsibility of technician.

REFERENCES

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

MATERIALS REQUIRED

1. Test Tubes.
2. Normal saline
3. Recipient's cells.
4. Anti Human Globulin (AHG)
5. Centrifuge.
6. Microscope.
7. Glass slide.

PROCEDURE

1. Label three test tubes as T (test serum) PC (positive control) and NC (Negative control).
2. Positive control – 1 drop Rh positive cells +1 drop anti D. Negative control- 1 drop Rh positive cells +1 drop of Bovine albumin.
3. Take 2-3 drops of blood to be tested in a clean labeled tube.
4. Wash the red cells 3-4 times in a large volume of saline to remove free globulin molecules. Remove all supernatant after each wash. Completely decant the final supernatant wash.
5. Add 2 drops of polyspecific AHG serum in 1 drop of washed red cells.
6. Mix, Centrifuge at 1000 rpm for 1 minute immediately.
7. Gently shake the tube to dislodge the cell button and see for agglutination.
8. Record the results.

9. Add 1 drop of IgG coated red cells to negative test. Mix, centrifuge at 1000 rpm for 1 min. immediately look for agglutination. If negative result (no agglutination) is obtained the test result is invalid and whole test should be repeated. If agglutination is obtained, the result is valid.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red Cell Serology lab	Indirect Coomb's Test
FUNCTION	**DISTRIBUTION**
The Indirect antiglobulin test (IAT) is done to determine the presence of sensitization of red cells with IgG	- Serology lab - Technician - Master File

SCOPE AND APPLICATION

The Indirect antiglobulin test (IAT) is done to determine the presence of Sensitization of red cells with in IgG.

RESPONSIBILITY

It is the responsibility of technician.

REFERENCES

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

MATERIALS REQUIRED

1. Test Tubes.
2. Normal saline
3. Recipient's cells.
4. Anti Human Globulin (AHG)
5. Centrifuge.
6. Microscope.
7. Glass slide.

PROCEDURE

1. Label three test tubes as T (test serum) PC (positive control) & NC (negative control)
2. In the tube labeled as T add two drops of test serum.
3. In the tube labeled as PC add two drops of Anti D serum.
4. In the tube labeled as NC add two drops of Bovine Serum albumin.
5. Add 1 drop of 5% suspension of the pooled O Rh positive red in each Tubes'
6. Incubate all three tubes for 37°C at 30 -45 min.
7. Wash cells three times in large volume of saline. Decant supernatant in each wash as

Completely as possible.

8. Add 2 drop of AHG serum to each tubes.
9. Mix and centrifuge at 1000 RPM for 1 min.
10. Gently shake the tubes to dislodge the button & examine for agglutination.
11. Add one drop of IgG coated red cells to negative test. Mix & centrifuge at 100 Rpm for 1 min.

12 Look for agglutination. If there is no agglutination, the test result is invalid & the whole test is repeated. If agglutination is obtained the result is valid.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Camp site to Blood Bank	Storage of blood bags during transportation
FUNCTION	**DISTRIBUTION**
Maintaining the temperature of blood bags at 2-6°C during transportation.	- Technician - Master File

SCOPE AND APPLICATION

Maintaining the temperature of blood bags at 2-6°C during transportation for preserving the viability of cells.

RESPONSIBILITY

It is the responsibility of all the blood bank staff attending the blood donation camp.

REFERENCES

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

MATERIAL REQUIRED

1. Cold box
2. Ice
3. Thermometer

PROCEDURE

1. After collecting the required quantity of blood, the unit is wrapped in a plastic bag.
2. The units are kept in vertical position in the cold box.
3. A layer of small pieces of ice is put on blood units
4. The thermometer is kept in the cold box
5. The temperature is observed frequently.

After transportation, at the receiving end the blood units are cleaned with clean towel & checked for any signs of deterioration or Haemolysis & also looked for any of the following.

- Leakage or breakage.
- Any change in colour of plasma.
- Any clots or abnormal mass.

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
TTD LAB	TTD TESTING
FUNCTION Assessing suitability of blood bag for transfusion & for detection of antibodies to HIV 1/2.	**DISTRIBUTION** - TTD Lab - Master File

Q UALISA HIV 1 /2

Principle: -

Microwell strips arecoated with synthetic peptides gp120,gp41,and gp36 representing both HIV-1 and HIV-2. Diluted samples along withpositive and negative controls are added in the coated wells and incubated. The wells are washed to remove to remove unbound compounds and goat antihuman IgG conjugated to horseradish peroxide (HRPO) is added. After a short incubation the wells are washed again and bound enzyme is detected by adding substrate. The reaction is stopped after specified time with with acid and absorbence is determined for each well at 450nm with an ELISA reader. The cut-off value is calculated by the given formula and absorbence of all the wells are compared with the cut-off value. Any sample havingabsorbence more than the cut-off value is considered reactive.

Specimen: Serum or plasma may be used for the test.

Material & instrument required:

1. Micropipettes & disposable tips.
2. Micro wells with reagents.
3. Hand gloves
4. Timer
5. ELISA washer
6. ELISA Reader
7. Incubator 37^0c
8. Tissue paper
9. D/W
10. Qualisa HIV 1 and HIV 2 kit

Procedure:

1. Bring all the reagents & test specimens at R.T. before use.
2. Take out required number of strips and remaining strips put immediately in pouch and close the pouch.
2. Add 200µl sample diluents to all micro wells.
3. Then add 10µl negative controls in A-1 & B-1 Wells. Add 10µl of positive control in C-1 & D-1 wells. Add test specimens to the Respective wells starting from E-1 wells.
4. Gently shake the plate to mix thoroughly. Cover the plate with cover sealer & incubate 30 min at 22-28^{0}c.
5. Prepare required amount of Conjugate solution by diluting Conjugate concentrate in conjugate diluent (e.g. for one strip add 20 µl enzyme Conjugate concentrates in to 980 µl conjugate diluent)
6. Aspirate the contents from all the wells & wash six times with 350µl of diluted washing solution.
7. Add 100µl of prepared conjugate to each well. Cover the plate with cover sealer & Incubate 30min at 22-28^{0}c.
8. After incubation. Aspirate the contents from all the wells & wash six times with 350µl of diluted washing solution
9. Add 100 µl of substrate solution and incubate at 22-28^{0}c. away from light. for 30 minutes.
10. After incubation add 100µl stop solution to each well & mix well.
11. Read absorbance at 450nm or 450/650nm within 30 minutes.
12. Write all results in respective register. Dually signed by B.T.O.

Calculation for cut-off value determination:

- **Positive control**: Average absorbance of all positive control should be greater than or equal to 0.1
- **Negative control**: Average absorbance of all negative control should be less than or equal to 0.1
- **Cut-off value formula** : NCx + 0.2

Interpretation of the result:

- **Non-reactive:** If the absorbance of the test serum is less than the cut-off value, then the sample is considered as non-reactive.
- **Reactive:** If the absorbance of the test serum is equal to or greater than the cut-off value, then it is considered as initial reactive. The absorbance value within grey zone should be retested. Retest results are less than cut-off value, and then the specimen is considered as non-reactive. If both of duplicate retest results are found reactive, then the specimen is considered as repeatedly reactive.

Reference: Qualisa HIV -1/2 ELISA Kit

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION TTD LAB **FUNCTION** Assessing suitability of blood bag for transfusion & detection of antibodies to Hepatitis B.	**SUBJECT** TTD TESTING **DISTRIBUTION** - TTD Lab - Master File

Qualisa HBsAg

PRINCIPLE:

Microwell strips are coated with monoclonal anti-HBsAg antibody. A polyclonal antibody to HBsAg is conjugated to horseradish peroxide (HRPO).The sample and the conjugate are added in the coated wells and incubated simultaneously. The wells are washed and unbound component s. Bound enzyme is detected by adding substrate.The reaction is stopped after specified time with with acid and absorbence is determined for each well at 450nm with an ELISA reader. The cut-off value is calculated by the given formula and absorbence of all the wells are compared with the cut-off value. Any sample having absorbance more than the cut-off value is considered reactive.

Specimen: Serum or plasma may be used for the test.

Materials and instruments required:

1. Distilled water.
2. Micropipette & micro tips.
3. Tissue paper
4. Timer
5. Incubator
6. Elisa Reader
7. Elisa washer
8. Disposable gloves
9. Sodium hypochlorite solution as disinfectant
10. Qualisa HBsAg kit

Test procedure:

1. Bring all the reagents & test specimens at R.T. before use.
2. Take out required number of strips and remaining strips put immediately in pouch and close the pouch.
3. Prepare required amount of Conjugate solution by diluting Conjugate activator in conjugate (e.g. for one strip add 10 µl Conjugate activator in to 500 µl conjugate).
4. Add 50µl of activated conjugate in all micro wells.
5. Then add 100µl negative controls in A-1 & B-1 Wells. Add 100µl of positive control in C-1 & D-1 wells. Add 100µl test specimens to the Respective wells starting from E-1 wells.
6. Apply plate sealer and incubate Cover the plate with black cover & incubate for 60min. at 37 ^{0}c.
7. Aspirate the contents from all the wells & wash six times with 350µl of diluted washing solution. Tap the micro plate on tissue paper.
8. Add 100 µl of Substrate to each well. Cover the plate with cover sealer & incubate for 30 Min. in dark at R.T.
10. At the end of incubation, take the plate from dark, remove the cover sealer and stop the reaction by adding 100 µl of stop solution to each well, mix gently
11. Read absorbance at 450nm within 30 mins.
12. Write all results in respective register. Dually signed by B.T.O.

Calculations of results:

Negative control mean (NCx) should be less than 0.1
Positive control mean (PCx) should be greater than 1.0

Cut of value:

Cut of value = NCx + 0.1

Interpretation of result:

- **Negative:** If the absorbance of the test serum is less than the cut-off value, then the sample is considered as Negative.
- **Positive:** If the absorbance of the test serum is equal to or greater than the cut-off value, then it is considered as initial Positive. The absorbance value within grey zone should be retested. Retest results are less than cut-off value, and then the specimen is considered as Negative. If both of duplicate retest results are found positive, then the specimen is considered as repeatedly positive.

Reference: Instructions manual Qualisa HBsAg

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	SUBJECT
TTD LAB	TTD TESTING
FUNCTION Assessing suitability of blood bag for transfusion & for detection of antibodies to HCV	**DISTRIBUTION** - TTD Lab - Master File

Qualisa HCV

Principle: -

Microwell strips are coated with synthetic peptides representing core, NS3,NS4 and NS5 antigens. Samples along with positive and negative controls are added in the coated wells and incubated. The walls are washed to remove unbound components and goat antihuman IgG conjugated to horseradish peroxide is added. After incubation the walls are washed again and bound enzyme is detected by adding substrate. The reaction is stopped after specified time with acid and absorbence is determined for each well at 450nm with an ELISA reader. The cut-off value is calculated by the given formula and absorbence of all the wells are compared with the cut- off value. Any sample having absorbance more than the cut-off value is considered reactive.

Specimen: Serum or plasma can be used for the test.

Material & instrument required:

1. Micropipettes & disposable tips.
2. Micro wells with reagents.
3. Hand gloves
4. Timer
5. ELISA washer
6. ELISA Reader
7. Incubator 37^0c
8. Tissue paper
9. D/W
10. HCV Qualisa kit

Procedure:

1. Bring all the reagents & test specimens at R.T. before use.
2. Take out required number of strips and remaining strips put immediately in pouch and close the pouch.

3. Add 200µl sample diluents to all micro wells.
4. Then add 10µl negative controls in A-1 & B-1 Wells. Add 10µl of positive control in C-1 & D-1 wells. Add test specimens to the Respective wells starting from E-1 wells.
5. Gently shake the plate to mix thoroughly. Cover the plate with cover sealer & incubate 30 min at 22-28^{0}c.
6. Prepare required amount of Conjugate solution by diluting Conjugate concentrate in conjugate diluent (e.g. for one strip add 20 µl enzyme Conjugate concentrates in to 980 µl conjugate diluent)
7. Aspirate the contents from all the wells & wash six times with 350µl of diluted washing solution.
8. Add 100µl of prepared conjugate to each well. Cover the plate with cover sealer & Incubate 30min at 22-28^{0}c.
9. After incubation. Aspirate the contents from all the wells & wash six times with 350µl of diluted washing solution
10. Add 100 µl of substrate solution and incubate at 22-28^{0}c. away from light. for 30 minutes.
11. After incubation add 100µl stop solution to each well & mix well.
12. Read absorbance at 450nm or 450/650nm within 30 minutes.
13. Write all results in respective register. Dually signed by B.T.O.

Calculation for cut-off value determination:

- **Positive control**: Positive control mean should be greater than 1.0

  Negative control: Negative control mean (NCx) should less than 0.1

- **Cut-off value formula: NCx + 0.3**

Interpretation of the result:

- **Negative:** If the absorbance of the test serum is less than the cut-off value, then the sample is considered as negative.

- **Positive** If the absorbency of the test serum is equal or greater than the cut-off value, then it is considered as initial positive. The absorbance value within grey zone should be retested. Retest results are less than cut-off value, and then the specimen is considered as negative. If one of the duplicate retest results is found positive, then the specimen is considered as repeatedly positive.

Reference: Qualisa HCV ELISA Kit)

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION TTD LAB **FUNCTION** Assessing suitability of Blood Bag for transfusion & providing guidelines for detection of syphilis antibodies.	**SUBJECT** TTD TESTING **DISTRIBUTION** -TTD ROOM - Master File

V.D.R.L. (R.P.R. Test)

Principle:

RPR test in which the antigens coated with carbon particle are react with antibodies present in sample forming visible black floccules due to aggression of carbon particals. If sample does not contain the antibody then there will not be any flocculation.

Responsibility: Technician

Reference: - Instructions manual R.P.R.Test Beacon for V.D.R.L.

Specimen: Fresh serum or plasma should be used for testing.

Material:

1. R.P.R. Antigen with the positive & negative control.
2. Disposable slide with eight reaction circle
3. Disposing pipette
4. Mixing stocks
5. Rubber teat
6. Rotary shaker with timer

Procedure :

1 Pipette one drop of the test specimen(50µl), positive & negative control on to separate reaction circles of the disposable slide using a sample dispensing pipette.
2 After gently mixing R.P.R. antigen suspension place drop (15-20µl)by antigen dropper.
3 Using a mixing stick, mix the test specimen & R.P.R. reagent thoroughly spreading uniformly over the entire reaction circle.
4 The slide is put on the rotary shaker & shaked for 6 minutes.
5 Observe the flocculation macroscopically.

Interpretation :

1. Large & medium black floccules against white background: Reactive.
2. No floccules; even grey background: Non- reactive.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology Lab	Quality control
FUNCTION	**DISTRIBUTION** Red cell Serology Lab Master File

Quality Control of ABO Antisera

Parameter	Quality requirement	Frequency of testing
Gross appearance	No turbidity, precipitate particles, or gel formation on visual examination	Daily
Specificity	Clear cut reaction with red cells having corresponding antigens & no reaction with negative control.	Daily
Avidity	Macroscopic agglutination with 50% red cell suspension in homologous saline using slide test. (10 seconds for Anti A, Anti B, & anti AB with A1& or B cells at R.T.& 20seconds with A2 & A2B cells.	Daily & every new lot no.
Reactivity	No immune haemolysis, Rouleaux formation orprozone	Each new lot.
Potency	Undiluted serum should give +++ /C reaction in saline tube test using a 3% red cell suspension at R.T. Titre should be at least 128 for Anti A, Anti B, & Anti AB with A1 & or B cells 64 with A2 & A2B cells.	Each new lot.

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology Lab	Quality control
FUNCTION	**DISTRIBUTION** - Red cell Serology Lab - Master File

Quality control of Rh (D) regents

Parameter	Quality requirement	Frequency of testing
Gross	No contamination, change in appearance, colour, turbidity, particles or gel formation on visual examination.	Daily
Specificity for anti-D	Clear cut reaction with $O+^{ve}$ cells & no reaction with O^{-ve} cells.	Daily & every new lot no.
Avidity	Time of start of visual agglutination in slide test with 40% red cells .	Daily & every new lot no.
Reactivity	No immune haemolysis, rouleaux formation or prozone phenomenon.	Each new lot.
Potency	Titre of antisera, anti-C, anti-c, anti-D, anti-E, & anti-e with corresponding cells, 3+ to 4+ reaction in undiluted antiserum.	Daily & every new lot no.

Anti D v/s R1r cells	Avidity spin	Intensity	1 min Test	Titer spin tube 15 min. - R.T.
1. IgM Monoclonal	5-10sec.	+++	++++	1:64 - 1:128
2. IgM+ IgG Monoclonal Blended	10-20sec.	+++	++++	1:32 - 1:64
3. Potentiated Polyclonal Anti-D	60sec.	+++	++++	1:32 (at 37°c)

ACCEPTABLE ACTIVITY, INTENSITY AND TITER OF ANTI-D.

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology Lab	Quality control
FUNCTION	**DISTRIBUTION** -Red cell Serology Lab - Master File

Quality control of Anti-globulin (AHG) reagent:

Procedure	Quality Requirements	Frequency of Control
Appearance	No precipitate, particles or gel formation by visual inspection	Each Day
Reactivity & specify	a. No Prozone Phenomenon.	Each new lot
	b. No Hemolytic activity, no agglutination of unsensitised	Each new lot
	c. red cells of any ABO group.	Each new lot
	d. Agglutination or red cells sensitized with anti-D serum containing not more than 0.2 mg/ml antibody activity.	Each day
	e. Agglutination of red cells sensitized with a complement binding antibody.	Each new lot
	f. Agglutination of red cells coated with c3b & c3d & no / or weak agglutination with C4 coated red cells	Each new lot
	Minimum requirement for quality product of AHG are :- Anti IgG :- 1: 64 Anti C3/ C4 :- 1:4	

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology Lab	Quality control
FUNCTION	**DISTRIBUTION** Red cell Serology Lab Master File

Titre & Avidity of ABO reagents

Antisera	Type of the reagent	Type of red cells	Titre	Avidity time	Intensity
Anti A	Monoclonal	A1	1:256	3-4 sec.	+++
		A2	1: 128	5-6 sec.	++ to +++
		A2B	1: 64	5-6 sec.	++++
	Polyclonal	A1	1:256	10- 12 sec.	+++
		A2	1: 128	15-18 sec.	++ to +++
		A2B	1: 64	15- 18 sec.	++
Anti B	Polyclonal	B	1: 256	10- 12 sec.	+++
		A1B	1: 128	12 – 15 sec.	++
	Monoclonal	B	1: 256	3-4 sec.	++++
		A1B	1: 128	5-6 sec.	++ to+++
Anti AB	Polyclonal	A1	1: 256	10- 12 sec.	+++
		B	1: 256	10– 12 sec.	+++
		A2	1 :64	15 -18 sec.	++ to +++
	Monoclonal	A1	1: 256	3-4 sec.	++++
		B	1: 256	3-4 sec.	++++
		A2	1: 128	5-6 sec.	+++

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location QC Laboratory **Function** Quality Control	**SUBJECT** Copper Sulphate Solution **DISTRIBUTION** - Quality Control room. - Master File

1. SCOPE AND APPLICATION

Copper Sulphate solution is used for screening blood donors for hemoglobin concentration used before blood donation.

2. RESPONSIBILITY

It is the responsibility of the Quality Control personnel to ensure testing of the reagent before use.

3. REFERENCES

Transfusion MedicineTechnical Manual Sponsored by WHO.
Transfusion MedicineTechnical Manual by R.K.Saran.

4. MATERIALS REQUIRED

Equipment:

(i) Urinometer

Reagents:

(i) Copper Sulphate working solution
(ii) Distilled water
(iii)EDTA Blood samples of known hemoglobin concentration

Glassware:

(i) Coplin jar
(ii) Heparinised capillaries
(iii) Tube racks

Miscellaneous:

(i) Tissue paper (ii) Copper Sulphate record book

3. PROCEDURE

Arrange the blood samples according to hemoglobin concentration in a rack.

↓

Obtain samples of known Hb values

↓

Transfer 30 ml copper sulphate working solution in a Couplin jar

↓

Mix the blood sample of known hemoglobin concentration by inversion

↓

Fill capillary up to ¾ capacities with the blood sample

↓

Allow the drop of blood to fall gently into the copper Sulphate solution

↓

Repeat the procedure for all the blood samples

↓

Note the result

↓

Record the results in the copper Sulphate record book.

4. RESULTS

(i) If the solution appears cloudy or precipitate is present, the solution is discarded

(ii) The result of testing the solution is interpreted as follows:

	RESULT	**Hb CONCENTRATION**	**INTERPRETATION**
(a)	Blood drops floats	Hb<12.5g%	Fail (F)
(b)	Blood drops sinks	Hb>12.5g%	Pass (P)
(c)	Blood drops sinks slowly Or Blood drop hesitates Midway and sinks slowly	Hb Less than or equal to12.5g%	Pass fail reaction (P/F)

5. DOCUMENTATION

The results are noted in the copper Sulphate record book.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location Donor Room Function Preparation of CuSO4 solution	SUBJECT Qualifying Test for Blood Donation DISTRIBUTION - Donor Area - Medical officer in charge - Master File

1. SCOPE & APPLICATION

The specific gravity of 1.053 is equivalent to 12.5 g/dl hemoglobin. Hence CuSO4 Solution of Specific Gravity 1.053 is used for pre-donation Hemoglobin test.

2. RESPONSIBILITY

The technician / laboratory assistant in the donor area.

3. REFERENCE

Transfusion MedicineTechnical Manual Sponsored by WHO.
Transfusion MedicineTechnical Manual by R.K.Saran.

4. PROCEDURE

Stock solution is made as follows and kept in a jar or bottle

1. Dissolve 159.63 g crystalline CuSO4, $5H_2O$ in 1000 ml in distilled water working solution.
2. Add 52 ml stock solution to 48 ml distilled water to make it 100 ml working solution.
3. Check Specific Gravity which should be 1.053. If not adjust it using either stock solution or Distilled water.

5. DOCUMENTATION

Record the volume of stock and working solution prepared on the register

END OF DOCUMENT

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION **FUNCTION**	**SUBJECT** Quality Control & Maintenance **DISTRIBUTION** - Equipment Site - Quality control lab - First page of register - Master File

Quality control & Maintenance of equipment:

1. **Water baths & incubators:**
   - Record temperature daily.
   - Maintain even temperature throughout using a stirrer.
   - Keep the water-clean.
   - Take extra care for the water baths to be used for thawing fresh frozen plasma & cryoprecipitate.

2. **Blood bank Refrigerators:**
   - Required temperature 4^0-6^0c.
   - Regular temperature recording by 7 day temperature chart recorder. CMS (Central Monitoring System) is recording temp. at intervals of 10 min.countinuously.
   - Check uniformity of temperature in upper & lower shelves.
   - Put Date, Time & Signature of technical staff responsible for the recording the temperature on the chart.
   - Ensure continuous power supply by emergency connections through generator.
   - Periodically check alarm system for temperature, fluctuations, which must be connected through a battery.
   - Keep the refrigerator clean & well-lit.

3. Freezer:

- Q.C. same as Blood Bank refrigerator.
- CMS is taking reading of temp. at 10 min. interval.

4. Microscope:

- Keep the Microscope covered when not in use.
- Keep the coarse adjustment & condenser well-lubricated.
- Clean the objectives, condenser & eyepiece with silk cloth or lens paper frequently.

5. PH meter:

- Check 2-point calibration (control buffer PH 4, 7) before each time of use.
- Get full maintenance every 6 month.

6. Balances & scales:

- Check the balances & scales used for Blood collection on receipt after repair & when in use.
- Check the balances with known weights.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Washing & Sterilization room	Disposal of blood bags
FUNCTION	**DISTRIBUTION**
This is used for proper discarding of blood bags to avoid infection in laboratory personal	- Washing & Sterilization room - Master File

SCOPE AND APPLICATION

Disposal of blood bags

1. Blood units which are positive for HIV/HCV/VDRL/HBsAg given to **WASTE DISPOAL CENTRE.**
2. Less collected blood bags.
3. Blood bag after expiry date
4. Haemolysed blood units

RESPONSIBILITY

It is the responsibility of technician and attendant.

MATERIALS REQUIRED

1. 10% Na Hypochlorite solution.
2. 10ml syringe.
3. Autoclave.
4. Gloves.

PROCEDURE

1. Wear hand gloves.
2. To each blood bag 15ml of 10% Na Hypochlorite solution is added through blood collection tube with the help of 10ml syringe.
3. Mix the contents thoroughly.
4. Keep the bag separately for 12 hrs. (Overnight)
5. Blood bag number and date of discarding is recorded in respective registers such as Discarding, Donor and Master register.
6. Signature of **Technician, BTO** & Person of **biomedical waste** is taken.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location Sterilization room **Function** Method of cleaning of floor	**SUBJECT** Cleaning of floor **DISTRIBUTION** - Sterilization room & master file

1. SCOPE & APPLICATION

This protocol provides the procedure for cleaning of floor.

2. RESPONSIBILITY

It is the responsibility of the attendant & the supervising nurse.

3. MATERAIL REQUIRED

1. Bucket
2. Tap water
3. Germ check
4. Phenols
5. Duster with handle
6. Soft Broom

4. PROCEDURE

1. The floor cleaning is done daily three times a day.
2. The floor should be cleaned & washed in morning, afternoon, & evening time and s.o.s.
3. Take 4 Liters of water in bucket. Add 30 ml of phenol & 30ml of Bacilocide solution.
4. The floor is initially swept with soft broom.
5. The floor should be cleaned, dried & mopped to remove retained dust & soaked in the above prepared solution & mopping is done of the floor.
6. Change the water in between the procedure.
7. Then it is allowed to dry.
8. Bucket should be emptied after each use & washed with detergent & warm water &stored dry.
9. The duster is washed with detergent & warm water & stored dry.
10. This procedure is followed after each cleaning.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location Registration Counter **Function** Issue record of Blood bags.	**SUBJECT** Issue of Blood bags. **DISTRIBUTION** - Registration room & master file - Master File

1. SCOPE & APPLICATION

This protocol provides the procedure to find out Records of **Issued Blood Bag.**

2. RESPONSIBILITY

It is the responsibility of the Technician & B. T. O.

3. MATERAIL REQUIRED

Issue Register, Cross match Register, Blood Stock Register, Donor Register & Master Register etc.

PROCEDURE

1. Check the blood bag No., blood group of bag, date of collection, date of expiry on the label.
2. Do entry in respective register with date and time of issue & signature of technician & Medical officer.
3. Take signature of blood bag receiving person.
4. Write the issued blood bag no. in respective register & deduct from the stock.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location Component Preparation Room	**SUBJECT** Blood Component
Function Component Preparation & Records.	**DISTRIBUTION** Component Preparation Room & Component Preparation Register

1. SCOPE & APPLICATION

This protocol provides the procedure to Preparation of the blood Components (Red Blood Cell, Platelet, and Plasma.)

2. RESPONSIBILITY

It is the responsibility of the Technician & Component Supervisor.

3. MATERAIL REQUIRED

Triple Blood bags 450ml (ADSOL), Laminar Air Flow, Refrigerated Centrifuge , Digital Weighing Machine, Tube sealer, Plasma Expresser, Blood component bag label, Component Register, Clamps, Scissor.

4. REFERENCE

Transfusion Medicine Technical Manual Sponsored by WHO.
Transfusion Medicine Technical Manual by R.K.Saran.

5.PROCEDURE

1. Check the blood bag No, blood group of bag, date of collection, date of expiry and enter number, Bl. group in the component register with respective segment number.
2. Process the collected blood within 6 hrs.
3. Keep the bags erect in the laminar air flow for the 30 to 45 minutes.
4. Balance the bags in the buckets using dry rubber or unused bags.
5. Keep equally balanced buckets diagonally opposite each other in the refrigerator

Centrifuge .

6. Centrifuge the bags at 1500 RPM for 14 minutes at 22^0 C (Soft Spin).
7. After centrifuge keep the bag on plasma expresser in the laminar air flow. Clamp the tube of plasma storage bag. Break the seal in the tube of the platelet storage bag. The plasma (PRP) automatically flows in the satellite bag (platelet storage bag). Sufficient plasma collected in the platelet storage bag then clamp the tube. Break the seal in the tube of additive solution bag . Keep additive solution bag in high position. Then additive slowly pass into the primary bag containing Red Cell.
8. Mix the contents thoroughly and seal the tube of red cells bag & detach the bag & keep it in untested blood storage refrigerator.
9. Rest of Platelet Rich Plasma Bag with empty bag kept in centrifuge. Position the balanced bags in bucket parallel to the direction of the spin. Centrifuge the bag at 2700 RPM for 14 minutes
10. After centrifuge keep the bag on plasma expresser in the laminar air flow. Open the clamps of the tubing of connected to the empty bag .The plasma automatically flow in the satellite bag (PPP) in the empty bags. Leave approximately 50 to 70 ml plasma in the platelet concentrate bag.
11. Seal the tubing & separate the platelet concentrate bag & Platelet poor plasma.
12. Weight the platelet concentrate bag, Plasma Bag & record the weight in respective book.
13. Keep the platelet concentrate bag in Platelet agitator with incubator at 22^0 C & keep the platelet poor plasma in deep fridge below -30^0 C.
14. Label, enter the register and place them in respective storage container after serological test result are available.

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STANDARD OPERATING PROCEDURE

Location Component Preparation Room **Function** Component Preparation & Records.	**SUBJECT** Blood Component **DISTRIBUTION** Component Preparation Room & Component Preparation Register -

1. SCOPE & APPLICATION

This protocol provides the procedure to Preparation of the blood Component (Cryoprecipitate)

2. RESPONSIBILITY

It is the responsibility of the Technician & Component Supervisor.

3. MATERAIL REQUIRED

Triple Blood bags 450ml(ADSOL), Laminar Air Flow, Refrigerated Centrifuge, Digital Weighing Machine, Tube sealer, Plasma Extractor, Blood component bag label, Component Register, Clamps, Scissor, Cryobath.

4. REFERENCE

Transfusion MedicineTechnical Manual Sponsored by WHO.
Transfusion MedicineTechnical Manual by R.K.Saran.

5.PROCEDURE

1. Check the blood bag No, blood group of bag, date of collection, date of expiry and enter number, Bl. group in the component register with respective segment number.
2. Process the collected blood within 6 hrs.
3. Keep the bags erect on the laminar air flow for the 30 to 45 minutes.

4. Balance the bags in the buckets using dry rubber or unused bags.

5. Keep equally balanced buckets diagonally opposite each other in the refrigerator Centrifuge .

6. Centrifuge the bags at 2700 rpm for 14 minutes at 22^0 C (Hard Spin).

7. After centrifuge keep the bag on plasma expresser in the laminar air flow. Clamp the tube of plasma storage bag. Break the seal in the tube of the platelet storage bag. The plasma automatically flows in the satellite bag. Sufficient plasma collected in the satellite bag clamp the tube. Break the seal in the tube of additive solution bag. Keep additive solution bag in high position then additive slowly pass into the primary bag containing red cell.

8. Mix the contents thoroughly and seal the tube of red cells bag & detach the bag & keep it in untested blood storage refrigerator.

9. The bag containing plasma with empty satellite bag are kept in deepfreeze below -30^0 C for one or two day (Plasma should be free from Red Cell.)

10. Fill the cryobath with water.

11. Maintain the temperature of water in continuous circular motion at 9^0 C.

12. Keep the frozen plasma bag in this cryobath. When the plasma is thowed, place the bags in centrifuges buckets with empty bag and the balance the bucket on weighing scale.

13. Keep the position of the bags in buckets parallel.

14. Spin the bucket at 5000 RPM for 15 min at 4^0 C.

15. After centrifuge keep the bag on plasma expresser in the laminar air flow. Open the clamp of the tubing of connected to the empty bag .The plasma automatically flow in
the satellite empty bag. Leave approximately 15 to 20 ml plasma as Cryoprecipitate

suspension in the bag.

16. Seal the tubing and separate the cryoprecipitate and the cryo poor plasma bags.

17. Weigh the cryoprecipitate bag and record.

18. Bag kept in deep freezing till the serological tests are completed.

19. Label, enter the register and place them in respective deep freez after serological test result are available.

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STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Red cell Serology lab	Blood Grouping
FUNCTION Testing of D^u by tube method.	**DISTRIBUTION** -Red cell serology room - Master File

SCOPE AND APPLICATION

In D^u person's D antigen is present but is undermined in some persons it is detected with anti-D & in others it is not. For practical purpose D^u positive persons are considered as Rh positive hence for Transfusion purpose all negative donors must be tested for D^u.

RESPONSIBILITY

It is the responsibility of blood bank technician to ensure proper testing of Rh typing.

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Test tubes
2. Centrifuge
3. Monoclonal Anti-D from two different manufacturers's labeled D1 &D2.
4. Rh (D) control cells.

METHOD

6. Label 3 test tubes as Test, Positive, and Negative Control.
7. Place one drop of 5%Red cell suspension of Pooled O Rh positive cell in Positive control labeled and Negative Control and one drop of 5% Red cell suspension of Patient / Donor to tube labeled as test.
8. Add one drop one drop of Anti D to Positive control and test and one drop of Bovine Albumin in tube labeled Negative control.
9. Mix well and incubate at 37°C, for 30 min (sedimentation method).
10. After incubation wash the all three test tubes with normal saline for 3 times
11. Add Anti Human Globulin to PC, NC, and Test.

12. Mix and centrifuge all 3 test tubes at 1000 rpm for 1 min.
13. Gently resuspend the cell button and observe for agglutination, all negative results must be confirmed under microscope.

INTERPRITATION

1. Agglutination in the tube test and in the tube positive control and the Smooth suspension of cells in the tubes negative control is interpreted as Test cells Rh (D) positive.
2. A smooth suspension of red cells in tubes of 'test' and negative 'controls' The test cells are Rh (D) negative. Agglutination in tube labeled positive Control.
3. If in any test 'negative control' gives agglutination, the results are invalid.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

Location	**SUBJECT**
Red cell serology room	Investigations of transfusion reaction. **DISTRIBUTION** - Red cell serology room & master file

INVESTIGATION TRANSFUSION REACTIONS

I) Whenever there is a report of Reaction to the patient after starting transfusion do the following :-

- Ask the person concerned to immediately stop the transfusion.
- Blood bag with donor set is to be returned to the blood bank for investigation.
- Ask for post transfusion sample.
- Ask for urine sample.
- Request the doctor to fill reaction report & send the cross match card along with above mentioned sample.

II) Clinical aspects:-

- Check the name of patient ,Blood group, bag number,& identity wether proper bag has been issued.

III) Technicial Aspects:-

1. On pretransfusion sample :-
   1) Blood group.
   2) Major & Minor cross match.

2. On Post transfusion sample :-
   1) see the evidence of Haemolysis.
   2) Blood group.
   3) Major & Minor cross match.
   4) ICT .

3. On Blood bag:-
   See for evidence of Hemolysis in Blood bag & amount of Blood that has been transfused.

4. On Urine sample :-
   Examine post transfusion urine sample for evidence of RBC Microscopically.& see for Hb-uria.

5. Do DCT on post transfusion sample.

6. Sent the bag for Culture & sensitivity.

IV) Prepare a report of investigations done which should be signed by technician & M.O.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Serology lab.	Staining smear of malarial parasite by Lieshman's stain.
FUNCTION	**DISTRIBUTION**
Assessing suitability of Blood Bag for transfusion & providing guidelines for detection of malarial parasite.	- Serology lab. - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Glass slide
2. Thick smear
3. Staining rack.
4. Lieshman stain.
5. Lieshman Buffer.
6. Digital Timer.

METHOD

1. Make a thick film of blood and dry at Room temp.
2. Dehaemoglobunise the smear.
3. Cover the smear with Lieshmans stain by adding 10 to 15 drops on smear.
4. Wait for 5 min.
5. Add 10 to 15 drops of Lieshmans Buffer
6. Mix the reaction mixture adequately by blowing on it through pipette. And wait for 10 min.
7. Wash the smear by using the tap water then dry the slide at room temp.
8. Examine under Microscope.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
TTD LAB	TTD TESTING
FUNCTION Assessing suitability of blood bag for transfusion & for detection of antibodies to HCV	**DISTRIBUTION** - TTD Lab - Master File

HCV GENERAL BIO

Principle: -

It is an enzyme Immuno Assay kit, which uses recombinant HCV Antigens (Core, NS3, NS4, & NS5 Antigens) for the detection Antibody to Hepatitis C virus in Human serum or plasma.These Antigens constitute the solid phase. When Human serum or plasma is added to the well, the HCV Antigens & Anti HCV will form complexes on the wells if Anti HCV is present in the Specimen. The wells are washed to remove the unbound materials. The diluted Anti Human IgG HRPO Conjugate is added to the well & results in the formation of (HCV). (Anti HCV). (Anti Human IgG HRPO) Complex. After washing out the unbound conjugate, TMB substrate solution is added for color development. The intensity of color development is proportionate to the amount of Antibodies present in the specimen.

Specimen: Serum /plasma can be used for the test.

Material & instrument required:

1. Micropipettes & disposable tips.
2. Micro wells with reagents.
3. Hand gloves
4. Timer
5. ELISA washer
6. ELISA Reader
7. Incubator 37^0c
8. Tissue paper
9. D/W
10. HCV General Bio kit

Procedure:

1. Add 200µl sample diluents to each well in HCV Antigens Plate except the blank. add 10µl controls (2x NC in B-1 & C-1 3xPC in D-1 & E-1 wells). Add 10µl of test specimens to the respective wells (starting from F-1 wells).Reserve 1 well for blank.
2. Incubate the plate at 37^0c for60 min.
3. Wash the plate as per micro plate washing procedure. Tap the micro plate on tissue paper. (Prepare required amount of diluted conjugate in advance).
4. Add 100µl of diluted conjugate to each well except the blank.
5. Incubate the plate at 37^0c for 30 min.
6. Wash the plate.
7. Add 50 µl of TMB substrate solution A to wells & then add 50 µl of TMB substrate solution B. Carefully mix well.
8. Incubate at room temperature for 30 min.
9. Add 100µl of 2N H2SO4 in to each well.
10. Determine absorbance using 450 nm as reading wavelength with 620 – 690 nm reference Wavelength

Calculation for cut-off value determination:

- **Positive control**: Positive control mean should be greater than or equal to 0.6

  Negative control: Negative control mean (NCx) should less than or equal to 0.200.

- **Cut-off value formula: NCx + PCx / 4**

Interpretation of the result:

- **Negative:** If the absorbance of the test serum is less than the cut-off value, then the sample is considered as negative.

- **Positive** If the absorbency of the test serum is equal or greater than the cut-off value, then it is considered as initial positive. The absorbance value within grey zone should be retested. Retest results are less than cut-off value, and then the specimen is considered as negative. If one of the duplicate retest results is found positive, then the specimen is considered as repeatedly positive.

Reference: General Bio HCV (3rd Generation ELISA Kit)

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Quality Control Room **FUNCTION** Quality control of Whole Blood 350ml. .	**SUBJECT** To check the quality control of whole blood bag collected. **DISTRIBUTION** -Quality Control Room - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Blood bag.
2. Weighting machine.
3. Calculator.
4. Serology reg.
5. Sterility reg.
6. Cell counter.
7. Ph meter.
8. Test tube.

METHOD

A) Quality Control of Whole blood volume:-Weigh 4 No. of blood bag of random donor. And calculate the volume from the formula given below.

$$\text{Volume (ML)} = \frac{\text{wt.of bag + wt.of blood (gm) - wt.of empty bag}}{1.05}$$

PH of the Blood :-

Adjust the ph of Buffer at 4.0 & at 7.0 ph. Then Take reading of blood sample on PH meter & record the reading.

Hemoglobin: - Run the sample of blood on cell counter. Write down the reading of Hb in gm%. Then calculate as follows.

Hemoglobin /unit = Hb in gm% × volume of blood.
100

Haemolysis: - Observe the bag against the light for haemolysis.

Prepare the report as follows:-

Parameter	Quality requirement	frequency of control
Volume	350 + 10 %	4 units per month.
Hemoglobin	up to 45 gm/unit	4 units per month
HCT	30 to 40 %	4 units per month
PH	> 6.0	4 units per month
Hemolysis	Absent	4 units per month

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Quality Control Room **FUNCTION** Quality control of Red Cell Concentrate (Prepared from 450ml Triple blood Bag.)	**SUBJECT** To check the quality control of R.B.C. bag collected. **DISTRIBUTION** -Quality Control Room - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Blood bag.
2. Weighting machine.
3. Calculator.
4. Serology reg.
5. Sterility reg.
6. Cell counter.
7. Ph meter.
8. Test tube.

METHOD

A) Quality Control of Red Blood Cell volume:-Weigh 4 no. of blood bag of random donor. And calculate the volume from the formula given below.

$$\text{Volume (ML)} = \frac{\text{wt.of bag + wt.of blood (gm) - wt.of empty bag}}{1.08}$$

PH of the Blood:-

Adjust the ph of Buffer at 4.0 & at 7.0 ph. Then Take reading of blood sample on

PH meter & record the reading.

Haemolysis: - Observe the bag against the light for haemolysis.

Prepare the report as follows:-

Parameter	**Quality requirement**	**frequency of control**
Volume	350 ± 20 ml	4 units per month.
HCT	55 % - 65%	4 units per month
PH	> 6.0	4 units per month
Hemolysis	Absent	4 units per month

END OF DOCUMENT.

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Quality Control Room **FUNCTION** Quality control of Platelet Concentrate. (Prepared from 450ml Triple blood Bag.) .	**SUBJECT** To check the quality control of Platelet bag collected. **DISTRIBUTION** -Quality Control Room - Master Fil

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Platelet bag.
2. Weighting machine.
3. Calculator.
4. Serology reg.
5. Sterility reg.
6. Cell counter.
7. Ph meter.
8. Test tube.

METHOD

A) Quality Control of Platelet Concentrate volume:-Weigh 4 No. of blood bag of random donor. And calculate the volume from the formula given below.

$$\text{Volume (ML)} = \frac{\text{wt.of bag + wt.of blood (gm) - wt.of empty bag}}{1.03}$$

Calculation of Platelet Yield :-

No. of plt. In P.C. = Plt. Per mm^3 × 1000 ×Volume of P.C.

PH of the Platelet bag:-

Adjust the ph of Buffer at 4.0 & at 7.0 ph. Then Take reading of blood sample on PH meter & record the reading.

Swirling: - Observe the bag against the light for presence of swirling Motion.

Prepare the report as follows:-

Parameter	Quality requirement	frequency of control
Volume	50 to 70 ml	4 units per month
Platelet Yield	5.5×10^{10}	4 units per month
PH	> 6.0	4 units per month
Swirling	Present	4 units per month
RBC contamination	Traces to 0.5 ml	

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SOP 45	01/01/16	1	Deepak Sawant	
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			Dr. Vijayalaxmi Patil	

BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Quality Control Room	To check the quality control of Platelet bag collected.
FUNCTION	**DISTRIBUTION**
Quality control of Platelet Concentrate. (Apheresis Bag.)	-Quality Control Room - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. Apheresis Platelet bag.
2. Weighting machine.
3. Calculator.
4. Serology reg.
5. Sterility reg.
6. Cell counter.
7. Ph meter.
8. Test tube.

METHOD

A) Quality Control of Platelet Concentrate(SDP) volume:-
Calculate the volume from the formula given below.

$$\text{Volume (ML)} = \text{wt.of } \frac{\text{bag + wt.of blood (gm) - wt.of empty bag}}{1.03}$$

Calculation of Platelet Yield:-

No. of plt. In P.C. = Plt. Per mm^3 × 1000 ×Volume of S.D.P.

PH of the Platelet bag:-

Adjust the ph of Buffer at 4.0 & at 7.0 ph. Then Take reading of blood sample on PH meter & record the reading.

Swirling: - Observe the bag against the light for presence of swirling Motion.

Prepare the report as follows:-

Parameter	Quality requirement	frequency of control
Volume	200 to 300 ml	Each unit
Platelet Yield	3.5×10^{11}	Each unit
PH	> 6.0	Each unit
Swirling	Present	Each unit
Residual leucocytes	$< 5.0 \times 10^{6}$	Each unit
RBC contamination	Traces to 0.5 ml	Each unit

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Quality Control Room **FUNCTION** Quality control of Fresh Frozen Plasma. (450 ml Triple blood Bag.)	To check the quality control of FFP bag collected. **DISTRIBUTION** -Quality Control Room - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician

REFERENCES

Transfusion Medicine Technical Manual Sponsor by WHO.
Transfusion Medicine Technical Manual R.K.Saran.

MATERIALS REQUIRED

1. F.F.P. bag.
2. Weighting machine.
3. Calculator.
4. Serology reg.
5. Sterility reg.
6. Cell counter.
7. Ph meter.
8. Test tube.

METHOD

B) Quality Control of Fresh Frozen Plasma volume:-
Calculate the volume from the formula given below.

$$\text{Volume (ML)} = \text{wt.of bag} + \frac{\text{wt.of blood (gm)} - \text{wt.of empty bag}}{1.02}$$

Prepare the report as follows:-

Parameter	**Quality requirement**	**frequency of control**
Volume	180 - 220 Plasma.	4 unit per month
Stable coagulation factors	200 units of each unit	4 unit per month
Factor VIII	.7units/ ml	4 unit per month
Fibrinogen	200-400mg	4 unit per month

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Aphaeresis room **FUNCTION** Platelet Aphaeresis procedure.	**SUBJECT** Selection criteria, steps of donor selection. & procedure. **DISTRIBUTION** -Aphaeresis room - Master File

GUIDELINES FOR DONOR SELECTION FOR SINGLE DONOR PLATELET PLATELET (Platelet Aphaeresis Procedure)

1. Donor should be in a good health.
2. Donor should fulfill all the criteria's required for general blood donation (Blood donor questionnaire attached along with this letter). Donor also should have normal Blood pressure and systemic examination showing no abnormal findings.
3. Good venous access is required. The veins in cubital fossa must be prominent elastic and well supported.
4. Donor should be healthy male with
   Weight - 60 kg or more.
   Age - 18 to 50 years.
   Hb. - 12.5 gm% or more.
   Platelet count - more than 2, 00,000/ml.
   (Other blood cell count preferably within normal range & free from Transfusion transmitted diseases like Hepatitis B, Hepatitis C, HIV, Syphilis, malaria.

5. Donor must be free from NSAID (Analgesic/pain killer) medication 3 days earlier.

6. Generally donor can undergo platelet aphaeresis procedure again after 3 days.(if there is significant loss of red cells during aphaeresis, donor cannot donate next 3 months) donor can undergo the platelet aphaeresis is maximum two times in a week or 24 times in a year. However if donor has done whole blood donation- he can't donate for 3 months. Repeating the same donors for particular
   patient is preferable as it will limit the platelet antibody formation.

7. Donor should be of same Blood group as that of patient .
8. Donor preferably should not be first degree relative to the patient.

9. It is advisable to have 2-3 donors for single donor platelets aphaeresis is Procedure for particular patient .other donor can donate for next aphaeresis procedure, without wasting precious time Required for investigation.

Steps for the donor selection:-

1. When donor fulfill all above criteria then ask to bring the new case paper of that Donor.
2. Label the test tube & vaccuntaner with donor name, age. Sex, weight, Height, blood group.
3. When CBC Report will receive check for Hb, HCT, & platelet count. If it Fulfill the criteria then proceed for serology.
4. After serology if all tests are negative, then do the Registration of the donor in donor register, take consent also.
5. Then do the entry in all serology report registers, master register & Component preparation register, aphaeresis register.

procedure:-

1. Start machine, choose procedure (Single needle), then install kit. Stick Details of kit information in Aphaeresis register.
2. When installation start, do preparation of donor (fix the pressure cup to the arm, Choose the vein, clean the area with betadine & then with spirit.)
3. When installation will complete 50% of installation, click to estimator on the Screen, select the procedure (Single needle), and fill the format.
4. When installation will complete, prick the donor & start the procedure. During Procedure observes the donor for any reaction. Follow instructions of machine. Give calcium tablets to donor during Procedure. After completion of the Procedure, Write donor no., collection date, expiry date & blood group on the bag. And keep the bag on platelet agitator for 30 mins.
5. Collect the CBC sample of the donor for post donation count.
6. Record the procedure result in Aphaeresis register & result sheet. Sign the Procedure result by technician & the medical officer.
7. Before issue of aphaeresis bag, collect the sample for QC.

End of Document

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION Component Entry room **FUNCTION** To maintain sterility in component room.	**SUBJECT** Wear the gown , Gloves & mask before entering in component preparation room. **DISTRIBUTION** -Component entry room - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician, Component Supervisor And Person entering in the Component preparation room.

Procedure :-

1. Before entering in the component room clean the hands with Sterillium.
2. Wear sterile gloves, Gown & Mask.
3. Then proceed for Component Preparation work

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BLOOD BANK

STANDARD OPERATING PROCEDURE

LOCATION	**SUBJECT**
Entry in blood bank. **FUNCTION** To maintain sterility of Blood bank.	To Remove shoes,Chapels &Wear the Slippers provided before entering in The Blood bank **DISTRIBUTION** -Blood bank entry. - Master File

RESPONSIBILITY

It is the responsibility of blood bank technician & staff Person entering in the Blood bank.

Procedure:-

1. While entering in the Blood bank, remove your Shoes, Chapels on the rack.
2. Wear the slippers provided by Blood Bank.
3. Then proceed for routine work

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SOP FOR BIO MEDICAL WASTE MANAGEMENT

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DOCUMENT TYPE	**STANDARD OPERATING PROCEDURE**
DOCUMENT NO.	**BLDEU, SBMPMCH&RC/BMWM -01**
TITLE	**Biomedical Waste Management**

Date implemented	**15.08.2016**

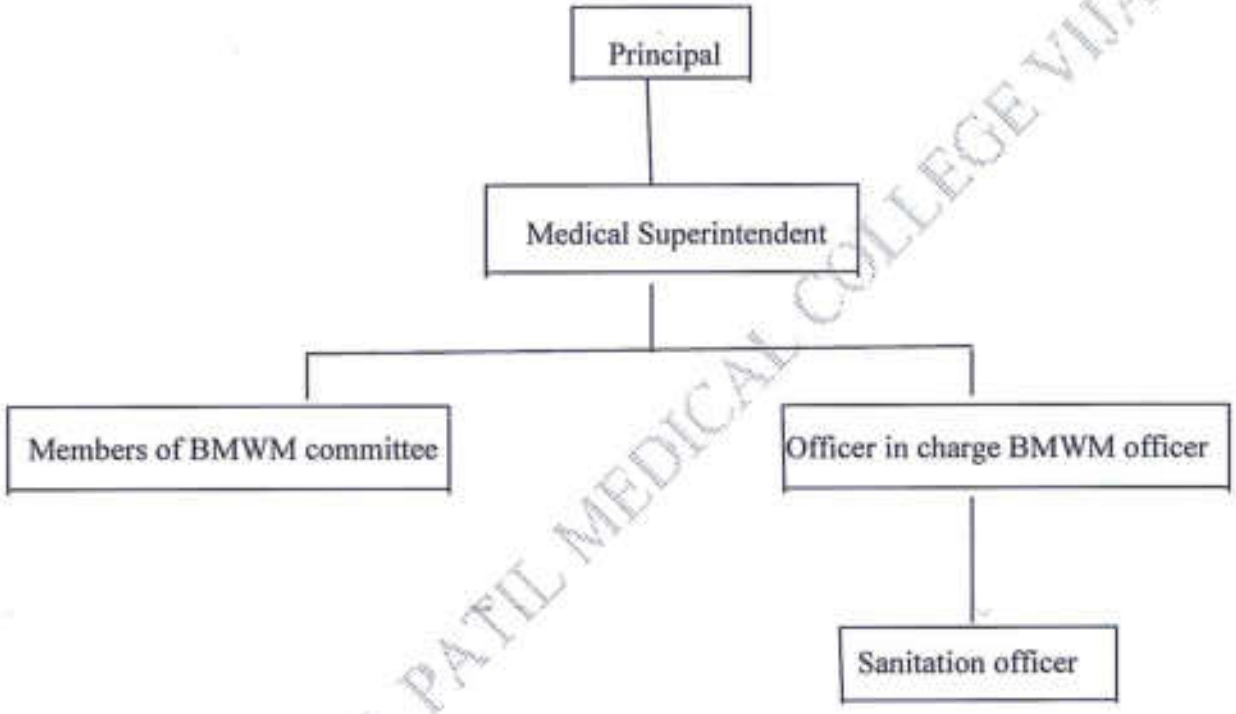
PREPARED BY		**VERIFIED & APPROVED BY**	
Name	Name: Dr Smitha Bagali	Name	Dr. Vijayakumar Kalyanappagol
Designation	Associate Professor (Member secretary, BMWM Committee)	Designation	Medical Superintendent **BLDE(DU's), SBMPMCH & RC**
Signature & Date		Signature & Date	

Table of Contents

AMENDMENT RECORD

Sl. No	Page No	Section/ Para/line (as applicable)	Date of amend ment	Amendment made	Reasons of amendment	Signature of Officer I/C BMW managem ent	Signature of Medical Superintendent

II. Organogram



III. Definitions:

Sl. No.	Term	Definition
1.	Authorisation	Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.
2	Authorised person	Authorised person means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.
3	Bio-medical waste	Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules
4	Handling	Handling in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste.
5	Major Accident	Major Accident means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.
6	Management	Management includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste.
7	Occupier	Occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

IV. Process :

1. Duties of the Occupier
2. Bio-Medical Waste Management
3. Segregation of Waste
4. Waste Removal & Transportation
5. Waste storage
6. Treatment and Disposal
7. Licensing and other requirement for Bio-medical Waste Management

1. Duties of the Occupier

It shall be the duty of every occupier to-

(a) Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules

(b) Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Table I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Table 1;

(c) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018).

(e) Not to give treated bio-medical waste with municipal solid waste;

(f) Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;

(g) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.

(h) Establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of Bio-Medical Waste Management Rules, 2016.

(i) Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;

(j) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

(k) Ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;

(l) Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;

(m) Maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Table 1;

(n) Report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority, and also along with the annual report;

(o) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018 for Hospitals which do not already have a Website).

(q) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months, The record of the minutes of the meetings of shall be submitted along with the annual report to the prescribed authority.

(r) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

(s) existing incinerators (where applicable) to achieve the standards for treatment and disposal of bio-medical waste as specified in Annexure 3, for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

2. Biomedical Waste Management

Objective: To provide guidelines for management of Bio-medical waste.

Purpose: To define the guidelines for segregation, handling, storage, transportation and disposal of various kinds of biomedical waste.

Scope: This SOP applies to all employees who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form. The scope of this SOP applies to biomedical waste only.
Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Table 1. Categories of Biomedical waste

Table 1: Categories of Biomedical waste

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time). **(b) Animal Anatomical** Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio- medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(e) **Chemical Waste:** Chemicals used in production of biological and used or discarded disinfectants	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	f) **Chemical Liquid Waste:** Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X- ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	g) **Discarded linen,** mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
	(h) **Microbiology, Biotechnology** and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines Thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	**Contaminated Waste** (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue	(a) **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. b) **Metallic Body Implants**	Cardboard boxes with blue coloured marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Annexure 3. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time

3. Segregation of Waste

Objective: Segregation of Bio-medical waste as per guidelines.

Job Responsibility: Doctors, Nurses, Technicians, all employees handling BMW.

Description

1. BMW will not be mixed with other non-infectious wastes. If by mistake this has occurred, this non-infectious waste will then be treated as BMW.
2. The bio-medical waste shall be segregated as per categories applicable, into containers or bags at the point of generation e.g., all patient care activity areas, diagnostic service areas, operation theatre areas, treatment rooms etc. prior to its storage, transportation, treatment and disposal.
3. Non-chlorinated bags will be used for collection of biomedical waste.
4. All bags, containers or bins directly used in the collection of bio-medical wastes are labelled with appropriate biohazard Symbol (Annexure 1) which will be non-washable and prominently visible.
5. Bins used for holding the colour coded bags should be of the same colour.

4. Biomedical Waste Removal & Transportation

Objective: Biomedical Waste removal & transportation to minimize the risk of any infection.

Job Responsibility: Housekeeping staff

Description:

1. The staff handling waste must use PPE.
2. The bags must be removed when ¾th full, if not earlier.
3. The waste bag is tied up & transferred in a closed designated closed trolley to central storage area .
4. The housekeeping staff to ensure that all bags are tied when being transported & there is no spillage or leakage.
5. In case any bags has a cut or tear, ensure that double bagging is done before moving it.

5. Biomedical Waste storage

Objective: Waste storage at biomedical waste treatment facility.

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. Storage of biomedical waste should not extend 48 hrs.
2. Bio-medical waste is not mixed with other waste. There is differentiation between the storage areas for different categories of Bio-medical waste
3. The Bio-medical waste is stored in safe, ventilated and secured location for storage of segregated biomedical waste in Coloured Bags or containers as per colour coding norms.
4. Weighing will be done at the central area and weight mentioned on a register maintained for this purpose.

6. Treatment and Disposal

Objective: Proper Treatment and disposal of biomedical waste

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. **Human Anatomical Waste**, Animal anatomical waste, soiled waste will be incinerated without pretreatment

2. **Chemical Liquid waste** generated due to use of chemicals in production of biological and used or discarded disinfectants like discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc is directed by Separate collection system leading to effluent treatment system .

3. After resource recovery, the chemical liquid waste shall be pre-treated at effluent treatment plant before mixing with other waste water in compliance with the standards provided in Annexure 2, by the health care facility.

4. **Clinical laboratory waste**: Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated with chemical disinfectant i.e 1% sodium hypochlorite for 30 mins.

5. **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, returned back to the manufacturer

6. Discarded linen, mattresses, beddings contaminated with blood or body fluid are treated by Non-chlorinated chemical disinfection followed by incineration

7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

8. **Recyclable waste** are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes followed by mutilation or shredding, the recyclables from the treated bio-medical wastes such as

plastics shall be given to recyclers having valid authorisation or registration from the respective prescribed authority.

9. The Occupier shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

10. **Waste sharps** including metals are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes and disposed into designated concrete waste sharp pit.

11. **Glassware**: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes are disinfected by soaking the washed glass waste with 1% Sodium Hypochlorite for 30 minutes and then sent to recyclers having valid authorisation or registration from the respective prescribed authority. .

7. Licensing & Other requirements for Bio-medical Waste Management

Objective: Licensing & Other requirements for Bio-medical Waste management

Job Responsibility: Head- Administration

Description:

1. Application for Authorization

a. Every occupier handling bio-medical waste, irrespective of the quantity shall make an application in Form II (Annexure 3) to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III (Annexure 4) and the validity of such authorisation for bedded health care facility shall be synchronised with the validity of the consents.

b. Disposal of this application shall be done by the authority (Pollution Control Board in states or Pollution Control Committee in union territories, as the case may be) within 90 days from the date of receipt, failing which it shall be deemed that the authorisation is granted under the Biomedical Waste Management Rules.

c. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II (Annexure 3) for modification of the conditions of authorisation.

d. Occupier should apply for Renewal at least 3 months prior to expiry of the Authorization.

2. **Annual Report**

a. Every occupier or operator of common bio-medical waste treatment facility shall submit an Annual Report to the prescribed authority in Form-IV (Annexure 5) on or before the 30th June of every year. The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.

b. The Annual Reports shall also be made available online on the websites of Occupier & all healthcare facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016 (i.e. latest by 27th March 2018).

c. The annual report shall also contain

i. Number of Beds

ii. Category wise quantity of waste generated or disposed in Kgs per annum (on monthly average basis). iii. General Solid Waste

iv. Details of the Storage, treatment, transportation, processing and disposal Facility. Minutes of Meeting of the Bio-Medical Waste Management Committee held during the reporting period.

vi. Records of all Trainings Conducted, including

- Number of Trainings Conducted on BMW Management
- Number of Personnel Trained
- Number of Personnel Trained at the time of induction
- Number of Personnel not undergone any training so far
- Whether any standard manual for training is available

vii. Report of all accidents (major and minor) and the remedial actions taken, including Nil Report in Form 1 (Annexure 5) including

- Number of Accidents occurred during the year
- Number of persons affected

- Remedial Actions taken with details (if any)
- Details of any Fatality occurred

viii. Liquid Waste generated and treatment methods in place including

- Number of times in a year when the standards were not met

ix. Whether disinfection methodor sterilization meeting the log 4 standards including

- Number of times in a year when the standards were not met

3. **Accident Reporting**

a. Report major accidents (accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills) including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I (Annexure 5) to the prescribed authority and also along with the annual report. In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken, in Form I (Annexure 5).

b. Information regarding all other accidents and remedial steps taken shall be provided in the annual report (including Nil report).

4. **Maintaining of Records**

a. Every occupier shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal or any form of handling of bio-medical waste for a period of 5 years in accordance with the Biomedical Waste Management Rules, 2016 and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

b. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years.

d. Maintain for five years all records pertaining to Bio-Medical Waste, including but not limited to

i. BMW Register

ii. On-site Pre-treatment

iv. Accidents with remedial actions taken

v. Trainings

vi. Committee Meetings

vii. Health Check Ups

viii. Vaccination

x. Correspondence to Authority

ANNEXURE: 1

LABEL FOR BIO-MEDICAL WASTE CONTAINERS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL

HANDLE WITH CARE

ANNEXURE: 2

STANDARDS FOR TREATMENT & DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARD FOR INCINERATION:-

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$CE = \frac{\%CO_2}{\%CO_2 + \%\,CO} \times 100$$

(3) The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050 ^{0}C $\pm$ 50 ^{0}

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm^3 unless stated	**Sampling Duration in minutes, unless stated**
1.	Particulate matter	50	30 or $1NM^3$ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO2 expressed as NO2	400	30 for online sampling or grab sample
3.	HCl	50	30 or $1NM^3$ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 ng TEQ/Nm3 (at 11% O2)	6 hours or 5NM3 of sample volume, whichever is more

C. Stack Height

Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

2. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kil " which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC 19659) in chemical treatment systems.

3. STANDARDS FOR LIQUID WASTE

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

Parameters	Permissible Limit
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

(2) Sludge from Effluent Treatment Plant shall be incinerated.

ANNEXURE: 3

FORM – II. APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To,

The Prescribed Authority

(Name of the State or UT Administration) Address.

1. Particulars of Applicant:

   (i) Name of the Applicant:

   (In block letters & in full)

   (ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF) :

   (iii) Address for correspondence:

   (iv) Tele No., Fax No.:

   (v) Email:

   (vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please

DOCUMENT TYPE	**STANDARD OPERATING PROCEDURE**
DOCUMENT NO.	**BLDEU, SBMPMCH&RC/BMWM -01**
TITLE	**Biomedical Waste Management**

Date implemented	**15.08.2017**

PREPARED BY		**VERIFIED & APPROVED BY**	
Name	Name: Dr Smitha Bagali	Name	Dr. Vijayakumar Kalyanappagol
Designation	Associate Professor (Member secretary, BMWM Committee)	Designation	Medical Superintendent **BLDE(DU's), SBMPMCH & RC**
Signature & Date		Signature & Date	

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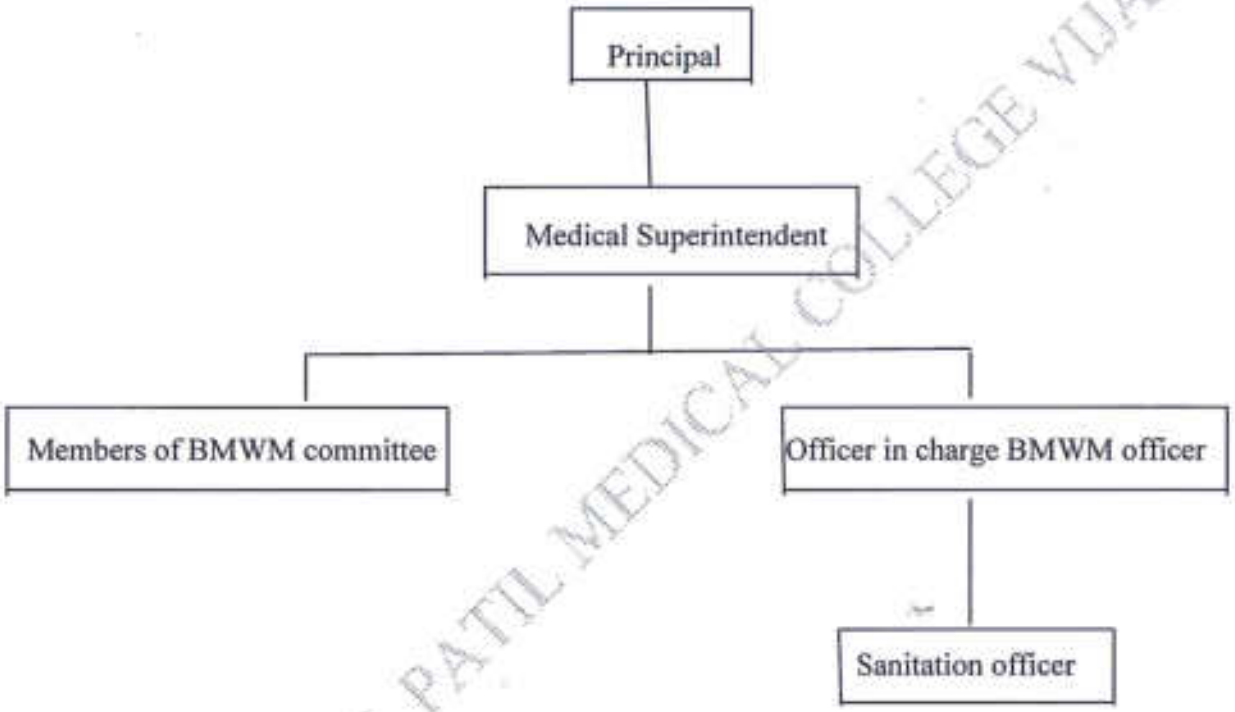
AMENDMENT RECORD

Sl. No	Page No	Section/ Para/line (as applicable)	Date of amend ment	Amendment made	Reasons of amendment	Signature of Officer I/C BMW managem ent	Signature of Medical Superintendent

II. Organogram



III. Definitions:

Sl. No.	Term	Definition
1.	Authorisation	Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.
2	Authorised person	Authorised person means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.
3	Bio-medical waste	Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules
4	Handling	Handling in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste.
5	Major Accident	Major Accident means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.
6	Management	Management includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste.
7	Occupier	Occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

IV. Process :

1. Duties of the Occupier
2. Bio-Medical Waste Management
3. Segregation of Waste
4. Waste Removal & Transportation
5. Waste storage
6. Treatment and Disposal
7. Licensing and other requirement for Bio-medical Waste Management

1. Duties of the Occupier

It shall be the duty of every occupier to-

(a) Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules

(b) Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Table I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Table 1;

(c) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018).

(e) Not to give treated bio-medical waste with municipal solid waste;

(f) Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;

(g) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.

(h) Establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of Bio-Medical Waste Management Rules, 2016.

(i) Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;

(j) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

(k) Ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;

(l) Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;

(m) Maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Table 1;

(n) Report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority, and also along with the annual report;

(o) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018 for Hospitals which do not already have a Website).

(q) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months, The record of the minutes of the meetings of shall be submitted along with the annual report to the prescribed authority.

(r) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

(s) existing incinerators (where applicable) to achieve the standards for treatment and disposal of bio-medical waste as specified in Annexure 3, for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

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Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio- medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(e) **Chemical Waste:** Chemicals used in production of biological and used or discarded disinfectants	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	f) **Chemical Liquid Waste:** Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X- ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	g) **Discarded linen,** mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
	(h) **Microbiology, Biotechnology** and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines Thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	**Contaminated Waste** (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals**: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue	(a) **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. b) **Metallic Body Implants**	Cardboard boxes with blue coloured marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Annexure 3. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time

3. Segregation of Waste

Objective: Segregation of Bio-medical waste as per guidelines.

Job Responsibility: Doctors, Nurses, Technicians, all employees handling BMW.

Description

1. BMW will not be mixed with other non-infectious wastes. If by mistake this has occurred, this non-infectious waste will then be treated as BMW.
2. The bio-medical waste shall be segregated as per categories applicable, into containers or bags at the point of generation e.g., all patient care activity areas, diagnostic service areas, operation theatre areas, treatment rooms etc. prior to its storage, transportation, treatment and disposal.
3. Non-chlorinated bags will be used for collection of biomedical waste.
4. All bags, containers or bins directly used in the collection of bio-medical wastes are labelled with appropriate biohazard Symbol (Annexure 1) which will be non-washable and prominently visible.
5. Bins used for holding the colour coded bags should be of the same colour.

4. Biomedical Waste Removal & Transportation

Objective: Biomedical Waste removal & transportation to minimize the risk of any infection.

Job Responsibility: Housekeeping staff

Description:

1. The staff handling waste must use PPE.
2. The bags must be removed when ¾th full, if not earlier.
3. The waste bag is tied up & transferred in a closed designated closed trolley to central storage area .
4. The housekeeping staff to ensure that all bags are tied when being transported & there is no spillage or leakage.
5. In case any bags has a cut or tear, ensure that double bagging is done before moving it.

5. Biomedical Waste storage

Objective: Waste storage at biomedical waste treatment facility.

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. Storage of biomedical waste should not extend 48 hrs.
2. Bio-medical waste is not mixed with other waste. There is differentiation between the storage areas for different categories of Bio-medical waste
3. The Bio-medical waste is stored in safe, ventilated and secured location for storage of segregated biomedical waste in Coloured Bags or containers as per colour coding norms.
4. Weighing will be done at the central area and weight mentioned on a register maintained for this purpose.

6. Treatment and Disposal

Objective: Proper Treatment and disposal of biomedical waste

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. **Human Anatomical Waste**, Animal anatomical waste, soiled waste will be incinerated without pretreatment

2. **Chemical Liquid waste** generated due to use of chemicals in production of biological and used or discarded disinfectants like discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc is directed by Separate collection system leading to effluent treatment system .

3. After resource recovery, the chemical liquid waste shall be pre-treated at effluent treatment plant before mixing with other waste water in compliance with the standards provided in Annexure 2, by the health care facility.

4. **Clinical laboratory waste**: Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated with chemical disinfectant i.e 1% sodium hypochlorite for 30 mins.

5. **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, returned back to the manufacturer

6. Discarded linen, mattresses, beddings contaminated with blood or body fluid are treated by Non-chlorinated chemical disinfection followed by incineration

7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

8. **Recyclable waste** are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes followed by mutilation or shredding, the recyclables from the treated bio-medical wastes such as

plastics shall be given to recyclers having valid authorisation or registration from the respective prescribed authority.

9. The Occupier shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

10. **Waste sharps** including metals are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes and disposed into designated concrete waste sharp pit.

11. **Glassware**: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes are disinfected by soaking the washed glass waste with 1% Sodium Hypochlorite for 30 minutes and then sent to recyclers having valid authorisation or registration from the respective prescribed authority. .

7. Licensing & Other requirements for Bio-medical Waste Management

Objective: Licensing & Other requirements for Bio-medical Waste management

Job Responsibility: Head- Administration

Description:

1. Application for Authorization

a. Every occupier handling bio-medical waste, irrespective of the quantity shall make an application in Form II (Annexure 3) to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III (Annexure 4) and the validity of such authorisation for bedded health care facility shall be synchronised with the validity of the consents.

b. Disposal of this application shall be done by the authority (Pollution Control Board in states or Pollution Control Committee in union territories, as the case may be) within 90 days from the date of receipt, failing which it shall be deemed that the authorisation is granted under the Biomedical Waste Management Rules.

c. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II (Annexure 3) for modification of the conditions of authorisation.

d. Occupier should apply for Renewal at least 3 months prior to expiry of the Authorization.

2. **Annual Report**

a. Every occupier or operator of common bio-medical waste treatment facility shall submit an Annual Report to the prescribed authority in Form-IV (Annexure 5) on or before the 30th June of every year. The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.

b. The Annual Reports shall also be made available online on the websites of Occupier & all healthcare facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016 (i.e. latest by 27th March 2018).

c. The annual report shall also contain

i. Number of Beds

ii. Category wise quantity of waste generated or disposed in Kgs per annum (on monthly average basis). iii. General Solid Waste

iv. Details of the Storage, treatment, transportation, processing and disposal Facility. Minutes of Meeting of the Bio-Medical Waste Management Committee held during the reporting period.

vi. Records of all Trainings Conducted, including

- Number of Trainings Conducted on BMW Management
- Number of Personnel Trained
- Number of Personnel Trained at the time of induction
- Number of Personnel not undergone any training so far
- Whether any standard manual for training is available

vii. Report of all accidents (major and minor) and the remedial actions taken, including Nil Report in Form 1 (Annexure 5) including

- Number of Accidents occurred during the year
- Number of persons affected

- Remedial Actions taken with details (if any)
- Details of any Fatality occurred

viii. Liquid Waste generated and treatment methods in place including

- Number of times in a year when the standards were not met

ix. Whether disinfection methodor sterilization meeting the log 4 standards including

- Number of times in a year when the standards were not met

3. **Accident Reporting**

a. Report major accidents (accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills) including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I (Annexure 5) to the prescribed authority and also along with the annual report. In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken, in Form I (Annexure 5).

b. Information regarding all other accidents and remedial steps taken shall be provided in the annual report (including Nil report).

4. **Maintaining of Records**

a. Every occupier shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal or any form of handling of bio-medical waste for a period of 5 years in accordance with the Biomedical Waste Management Rules, 2016 and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

b. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years.

d. Maintain for five years all records pertaining to Bio-Medical Waste, including but not limited to

i. BMW Register

ii. On-site Pre-treatment

iv. Accidents with remedial actions taken

v. Trainings

vi. Committee Meetings

vii. Health Check Ups

viii. Vaccination

x. Correspondence to Authority

ANNEXURE: 1

LABEL FOR BIO-MEDICAL WASTE CONTAINERS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL

HANDLE WITH CARE

ANNEXURE: 2

STANDARDS FOR TREATMENT & DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARD FOR INCINERATION:-

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$CE = \frac{\%CO_2}{\%CO_2 + \%\,CO} \times 100$$

(3) The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050 ^{0}C $\pm$ 50 ^{0}

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm^3 unless stated	**Sampling Duration in minutes, unless stated**
1.	Particulate matter	50	30 or $1NM^3$ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO2 expressed as NO2	400	30 for online sampling or grab sample
3.	HCl	50	30 or $1NM^3$ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 ng TEQ/Nm3 (at 11% O2)	8 hours or 5NM3 of sample volume, whichever is more

C. Stack Height

Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

2. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kil " which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC 19659) in chemical treatment systems.

3. STANDARDS FOR LIQUID WASTE

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

Parameters	Permissible Limit
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

(2) Sludge from Effluent Treatment Plant shall be incinerated.

ANNEXURE: 3

FORM – II. APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To,

The Prescribed Authority

(Name of the State or UT Administration) Address.

1. Particulars of Applicant:

   (i) Name of the Applicant:

   (In block letters & in full)

   (ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (iii) Address for correspondence:

   (iv) Tele No., Fax No.:

   (v) Email:

   (vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please

	tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	

Activity	Please tick
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. Application for □ fresh or □ renewal of authorisation (please tick whatever is applicable):
   (i) Applied for CTO/CTE Yes/No
   (ii) In case of renewal previous authorisation number and date:

   (iii) Status of Consents:
      i. under the Water (Prevention and Control of Pollution) Act, 1974
      ---
      ii. under the Air (Prevention and Control of Pollution) Act, 1981:

4.
   (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility

(CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):
   - (i) Number of beds of HCF:
   - (ii) Number of patients treated per month by HCF:
   - (iii) Number healthcare facilities covered by CBMWTF: _____
   - (iv) No. of beds covered by CBMWTF: _____
   - (v) Installed treatment and disposal capacity of CBMWTF: _____ Kg per day
   - (vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/ day
   - (vii) (vii) Area or distance covered by CBMWTF:_____ (pl. attach map a map with GPS locations of CBMWTF and area of coverage)
   - (viii) Quantity of Biomedical waste handled, treated or disposed

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of Treatment and Disposal (Refer Schedule-I)
(1)	(2)	(3)	(4)
Yellow	(i) Human Anatomical Waste:		
	(ii) Animal Anatomical Waste:		
	(iii) Soiled Waste:		
	(iv) Expired or Discarded Medicines:		
	(v) Chemical Solid Waste:		
	(vi) Chemical Liquid Waste :		
	(vii) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		
	viii) Microbiology, Biotechnology and other clinical laboratory waste:		
Red	Contaminated Waste (Recyclable)		
White (Transluce nt)	Waste sharps including Metals:		
Blue	Glassware:		
	Metallic Body Implants		

6. Brief description of arrangements for handling of biomedical waste (attach details):
   (i) Mode of transportation (if any) of bio-medical waste:
   (ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

	No. of units	Capacity of each unit
Incinerators :		
Plasma Pyrolysis:		
Autoclaves:		
Microwave:		
Hydroclave:		
Shredder:		
Needle tip cutter or destroyer		
Sharps encapsulation or		
concrete pit:		
Deep burial pits:		
Chemical disinfection:		
Any other treatment equipment:		

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):
8. Details of directions or notices or legal actions if any during the period of earlier authorisation.
9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfil any conditions stipulated by the prescribed authority.

Date: Sign of the Applicant

Place: Designation of the Applicant

ANNEXURE 4

FORM –III. AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical wastes)

1. File number of authorisation and date of issue.....
2. M/s _____an occupier or operator of the facility located at _____is hereby granted an authorisation for;

Activity	Please tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. M/s_____is hereby authorized for handling of biomedical waste as per the capacity given below;
   (i) Number of beds of HCF:
   (ii) Number healthcare facilities covered by CBMWTF: _____ (iii)Installed treatment and

disposal capacity:_____Kg per day

(iv) Area or distance covered by CBMWTF:_____

(v) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow	
Red	
White (Translucent)	
Blue	

4. This authorisation shal be in force for a period of ..... Years from the date of issue.
5. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date: ..... Sign .....

Place ..... Designation: .....

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

ANNEXURE 5: FORM IV ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

S.No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorised person (occupier or operator of facility)	:	
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility	:	
	(v) Tel. No, Fax. No	:	
	(vi) E-mail ID	:	
	(vii) URL of Website	:	
	(viii) GPS coordinates of HCF or CBMWTF	:	
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or Semi Govt. or any other)
	(x) Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.: ....valid up to .....

	(x i) Status of Consents under Water Act and Air Act	:	Valid up to:
S.No.	**Particulars**		
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of beds
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	
	(iii) License number and its date of expiry	:	
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF	:	
	(ii) No. of beds covered by CBMWTF	:	
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	_____Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	_____Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category: Red Category: White:

		Blue Category :
		General Solid waste:
5.	Details of the Storage, treatment, transportation, processing and Disposal Facility	
	(i) Details of the on-site storage facility	Size:
		Capacity:
		Provision of on-site storage : (cold storage or any other provision)

(ii) Disposal facilities

Type of treatment equipment	No. of units	Capacity Kg/day	Quantity treated or disposed in kg per annum
Incinerators			
Plasma Pyrolysis			
Autoclaves			
Microwave			
Hydroclave			
Shredder			
Needle tip cutter or destroyer			
Sharps encapsulation or concrete pit			
Deep burial pits:			
Chemical disinfection:			

		Any other treatment equipment:	
	(iii)Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	Red Category (like plastic, glass etc.)	
	(iv) No of vehicles used for collection and transportation of biomedical waste		
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum		Quantity generated / Where disposed
		Incineration Ash	
		ETP Sludge	
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of		
	(vii) List of member HCF not handed over bio-medical waste		
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period		
7.	Details trainings conducted on BMW		

	(i) Number of trainings conducted on BMW Management.		
	(ii) number of personnel trained		
	(iii) number of personnel trained at the time of induction		
	(iv) number of personnel not undergone any training so far		
	(v) whether standard manual for training is available?		
	(vi) any other information)		
8.	Details of the accident occurred during the year		
	(i) Number of Accidents occurred		
	(ii) Number of the persons affected		
	(iii) Remedial Action taken (Please attach details if any)		
	(iv) Any Fatality occurred, details		
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		
	Details of Continuous online emission monitoring systems installed		

10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		
11.	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		
12.	Any other relevant information		(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from .....

..... Date:

Name and Signature of the Head of the Institution Place:

ANNEXURE: 6

FORM I: ACCIDENT REPORTING

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately:
5. The type of waste involved in accident:
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to alleviate the effects of accidents:
9. Steps taken to prevent the recurrence of such an accident:
10. Does you facility has an Emergency Control policy? If yes give details:

Date..... Signature.....

Place..... Designation.....

DOCUMENT TYPE	**STANDARD OPERATING PROCEDURE**
DOCUMENT NO.	**BLDEU, SBMPMCH&RC/BMWM -01**
TITLE	**Biomedical Waste Management**

Date implemented	**15.08.2018**

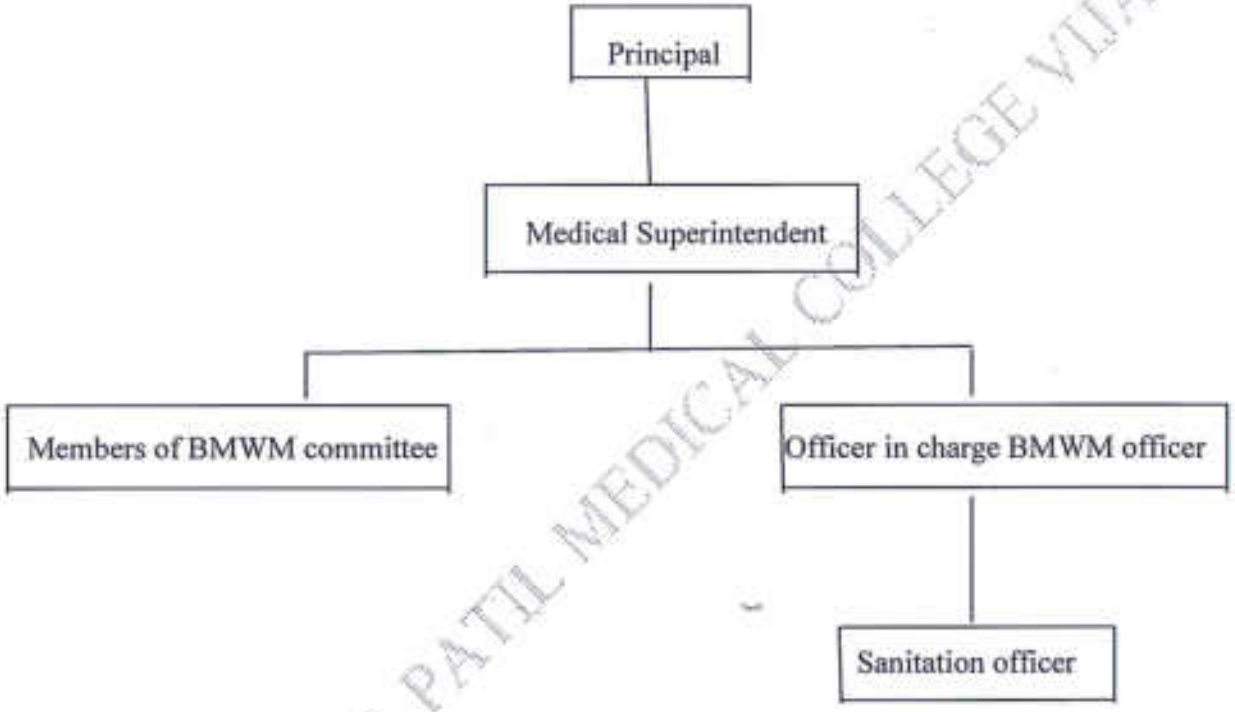
PREPARED BY		**VERIFIED & APPROVED BY**	
Name	Name: Dr Smitha Bagali	Name	Dr. Vijayakumar Kalyanappagol
Designation	Associate Professor (Member secretary, BMWM Committee)	Designation	Medical Superintendent **BLDE(DU's), SBMPMCH & RC**
Signature & Date		Signature & Date	

Table of Contents

AMENDMENT RECORD

Sl. No	Page No	Section/ Para/line (as applicable)	Date of amendment	Amendment made	Reasons of amendment	Signature of Officer I/C BMW management	Signature of Medical Superintendent
1	14	3rd column	12.08.2018	Cardboarbox with blue marking boxes replaced puncture proof leak proof blue coloured container	Amenended as per BMWM Rules amendment 2018		

II. Organogram



III. Definitions:

Sl. No.	Term	Definition
1.	Authorisation	Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.
2	Authorised person	Authorised person means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.
3	Bio-medical waste	Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules
4	Handling	Handling in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste.
5	Major Accident	Major Accident means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.
6	Management	Management includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste.
7	Occupier	Occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

IV. Process :

1. Duties of the Occupier
2. Bio-Medical Waste Management
3. Segregation of Waste
4. Waste Removal & Transportation
5. Waste storage
6. Treatment and Disposal
7. Licensing and other requirement for Bio-medical Waste Management

1. Duties of the Occupier

It shall be the duty of every occupier to-

(a) Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules

(b) Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Table I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Table 1;

(c) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018).

(e) Not to give treated bio-medical waste with municipal solid waste;

(f) Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;

(g) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.

(h) Establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of Bio-Medical Waste Management Rules, 2016.

(i) Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;

(j) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

(k) Ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;

(l) Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;

(m) Maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Table 1;

(n) Report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority, and also along with the annual report;

(o) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018 for Hospitals which do not already have a Website).

(q) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months, The record of the minutes of the meetings of shall be submitted along with the annual report to the prescribed authority.

(r) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

(s) existing incinerators (where applicable) to achieve the standards for treatment and disposal of bio-medical waste as specified in Annexure 3, for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

2. Biomedical Waste Management

Objective: To provide guidelines for management of Bio-medical waste.

Purpose: To define the guidelines for segregation, handling, storage, transportation and disposal of various kinds of biomedical waste.

Scope: This SOP applies to all employees who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form. The scope of this SOP applies to biomedical waste only.
Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Table 1. Categories of Biomedical waste

Table 1: Categories of Biomedical waste

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time). **(b) Animal Anatomical** Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio- medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(e) **Chemical Waste:** Chemicals used in production of biological and used or discarded disinfectants	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	f) **Chemical Liquid Waste**: Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X- ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	g) **Discarded linen,** mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
	(h) **Microbiology, Biotechnology** and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines Thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	**Contaminated Waste** (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue	(a) **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Puncture proof, Leak proof blue coloured containers	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	b) **Metallic Body Implants**		

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Annexure 3. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time

3. Segregation of Waste

Objective: Segregation of Bio-medical waste as per guidelines.

Job Responsibility: Doctors, Nurses, Technicians, all employees handling BMW.

Description

1. BMW will not be mixed with other non-infectious wastes. If by mistake this has occurred, this non-infectious waste will then be treated as BMW.
2. The bio-medical waste shall be segregated as per categories applicable, into containers or bags at the point of generation e.g., all patient care activity areas, diagnostic service areas, operation theatre areas, treatment rooms etc. prior to its storage, transportation, treatment and disposal.
3. Non-chlorinated bags will be used for collection of biomedical waste.
4. All bags, containers or bins directly used in the collection of bio-medical wastes are labelled with appropriate biohazard Symbol (Annexure 1) which will be non-washable and prominently visible.
5. Bins used for holding the colour coded bags should be of the same colour.

4. Biomedical Waste Removal & Transportation

Objective: Biomedical Waste removal & transportation to minimize the risk of any infection.

Job Responsibility: Housekeeping staff

Description:

1. The staff handling waste must use PPE.
2. The bags must be removed when ¾th full, if not earlier.
3. The waste bag is tied up & transferred in a closed designated closed trolley to central storage area .
4. The housekeeping staff to ensure that all bags are tied when being transported & there is no spillage or leakage.
5. In case any bags has a cut or tear, ensure that double bagging is done before moving it.

5. Biomedical Waste storage

Objective: Waste storage at biomedical waste treatment facility.

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. Storage of biomedical waste should not extend 48 hrs.
2. Bio-medical waste is not mixed with other waste. There is differentiation between the storage areas for different categories of Bio-medical waste
3. The Bio-medical waste is stored in safe, ventilated and secured location for storage of segregated biomedical waste in Coloured Bags or containers as per colour coding norms.
4. Weighing will be done at the central area and weight mentioned on a register maintained for this purpose.

6. Treatment and Disposal

Objective: Proper Treatment and disposal of biomedical waste

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. **Human Anatomical Waste**, Animal anatomical waste, soiled waste will be incinerated without pretreatment

2. **Chemical Liquid waste** generated due to use of chemicals in production of biological and used or discarded disinfectants like discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc is directed by Separate collection system leading to effluent treatment system .

3. After resource recovery, the chemical liquid waste shall be pre-treated at effluent treatment plant before mixing with other waste water in compliance with the standards provided in Annexure 2, by the health care facility.

4. **Clinical laboratory waste**: Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated with chemical disinfectant i.e 1% sodium hypochlorite for 30 mins.

5. **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, returned back to the manufacturer

6. Discarded linen, mattresses, beddings contaminated with blood or body fluid are treated by Non-chlorinated chemical disinfection followed by incineration

7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

8. **Recyclable waste** are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes followed by mutilation or shredding, the recyclables from the treated bio-medical wastes such as

plastics shall be given to recyclers having valid authorisation or registration from the respective prescribed authority.

9. The Occupier shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

10. **Waste sharps** including metals are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes and disposed into designated concrete waste sharp pit.

11. **Glassware**: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes are disinfected by soaking the washed glass waste with 1% Sodium Hypochlorite for 30 minutes and then sent to recyclers having valid authorisation or registration from the respective prescribed authority. .

7. Licensing & Other requirements for Bio-medical Waste Management

Objective: Licensing & Other requirements for Bio-medical Waste management

Job Responsibility: Head- Administration

Description:

1. Application for Authorization

a. Every occupier handling bio-medical waste, irrespective of the quantity shall make an application in Form II (Annexure 3) to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III (Annexure 4) and the validity of such authorisation for bedded health care facility shall be synchronised with the validity of the consents.

b. Disposal of this application shall be done by the authority (Pollution Control Board in states or Pollution Control Committee in union territories, as the case may be) within 90 days from the date of receipt, failing which it shall be deemed that the authorisation is granted under the Biomedical Waste Management Rules.

c. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II (Annexure 3) for modification of the conditions of authorisation.

d. Occupier should apply for Renewal at least 3 months prior to expiry of the Authorization.

2. **Annual Report**

a. Every occupier or operator of common bio-medical waste treatment facility shall submit an Annual Report to the prescribed authority in Form-IV (Annexure 5) on or before the 30th June of every year. The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.

b. The Annual Reports shall also be made available online on the websites of Occupier & all healthcare facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016 (i.e. latest by 27th March 2018).

c. The annual report shall also contain

i. Number of Beds

ii. Category wise quantity of waste generated or disposed in Kgs per annum (on monthly average basis). iii. General Solid Waste

iv. Details of the Storage, treatment, transportation, processing and disposal Facility. Minutes of Meeting of the Bio-Medical Waste Management Committee held during the reporting period.

vi. Records of all Trainings Conducted, including

- Number of Trainings Conducted on BMW Management
- Number of Personnel Trained
- Number of Personnel Trained at the time of induction
- Number of Personnel not undergone any training so far
- Whether any standard manual for training is available

vii. Report of all accidents (major and minor) and the remedial actions taken, including Nil Report in Form 1 (Annexure 5) including

- Number of Accidents occurred during the year
- Number of persons affected

- Remedial Actions taken with details (if any)
- Details of any Fatality occurred

viii. Liquid Waste generated and treatment methods in place including

- Number of times in a year when the standards were not met

ix. Whether disinfection methodor sterilization meeting the log 4 standards including

- Number of times in a year when the standards were not met

3. **Accident Reporting**

a. Report major accidents (accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills) including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I (Annexure 5) to the prescribed authority and also along with the annual report. In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken, in Form I (Annexure 5).

b. Information regarding all other accidents and remedial steps taken shall be provided in the annual report (including Nil report).

4. **Maintaining of Records**

a. Every occupier shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal or any form of handling of bio-medical waste for a period of 5 years in accordance with the Biomedical Waste Management Rules, 2016 and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

b. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years.

d. Maintain for five years all records pertaining to Bio-Medical Waste, including but not limited to

i. BMW Register

ii. On-site Pre-treatment

iv. Accidents with remedial actions taken

v. Trainings

vi. Committee Meetings

vii. Health Check Ups

viii. Vaccination

x. Correspondence to Authority

ANNEXURE: 1

LABEL FOR BIO-MEDICAL WASTE CONTAINERS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL

HANDLE WITH CARE

ANNEXURE: 2

STANDARDS FOR TREATMENT & DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARD FOR INCINERATION:-

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$CE = \frac{\%CO2}{\%CO2 + \%CO} - X\ 100$$

(3) The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050 ^{0}C $\pm$ 50 ^{0}

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm^3 unless stated	**Sampling Duration in minutes, unless stated**
1.	Particulate matter	50	30 or $1NM^3$ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO2 expressed as NO2	400	30 for online sampling or grab sample
3.	HCl	50	30 or $1NM^3$ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 ng TEQ/Nm3 (at 11% O2)	6 to 8 hours or $5NM^3$ of sample volume, whichever is more
	Hg and its compounds	0.05 mg/Nm3	30 or 1NM3 of sample volume, whichever is more

C. Stack Height

Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

2. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kil " which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC 19659) in chemical treatment systems.

3. STANDARDS FOR LIQUID WASTE

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

Parameters	Permissible Limit
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

(2) Sludge from Effluent Treatment Plant shall be incinerated.

ANNEXURE: 3

FORM – II. APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To,

The Prescribed Authority

(Name of the State or UT Administration) Address.

1. Particulars of Applicant:

   (i) Name of the Applicant:

   (In block letters & in full)

   (ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (iii) Address for correspondence:

   (iv) Tele No., Fax No.:

   (v) Email:

   (vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please

	tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	

Activity	Please tick
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. Application for □ fresh or □ renewal of authorisation (please tick whatever is applicable):
   (i) Applied for CTO/CTE Yes/No
   (ii) In case of renewal previous authorisation number and date:

   (iii) Status of Consents:
      i. under the Water (Prevention and Control of Pollution) Act, 1974
      ---
      ii. under the Air (Prevention and Control of Pollution) Act, 1981:

4.
   (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility

(CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):
   - (i) Number of beds of HCF:
   - (ii) Number of patients treated per month by HCF:
   - (iii) Number healthcare facilities covered by CBMWTF: _____
   - (iv) No. of beds covered by CBMWTF: _____
   - (v) Installed treatment and disposal capacity of CBMWTF: _____ Kg per day
   - (vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/ day
   - (vii) (vii) Area or distance covered by CBMWTF:_____ (pl. attach map a map with GPS locations of CBMWTF and area of coverage)
   - (viii) Quantity of Biomedical waste handled, treated or disposed

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of Treatment and Disposal (Refer Schedule-I)
(1)	(2)	(3)	(4)
Yellow	(i) Human Anatomical Waste:		
	(ii) Animal Anatomical Waste:		
	(iii) Soiled Waste:		
	(iv) Expired or Discarded Medicines:		
	(v) Chemical Solid Waste:		
	(vi) Chemical Liquid Waste :		
	(vii) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		
	viii) Microbiology, Biotechnology and other clinical laboratory waste:		
Red	Contaminated Waste (Recyclable)		
White (Transluce nt)	Waste sharps including Metals:		
Blue	Glassware:		
	Metallic Body Implants		

6. Brief description of arrangements for handling of biomedical waste (attach details):
   (i) Mode of transportation (if any) of bio-medical waste:
   (ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

	No. of units	Capacity of each unit
Incinerators :		
Plasma Pyrolysis:		
Autoclaves:		
Microwave:		
Hydroclave:		
Shredder:		
Needle tip cutter or destroyer		
Sharps encapsulation or		
concrete pit:		
Deep burial pits:		
Chemical disinfection:		
Any other treatment equipment:		

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):
8. Details of directions or notices or legal actions if any during the period of earlier authorisation.
9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfil any conditions stipulated by the prescribed authority.

Date: Sign of the Applicant

Place: Designation of the Applicant

ANNEXURE 4

FORM –III. AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical wastes)

1. File number of authorisation and date of issue.....
2. M/s _____an occupier or operator of the facility located at _____is hereby granted an authorisation for;

Activity	Please tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. M/s_____is hereby authorized for handling of biomedical waste as per the capacity given below;
   (i) Number of beds of HCF:
   (ii) Number healthcare facilities covered by CBMWTF: _____ (iii)Installed treatment and

disposal capacity:_____Kg per day

(iv) Area or distance covered by CBMWTF:_____

(v) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow	
Red	
White (Translucent)	
Blue	

4. This authorisation shal be in force for a period of ..... Years from the date of issue.
5. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date: ..... Sign .....

Place ..... Designation: .....

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

ANNEXURE 5: FORM IV ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

S.No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorised person (occupier or operator of facility)	:	
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility	:	
	(v) Tel. No, Fax. No	:	
	(vi) E-mail ID	:	
	(vii) URL of Website	:	
	(viii) GPS coordinates of HCF or CBMWTF	:	
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or Semi Govt. or any other)
	(x) Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.: ....valid up to .....

	(x i) Status of Consents under Water Act and Air Act	:	Valid up to:
S.No.	**Particulars**		
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of beds
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	
	(iii) License number and its date of expiry	:	
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF	:	
	(ii) No. of beds covered by CBMWTF	:	
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	_____Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	_____Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category: Red Category: White:

		Blue Category :	
		General Solid waste:	
5.	Details of the Storage, treatment, transportation, processing and Disposal Facility		
	(i) Details of the on-site storage facility	Size:	
		Capacity:	
		Provision of on-site storage : (cold storage or any other provision)	

(ii) Disposal facilities

Type of treatment equipment	No. of units	Capacity Kg/day	Quantity treated or disposed in kg per annum
Incinerators			
Plasma Pyrolysis			
Autoclaves			
Microwave			
Hydroclave			
Shredder			
Needle tip cutter or destroyer			
Sharps encapsulation or concrete pit			
Deep burial pits:			
Chemical disinfection:			

			Any other treatment equipment:
	(iii)Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.		Red Category (like plastic, glass etc.)
	(iv) No of vehicles used for collection and transportation of biomedical waste		
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum		Incineration Ash / ETP Sludge — Quantity generated / Where disposed
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of		
	(vii) List of member HCF not handed over bio-medical waste		
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period		
7.	Details trainings conducted on BMW		

	(i) Number of trainings conducted on BMW Management.		
	(ii) number of personnel trained		
	(iii) number of personnel trained at the time of induction		
	(iv) number of personnel not undergone any training so far		
	(v) whether standard manual for training is available?		
	(vi) any other information)		
8.	Details of the accident occurred during the year		
	(i) Number of Accidents occurred		
	(ii) Number of the persons affected		
	(iii) Remedial Action taken (Please attach details if any)		
	(iv) Any Fatality occurred, details		
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		
	Details of Continuous online emission monitoring systems installed		

10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		
11.	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		
12.	Any other relevant information		(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from .....

..... Date:

Name and Signature of the Head of the Institution Place:

ANNEXURE: 6

FORM I: ACCIDENT REPORTING

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately:
5. The type of waste involved in accident:
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to alleviate the effects of accidents:
9. Steps taken to prevent the recurrence of such an accident:
10. Does you facility has an Emergency Control policy? If yes give details:

Date..... Signature.....

Place..... Designation.....

DOCUMENT TYPE	**STANDARD OPERATING PROCEDURE**
DOCUMENT NO.	**BLDEU, SBMPMCH&RC/BMWM -01**
TITLE	**Biomedical Waste Management**

Date implemented	**15.08.2019**

PREPARED BY		**VERIFIED & APPROVED BY**	
Name	Name: Dr Smitha Bagali	Name	Dr. Vijayakumar Kalyanappagol
Designation	Associate Professor (Member secretary, BMWM Committee)	Designation	Medical Superintendent **BLDE(DU's), SBMPMCH & RC**
Signature & Date		Signature & Date	

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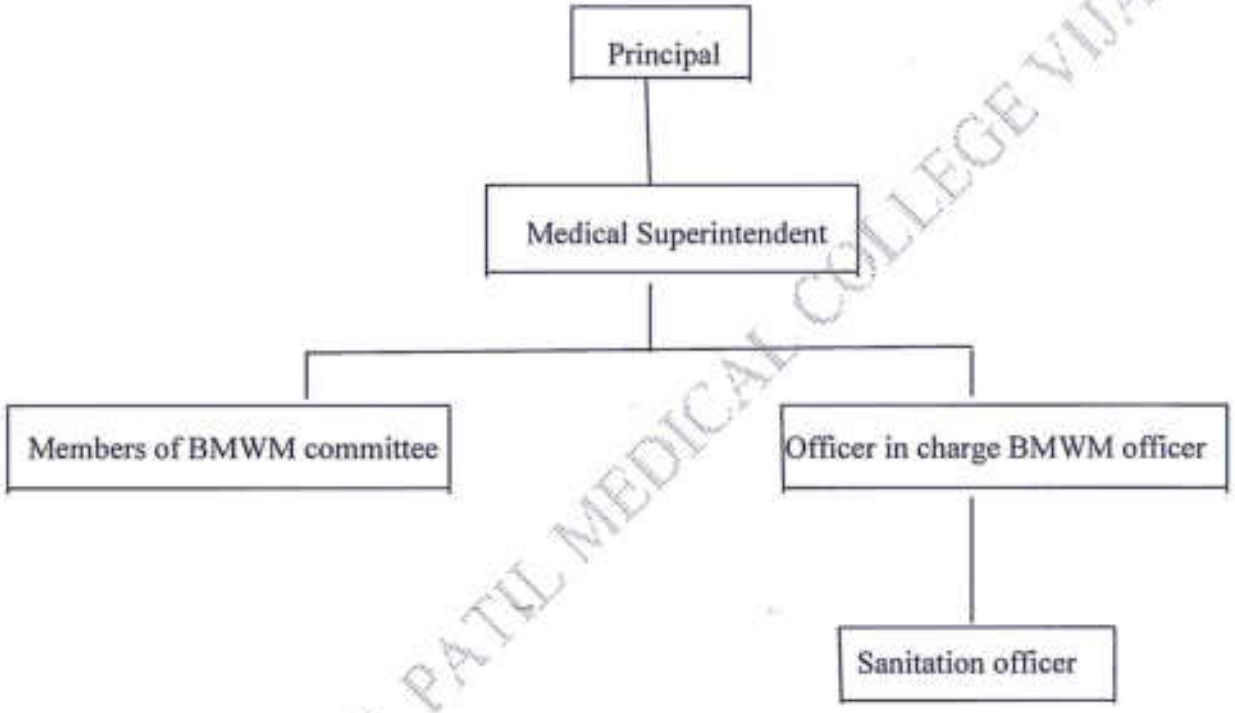
AMENDMENT RECORD

Sl. No	Page No	Section/ Para/line (as applicable)	Date of amend ment	Amendment made	Reasons of amendment	Signature of Officer I/C BMW managem ent	Signature of Medical Superintendent

II. Organogram



III. Definitions:

Sl. No.	Term	Definition
1.	Authorisation	Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.
2	Authorised person	Authorised person means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.
3	Bio-medical waste	Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules
4	Handling	Handling in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste.
5	Major Accident	Major Accident means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.
6	Management	Management includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste.
7	Occupier	Occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

IV. Process :

1. Duties of the Occupier
2. Bio-Medical Waste Management
3. Segregation of Waste
4. Waste Removal & Transportation
5. Waste storage
6. Treatment and Disposal
7. Licensing and other requirement for Bio-medical Waste Management

1. Duties of the Occupier

It shall be the duty of every occupier to-

(a) Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules

(b) Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Table I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Table 1;

(c) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018).

(e) Not to give treated bio-medical waste with municipal solid waste;

(f) Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;

(g) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.

(h) Establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of Bio-Medical Waste Management Rules, 2016.

(i) Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;

(j) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

(k) Ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;

(l) Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;

(m) Maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Table 1;

(n) Report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority, and also along with the annual report;

(o) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018 for Hospitals which do not already have a Website).

(q) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months, The record of the minutes of the meetings of shall be submitted along with the annual report to the prescribed authority.

(r) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

(s) existing incinerators (where applicable) to achieve the standards for treatment and disposal of bio-medical waste as specified in Annexure 3, for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

2. Biomedical Waste Management

Objective: To provide guidelines for management of Bio-medical waste.

Purpose: To define the guidelines for segregation, handling, storage, transportation and disposal of various kinds of biomedical waste.

Scope: This SOP applies to all employees who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form. The scope of this SOP applies to biomedical waste only.
Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Table 1. Categories of Biomedical waste

Table 1: Categories of Biomedical waste

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time). **(b) Animal Anatomical** Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio- medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(e) **Chemical Waste:** Chemicals used in production of biological and used or discarded disinfectants	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	f) **Chemical Liquid Waste**: Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X- ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	g) **Discarded linen,** mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
	(h) **Microbiology, Biotechnology** and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines Thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	**Contaminated Waste** (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals**: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue	(a) **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. b) **Metallic Body Implants**	Cardboard boxes with blue coloured marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Annexure 3. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time

3. Segregation of Waste

Objective: Segregation of Bio-medical waste as per guidelines.

Job Responsibility: Doctors, Nurses, Technicians, all employees handling BMW.

Description

1. BMW will not be mixed with other non-infectious wastes. If by mistake this has occurred, this non-infectious waste will then be treated as BMW.
2. The bio-medical waste shall be segregated as per categories applicable, into containers or bags at the point of generation e.g., all patient care activity areas, diagnostic service areas, operation theatre areas, treatment rooms etc. prior to its storage, transportation, treatment and disposal.
3. Non-chlorinated bags will be used for collection of biomedical waste.
4. All bags, containers or bins directly used in the collection of bio-medical wastes are labelled with appropriate biohazard Symbol (Annexure 1) which will be non-washable and prominently visible.
5. Bins used for holding the colour coded bags should be of the same colour.

4. Biomedical Waste Removal & Transportation

Objective: Biomedical Waste removal & transportation to minimize the risk of any infection.

Job Responsibility: Housekeeping staff

Description:

1. The staff handling waste must use PPE.
2. The bags must be removed when ¾th full, if not earlier.
3. The waste bag is tied up & transferred in a closed designated closed trolley to central storage area .
4. The housekeeping staff to ensure that all bags are tied when being transported & there is no spillage or leakage.
5. In case any bags has a cut or tear, ensure that double bagging is done before moving it.

5. Biomedical Waste storage

Objective: Waste storage at biomedical waste treatment facility.

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. Storage of biomedical waste should not extend 48 hrs.
2. Bio-medical waste is not mixed with other waste. There is differentiation between the storage areas for different categories of Bio-medical waste
3. The Bio-medical waste is stored in safe, ventilated and secured location for storage of segregated biomedical waste in Coloured Bags or containers as per colour coding norms.
4. Weighing will be done at the central area and weight mentioned on a register maintained for this purpose.

6. Treatment and Disposal

Objective: Proper Treatment and disposal of biomedical waste

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. **Human Anatomical Waste**, Animal anatomical waste, soiled waste will be incinerated without pretreatment
2. **Chemical Liquid waste** generated due to use of chemicals in production of biological and used or discarded disinfectants like discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc is directed by Separate collection system leading to effluent treatment system.
3. After resource recovery, the chemical liquid waste shall be pre-treated at effluent treatment plant before mixing with other waste water in compliance with the standards provided in Annexure 2, by the health care facility.
4. **Clinical laboratory waste**: Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated with chemical disinfectant i.e 1% sodium hypochlorite for 30 mins.
5. **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, returned back to the manufacturer
6. Discarded linen, mattresses, beddings contaminated with blood or body fluid are treated by Non-chlorinated chemical disinfection followed by incineration
7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.
8. **Recyclable waste** are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes followed by mutilation or shredding, the recyclables from the treated bio-medical wastes such as

plastics shall be given to recyclers having valid authorisation or registration from the respective prescribed authority.

9. The Occupier shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

10. **Waste sharps** including metals are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes and disposed into designated concrete waste sharp pit.

11. **Glassware**: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes are disinfected by soaking the washed glass waste with 1% Sodium Hypochlorite for 30 minutes and then sent to recyclers having valid authorisation or registration from the respective prescribed authority. .

7. Licensing & Other requirements for Bio-medical Waste Management

Objective: Licensing & Other requirements for Bio-medical Waste management

Job Responsibility: Head- Administration

Description:

1. Application for Authorization

a. Every occupier handling bio-medical waste, irrespective of the quantity shall make an application in Form II (Annexure 3) to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III (Annexure 4) and the validity of such authorisation for bedded health care facility shall be synchronised with the validity of the consents.

b. Disposal of this application shall be done by the authority (Pollution Control Board in states or Pollution Control Committee in union territories, as the case may be) within 90 days from the date of receipt, failing which it shall be deemed that the authorisation is granted under the Biomedical Waste Management Rules.

c. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II (Annexure 3) for modification of the conditions of authorisation.

d. Occupier should apply for Renewal at least 3 months prior to expiry of the Authorization.

2. **Annual Report**

a. Every occupier or operator of common bio-medical waste treatment facility shall submit an Annual Report to the prescribed authority in Form-IV (Annexure 5) on or before the 30th June of every year. The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.

b. The Annual Reports shall also be made available online on the websites of Occupier & all healthcare facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016 (i.e. latest by 27th March 2018).

c. The annual report shall also contain

i. Number of Beds

ii. Category wise quantity of waste generated or disposed in Kgs per annum (on monthly average basis). iii. General Solid Waste

iv. Details of the Storage, treatment, transportation, processing and disposal Facility. Minutes of Meeting of the Bio-Medical Waste Management Committee held during the reporting period.

vi. Records of all Trainings Conducted, including

- Number of Trainings Conducted on BMW Management
- Number of Personnel Trained
- Number of Personnel Trained at the time of induction
- Number of Personnel not undergone any training so far
- Whether any standard manual for training is available

vii. Report of all accidents (major and minor) and the remedial actions taken, including Nil Report in Form 1 (Annexure 5) including

- Number of Accidents occurred during the year
- Number of persons affected

- Remedial Actions taken with details (if any)
- Details of any Fatality occurred

viii. Liquid Waste generated and treatment methods in place including

- Number of times in a year when the standards were not met

ix. Whether disinfection methodor sterilization meeting the log 4 standards including

- Number of times in a year when the standards were not met

3. **Accident Reporting**

a. Report major accidents (accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills) including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I (Annexure 5) to the prescribed authority and also along with the annual report. In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken, in Form I (Annexure 5).

b. Information regarding all other accidents and remedial steps taken shall be provided in the annual report (including Nil report).

4. **Maintaining of Records**

a. Every occupier shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal or any form of handling of bio-medical waste for a period of 5 years in accordance with the Biomedical Waste Management Rules, 2016 and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

b. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years.

d. Maintain for five years all records pertaining to Bio-Medical Waste, including but not limited to

i. BMW Register

ii. On-site Pre-treatment

iv. Accidents with remedial actions taken

v. Trainings

vi. Committee Meetings

vii. Health Check Ups

viii. Vaccination

x. Correspondence to Authority

ANNEXURE: 1

LABEL FOR BIO-MEDICAL WASTE CONTAINERS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL

HANDLE WITH CARE

ANNEXURE: 2

STANDARDS FOR TREATMENT & DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARD FOR INCINERATION:-

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$CE = \frac{\%CO_2}{\%CO_2 + \%\,CO} \times 100$$

(3) The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050 ^{0}C $\pm$ 50 ^{0}

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm^3 unless stated	**Sampling Duration in minutes, unless stated**
1.	Particulate matter	50	30 or $1NM^3$ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO2 expressed as NO2	400	30 for online sampling or grab sample
3.	HCl	50	30 or $1NM^3$ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 ng TEQ/Nm3 (at 11% O2)	6 to 8 hours or 5NM3 of sample volume, whichever is more

C. Stack Height

Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

2. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kil " which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC 19659) in chemical treatment systems.

3. STANDARDS FOR LIQUID WASTE

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

Parameters	Permissible Limit
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

(2) Sludge from Effluent Treatment Plant shall be incinerated.

ANNEXURE: 3

FORM – II. APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To,

The Prescribed Authority

(Name of the State or UT Administration) Address.

1. Particulars of Applicant:

   (i) Name of the Applicant:

   (In block letters & in full)

   (ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (iii) Address for correspondence:

   (iv) Tele No., Fax No.:

   (v) Email:

   (vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please

	tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	

Activity	Please tick
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. Application for □ fresh or □ renewal of authorisation (please tick whatever is applicable):
   (i) Applied for CTO/CTE Yes/No
   (ii) In case of renewal previous authorisation number and date:

   (iii) Status of Consents:
      i. under the Water (Prevention and Control of Pollution) Act, 1974
      ---
      ii. under the Air (Prevention and Control of Pollution) Act, 1981:

4.
   (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility

(CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):
   - (i) Number of beds of HCF:
   - (ii) Number of patients treated per month by HCF:
   - (iii) Number healthcare facilities covered by CBMWTF: _____
   - (iv) No. of beds covered by CBMWTF: _____
   - (v) Installed treatment and disposal capacity of CBMWTF: _____ Kg per day
   - (vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/ day
   - (vii) (vii) Area or distance covered by CBMWTF:_____ (pl. attach map a map with GPS locations of CBMWTF and area of coverage)
   - (viii) Quantity of Biomedical waste handled, treated or disposed

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of Treatment and Disposal (Refer Schedule-I)
(1)	(2)	(3)	(4)
Yellow	(i) Human Anatomical Waste:		
	(ii) Animal Anatomical Waste:		
	(iii) Soiled Waste:		
	(iv) Expired or Discarded Medicines:		
	(v) Chemical Solid Waste:		
	(vi) Chemical Liquid Waste :		
	(vii) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		
	viii) Microbiology, Biotechnology and other clinical laboratory waste:		
Red	Contaminated Waste (Recyclable)		
White (Transluce nt)	Waste sharps including Metals:		
Blue	Glassware:		
	Metallic Body Implants		

6. Brief description of arrangements for handling of biomedical waste (attach details):
   (i) Mode of transportation (if any) of bio-medical waste:
   (ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

	No. of units	Capacity of each unit
Incinerators :		
Plasma Pyrolysis:		
Autoclaves:		
Microwave:		
Hydroclave:		
Shredder:		
Needle tip cutter or destroyer		
Sharps encapsulation or		
concrete pit:		
Deep burial pits:		
Chemical disinfection:		
Any other treatment equipment:		

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):
8. Details of directions or notices or legal actions if any during the period of earlier authorisation.
9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfil any conditions stipulated by the prescribed authority.

Date: Sign of the Applicant

Place: Designation of the Applicant

ANNEXURE 4

FORM –III. AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical wastes)

1. File number of authorisation and date of issue……
2. M/s _____an occupier or operator of the facility located at _____is hereby granted an authorisation for;

Activity	**Please tick**
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. M/s_____is hereby authorized for handling of biomedical waste as per the capacity given below;
   (i) Number of beds of HCF:
   (ii) Number healthcare facilities covered by CBMWTF: _____ (iii)Installed treatment and

disposal capacity:_____Kg per day

(iv) Area or distance covered by CBMWTF:_____

(v) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow	
Red	
White (Translucent)	
Blue	

4. This authorisation shal be in force for a period of ..... Years from the date of issue.
5. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date: ..... Sign .....

Place ..... Designation: .....

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

ANNEXURE 5: FORM IV ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

S.No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorised person (occupier or operator of facility)	:	
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility	:	
	(v) Tel. No, Fax. No	:	
	(vi) E-mail ID	:	
	(vii) URL of Website	:	
	(viii) GPS coordinates of HCF or CBMWTF	:	
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or Semi Govt. or any other)
	(x) Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.: ....valid up to .....

	(x i) Status of Consents under Water Act and Air Act	:	Valid up to:
S.No.	**Particulars**		
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of beds
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	
	(iii) License number and its date of expiry	:	
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF	:	
	(ii) No. of beds covered by CBMWTF	:	
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	_____Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	_____Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category: Red Category: White:

		Blue Category :
		General Solid waste:
5.	Details of the Storage, treatment, transportation, processing and Disposal Facility	
	(i) Details of the on-site storage facility	Size:
		Capacity:
		Provision of on-site storage : (cold storage or any other provision)

(ii) Disposal facilities

Type of treatment equipment	No. of units	Capacity Kg/day	Quantity treated or disposed in kg per annum
Incinerators			
Plasma Pyrolysis			
Autoclaves			
Microwave			
Hydroclave			
Shredder			
Needle tip cutter or destroyer			
Sharps encapsulation or concrete pit			
Deep burial pits:			
Chemical disinfection:			

			Any other treatment equipment:
	(iii)Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.		Red Category (like plastic, glass etc.)
	(iv) No of vehicles used for collection and transportation of biomedical waste		
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum		

	Quantity generated	Where disposed
Incineration Ash		
ETP Sludge		

	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of		
	(vii) List of member HCF not handed over bio-medical waste		
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period		
7.	Details trainings conducted on BMW		

	(i) Number of trainings conducted on BMW Management.		
	(ii) number of personnel trained		
	(iii) number of personnel trained at the time of induction		
	(iv) number of personnel not undergone any training so far		
	(v) whether standard manual for training is available?		
	(vi) any other information)		
8.	Details of the accident occurred during the year		
	(i) Number of Accidents occurred		
	(ii) Number of the persons affected		
	(iii) Remedial Action taken (Please attach details if any)		
	(iv) Any Fatality occurred, details		
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		
	Details of Continuous online emission monitoring systems installed		

10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		
11.	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		
12.	Any other relevant information		(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from .....

..... Date:

Name and Signature of the Head of the Institution Place:

ANNEXURE: 6

FORM I: ACCIDENT REPORTING

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately:
5. The type of waste involved in accident:
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to alleviate the effects of accidents:
9. Steps taken to prevent the recurrence of such an accident:
10. Does you facility has an Emergency Control policy? If yes give details:

Date..... Signature.....

Place..... Designation.....

DOCUMENT TYPE	**STANDARD OPERATING PROCEDURE**
DOCUMENT NO.	**BLDEU, SBMPMCH&RC/BMWM -01**
TITLE	**Biomedical Waste Management**

Date implemented	**15.08.2020**

PREPARED BY		**VERIFIED & APPROVED BY**	
Name	Name: Dr Rashmi M Karigoudar	Name	Dr. Rajesh Honnutagi
Designation	Associate Professor (Member secretary, BMWM Committee)	Designation	Medical Superintendent **BLDE(DU's), SBMPMCH & RC**
Signature & Date		Signature & Date	

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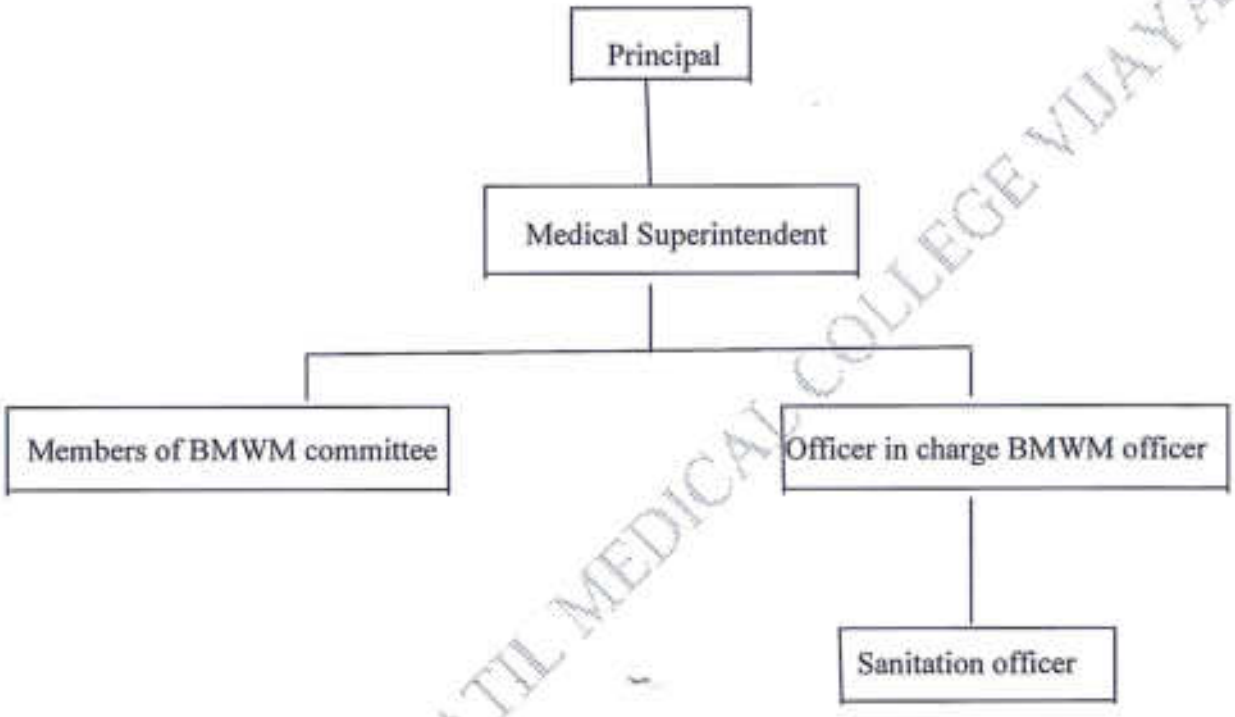
AMENDMENT RECORD

Sl. No	Page No	Section/ Para/line (as applicable)	Date of amendment	Amendment made	Reasons of amendment	Signature of Officer I/C BMW management	Signature of Medical Superintendent
1	18	Line 12	10.08.2020	Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated by autoclaving at 121°C under 15 lbs for 60 mins	Amended as per BMWM rules 2016		

II. Organogram



III. Definitions:

Sl. No.	Term	Definition
1.	Authorisation	Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.
2	Authorised person	Authorised person means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.
3	Bio-medical waste	Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules
4	Handling	Handling in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste.
5	Major Accident	Major Accident means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.
6	Management	Management includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste.
7	Occupier	Occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

IV. Process :

1. Duties of the Occupier

2. Bio-Medical Waste Management
3. Segregation of Waste
4. Waste Removal & Transportation
5. Waste storage
6. Treatment and Disposal
7. Licensing and other requirement for Bio-medical Waste Management

1. Duties of the Occupier

It shall be the duty of every occupier to-

(a) Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules

(b) Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Table I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Table 1;

(c) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018).

(e) Not to give treated bio-medical waste with municipal solid waste;

(f) Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;

(g) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.

(h) Establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of Bio-Medical Waste Management Rules, 2016.

(i) Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;

(j) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

(k) Ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;

(l) Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;

(m) Maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Table 1;

(n) Report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority, and also along with the annual report;

(o) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016; (i. e. latest by 27th March 2018 for Hospitals which do not already have a Website).

(q) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months, The record of the minutes of the meetings of shall be submitted along with the annual report to the prescribed authority.

(r) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

(s) existing incinerators (where applicable) to achieve the standards for treatment and disposal of bio-medical waste as specified in Annexure 3, for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

2. Biomedical Waste Management

Objective: To provide guidelines for management of Bio-medical waste.

Purpose: To define the guidelines for segregation, handling, storage, transportation and disposal of various kinds of biomedical waste.

Scope: This SOP applies to all employees who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form. The scope of this SOP applies to biomedical waste only.
Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Table 1. Categories of Biomedical waste

Table 1: Categories of Biomedical waste

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time). **(b) Animal Anatomical** Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio- medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	(e) **Chemical Waste:** Chemicals used in production of biological and used or discarded disinfectants	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	f) **Chemical Liquid Waste:** Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X- ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.

Category	Type of Waste	Type of Bag or Container to be Used	Treatment and Disposal options
	g) **Discarded linen,** mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
	(h) **Microbiology, Biotechnology** and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines Thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	**Contaminated Waste** (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals**: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue	(a) **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. b) **Metallic Body Implants**	Cardboard boxes with blue coloured marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Annexure 3. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time

3. Segregation of Waste

Objective: Segregation of Bio-medical waste as per guidelines.

Job Responsibility: Doctors, Nurses, Technicians, all employees handling BMW.

Description

1. BMW will not be mixed with other non-infectious wastes. If by mistake this has occurred, this non-infectious waste will then be treated as BMW.
2. The bio-medical waste shall be segregated as per categories applicable, into containers or bags at the point of generation e.g., all patient care activity areas, diagnostic service areas, operation theatre areas, treatment rooms etc. prior to its storage, transportation, treatment and disposal.
3. Non-chlorinated bags will be used for collection of biomedical waste.
4. All bags, containers or bins directly used in the collection of bio-medical wastes are labelled with appropriate biohazard Symbol (Annexure 1) which will be non-washable and prominently visible.
5. Bins used for holding the colour coded bags should be of the same colour.

4. Biomedical Waste Removal & Transportation

Objective: Biomedical Waste removal & transportation to minimize the risk of any infection.

Job Responsibility: Housekeeping staff

Description:

1. The staff handling waste must use PPE.
2. The bags must be removed when ¾th full, if not earlier.
3. The waste bag is tied up & transferred in a closed designated closed trolley to central storage area .
4. The housekeeping staff to ensure that all bags are tied when being transported & there is no spillage or leakage.
5. In case any bags has a cut or tear, ensure that double bagging is done before moving it.

5. Biomedical Waste storage

Objective: Waste storage at biomedical waste treatment facility.

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. Storage of biomedical waste should not extend 48 hrs.
2. Bio-medical waste is not mixed with other waste. There is differentiation between the storage areas for different categories of Bio-medical waste
3. The Bio-medical waste is stored in safe, ventilated and secured location for storage of segregated biomedical waste in Coloured Bags or containers as per colour coding norms.
4. Weighing will be done at the central area and weight mentioned on a register maintained for this purpose.

6. Treatment and Disposal

Objective: Proper Treatment and disposal of biomedical waste

Job Responsibility: Housekeeping Staff / Sanitation officer

Description:

1. **Human Anatomical Waste**, Animal anatomical waste, soiled waste will be incinerated without pretreatment

2. **Chemical Liquid waste** generated due to use of chemicals in production of biological and used or discarded disinfectants like discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc is directed by Separate collection system leading to effluent treatment system .

3. After resource recovery, the chemical liquid waste shall be pre-treated at effluent treatment plant before mixing with other waste water in compliance with the standards provided in Annexure 2, by the health care facility.

4. **Clinical laboratory waste**: Blood bags or specimens of microorganisms cultures, stocks of microorganisms are pretreated by autoclaving at 121°C under 15 lbs for 60 mins followed by incineration.

5. **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, returned back to the manufacturer

6. Discarded linen, mattresses, beddings contaminated with blood or body fluid are treated by Non-chlorinated chemical disinfection followed by incineration

7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

8. **Recyclable waste** are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes followed by mutilation or shredding, the recyclables from the treated bio-medical wastes such as

plastics shall be given to recyclers having valid authorisation or registration from the respective prescribed authority.

9. The Occupier shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

10. **Waste sharps** including metals are treated by chemical disinfection with 1% sodium hypochlorite for 30 minutes and disposed into designated concrete waste sharp pit.

11. **Glassware**: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes are disinfected by soaking the washed glass waste with 1% Sodium Hypochlorite for 30 minutes and then sent to recyclers having valid authorisation or registration from the respective prescribed authority. .

7. Licensing & Other requirements for Bio-medical Waste Management

Objective: Licensing & Other requirements for Bio-medical Waste management

Job Responsibility: Head- Administration

Description:

1. Application for Authorization

a. Every occupier handling bio-medical waste, irrespective of the quantity shall make an application in Form II (Annexure 3) to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III (Annexure 4) and the validity of such authorisation for bedded health care facility shall be synchronised with the validity of the consents.

b. Disposal of this application shall be done by the authority (Pollution Control Board in states or Pollution Control Committee in union territories, as the case may be) within 90 days from the date of receipt, failing which it shall be deemed that the authorisation is granted under the Biomedical Waste Management Rules.

c. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II (Annexure 3) for modification of the conditions of authorisation.

d. Occupier should apply for Renewal at least 3 months prior to expiry of the Authorization.

2. **Annual Report**

a. Every occupier or operator of common bio-medical waste treatment facility shall submit an Annual Report to the prescribed authority in Form-IV (Annexure 5) on or before the 30th June of every year. The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.

b. The Annual Reports shall also be made available online on the websites of Occupier & all healthcare facilities shall make own website within two years from the date of notification of Bio-Medical Waste Management Rules, 2016 (i.e. latest by 27th March 2018).

c. The annual report shall also contain

i. Number of Beds

ii. Category wise quantity of waste generated or disposed in Kgs per annum (on monthly average basis). iii. General Solid Waste

iv. Details of the Storage, treatment, transportation, processing and disposal Facility. Minutes of Meeting of the Bio-Medical Waste Management Committee held during the reporting period.

vi. Records of all Trainings Conducted, including

- Number of Trainings Conducted on BMW Management
- Number of Personnel Trained
- Number of Personnel Trained at the time of induction
- Number of Personnel not undergone any training so far
- Whether any standard manual for training is available

vii. Report of all accidents (major and minor) and the remedial actions taken, including Nil Report in Form 1 (Annexure 5) including

- Number of Accidents occurred during the year
- Number of persons affected

- Remedial Actions taken with details (if any)
- Details of any Fatality occurred

viii. Liquid Waste generated and treatment methods in place including

- Number of times in a year when the standards were not met

ix. Whether disinfection methodor sterilization meeting the log 4 standards including

- Number of times in a year when the standards were not met

3. **Accident Reporting**

a. Report major accidents (accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills) including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I (Annexure 5) to the prescribed authority and also along with the annual report. In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken, in Form I (Annexure 5).

b. Information regarding all other accidents and remedial steps taken shall be provided in the annual report (including Nil report).

4. **Maintaining of Records**

a. Every occupier shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal or any form of handling of bio-medical waste for a period of 5 years in accordance with the Biomedical Waste Management Rules, 2016 and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

b. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years.

d. Maintain for five years all records pertaining to Bio-Medical Waste, including but not limited to

i. BMW Register

ii. On-site Pre-treatment

iv. Accidents with remedial actions taken

v. Trainings

vi. Committee Meetings

vii. Health Check Ups

viii. Vaccination

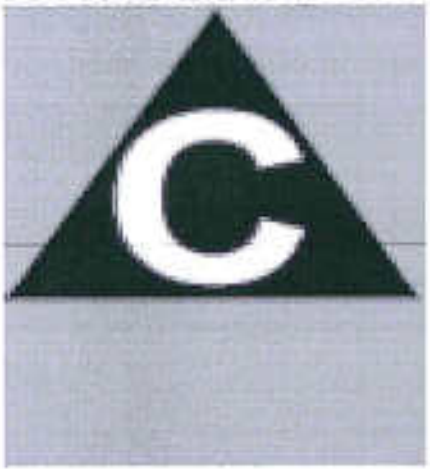
x. Correspondence to Authority

ANNEXURE: 1

LABEL FOR BIO-MEDICAL WASTE CONTAINERS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL



HANDLE WITH CARE

ANNEXURE: 2

STANDARDS FOR TREATMENT & DISPOSAL OF BIO-MEDICAL WASTES

1. **STANDARD FOR INCINERATION:-**

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$CE = \frac{\%CO_2}{\%CO_2 + \%\,CO} \times 100$$

(3) The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050 ^{0}C $\pm$ 50 ^{0}

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm^3 unless stated	**Sampling Duration in minutes, unless stated**
1.	Particulate matter	50	30 or $1NM^3$ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO2 expressed as NO2	400	30 for online sampling or grab sample
3.	HCl	50	30 or $1NM^3$ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 nanogms TEQ/Nm3 (at 11% O2)	6 hours or 5NM3 of sample volume, whichever is more

C. Stack Height

Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

2. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kil " which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC 19659) in chemical treatment systems.

3. STANDARDS FOR LIQUID WASTE

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

Parameters	Permissible Limit
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

(2) Sludge from Effluent Treatment Plant shall be incinerated.

ANNEXURE: 3

FORM – II. APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To,

The Prescribed Authority

(Name of the State or UT Administration) Address.

1. Particulars of Applicant:

   (i) Name of the Applicant:

   (In block letters & in full)

   (ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF) :

   (iii) Address for correspondence:

   (iv) Tele No., Fax No.:

   (v) Email:

   (vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please

	tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	

Activity	Please tick
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. Application for ☐ fresh or ☐ renewal of authorisation (please tick whatever is applicable):
   (i) Applied for CTO/CTE Yes/No
   (ii) In case of renewal previous authorisation number and date:

   (iii) Status of Consents:
      i. under the Water (Prevention and Control of Pollution) Act, 1974
      ---
      ii. under the Air (Prevention and Control of Pollution) Act, 1981:

4.
   (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

   (ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility

(CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):
   - (i) Number of beds of HCF:
   - (ii) Number of patients treated per month by HCF:
   - (iii) Number healthcare facilities covered by CBMWTF: _____
   - (iv) No. of beds covered by CBMWTF: _____
   - (v) Installed treatment and disposal capacity of CBMWTF: _____ Kg per day
   - (vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/ day
   - (vii) (vii) Area or distance covered by CBMWTF:_____ (pl. attach map a map with GPS locations of CBMWTF and area of coverage)
   - (viii) Quantity of Biomedical waste handled, treated or disposed

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of Treatment and Disposal (Refer Schedule-I)
(1)	(2)	(3)	(4)
Yellow	(i) Human Anatomical Waste:		
	(ii) Animal Anatomical Waste:		
	(iii) Soiled Waste:		
	(iv) Expired or Discarded Medicines:		
	(v) Chemical Solid Waste:		
	(vi) Chemical Liquid Waste :		
	(vii) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		
	viii) Microbiology, Biotechnology and other clinical laboratory waste:		
Red	Contaminated Waste (Recyclable)		
White (Transluce nt)	Waste sharps including Metals:		
Blue	Glassware:		
	Metallic Body Implants		

6. Brief description of arrangements for handling of biomedical waste (attach details):
   (i) Mode of transportation (if any) of bio-medical waste:
   (ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

	No. of units	Capacity of each unit
Incinerators :		
Plasma Pyrolysis:		
Autoclaves:		
Microwave:		
Hydroclave:		
Shredder:		
Needle tip cutter or destroyer		
Sharps encapsulation or		
concrete pit:		
Deep burial pits:		
Chemical disinfection:		
Any other treatment equipment:		

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):
8. Details of directions or notices or legal actions if any during the period of earlier authorisation.
9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfil any conditions stipulated by the prescribed authority.

Date: Sign of the Applicant

Place: Designation of the Applicant

ANNEXURE 4

FORM –III. AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical wastes)

1. File number of authorisation and date of issue.....
2. M/s _____an occupier or operator of the facility located at _____is hereby granted an authorisation for;

Activity	Please tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. M/s_____is hereby authorized for handling of biomedical waste as per the capacity given below;
   (i) Number of beds of HCF:
   (ii) Number healthcare facilities covered by CBMWTF: _____ (iii)Installed treatment and

disposal capacity:_____Kg per day

(iv) Area or distance covered by CBMWTF:_____

(v) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow	
Red	
White (Translucent)	
Blue	

4. This authorisation shal be in force for a period of ..... Years from the date of issue.
5. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date: ..... Sign .....

Place ..... Designation: .....

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

ANNEXURE 5: FORM IV ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

S.No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorised person (occupier or operator of facility)	:	
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility	:	
	(v) Tel. No, Fax. No	:	
	(vi) E-mail ID	:	
	(vii) URL of Website	:	
	(viii) GPS coordinates of HCF or CBMWTF	:	
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or Semi Govt. or any other)
	(x) Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.: ....valid up to .....

	(x i) Status of Consents under Water Act and Air Act	:	Valid up to:
S.No.	**Particulars**		
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of beds
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	
	(iii) License number and its date of expiry	:	
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF	:	
	(ii) No. of beds covered by CBMWTF	:	
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	_____Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	_____Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category: Red Category: White:

		Blue Category :	
		General Solid waste:	
5.	Details of the Storage, treatment, transportation, processing and Disposal Facility		
	(i) Details of the on-site storage facility	Size:	
		Capacity:	
		Provision of on-site storage : (cold storage or any other provision)	

(ii) Disposal facilities

Type of treatment equipment	No. of units	Capacity Kg/day	Quantity treated or disposed in kg per annum
Incinerators			
Plasma Pyrolysis			
Autoclaves			
Microwave			
Hydroclave			
Shredder			
Needle tip cutter or destroyer			
Sharps encapsulation or concrete pit			
Deep burial pits:			
Chemical disinfection:			

		Any other treatment equipment:	
	(iii)Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.		Red Category (like plastic, glass etc.)
	(iv) No of vehicles used for collection and transportation of biomedical waste		
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum		Quantity generated / Where disposed Incineration Ash ETP Sludge
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of		
	(vii) List of member HCF not handed over bio-medical waste		
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period		
7.	Details trainings conducted on BMW		

	(i) Number of trainings conducted on BMW Management.		
	(ii) number of personnel trained		
	(iii) number of personnel trained at the time of induction		
	(iv) number of personnel not undergone any training so far		
	(v) whether standard manual for training is available?		
	(vi) any other information)		
8.	Details of the accident occurred during the year		
	(i) Number of Accidents occurred		
	(ii) Number of the persons affected		
	(iii) Remedial Action taken (Please attach details if any)		
	(iv) Any Fatality occurred, details		
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		
	Details of Continuous online emission monitoring systems installed		

10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		
11.	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		
12.	Any other relevant information		(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from .....

..... Date:

Name and Signature of the Head of the Institution Place:

ANNEXURE: 6

FORM I: ACCIDENT REPORTING

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately:
5. The type of waste involved in accident:
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to alleviate the effects of accidents:
9. Steps taken to prevent the recurrence of such an accident:
10. Does you facility has an Emergency Control policy? If yes give details:

Date..... Signature.....

Place..... Designation.....

BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

SOP FOR FIRE SAFETY

PRINCIPAL
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Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

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SHRI B M PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE,
VIJAYAPURA-586103

FIRE SAFETY MANUAL

INTRODUCTION

It has plan for fire prevention & control, systems for fire prevention and control, maintenance schedules/ SOPs for operations related to fire prevention and control, Inspection protocols for fire safety installation, codes for the announcement of fire-related emergency, procedures and communication protocols for the same, Responsibilities of different departments in case of fire, Procedures, frequency & protocols for mock drills, Constitution of Fire Fighting & Evacuation Teams, Evacuation Plan and Electrical Safety & System.

Fire safety installation:

1. Portable fire Extinguishers
2. Fire Hydrant System
3. Fire Sprinklers System
4. Fire detection and alarm system
5. Public announcement system.

FIRE INCIDENT PROTOCOL

Purpose: The purpose of the policy on general fire incident protocol is to ensure the safety of Personnel by providing a means of reporting a fire and its location to the building occupants and to the local fire department.

Scope: To establish a fire incident protocol.

Policy & General Requirements:

- It is the policy of the Hospital that upon the discovery of smoke or fire, the fire alarm is to be pushed and proper fire protocol is to be followed.
- The potential for under estimating the seriousness of a fire dictates that there are no exceptions to this policy.

General Fire Emergency Instructions: If a fire is suspected or discovered the nearest fire alarm should be pushed in order to get help. This is essential because small fires can rapidly become out of hand to push the alarm:

a) Break the glass of fire alarm switch box.
b) Push the red push button.
c) Call Emergency Number and tell your name, extension and the location of the fire or smoke condition including the building, floor and room number.

Implement the following fire protocol:

- Call out for help immediately
- Remove all people in immediate danger to a safe area away from the fire.
- Close all windows and doors in the area to prevent the spread of fire and smoke.
- Turn off all electrical equipment, i.e. computer, printer and non-essential clinical apparatus. The lights should be left on.
- Remove gas cylinders and flammable liquids from the immediate fire vicinity.
- Use an appropriate type of portable fire extinguisher to put out the fire.
- Extinguishers are only effective on small first that can be extinguished quickly without endangering yourself.
- Fires should never be fought alone.

Clinical areas (Operating Room, Diagnostic and Therapeutic Areas): Patients undergoing an operation or treatment, who are in immediate danger, should be moved under the direction of the operation room physician, nurse, therapist or technician in attendance.

- If the patients are not in immediate danger they are to remain in the operating or treatment rooms until the "All Clear" is sounded or until instructed to do otherwise by the fire brigade.

- Give exact location (level, room no.) extent and type of fire, e.g. such as paper, wood, oil, kerosene, LPG or electrical fire.
- Without panic, try to beat the fire with the assistance of colleagues, in close vicinity.
- Do not open doors / windows in rooms (specially the one where the fire has started) passages or corridors.
- With the fire extinguisher start fighting with fire
- Wait for the fire response team to arrive and then move out of their was but to be available for questioning later.

Support team of A/C. Electrical staff:

As soon as the control room attended receives information about fire, he will inform shift In-charge in turn will assemble the following and depute them for the required work:-

- Electrician to cut off the power to the affected areas.
- Technician to cut off A/C. supply (effected areas).
- Remain in their respective places till fire has been extinguished.

Duties of Fire response team:

- Locate and determine the sources of ignition and evaluate the severity of the situation and extent of the areas threatened bed by fire.
- Implement basic fire and smoke containment techniques.
- Use portable fire extinguishers to contain a fire or extinguish a small and confined fire
- Clear aisles and corridors when necessary to provide unobstructed egress routes.
- Provide direction as to the safest means of egress when evacuation is deemed necessary during an emergency and assisting staff to perform horizontal evacuation.
- Canvas fire areas to insure all occupants have been evacuated.
- Remove combustibles and flammables to reduce the fire loading from threatened areas.
- Inform the fire department as to the nature and location of any special hazards in order to facilitate the fire department in controlling and extinguishing the fire to minimize loss of property.
- Provide the fire department upon request information about the hospital's fire safety systems including fire alarm and fire suppression systems.
- Implement property conservation techniques to minimize water damage to critical areas.
- Capture responding fire department units and transporting them to the scene of the alarm.

Duties of Maintenance Engineer:

They will be overall in charge in an emergency and will be responsible for the following

- Assess the state and extent of fire.
- Cut off electricity to the fire location.
- Inform the General Manager/ Manager-hospital Administration about the fire situation.

- Arrange for first aid for employees if required.
- Send all available vehicles at main entrance for the evacuation of patients to other hospitals is required.
- Be responsible to take a roll call of all employees on duty at the lawn area opposite the main entrance.

Duties of Financial Controller / Cashier on duty:

- Seal cash and account books and carry them to secure areas as directed.
- Move safely, all vital documents in the office and make arrangements to put cash in sage deposit lockers.
- Secure all licenses.
- Carry out an assessment of losses / damages to facilitate filling of claims with insurance company.

Duties of Nursing Supervisor

- Send maximum assistance to wards where there are more patients.
- Be responsible for evacuation of patients.
- Keep the control center informed about the progress of evacuation.
- Inform immediately the control center if any patient is missing or any patient requires to be transferred to other hospital.

Duties of other Staff Members:

- Proceed to safe areas.
- Keep away un-authorized person from entering the area.

FIRE DETECTION AND FIGHTING SYSTEM

Purpose: To ensure that the Hospital fire detection and alarm system is maintained 24 hours a day, 365 days a year and also to insure the proper operation of fire fighting equipments like hydrants, extinguishers during a fire emergency, to provide a mechanism for rapid identification and replacement of missing, damaged or undercharged extinguishers or malfunction in hydrant system to Provide for routine maintenance as per standards.

Scope: The policy enforces the correct and proper maintenance of the fire detection, alarm and fighting system.

Responsibilities and Authorities: Safety officer
Maintenance Engineer

Procedure:

Policy and general information:

1. Hospital fire alarm and detection system will be tested by activating a smoke detector periodically. This procedure will be conducted by maintenance department, all malfunctioning and incorrectly functioning smoke detectors should be corrected with immediate repair.
2. Hospital fire hydrant system will be tested daily by running diesel engine for five minutes.

Maintenance:

1. Fire detection and alarm system
   - Maintenance department will carry out the maintenance of the fire alarm and detection system. They will ensure that all subsystems are checked periodically and that the entire alarm and detection system is functional.
   - Testing and maintenance will be in accordance with the manufacturers standards.
   - Records of all maintenance shall be kept with maintenance department.

2. Fire Extinguisher:
   - Inspection serves to assure that all extinguishers are fully charged and operable. This is accomplished by seeing that it is visible and accessible in its designated place that all operating instructions are legible, that it has not been tampered with and that there is no obvious physical damage or condition to prevent operation.
   - To facilitate locating extinguisher sites, the Maintenance department will label such sites.
   - Extinguishers shall be inspected monthly, or at more frequent intervals when circumstances require. Inspection forms listing all extinguisher sites will be updated at the beginning of every month.
   - Maintenance department will conduct the monthly inspections, note all obvious physical damage or conditions that would prevent operations, and note this finding s on the report forms.
   - The forms will be reviewed upon completion of the inspection. The maintenance department will maintain inventory of all extinguishers, keep a record of those found to require corrective action and follow up when corrective action is needed.

Safety officer
Hospital Administration
Hospital Human Resources
Respective department heads

Procedure:

Policy and General information:

- For an evacuation procedure of the hospital premises to be effective it should have a distinct purpose. The same is spelt out below:-
- Suppress panic and act in a calm manner.
- Person designated specific duties should ensure execution to the best of ability, thereby minimizing chances of loss to the life and property and safety of all.
- Means of escape are used in accordance with predetermined and practical plan.
- Evacuation is executed speedily and in orderly manner.

PLAN OF ACTION:

All persons in the hospital complex, should be instructed and trained to ensure that they are familiar with and understand, the fire precautions and actions to be taken in the event of fire. As such the plan of action and duties need to be spelt out in writing and rehearsed.

- Raising of alarm
- Calling of fire brigade
- Disconnecting certain machines and isolation of power supplies.
- Implementation of evacuation plans.
- Designation of assembly points.
- Roll call at designated areas.
- Fighting the fire.

Evacuation Procedure:

- In event of outbreak of fire or emergency, we would be required to evacuate a portion/the entire hospital, on the instruction of General Manager / Head Administration.
- A quick decision and efficient evacuation operation is of utmost importance in order to prevent damage to loss to lives and property.
- The procedure for evacuation should be handled with expertise and without loss of time.
- On receipt of specific instruction from the General Manager/ Head Administration /Senior Doctor the telephone operator will inform all the head of department through cell phone and telephone.
- Since the situation would be sensitive, utmost care must be taken to deal with patient. Employees involved in the evacuation procedure must talk to the patients where possible, to give first hand information, and take all necessary measures to suppress panic.

Points of Assembly: In front of main door of hospital.

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SOP on Spillage Management of Blood and Body Fluids

Policy- "ALL SPILLS LARGE (>30m1) OR SMALL (< 30 ml) must be reported to the ICN immediately.

Body Fluid Spillage

Body fluid spills are divided in to two categories, those which are visibly contaminated with blood and those which are not

Management blood spillage. (For small and large spill)

1. Make the people aware about spill
2. Cordon off the area.
3. Identify the spill kit.
4. Wear PPE.
5. Put soaking paper (brown paper, newspaper and tissue paper) over the spill.
6. Pour 1% hypochlorite solution over the spill.
8. Leave for contact time ideally 10 minutes
9. After contact time put another paper covering the soaked paper and then remove the soaked paper and put it in the yellow bag.
10. Discard this yellow bag in main yellow bin the unit.
11. Clean the area with floor cleaning solution
12. Remove the PPE & discard it in the red bag.
13. Do the hand washing.
14. Report the spill in incident reporting form

Urine Spills

Chlorine releasing agents are not be used for urine spillages even if it contains visible blood. The recommended practice is:

1. Wearing non-sterile, non-powdered latex gloves and plastic apron. Soak up with paper.
2. Use detergent and water on area after soaking up the spill.
3. A chlorine-releasing agent (1% hypochlorite) may now be used on the area if necessary. Discard gloves, waste materials and apron in a Red bag .
4. Wash hands thoroughly

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Spillages of Body Fluids not visibly contaminated with Blood

These spillages will include faeces, vomit, urine and sputum.

Always wear protective clothing, i.e. plastic disposable apron, disposable powder-free, non-sterile latex or similar.

Use paper towels to soak up the spill.

If there is broken glass do not use hands even if gloved - use a paper or plastic scoop and dispose in the sharps box.

Discard paper towels and any other waste from the spillage into clinical waste bags.
Clean the contaminated area with water and detergent.

Discard gloves and apron into a red bag Wash hands.

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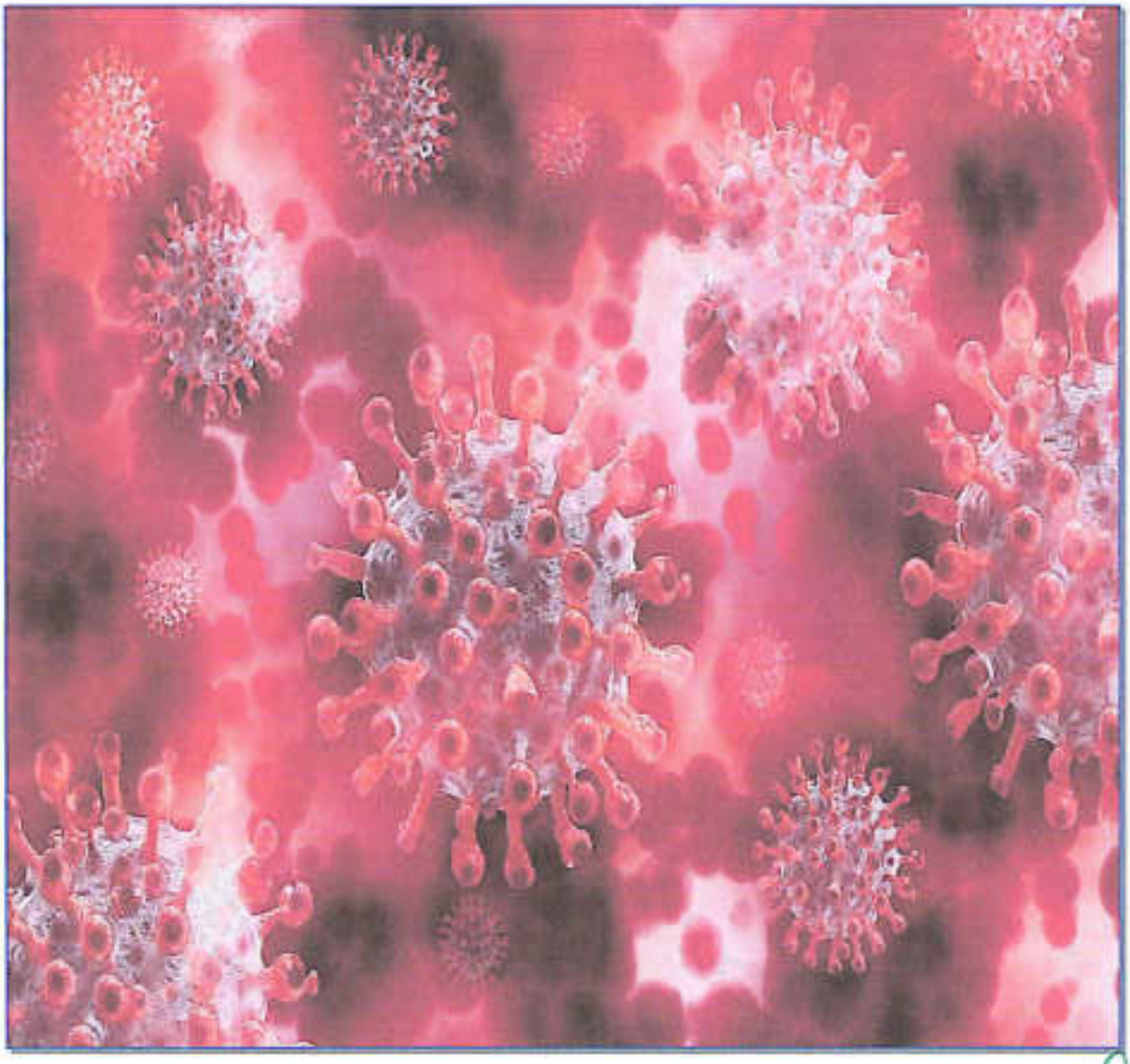
SOP FOR REOPENING OF CLASSES FOR MEDICAL STUDENTS DURING COVID-19



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BLDE (DEEMED TO BE UNIVERSITY)

SHRI B M PATIL MEDICAL COLLEGE & RESEARCH CENTRE

SOP FOR REOPENING OF CLASSES FOR MEDICAL STUDENTS DURING COVID -19

FORWARD

The IQAC and preclinical dept HODs Team of Shri B M Patil Medical College and Research Centre BLDE (DU) Vijayapur -586103 has prepared the Standard Operating Procedure in line with the Institution policy for Quality Monitoring and Quality Improvement. The feedback was taken from all stakeholders for the preparation of the Standard Operating Procedures (SOP). The SOP was reviewed and approved by the Principal.

SIGN AND SEAL OF DEAN

A. INTRODUCTION

1. "The students today (would-be doctors tomorrow) should also be familiar with the inherent threats and opportunities in the healthcare system which they would eventually handle themselves. It should not become a missed opportunity for medical students to learn the skills of epidemic management as a public health professional's

The IQAC and preclinical dept HODs team of Shri B M Patil Medical College and Research Centre BLDE (DU) Vijayapur -586103 is preparing to resume Academic activities and to monitor Quality Improvement of the Institute subject to directions of the Central/ State Government. The Institute adopts a set of Standard Operating Procedures (SoPs)/ guidelines with respect to social distancing to prevent and deal with COVID-19 pandemic by setting the policy and procedural guidelines for the students, faculty, officers, staff and workers

B. AIM

1. Aim of the SoP is to orient all the staff and students of the Institute to strictly observe self-discipline in adopting COVID responsible behaviour and under all circumstances.
2. The policy and actionable guidelines for safe operations to adopt individual and collective measures to prevent early detection and control of COVID-19 pandemic spread among the Students and Staff after Academic activities' resumption.
3. The Institute aims to ensure measures to encourage individual and collective COVID- 19 responsible behaviour to prevent community spread of the disease.

C. SCOPE of SOP

This SOP applies to the following areas in the Campus:

1. Administrative building including College Library
2. Preclinical Departments of Anatomy, Biochemistry and Physiology
3. Para Clinical Building
4. Lecture Halls & Examination Hall
6. Post office/ Bank/
8. Ladies and Gents Hostel/Canteen/Spa
9. Guest house/Residential complexes

D. GENERAL GUIDELINES

1. Students from outside and within the state will undergo Rapid Antigen Testing at Central diagnostic laboratory BLDE (DU) Hospital on Arrival and undergo quarantine for 7 days in Hospital Quarantine Centre (HQC) (flow chart1).

2. Appropriate clinical assessments will be done regularly, and actions will be taken accordingly if required. If and when found negative, they will be allowed to resume classes. The students will be quarantined in separate locations inside the Campus. Breakfast, lunch and dinner and other essential items will be provided by the Institute in the canteen under Covid-19.

3. Immunity boosters (Juices and antiviral churna) will be served within the hostel canteen and in teaching departments

4. Strict guidelines as per State and Central Govt. rules will be maintained during quarantine

5. During their stay in the Hostel, Students will not be allowed to leave the premises of the Hostel compound except to attend classes or to return to their homes, with prior approval of the competent authority. Strict hostel rules will be maintained at all times.

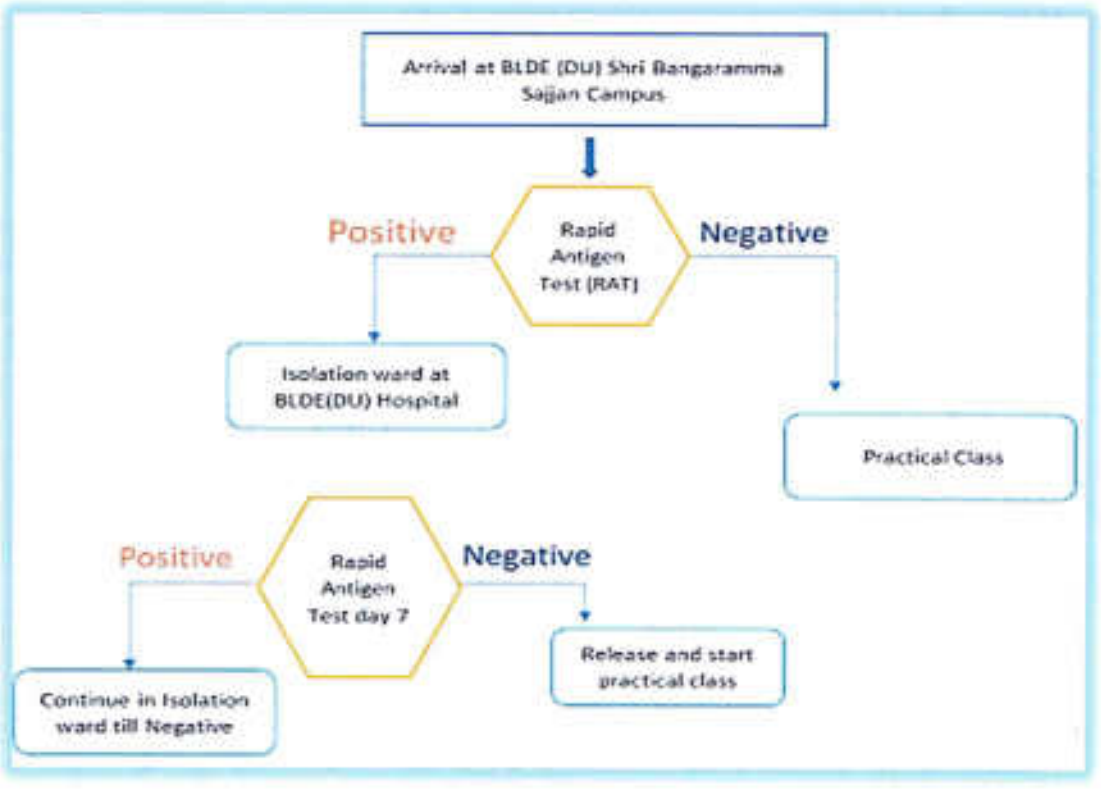
6. Academic activities will focus on the practical aspects. So, students should prepare themselves for such academic programme.

7. The first day of class will be spent in orienting the Students about the Covid situation and Standard Operating Procedures of the college during this time.

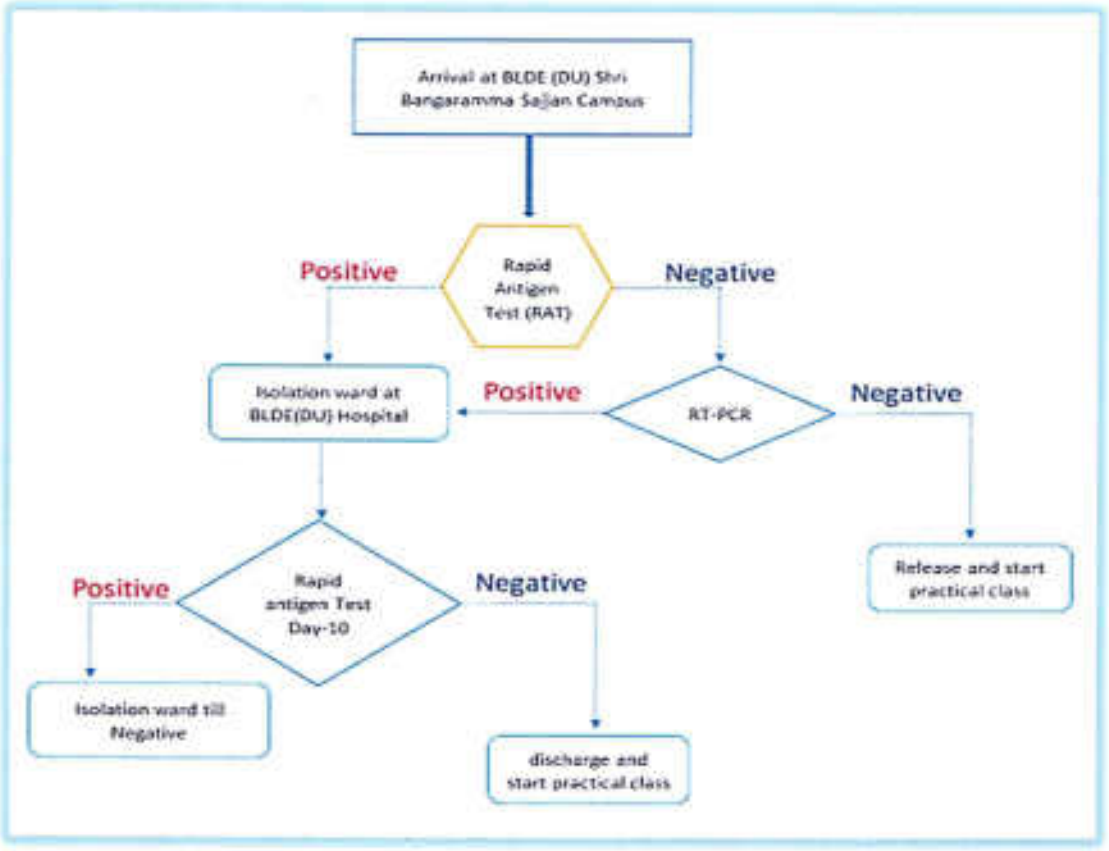
8. Safety guidelines as prescribed by the Ministry of Health and Family Welfare shall be followed during the conduct of these classes. The guidelines are appended as Annexure I.

9. Conduct of Examination: After classes have been completed, Examinations will be conducted following all safety guidelines as given by the Ministry of Health and Family Welfare. The guidelines are appended as Annexure-II.

1. FLOW CHART FOR SBMPMC (KARNATAKA STATE) STUDENT



2. FLOW CHART FOR OTHER STATE STUDENTS



Annexure-1

SOP on preventive measures to contain the spread of COVID-19in skill or entrepreneurship training institutions, higher educational institutions conducting doctoral courses and postgraduate studies in technical & professional programs requiring laboratory /experimental work.

1. Background

1. Government of India is following a phase-wise unlocking of activities. In days to come, this would also involve resumption of activities in skill or entrepreneurship training institutions, higher educational institutions conducting doctoral courses and postgraduate studies in technical & professional programs requiring laboratory /experimental work.

2. This SOP aims to enable safe resumption of teaching/ training activities in skill or entrepreneurship training institutions, higher educational institutions conducting doctoral courses and postgraduate studies in technical & professional programs requiring laboratory /experimental work.

2. Generic Preventive Measures/COVID-19 Appropriate Behaviour

The following public health measures are to be followed to reduce the risk of COVID-19 by all (faculty members, employees, students and visitors) in these places at all times: These include:

i. Physical distancing of at least 6 feet to be followed as far as feasible.

ii. Use of face covers/masks to be made mandatory.

iii. Frequent hand washing with soap (for at least 40-60 seconds) even when hands are not visibly dirty. Use of alcohol-based hand sanitizers (for at least 20 seconds) can be done wherever feasible.

iv. Respiratory etiquettes to be strictly followed. This involves strict practice of covering one's mouth and nose while coughing/sneezing with a tissue/handkerchief/flexed elbow and disposing off used tissues properly.

v. Self-monitoring of health by all and reporting any illness at the earliest.

vi. Spitting shall be strictly prohibited.

vii. Installation & use of Aarogya Setu App shall be advised wherever feasible.

3. Self-monitoring of health by all and reporting any illness at the earliest. vi. Spitting shall be strictly prohibited. higher educational institutions conducting doctoral courses and post graduate studies shall specifically ensure the following arrangements

i. Online/distance learning shall continue to be permitted and shall be encouraged.

ii. Skill or entrepreneurship training will be permitted with effect from 21st September 2020

iii. Higher educational institutions conducting PhD or technical and professional programs requiring laboratory / experimental works will be permitted by Department of Higher Education in consultation with MHA strictly following guidelines as indicated in the SOP.

4. Before opening up of the Institution

a) Planning of reopening of institutions i. The institutions conducting on skill or entrepreneurship training institutions, higher education institutions conducting doctoral courses and post graduate studies shall only be allowed to open if they are outside the containment zones. Further, students and staff living in containment zones will not be allowed to attend the Institution. Students and staff shall also be advised not to visit areas falling within containment zones.

b). Prior to resumption of activities, all work areas intended for conduct of skill or entrepreneurship training, doctoral courses and post graduate studies including hostels, laboratories, other common utility areas shall be sanitized with 1% sodium hypochlorite solution, with particular attention to frequently touched surfaces.

c). Taskforce to be constituted that would ensure complete and regular sanitisation of the Campus as prescribed – every week

d). Wherever skill-based training on equipments are envisaged to be utilized, place the equipment 6 feet apart, wherever feasible, to facilitate physical distancing. Similarly, utilize any outdoor space by relocating equipment outside like in the verandah, courtyard, shed, etc.

e. Instead of biometric attendance alternate arrangements for contactless attendance may be made. v. For ensuring queue management, inside and outside the premises, specific markings on the floor. with a gap of 6 feet may be made and be adhered to.

f. The Institute should display State helpline numbers and also numbers of local health authorities etc.to faculty /trainees/staff to contact in case of any emergency.

g. For air-conditioning/ventilation, the guidelines of CPWD shall be followed which emphasizes that the temperature setting of all air conditioning devices should be in the range of 24-30o C, relative humidity should be in the range of 40-70%, intake of fresh air should be as much as possible and cross ventilation should be there.

h. Lockers of students will remain in use, as long as physical distancing and regular disinfection is maintained.

i. Gymnasiums shall follow MoHFW guidelines (available at: (https://www.mohfw.gov.in/pdf/GuidelinesonyogainstitutesandgymnasiumS03082020.pdf)

j. Swimming Pool shall remain closed.

k. Prominently display signages, posters, and standees must indicate the staff and students' dos and don'ts.

B) **Planning and scheduling of activities**

1. The academic calendar shall be planned with a view to avoiding overcrowding, congregation etc. As far as possible, the academic calendar should promote a mix of regular classes and online teaching/ training, assessment.

2. The day-wise, time-wise scheduling of teaching/training activities may be done in a staggered manner to avoid overcrowding at any one location on any day.

3. For practical activities in laboratories maximum capacity per session based on redesigned spaces, may be planned and scheduled accordingly.

4. All employees who are at higher risk i.e. older employees, pregnant employees and employees who have underlying medical conditions to take extra precautions. They should preferably not be exposed to any front-line work requiring direct contact with the students.

C) **Availability and management of supplies**

1. Appropriate back-up stock of personal protection items like face covers/masks, visors, hand sanitisers etc. shall be made available by management to the teachers and staff.

2. Provide an adequate supply of thermal guns, alcohol wipes or 1% sodium hypochlorite solutions and disposable paper towels, soap, IEC materials on COVID.

3. Pulse oximeter to check oxygen saturation levels of any symptomatic person must be arranged.

4. Ensure availability of sufficient covered dustbins and trash cans

Provision for proper disposal of used personal protection items and general waste in accordance with CPCB guidelines (available at: https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/BMW- GUIDELINES-COVID_1.pdf)

5. Housekeeping staff to be informed & trained about norms for waste management & disposal

D. Safety Measures at Entry/ Exit Point(s) level of the Institute

a) At the entry and exit point

i. Adequate arrangements of thermal scanners, sanitizers, face masks should be made available at all entry and exit points, including the reception area.

ii. Crowding must be avoided at entry/ exit points. Staggered timings of entry and exit with limited strength for different programmes should be followed.

iii. To ensure queue management, inside and outside the premises, specific markings on the floor with a gap of 6 feet may be made and adhered to.

iv. If the Institution has more than one gate for entry/ exit, all the gates should be used, with adequate care, to avoid crowding.

v. Monitoring of the entry and exit of the students should be done. vi. Screening of students, faculty and staff, wearing face covers/ mask, sanitizing of hands etc. must be ensured at all entry points.

vii. Those having symptoms of fever, cough or difficulty in breathing should not be allowed to enter

b) Conduct of teaching activities in the classrooms

i. Seating arrangement to ensure a distance of 6 feet between chairs, desks etc.

ii. Staggering of classroom activities to be done, with separate timing slots, to allow for adequate physical distancing and disinfection of classroom premises

iii. Academic scheduling should have intermix of regular classroom teaching and online teaching/assessments

iv. The teaching faculty will ensure that they as well as the students wear masks throughout the conduct of the teaching activities

v. Sharing of items like laptops, notebook, stationery etc. amongst students should not be allowed.

c). Conduct of skill-based training in workshops/laboratories

i. Ensure that the equipment has been disinfected, particularly the frequently touched surfaces before each use

ii. Ensure a floor area of $4m^2$ per person is available for working on equipment/workstation

iii. Ensure that members sanitize their hands before and after using training equipment. For such purpose, hand sanitizer should be provided at workstations/simulation labs etc.

d). Activities in the common area – library, canteen, common rooms, gymnasium, etc.

i. Physical distancing of 6 feet needs to be maintained

ii. Person using the common areas need to use mask/face cover all the time

iii. Canteens may remain closed as far as possible.

iv. Wherever applicable, avoid cash transactions and e-wallets etc may be promoted.

e). Transportation to and from the Institution

If transportation facility is being managed by the Institution, proper physical distancing, sanitization of buses/ other transport vehicles (with 1% sodium hypochlorite) shall be ensured.

5. Hygiene and Sanitation

i. Daily cleaning of the floors shall be taken up.

ii. Provision of soap in toilets and hand sanitizers in other common areas in sufficient quantity must be ensured.

iii. Cleaning and regular disinfection (using 1% sodium hypochlorite) of frequently touched surfaces (door knobs, elevator buttons, hand rails, chairs, benches, washroom fixtures, etc.) to be made mandatory in all class rooms, laboratories, lockers, parking areas, other common areas etc. before beginning of classes and at the end of the day.

iv. Teaching materials, computers, laptops, printers, shall be regularly disinfected with 70% alcohol swipe.

v. Deep cleaning of all drinking and hand washing stations, washrooms and lavatories shall be ensured.

vi. Students and staff should be advised to dispose of used face covers / masks in separate covered bins placed in classrooms, workstations and other common areas. The same may remain stored in the bins for 3 days and disposed of as dry general solid waste after cutting/shredding.

vii. Residential buildings, if any, also needs to be sanitized regularly.

6. Risk Communication

i. Create awareness to ensure the students do not gather when leaving the Institute and in their time.

ii. Create awareness among the students to follow simple preventive health measures like hand hygiene, respiratory hygiene, physical distancing and wearing of masks.

iii. Ensure regular counselling is done for students reporting mental health issues such as anxiety and depression

vi. If a student, faculty or staff is sick, she/he should not come to Institute and follow necessary protocols in this regard

7. Additional considerations for medical postgraduate students needs to be ensured

Postgraduate medical students involved in COVID patient care and in essential non-COVID work shall familiarize themselves with the Infection Prevention and Control protocol guidelines available at: (https://www.mohfw.gov.in/pdf//National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf) besides guidelines on rational use of Personal Protective Equipment available at : (https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf and https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf)

8. Ensure Safe Stay at Hostels, guest houses and other residential complexes

The measures as proposed above related to use of mask/face cover, hand hygiene, respiratory hygiene, physical distancing norms and environmental sanitation will apply to hostels and other residential buildings. Further, the following specific points for Hostels/guest houses/other residential complexes shall also be followed:

i. Hostels may be opened only in such cases where it is necessary while strictly observing the safety and health preventive measures. However, the sharing of rooms may not be allowed in hostels. Symptomatic students should not be permitted to stay in the hostels under any circumstances.

ii. Since students may be coming from different locations, they shall remain in quarantine and self- monitor their health for a period of 14 days before being allowed to attend classes or as per the policy opted by the State Government for quarantine.

iii. Screening of every boarder needs to be done before they start staying at the hostel. Only asymptomatic boarders should be allowed to join. Symptomatic boarders shall be isolated in the designated isolation facility at the Institute, till such time, they are seen by a doctor.

iv. Proper crowd management in the hostel as well as in outside premises like parking lots – duly following physical distancing norms shall be ensured. Gatherings/congregations shall continue to remain prohibited.

v. In shared rooms/dormitories, the beds should be placed at a distance of 6 feet from each other. Temporary partitions may be considered, if feasible. Any symptomatic student should be immediately given a single room and then provided requisite medical care.

vi. Mess facility, if any within the premises, shall follow physical distancing norms at all times. Staggering of meal timings may be done to prevent overcrowding.

vii. Hostel should be out of bound for all persons except essential staff with known health status.

Viii. It must be ensured that the meals are freshly cooked. A senior staff should monitor the same.

ix. Utensils should be properly cleaned.

x. Wearing of face covers/ masks and proper sanitization of hands of the staff engaged for the preparation and distribution of meals should be ensured.

xi. Resident students and staff should avoid or limit visiting the markets. As far as possible, essential items may be made available within the Campus.

xii. Hostels may define the number of students in dining halls at any point in time. Mess timings may be increased to avoid overcrowding.

9. Regular monitoring of health

(SOP to be followed in case a student/faculty/staff develops symptoms)

(fever, cough, difficulty in breathing)

i. Every Institution should regularly monitor the health of its students, faculty, and staff.

ii. Faculty, staff and students should also be sensitized on self-monitoring of their health.

iii. Faculty, Staff and students should submit self-disclosure, if any of their family members have been infected/availed treatment for COVID-19.

vi. Place the ill person in a room or area where they are isolated from others and inform to the parent and guardian

iv. Patient will remain isolated while wearing a mask/face cover till such time they are examined by a doctor.

v. Immediately inform the nearest medical facility (hospital/clinic) or call the state or district helpline.

v. A risk assessment shall be undertaken by the designated public health authority (district RRT/treating physician) and accordingly further action be initiated regarding management of case, their contacts and need for disinfection.

vi. Disinfection of the premises to be taken up if the person is found positive.

vii. If there is clustering of cases in hostel/residential building, inform local health authorities immediately.

ANNEXURE -II

Revised SOP on preventive measures to be followed while conducting examinations to contain the spread of COVID-19

Examination centres are frequented by the large number of students (as well as their parents) and staff till the entire duration of the exam and therefore, it's vital to plan and conduct these examinations, while following specific preventive measures, as detailed in the paragraphs below.

1. Generic preventive measures

The generic measures include simple public health measures that are to be followed to reduce the risk of COVID-19. These measures need to be observed by all (staff, students and parents) in these places at all times.

These include:

i. Physical distancing of at least 6 feet to be followed as far as feasible.

ii. Use of face covers/masks to be made mandatory.

iii. Practice frequent hand washing with soap (for at least 40 -60 seconds) even when hands are not visibly dirty. Use of alcohol-based hand sanitizers (for at least 20 seconds) can be made wherever feasible.

iv. Respiratory etiquette to be strictly followed. This involves strict practice of covering one's mouth and nose while coughing/sneezing with a tissue/handkerchief/flexed elbow and disposing off used tissues properly.

v. Self-monitoring of health by all and reporting any illness at the earliest.

vi. Spitting shall be strictly prohibited.

vii. Installation & use of Aarogya Setu App shall be advised to all, as far as feasible.

2. All Universities/Educational Institutions/Examination Conducting Authorities/Examination centers shall specifically ensure the following arrangements:

a) <u>Planning of examinations</u>

i. Only those examination centers which are outside the containment zone shall be allowed to function. Staff/examinees from containment zones shall not be permitted. Such examinees shall be given an opportunity to undertake the examination through other means or the Universities/Educational Institution/ Agency may consider appropriate measures in this regard.

ii. Universities/ Educational Institutions/ Examination Conducting Authorities/ Examination centers may plan out the examination schedule in a staggered manner so as to avoid overcrowding at any examination center on any day.

iii. Keeping in view the physical distancing norms, institutions should have adequate room capacity to ensure proper seating arrangement for examination.

iv. Appropriate arrangements for personal protection gears like face covers/masks, and other logistic like hand sanitizers, soap, sodium hypochlorite solution etc. shall be made available by Universities/ Educational Institutions/Examination Conducting Authorities/Examination centers to the staff as well as students as per requirements.

v. Exam functionary and examinees may also submit self-declaration about health status at the time of entrance to the examination center. Such self-declaration form may be circulated at the time of issue of admit tickets. A simple do's and dont's/ Advisory may also be circulated at the time of issue of admit tickets.

vi. Students should also be given prior information on what they should carry, which includes exam related documents (Admit card, ID card etc), face mask, water bottle, hand sanitizer etc.

vii. Adequate manpower shall be deployed by the Institution for maintaining discipline (to ensure observance to distancing norms and other preventive measures at all times) during conduct of the examination.

viii. Adequate number of registration rooms and manpower for document verification and recording of attendance shall be planned duly ensuring social distancing norms.

ix. Invigilators and supervisory staff need to be briefed on the code of conduct in the context of COVID.

x. Provisions must be made for display of Posters/standees/AV media on preventive measures about COVID-19 prominently at the examination center (outside and inside).

xi. The examination center should have a designated isolation room for isolating any person who is found symptomatic at the time of screening or during examination, till such time medical advice may be sought. A clear policy on allowing/disallowing symptomatic candidates to undertake examinations shall be delineated by the Examination Conducting Authorities in advance.

b) <u>Transportation to and from the examination center</u>

If any transportation is arranged by educational institutions conducting examinations, proper sanitization of buses/other transport vehicles shall be ensured.

c) <u>Entry and exit to the examination center</u>

i. Entrances to have mandatory hand hygiene and thermal screening provisions. If any examination functionary/examinee fails to meet the self-declaration criteria, they shall not be allowed entry.

ii. Only asymptomatic staff and students shall be allowed inside the examination hall.

iii. In regular course, a symptomatic candidate should be referred to the nearest health center and given an opportunity to undertake the examination through other means or the Universities/Educational Institution shall arrange for taking exam at a later date when the student is declared physically fit. However, if a student is found to be symptomatic, the permission or denial thereof, in such cases shall be granted as per the policy already enunciated on the issue by the Examination Conducting Authorities.

iv. All staff and students to be allowed entry only if using face cover/masks. The face cover/mask has to be worn at all times inside the examination center by all.

v. Enough entry & exits gates for students and staff shall be ensured to avoid overcrowding.

vi. Maintaining physical distancing of a minimum of 6 feet, when queuing up for entry and inside the center as far as feasible.

vii. Specific markings may be made with sufficient distance to manage the queue and ensure social distancing in the premises.

viii. Proper crowd management in the examination center as well as outside premises like parking lots, waiting areas — duly following physical distancing norms shall be ensured.

ix. Bags/books/mobiles should not be allowed in the examination center.

x. The examinees will be taken to a registration room in batches maintaining adequate physical distancing norms for document verification and recording of attendance. Thereafter they will be escorted in batches to the allotted examination hall.

xi. Frisking of examinees, if needed, shall be undertaken after thermal screening. Personnel involved in frisking shall wear triple layer medical mask in addition to gloves. Proper hand hygiene shall be maintained by such personnel every time they change their gloves.

xii. On completion of exam, the candidates should be permitted to move out in an orderly manner

d) Special precautions for high risk individuals

i. All staff that is at high risk (older employees, pregnant employees and employees who have underlying medical conditions) shall not be deployed for invigilation/conduct of examination.

ii. Such staff should preferably be deployed in tasks not requiring direct contact with the students.

e) Movement within the examination center, seating arrangement including conduct of examination

i. Number of people in the elevators shall be restricted, duly maintaining physical distancing norms.

ii. Provision of wheelchairs, if warranted, should be ensured and these should be disinfected regularly.

iii. In case of PwD candidate availing a scribe, both the candidate and scribe must wear the masks and be made to sit with adequate physical distancing.

iv. Institutions may adopt contact less processes like OR code, online forms, digital signatures for the examination.

v. Adequate arrangements for safe drinking water (preferably with disposable cups/glasses) be made in the examination hall.

vi. Seating arrangement in the examination hall to be made in such a way that adequate social distancing is maintained.

vii. For pen & paper based tests, the invigilator will sanitize his hands prior to distribution of question papers/answer sheets. The examinees will also sanitize their hands before receiving such papers and handing them back to invigilators. The collection and packing of the answer sheets, at every stage will involve sanitization of the hands. The answer sheets will preferably be opened up after 72 hours have elapsed post collection of papers.

viii. Use of spit/saliva for counting/distributing sheets shall not be allowed.

ix. Sharing of personal belongings/stationery shall not be allowed.

x. For online/computer-based examination, the systems shall be disinfected using alcohol wipes before and after conduct of examination.

xi. Record of all exam functionaries/examinees shall be maintained in the system for future reference and traceability.

xii. For air-conditioning/ventilation, the guidelines of CPWD shall be followed which emphasize that the (i) temperature setting of all air conditioning devices should be in the range of 24-30°C, (ii) relative humidity should be in the range of 40- 70%, (iii) re-circulation of air to be avoided to the extent possible, (iv) intake of fresh air should be as much as possible and (v)cross ventilation should be adequate.

f) Sanitation and Hygiene

i. Examination hall and other common areas shall be sanitized each time before and after examination.

ii. Effective and frequent sanitation within the premises shall be maintained with particular focus on lavatories, drinking and hand washing stations/areas.

iii. Cleaning and regular disinfection (using 1% sodium hypochlorite) of frequently touched surfaces (door knobs, elevator buttons, hand rails, benches, washroom fixtures, etc.) to be made mandatory in all examination hall and other common areas.

iv. Students and staff should be advised to dispose of used face covers / masks in covered bins available at the center. The waste thus generated may be disposed off in accordance with the hazardous waste disposal guidelines.

g) **SOP to be followed in case a student/faculty/staff develops symptoms (fever, cough, difficulty in breathing)**

i. Place the ill person in a room or area where they are isolated from others.

ii. The person will remain isolated while wearing a mask/face cover till such time he/she is examined by a doctor.

iii. If symptoms deteriorate, inform the nearest medical facility (hospital/clinic) or call the state or district helpline.

iv. A risk assessment shall be undertaken by the designated public health authority (district RRT/treating physician) and accordingly further action be initiated regarding management of case, his/her contacts and need for disinfection.

v. Disinfection of the premises to be taken up if the person is found positive.

Role of Stakeholders

5.1 Central/ State Government(s)

i. The Government should help educational institutions to prepare an effective plan for reopening their campuses. The plan may vary from Institution to Institution, keeping in view the situation regarding spread of COVID-19 pandemic in a particular area/region/zone.

ii. The Governments may issue clear instructions to the universities and colleges to ensure the safety and health of all concerned. This may include instructions for wearing of face masks, physical distancing, and the number of students in a class, library, hostels, and dining halls etc.

iii. State governments, in consultations with higher education institutions, should prepare an estimate of requirement in each of their districts and zones, of disinfectants, facemasks and prepare a plan in advance for their procurement and distribution. Universities and colleges should ensure sufficient supplies of these items to their students, faculty and staff.

iv. Keeping in view the varying conditions in any state at district and zonal levels, the Government concerned should prepare a region-specific plan, instead of a uniform plan for the entire state. v. State health departments should remain in touch with the universities and colleges and work to ensure that the campuses are well prepared to maintain the safe and healthy conditions and also to deal with the COVID-19 related unexpected situations.

vi. The Governments should keep a constant touch with the universities and colleges regarding the status of COVID-19. The government may call information regarding COVID-19 related condition in the campuses and also call meetings at appropriate intervals with the Head of institutions through video conferencing.

5.2 **Head of the Institution**

i. Vice- Chancellors/ Principals may get Standard Operating Procedures (SOPs) worked out in view of COVID-19 outbreak, in accordance with the Government orders and guidelines.

ii. A detailed institutional plan which may, inter alia, include sanitization, safety and health measures should be prepared and kept ready, before reopening of Campus. Proper implementation of the institutional plan should be ensured, and regular monitoring should be done with the help of faculty and the staff.

iii. Tie-ups may be established with nearby hospitals, health centres, NGOs, health experts for help and support in fighting COVID-19. 16

iv. A plan for all academic activities, i.e., the academic calendar, teaching-learning modes, examinations, evaluation etc. should be kept ready well in advance.

v. A Task Group should be created to handle varied situations and issues related to the COVID-19 pandemic. Such Task Group may consist of senior persons from faculty and staff, students, volunteers from communities, NGOs, health organisations and Government officials etc. as the case may be.

vi. Teachers, students and staff should be made aware of all relevant plans and activities on the Campus.

5.3 **Teachers**

i. Teachers should make themselves fully aware of institutional plans and Standard Operating Procedures.

ii. Every teacher should prepare a detailed teaching plan for the subjects taught by him/her, including time table, class size, modes of delivery, assignments, theory, practical, continuous evaluation, end- semester evaluation etc.

iii. Teachers should keep themselves updated with the latest teaching- learning methods and availability of e-resources.

iv. Teachers should make the students aware of the COVID-19 related situation, precautions and steps to be taken to stay safe and healthy.

v. Teachers should monitor and keep track of the physical and mental health of their students.

5.4 **Parents**

i. The parents should ensure that their children observe safety norms at home and whenever they go out.

ii. Parents should not allow their children to go out, if they are not feeling well.

iii. Parents may be advised that the 'Aarogya Setu App' has been downloaded by their children.

iv. Parents should sensitize them of healthy food habits and measures to increase immunity. v. Parents should ask them to do exercise, yoga, meditation and breathing exercises to keep them mentally and physically fit.

5.5. Students

i. Self-discipline is most important to contain the spread of COVID-19 pandemic through social distancing and maintaining hygienic condition.

ii. All students should wear face covers/ masks and take all preventive measures.

iii. May consider installing 'Aarogya Setu App' in the mobile.

iv. It is important for the students to be physically and mentally fit to handle any exigencies. By remaining fit, they can take care of others also.

v. The students must inculcate activities that will increase the immunity-boosting mechanism, including exercise, yoga, eating fresh fruits and healthy food (avoid fast food), and sleep timely.

vi. Discrimination of fellow students in respect of whom there is a history of COVID-19 disease in the family be avoided. vii. Give support to your friends under stress due to COVID-19 pandemic.

viii. Students should follow the guidelines, advisories and instructions issued by the Government authorities as well as by the universities and colleges regarding health and safety measures in view of COVID-19 pandemic.It may be noted that the SOP detailed above provides for minimum precautions to be followed during the planning and conduct of examinations. Universities/ Educational Institutions/ Examination Conducting Authorities/ Examination centers may put additional measures in place as per their local assessment and in line with activities permitted by Ministry of Home Affairs (MHA) as per MHA orders issued under Disaster Management Act, 2005 from time to time.