

QUALITY MANUAL

ISO-9001:2015

MAHARASHTRA AROGYA
MANDAL'S

SUMATIBHAI SHAH AYURVED
MAHAVIDYALAYA

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SECTION: 1.0

TITLE, SCOPE AND FIELD OF APPLICATION

TITLE : ISO 9001: 2015- QUALITY MANAGEMENT SYSTEM

REQUIREMENTS

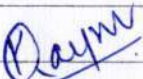
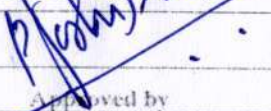
SCOPE : Imparting Teaching & Training for Undergraduate Course
B.A.M.S (Bachelor of Ayurved Medicine & Surgery)

And Post Graduate Degree in Ayurved MD/MS under
The Affiliation of Maharashtra University of Health
Sciences, Nashik, Maharashtra, National Commission for Indian
System of Medicine, New Delhi. (Ministry of AYUSH), New Delhi.

FIELD OF : Academic Research and outreach trainings for Pune and also from all over
Maharashtra & India.

APPLICATION NON APPLICABILITY OF ANY CLAUSE

Clause or sub clause No	Non Applicability	Justification
8.3	Design & Development of Products & Services	SSAM is providing education as per Guidelines/Syllabus provided by National Commission for Indian System of Medicine, New Delhi and adopted by Maharashtra University of Health Sciences, Nashik.
8.5.1 f	Validation of Processes for Service Provision	This clause is not applicable as Validation is done through the Examination process is directly controlled by Maharashtra University of Health Sciences, Nasik.


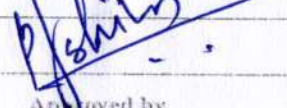
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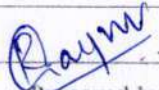
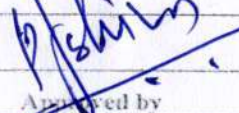
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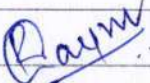
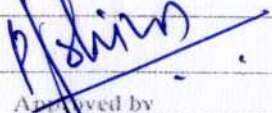
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SECTION: 2.0 REVISION STATUS:

ISSUE No.	DESCRIPTION	DATE	APPROVED BY
02	Second issue of Quality Manual based on ISO 9001-2015	06.07.2023	<i>[Signature]</i>

SECTION No.	REVISION		BRIEF DESCRIPTION OF REVISION	DATE	APPROVED BY
	FROM	TO			
All Sections			Second Issue of Quality Manual based on ISO-9001:2015	06.07.2023	<i>[Signature]</i>

<i>[Signature]</i> Prepared by	Issue No.:-02 -06.07.2023	<i>[Signature]</i> Approved by
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SECTION: 2.5 LISTS OF COPY HOLDERS

COPY NO.	TITLE HOLDER
MASTER COPY	MANAGEMENT SYSTEM COORDINATOR Editable – on Pen Drive back up

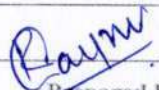
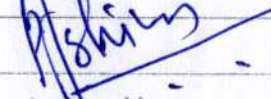
For all other departments PDF version is available on shared folder for reference.

The department manual is as under. Department manuals are accessible to Principal & ISO Committee Members. For any alterations permission from the Principal is mandatory.

Sr. No	Document	Ref no of Manual	Rev. Status	Holder of Document
1	Quality Manual	SSAM/QM	1	Secretary
2	Quality Manual	SSAM/QM	1	Principal
3	Quality Manual	SSAM/QM	1	ISO Committee Members

The manual covers the quality-related activities of offering Degree of AYURVEDACHARYA (Bachelor of Ayurvedic Medicine and Surgery) by Maharashtra University of Health Sciences (MUHS), Nashik after completion of prescribed courses of study extending over 01 academic year 18 months, 4.5 Years and satisfactory completion of 1 year compulsory Internship Training in Rural and Urban areas. Three years full time Post Graduate courses are offered under the affiliation of MUHS, Nashik, leading to P.G. Degree. The above activities are supported by various other departments like spacious Lecture Halls, Conference hall, Seminar Hall, well established Library with large number of books, Journals, Magazines and other reading materials, well equipped Laboratories, Museums with large number of specimens, Dissection Hall, well equipped in house Ayurvedic Pharmacy and others.

The regulatory authority for MUHS affiliated college in NCISM, (Previously CCIM) New Delhi

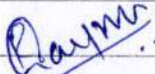
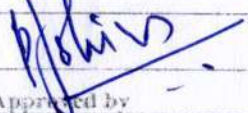
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SECTION: 3.0 ABBREVIATIONS

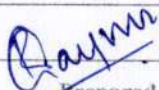

Following abbreviations are used in the Quality System Manual with Procedures		
Sr. No.	Abbreviations	Description
1.	SSAM	Sumatibhai Shah Ayurved Mahavidyalaya
2.	QC	Quality Control
3.	REV	Revision
4.	QMS	Quality Management System
5.	QSP	Quality System Procedures
6.	MRM	Management Review Meeting.
7.	WI	Work Instruction
8.	RM	Raw Material
9.	SR	System Representative
10.	QP	Quality Plan
11.	NCR	Non Conforming Reports
12.	IQA	Internal Quality Audit
13.	QM	Quality Manual
14.	HOD	Head of Department
15.	PUR	Purchase
16.	a) CCIM	Central Council of Indian Medicine
	b) NCISM	National Commission for Indian System of Medicine
17.	MCIM	Maharashtra Council of Indian Medicine
18.	MUHS	Maharashtra University of Health Sciences
19.	AYUSH	Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homeopathy
20.	BAMS	Bachelor of Ayurvedic Medicine & Surgery
21.	MS	Master of Surgery
22.	MD	Doctor of Medicine
23.	HR	Human Resources
24.	CET	Common Entrance Test
25.	LAB	Laboratory

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26.	CR	Class Representative
27.	LIB	Library
28.	CL	Clause
29.	REF	Reference
30.	QM	Quality Manual
31.	SR	System Representative
32.	HOD	Head Of The Dept.
33.	NC	Non Conformity
34.	M&M	Monitoring & Measurement
35.	MKT	Marketing
36.	QCI	Quality Council of India.

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SECTION: 3.5 INTRODUCTION

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya

was established in the year 1990 with permission from The Ministry of Health & Family Welfare, New Delhi and Central Council of Indian Medicine to help in achieving the quality education in Ayurveda. It is important that education in such a specialized field be imparted to the students who wish to pursue as a career. The college aspires to produce outstanding Doctors who can contribute to this ancient science at large. The college provides the students with practical training since first year to bring out the best in them and to develop them as qualified graduates in Ayurvedic Medicine & Surgery.

There is a fully equipped 250 bedded Ayurvedic Hospital, ISO Certified and NABH Accredited "Sane Guruji Arogya Kendra" adjacent to the SSAM with specialized departments of Kayachikitsa , Streerog Prasuti Tantra, Kaumarbhritya , Shalya Tantra, Shalakyta Tantra and Panchakarma. The Institute's Panchakarma Department is one of the best in Pune with all necessary equipments, Instruments and the specialized persons in the field. It caters to the need of the citizens of Hadapsar and nearby areas around Hadapsar. The Hospital provides Medicines and Treatment at concessional rates to all the patients, who visit for Medical Treatments.

The Post Graduate Courses in Thirteen Subjects are also part of the Academic Centre of the Institution and is also engaged in Research of Diseases like 'Sickle Cell Anemia'.

Maharashtra Arogya Mandal is proud to carry the legacy of Late Dr. S. T. Gujar alias Dada Gujar as it's devoted founder member. Amongst the founder members, he is the one, who worked selflessly over the years for the Institution. He was the chairman of the Scientific Advisory Committee of Central Council for research in Ayurved and Siddha for Six Years and an Executive Committee Member of the Central Council of Indian Medicine under the Ministry of Health, Government of India. In appreciation of the Excellent Development work, which always focused on the improvement of the living conditions of the poorest strata of the society.

Arbeiterwohlfahrt Bundesverband, Bonn, Germany, Awarded Dr Dada Gujar the "Merry-Juchaz- Medal", the highest distinction along with the cash award of Rs 1.8 Lakhs at the ceremony in Bonn, Germany, on 2nd April, 1992. He cherished the dream of producing " Socially Oriented Basic Doctors" having sound faith in Ayurveda, a rich ancient heritage of India. At present Maharashtra Arogya Mandal, Hadapsar, Pune has Hon. Shri Anil Gujar is the Secretary and Hon. Shri Arun Gujar Joint Secretary since May 2023. Besides well equipped Ayurveda Hospital ,he has also taken keen interest in developing I.C.U, and modernization of special rooms, Neonatal I.C.U., Pathology Laboratory and various college departments. He has been encouraging teachers and students to take interest in Research Programmes and various Training Programmes. College is also in the process of implementation of NAAC.

A. Gujar

SECRETARY

A. Gujar

JOINT SECRETARY

MAHARASHTRA AROGYA MANDAL
MALWADI, HADAPSAR, PUNE-28

Date : 06/07/2023

<i>A. Gujar</i> Prepared by	Issue No.: -02 -06.07.2023	<i>A. Gujar</i> Approved by
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SECTION: 4.0 CONTEXTS OF SSAM

4.0 Context of SSAM

4.1 Understanding SSAM and its context

SSAM determines external and internal issues which is relevant to its purpose of demonstrating ability to consistently provide Education to students in BAMS and MD/MS. Factors or conditions for consideration, understanding the external factors which can be issued arising from legal, technological, competitive, market, cultural, social and economic environments as applicable. This becomes input in the Management Review section 9.3. Understanding the internal issues related to values, culture, knowledge and performance of organization.

Following are the external & internal issues, impact & remedial action will be reviewed in the Management Review meeting. (Section 9.3.2)

External Issues:

1. Reliance on customer (Parents of Students) commitment for payment of College Fees.
2. Competitiveness for large projects on further expansion of Infrastructure.
3. Understanding Market share of College in the locality.
4. Control on students to bring motivation among them regarding study in the College with satisfactory results.
5. Suppliers for various stationaries and Sports Equipment, Computer Hardware on E-Learning by students.
6. Working capital availability to be explored for undertaking big projects.
7. Students communication to keep track of interaction
8. Compliance to various agreements for running the College, and monitoring the terms of contract & validity.
9. Compliance to statutory & regulatory requirements viz MUHS & NCISM to run the college and also the affiliation with MUHS/NCISM/AYUSH.
10. Improving the quality of health care in the academic hospital SGAK to increase the patient material for students.

List of statutory approvals is available with administration doc no. SSAM/Admin/SD/01

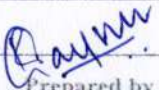
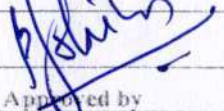
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Internal Issues:

1. Inter departmental coordination will improve because of QMS implementation.
2. Costing & estimation against various administrative expenses
3. New Course development: In house service control: By SSAM
4. Providing suitable infrastructure, resources & environment.
5. Motivation & involvement of employees: Introduction of annual celebration, long service award, P.F & Insurance facility.
6. Absenteeism: Creating awareness regarding customer commitment.
7. Reliance on skilled Teachers: Multi skilled Teachers through on job training.
8. Affiliation and its continuation requirements are needed to be focused.
9. Practical issues related to new guidelines and amendments in curriculum & implementation.

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4.2 Understanding the needs and expectation of Interested Parties

Due to their effect or potential effect on SSAM's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, MAM's RAP shall determine

- a) the interested parties are relevant to the QMS
- b) the requirements of these interested parties that are relevant to the QMS

SSAM shall monitor and review information about these interested parties and their relevant requirements.

Doc Ref F/MGMT/02.

4.3 Determining the scope of the Quality Management System

SSAM determines boundaries & applicability of QMS to establish Scope for that consideration is given to

- ✓ Internal and external issues
- ✓ Requirements of relevant interested parties
- ✓ SSAM products and services

SSAM shall apply all the requirements of this ISO 9001:2015 if they are applicable within the determined scope of SSAM QMS.

The scope of its QMS is defined in section 1, after giving consideration to a, b, c above and is maintained as documented information in the form of quality manual, work instruction and formats. Justification requirements as mentioned in standard its non applicability is explained as documented information in line with purpose.

4.4 Quality Management System and its processes

SSAM has established, implemented, maintained and continually improve QMS, including the processes needed and their interactions in accordance with requirements of this international standard:

4.4.1 The SSAM determined the processes needed for the QMS and their application throughout the Organization and should:

- a. Determine the inputs required and the output expected from these processes.
- b. Determine the sequence and interaction of these processes in the form of Flowchart.
- c. Determine and apply the criteria and methods including monitoring and measurements and related performance indicators needed to ensure the effective operation and control of these processes

This is done primarily through monitoring of performance indicators quarterly basis.

- d. Determine the resources needed for these processes and ensure their availability.

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- e. Assign the responsibilities and authorities needed for these processes
- f. Address the risks and opportunities as determined in accordance with requirements to:
- g. Give assurance that QMS can achieve its intended results
 - ✓ Enhance desirable effects.
 - ✓ Prevent or reduce undesired effects.
 - ✓ Achieve improvements.
 - ✓ Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- h. Improve the QMS

The College vides flow chart is given in Annexure: 1 for department process flow chart is available in the respective department manual.

4.4.2 To the extent necessary, SSAM should

- ✓ Maintain documented information to support the operation of its processes
- ✓ Retain documented information to have confidence that the processes are being carried out as per plan.

These processes are managed by SSAM in accordance with the requirements of the standard. Teachers a selected based on qualification & experience. Refer teaching plan as per classes.

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SECTION: 5.0 LEADERSHIP

5.1 Leadership and commitment

5.1.1 General

Principal of SSAM always demonstrates leadership and commitment with respect to QMS by:

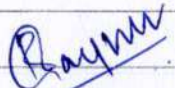

- ✓ Taking accountability for the effectiveness of the QMS;
- ✓ Ensuring that the Quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the SSAM.
- ✓ Ensuring the integration of the Teaching Plan into Teaching Processes
- ✓ Promoting the use of process approach and risk based thinking;
- ✓ Ensuring that the resources needed for the QMS are available;
- ✓ Communicating the importance of effective QMS and of conforming to the Syllabus and Guidelines as provided by CCIM & MUHS.
- ✓ Ensuring that the QMS achieves its intended results;
- ✓ Engaging, directing, & supporting person to contribute to the effectiveness of the QMS;
- ✓ Promoting improvement;
- ✓ Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
- ✓ For all above points respective class teachers are responsible towards their activities & reporting staff.

5.1.2 Customer Focus

Principal of SSAM always demonstrates leadership and commitment with respect to customer focus by ensuring:

- ✓ Customer (Parents) and applicable statutory and regulatory requirements are determined, understood and consistently met.
- ✓ The risks and opportunities that can affect conformity to products and services and the ability to enhance customer satisfaction are determined and addressed.
- ✓ The focus of enhancing customer satisfaction is maintained.
- ✓ Explained in Process mapping doc. no. SSAM/PM/01.

Every student is allotted a guardian teacher throughout the course every year. The student informs the guardian teacher whenever he/she needs guidance or taking a medical/long leave. (Attached in Annexure - III)

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5.2 QUALITY POLICY

QUALITY POLICY

We, at Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune, are committed to provide Education & Training, to our students for Bachelor of Ayurved Medicine & Surgery (B.A.M.S.) and also for Post Graduate degree courses in thirteen specialties and two Post Graduate diploma. The education shall be imparted in an environment, characterized by mutual affection and respect between the teachers and students under the permission of Govt. of India, Ministry of Health & Family Welfare, Dept. of AYUSH, New Delhi, National Commission for Indian System of Medicine, New Delhi and affiliation of Maharashtra University of Health Sciences, Nashik. Our motto is to produce "Socially Oriented Doctors" having sound faith in Ayurved, to cater the various health care needs of the society.

We are dedicated to our student's aspirations for excellence in Medical Education and our vision is to be amongst the first ten of most preferred Ayurved Institutions in India in near future.

This will be achieved through:-

A strong and disciplined character shaped by philosophical values of Ayurved.

Highest Quality Education, Training, Teaching, Health Care, Publication & Research in the field of Ayurved.

Continual improvement in Quality Management System by monitoring, measuring and analyzing our objectives and mission from time to time.



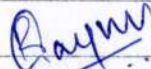
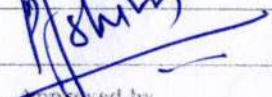
PRINCIPAL

MAM's, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune.

Principal

**M. A. M's, Sumatibhai Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune- 411 028.**



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- ✓ Continual Improvement in Academic, Social, Cultural, Physical, Psychological development of students.
- ✓ Maintaining safe atmosphere within the premises of the College.
- ✓ Continual Improvement of Quality Management System by monitoring, measuring and analyzing our objectives and mission time to time.
- ✓ On time delivery of lectures as per teaching plan.
- ✓ Right at the first time attitude.
- ✓ Independent audit demonstrates commitment to quality.
- ✓ Providing an outline for creating, stating and measuring performance of the quality objectives.

QUALITY OBJECTIVES

- 1) Providing teaching as per Teaching Plan (Target >90%).
- 2) Aiming for Students' Satisfaction (Target > 80%)
- 3) Providing Training to Teaching and Non-Teaching staff (4 Trainings/Year)
- 4) Continual Improvement Project once in Six Months.
- 5) Participation of students in physical education > 80%.
- 6) System coordinator function – No NC in internal audit of maximum 1 Number.
- 7) Time bound measurable targets are monitored for above objectives & are reviewed in six monthly management review meeting.

(Attached in Annexure - II)



PRINCIPAL

MAM's Suamtibhai Shah Ayurved Mahavidyalaya,
Hadapsar, Pune

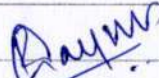
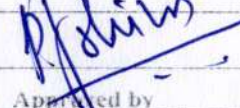
Principal

**M. A. M's, Sumatibhai Shah
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Rev: 01



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5.2.1 Establishing the Quality Policy

The Principal has established, implemented and maintained a Quality Policy that:

- ✓ Is appropriate to the purpose and context of SSAM and supports its strategic direction.
- ✓ Provides a framework for setting quality objectives.
- ✓ Includes a commitment to satisfy applicable requirements
- ✓ Includes a commitment to continual improvement of the QMS

SSAM management has defined the Quality Policy and Objectives to ensure

- a. That it is appropriate to the purpose of the organization
- b. There is a commitment to comply with requirements and to bring with continual improvement in the effectiveness of Quality Management System.
- c. That Quality Objectives are established & reviewed with a framework of SMART (Specific, Measurable, Achievable, Realistic & Time bound)
- d. Awareness is created among the employees and the concerned people for understanding and maintaining the Quality Policy and its Objectives
- e. Review is done for continual suitability through Management Review of the Quality Policy and its Objectives integrated with respect to internal and external dynamics.

5.2.2 Communicating the Quality Policy:

Quality policy should:

- ✓ Be available and be maintained as documented information
- ✓ Be communicated, understood and applied within SSAM
- ✓ Be available to relevant interested parties the policy is displayed for ease in understanding along with objectives.

Quality policy & College objectives are displayed in ease in understanding of workmen along with that department Objective/indicator are also displayed.

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5.3 SSAM 's Roles, Responsibility and authority:

The Principal of college has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood among employees of SSAM. Principal. has assigned responsibility and authority for:


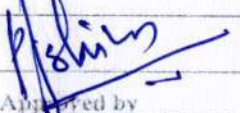
- 1) Ensuring that QMS conforms to requirements of ISO9001:2015 Standard.
- 2) Ensuring that processes are delivering their intended outputs
- 3) Reporting on the performance of the QMS and on opportunities on improvement as per section 10.1
- 4) Ensuring the promotion of customer focus throughout SSAM i.e. among employees at office and works.
- 5) Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

ORGANIZATION CHART

(Attached in Annex-1)

Responsibility, Authority & Communication

Note: Prof. Dr Pranita Joshi-Deshmukh, Principal, SSAM, is appointed as system coordinator by the Secretary of Maharashtra Arogya Mandal, Hadapsar, Pune for documentation; internal audit & organizing management review as per ISO 9001:2015 QMS requirements in addition to her responsibility as Principal in day to day activities.

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MAHARASHTRA AROGYA MANDAL'S SECRETARY :-

Responsibility :-

Overall responsible for decision making in running the institution.

Authorities :-

- 1) Authorized for taking decisions on any financial applications relating to Institutes.
- 2) Operations.
- 3) Authorized for taking decisions on administration functions relating to Teaching & Non-Teaching Staff.

1) Principal:

Responsible for

- ✓ Daily functioning and execution of daily activities of College including administration & guidance to the teaching & non-teaching staff.
- ✓ Execution of various activities under the MUHS in connection with examination related work viz theories & practical's.
- ✓ To attend representative during their visit to SSAM from NCISM, MUHS, State Government.
- ✓ As Ex-officio Medical superintendent of Sane Guruji Hospital to look after certain Management Functions of the Hospital.
- ✓ Planning about Development of the College.
- ✓ Organizing Training program of the faculty.
- ✓ Public Relations.
- ✓ Finalization of Quality Policy & quality Objectives.

Authorized for

- ✓ Recruitment of Faculty & Supporting Staff.
- ✓ Approving Quality Manual & Procedure.
- ✓ Approval of purchase orders as recommended by/ through HOD's.
- ✓ Sanctioning Leave till 07 days.

2) Vice Principal:-

Responsibilities

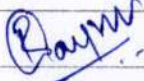
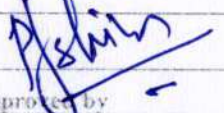
- ✓ To assist Principal in all her activities academic helps.
- ✓ Execution of aforesaid duties of principal.

Authorities:-

- a) Academic work in collaboration with Principal.
- b) To look after various duties & activities in absence of principal.
- c) Sanctioning of Leave ½ to 01 day.

3) PG Co-ordinator:-

- a) Academic work related to PG & Ph. D. Courses with the Principal.

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4) HOD's (Professor):-

Responsibilities

- ✓ To carry out allotted duties regarding academics and Hospital cases wherever applicable.
- ✓ To ensure that Academic Term plan is followed.

Authorities:-

- d) To fill the confidential reports of all the teachers working under him/ her in the department.

5) Associate Professor (Reader):-

Responsibilities

- ✓ To carry out allotted duties regarding academic and Hospital function wherever applicable.
- ✓ To assist the Professors in their respective duties.

6) Assistant Professor (Lecturer)

Responsibilities

- ✓ To carry out allotted duties regarding Academic & Hospital Functions wherever applicable.
- ✓ To assist Professor & Associate Professor in their respective duties.

7) System Co-ordinator

Responsibility:-

Principal herself has taken the responsibility to bear the function of System Representative apart from her responsibilities in her work area.

SR has the following responsibilities :-

- a) Establishing, implementing & maintaining the Quality Management System in accordance with ISO-9001:2015 International Standard.
- b) To review the documents related to QMS.
- c) To control the QMS documentation.
- d) To conduct Management Review meeting & prepare & maintain the record.
- e) Ensuring the promotion & awareness of students requirements.



8) Administrative Officer:

Responsibilities

- ✓ To manage & execute the day to day functions of the college administration.
- ✓ To keep records, communicate on behalf of the college & principal to the various bodies viz. NCISM, MUHS, Govt. of Maharashtra, Director of Ayurved & Others.
- ✓ Getting the work done from the Non-Teaching subordinates encompassing Academic Section, Account Section, Computer Section, Stores Dept. & head clerks.

9) Non-Teaching Staff

Responsibilities & authorities of all Non-Teaching Staff is maintained by Admin Officer.

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10) Librarian

Responsibilities:-

- √ To maintain all study books & journals in safe condition with books identification
- √ To maintain records of issue & return of books from students & Teachers.
- √ To maintain the atmosphere within the library for reading purpose by the teachers & Students.

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SECTION: 6.0 PLANNING

6.1 ACTION TO ADDRESS RISK AND OPPORUNITIES

6.1.1 SSAM has considered the issues referred in CI 4.1 ensured that Quality Management System Planning is carried out to meet the requirements as mentioned in Sec4.1.and 4.2 i.e. Internal and external issues that affect the purpose and strategic direction and ability to achieve intended results of QMS of SSAM plus understanding the needs and expectations of interested parties. Determine the risks and opportunities that need to be addressed to

- a) Give assurance that QMS can achieve its intended results
- b) Enhance desirable effects
- c) Prevent or reduce undesired effects
- d) Achieve improvements

Explained in Doc No: SSAM/MGMT/02.

√ SSAM should plan Actions to address these risks and opportunities. How to:

√ Integrate and implement the actions in to its QMS

√ Evaluate effectiveness of these actions taken.

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6.2 QUALITY OBJECTIVES & PLANNING TO ACHIEVE THEM

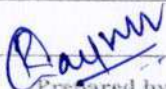
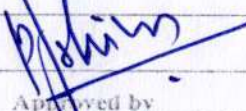
6.2.1 SSAM shall establish quality objectives at relevant functions, levels and Processes needed for the quality management system.

- a) Be consistent with the quality policy;
- b) Be Measurable;
- c) Take into account applicable requirements;
- d) Be relevant to conformity of products and services and to enhancement of customers satisfaction;
- e) Be monitored;
- f) Be communicated;
- g) Be updated as appropriate.

The SSAM shall maintain documented information on the Quality Objectives.

6.2.2 Planning of achievement of quality objective SSAM should determine:

- a) What will be done?
- b) What Resources are required?
- c) Define responsibility
- d) When it will be completed?
- e) How the results will be evaluated.

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6.3 PLANNING OF CHANGES

SSAM determines the need for changes to QMS and the same are carried out:

- a) The purpose of changes and their consequences
- b) The integrity of the QMS
- c) The availability of resources
- d) Allocation and reallocation of responsibilities and authorities.

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SECTION: 7.0 SUPPORTS

7.1 Resources

7.1.1 General

SSAM should determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS

SSAM should consider

- a) The capabilities of, and constraints on, existing internal resources.
- b) What needs to be obtained from external providers?

Refer for list of machinery doc no. SSAM/ML/01

7.1.2 PEOPLE

SSAM should determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes

7.1.3 INFRASTRUCTURE

The SSAM should determine , provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity to products and services Infrastructure may include

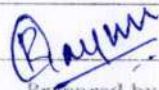
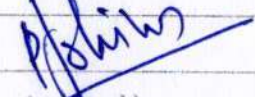
- f) Buildings and utilities
- g) Equipment including hardware and software
- h) Transportation resources
- i) Information and communication technology.

7.1.4 Environment for the operation of processes

SSAM should determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

Suitable environment can be a combination of human and physical factors such as:

- a) social (non-discriminatory, calm, non-confrontational)
- b) psychological (stress-reducing, burnout prevention, emotionally protective)
- c) Physical (temperature, heat, humidity, light, airflow, hygiene, noise) these factors can differ substantially depending on the products and services provided.

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7.1.5 Monitoring and measuring resources

7.1.5.1 General

SSAM determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products a services to requirements.

SSAM should ensure that resources provided:

- a) Are suitable for the specific type of monitoring and measurement activities undertaken
- b) Are maintained to ensure their continuing suitability for their purpose.

The SSAM should retain appropriate documented information as evidence of fitness for the purpose of monitoring and measurement resources.

Presently no measuring Instruments are made available. In future in higher classes instruments may be needed and at that time the same would be under the control of Principal as explained in DQM/QA/06


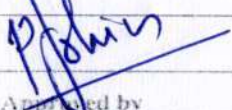
7.1.5.2 Measurement traceability

When the measurement traceability is a requirement, or is considered by SSAM to be an essential part of providing confidence in the validity of measurement results, measuring equipment should be:

- a) Calibrated or verified or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards exist, the basis used for calibration or verification should be retained as documented information
- b) Identified in order to determine their status
- c) Safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

SSAM should determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and should take appropriate action as necessary.

Presently calibration record of all the instruments is maintained with extended due date of calibration due to limited use by the students.

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7.1.6 SSAM Knowledge

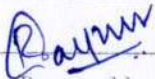
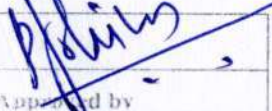
SSAM should determine the knowledge necessary for the operation of its processes and to achieve conformity of services.

This knowledge should be maintained and be available to the extent necessary.

When addressing changing needs and trends, SSAM should consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

SSAM knowledge can be based on:

- a) Internal sources (e.g. intellectual property; knowledge gained from experience, lessons learnt from Teaching in order to achieve better results by students; capturing and sharing undocumented knowledge and experience, the results of improvements in processes, and services)
- b) External sources (e.g. standards, academia, conferences; gathering knowledge from Parent Teachers meet or external providers).
- c) Refer Organization knowledge Sec 7.1.6 doc no. F/MGNT/04

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7.2 Competence

SSAM should

- a) Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS
- b) Ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
- d) Retain appropriate documented information as evidence of competence.

(Applicable actions can include e.g. the provision training to, the mentoring of, or the reassignment of employees, or the hiring or the contracting of competent persons.)

7.3 Awareness

SSAM should ensure that persons working under the control organization

Are aware:

- a) The Quality Policy
- b) Relevant quality objectives
- c) For their contribution to the effectiveness of QMS, including the benefits of improved performance.
- d) Implementation of not conforming with QMSR

7.4 Communication

The SSAM should determine the internal and external communications relevant to the QMS including:

- a) On what it will communicate
- b) When to communicate
- c) With whom to communicate
- d) How to communicate
- e) Who communicates

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7.5 Documented information

7.5.1 General

The SSAM's QMS should include:

- a) Documentation information required by this QMSR
- b) Documented information determined by SSAM as being necessary for the effectiveness of QMS.(The extent of documented information for a QMS may be different from other Organization)

7.5.2 Creating and updating

When creating and updating documented information SSAM should ensure appropriate:

- a) Identification and description (e.g. title, date, author, or reference no)
- c) Format e.g. language, software version, graphics)
- d) Review and approve for suitability and adequacy

7.5.3 Control of documented information

7.5.3.1 Documented information required by the ISO 9001:2015 QMSR should be controlled to ensure

- a) It is available and suitable for use
- b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss integrity)

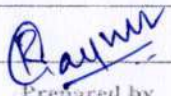

7.5.3.2 For the control of documented information, the SSAM should address the following activities, as applicable

- a) Distribution, access, retrieval, and use
- b) Storage and preservation, including preservation of legibility
- c) Control of changes (e.g. Version control)
- d) Retention and disposition

Documented information of external origin determined by the SSAM to be necessary for the planning and operation of the QMS should be determined as appropriate and be controlled.

Documented information retained as evidence of conformity should be protected from unintended alterations.

(Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information)

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SECTION: 8.0 OPERATIONS

8.1 Operational planning and control

SSAM plans and implements and control the processes [See 4.4] needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, By:

a. Determining the requirements for the products and services;

Establishing Criteria for:-

√ The processes;

√ The acceptance of products and services;

√ Determining The resources needed to achieve conformity to the product and services requirements;

√ Implementing control of the processes in accordance with the criteria;

√ Determining, maintaining and retaining documented information to the extent necessary;

√ To have confidence that the processes have been carried out as planned;

√ To demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the SSAM operations.

The SSAM shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The SSAM shall ensure that outsourced processes are controlled [see 8.4].

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8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customer should include:

- a) Providing information related to product & services
- b) Handling enquiries, contracts or orders including changes.
- c) Obtaining customer feedback related to panels & services including customer complaints.
- d) Handling or controlling customer property, establishing specific requirements for contingency actions when relevant.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers the SSAM shall ensure:

A] The requirements for the products and services to be offered to customers the SSAM ensures:

- √ Any applicable statutory and regulatory requirements
- √ Those Considered Necessary by the SSAM.

B] The SSAM can meet the claims for the products and services it offers.

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8.2.3 Review of the requirements for products and services

8.2.3.1

SSAM ensures that it has ability to meet requirements for products and services to be offered to customers. SSAM shall review before committing to supply products and services to the customer to include,

- a. Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b. Requirements not stated by customer, but necessary for the specified or intended use, when known;
- c. Requirements specified by the SSAM;
- d. Statutory and regulatory requirements applicable to the products and services;
- e. Contract or order requirements differing from those previously expressed.

SSAM shall ensure that contract or order requirements differing from those previously defined are resolved.

Customer requirements shall be confirmed by the

SSAM before acceptance, when the customer does not provide documented statement of their requirements (it can be such as Internet Cell, A formal review is impractical for each order instead the review can cover relevant product information such as catalogues.

8.2.3.2

SSAM shall retain documented information as applicable;

- a) On the results of the review;
- b) On any new requirements for product and services.

8.2.4. Changes to requirement for products and services

The SSAM shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of products and services.

Design and Development is not applicable for the SSAM for imparting education in BAMS band MD/MS courses as all syllabus and guidelines are followed as per MUHS/NCISM guidelines.

8.4 Control of externally provided processes, products and services

Details available in the Purchase department manual DQM/PUR/01 (8.4.1, 8.4.2, 8.4.3)

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8.4.1 General

The SSAM shall ensure that externally provided processes, products and services conform to requirements.

The SSAM shall determine the controls to be applied to externally provided processes, products and services when:-

- a) Products and services from external providers are intended for incorporation into the organization's own products and services;
- b) Products and services are provided directly to the customer[s] by external providers on behalf of the organization;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by the SSAM.

The SSAM shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The SSAM shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

SSAM ensures that externally provided processes, products and services do not adversely affect the SSAM's ability to consistently deliver conforming services to its customers as parents. SSAM should:

- a) Ensure that externally provided processes remain within the control of its QMS;
- b) Define both controls that SSAM intends to apply to an external provider and those SSAM intends to apply to the resulting output;
- c) SSAM takes in to consideration
 - 1] The potential impact of the externally provided processes, products, and services on the SSAM's ability to consistently meet customer and applicable statutory and regulatory requirements.
 - 2] The effectiveness of controls applied by the external providers.
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

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8.4.3 Information for external providers

SSAM shall insure the adequacy of requirements prior to their communication external provider.

SSAM shall communicate to external providers its requirement for;

- a) The Processes, products and services to be provided
- b) The approval of;
 - 1) Products and services
 - 2) Methods, Processes and equipment
 - 3) The release of products and services.,
- c) Competence, including any required qualification of persons.
- d) The external provider's interactions with the SSAM
- e) Control and monitoring of the external providers, performance to be applied by the SSAM
- f) Verification or validation activities that the SSAM or its customers intends to perform at the external providers premises.

Outsource Activity

1) Visiting Lecturers: -

- ✓ The visiting faculty is evaluated by the System Coordinator for performance annually.
- ✓ The Skill Matrix of visiting faculty is as follows: -

2) Resource Organizations:-

Post Graduate students avail facilities for Thesis work from resource organizations which provide them guidance and conduct experiments for them. Animal's studies and Drug Standardization are done from Various Research Organization. The organizations are approved by SSAM & MOU are signed.

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8.5 Production and Service Provision

8.5.1 Control Service Provision

SSAM shall implement service provision under controlled condition continually. Controlled conditions shall include as applicable

- A) The availability of documented information that defines ;
- 1 The characteristics of the Services to be produced the services to be provided or the activities to be performed;
 - 2 The results to be achieved;
- B) The availability and use of suitable monitoring and measuring resources;
- C) The implementation of monitoring and measurement activity at appropriate stages verifies that criteria for control of processes are outputs, and acceptance criteria for products and services have been met.
- D) Use of suitable infrastructure and environment for the operation of processes.
- E) The appointment of competent persons, including required qualification.
- F) The validation and periodic revalidation of the ability to achieve planned results of the processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.
- G) The implementation of actions to prevent human error.
- H) The implementation of release, delivery and post delivery activities.

SSAM is carrying out plan and processes under controlled condition which include :

- Availability of information that describes the characteristics of the Course & Curriculum.
- Availability of work instructions as required in laboratory.
- Proper use of equipment / instrument.
- Use of suitable methods.
- Release, delivery & post delivery activities i.e. Examination.

Teaching Process

All Courses & Syllabus are provided by NCISM & MUHS, Nashik for B.A.M.S., P.G. & Ph. D. degree Courses.

Following Courses are affiliated to the MUHS & NCISM regarding B.A.M.S. :

B.A.M.S

BAMS total course duration 5.5 years, academic course 4.5 Years divided in three academic years, 18 months per year followed by one year Compulsory Internship Training.

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POST GRADUATE COURSE & PERIOD

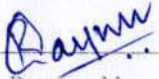

Following are three year full time Post Graduate Courses offered under the affiliation of Maharashtra University of Health Sciences, Nashik. (MUHS) leading to P. G. Degree

Sr. No.	Name of the Course	Intake Capacity
1	Ayurved Vachaspati (MD Ayurveda) Ayurved Samhita Siddhant	06
2	Ayurved Vachaspati (MD Ayurveda) Kriya Sharir	06
3	Ayurved Vachaspati (MD Ayurveda) Dravyaguna Vidyana	06
4	Ayurved Vachaspati (MD Ayurveda) Rasashastra Bhaishajya Kalpana	06
5	Ayurved Vachaspati (MD Ayurveda) Rognidan Avum Vikruti Vigyan	06
6	Ayurved Vachaspati (MD Ayurveda) Agadtantra Avum Vidhi Vaidyaka	06
7	Ayurved Dhanwantri (MS Ayurveda) Prasuti Tantra Avum Striroga	06
8	Ayurved Vachaspati (MD Ayurveda) Balrog (Kaumarbhritya)	06
9	Ayurved Vachaspati (MD Ayurveda) Kayachikitsa	06
10	Ayurved Dhanwantri (MS Ayurveda) Shalya Tantra-Samanya	06
11	Ayurved Vachaspati (MD Ayurveda) Swasthavritta & Yoga	06
12	Ayurved Vachaspati (MD Ayurveda) Panchakarma	06
13	Ayurved Dhanwantri (MS Ayurveda) Shalakya Tantra	06

Teaching process is controlled by Academic Term Plan duly prepared for each Subject & courses and the same are taught to the students accordingly.

During above process various laboratory classes are conducted.

Details of Academic Term Plan & Laboratory Class details are recorded vide SSAM/D/001.

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VALIDATION OF PROCESSES FOR SERVICE PROVISION

(Clause No: 8.5.1 f)

This clause is excluded. In case of SSAM in connection with teaching services for BAMS, PG, Ph. D. Degree, Fellowship & PG Diploma courses validation is done through the examination process. Record is maintained.

8.5.2 Identification and traceability

SSAM shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

SSAM shall identify the status of outputs with respect to monitoring and measurement requirements throughout the production and service provision.

SSAM shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability.

Traceability of students is maintained through Roll no. i.e. daily attendance of pupils (SSAM/ATT/01). MUHS provides PRN (Permanent Registration Number) for each student during admission in UG & PG Class which is maintained throughout till final examinations are conducted by them.

Traceability of library books is as per Accession No. and Call numbers. (SSAM/LIB/01).

Racks in library are identified with labels for easy traceability of the library books. Journals/magazines are also kept as reference materials. Students are provided with Master cards with Bar Coding System for easy accessibility after scanning of the same in computer monitor and all details of the students can be verified. (SSAM/LIB/02).

Books are issued to the students for seven days duration and after any delay a fine is charged @ Rs. 1/Day. A Due entry register is maintained by the Library (SSAM/LIB/03).

Each book is provided with Bar Coding System so that on scanning details of books with ACC No, Call No etc can be verified

Traceability of Class test / Unit Test/ Final Exam answer sheets is kept as per student name & Roll no. & Permanent Registration Numbers. (PRN).

Computers are identified as per list. (SSAM/List/01)).

Testing equipments are identified as per list (SSAM/List/02).

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8.5.3 Property belonging to customers or external providers

SSAM shall exercise care with property belonging to Students or external providers while it is under the SSAM control or being used by SSAM.

The SSAM shall identify, verify, protect, and safeguard Students or external providers' property provided for use or incorporation in to the products and services.

When the property of a customer or external provider is lost damaged or otherwise found to be unsuitable for use the SSAM shall report this to the customer or external provider and retain documented information on what has occurred.(A customers or external provider property can include materials, components, tools, and equipments, premises, intellectual property and personal data).

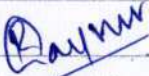

The moment students enter the premises of the SSAM, up to the time they leave the premises, they are covered as Customer Property. The Organization has established to identify, protect and safeguard the students during this period. Similar process of safeguarding of the original testimonial of students has been established by Administration department. One folder is maintained for each student starting from First year till he/she passes out from the college and maintained by Admin Officer vide SSAM/Admin/01.

Class Hours of students is maintained from 9-30 AM to 4-30 PM. Class duration is one hour for each Lecture. Lunch Break is for one Hour i.e. from 1-30 PM to 2-30 PM.

Lecture details are maintained as per NCISM Guidelines.

Post Graduates

In case of PG Course the number of classes is depending on the respective subjects.

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8.5.4 Preservation

SSAM preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Intended destination as per the contractual requirement and in order to maintain conformity to requirements. The preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation and protection. the preservation is ensured during all stages of manufacturing starting from identification, handling, packaging, storage and protection.

Presently the Institution has a storing place for documents related to the admission of each student for BAMS & PG Courses and proper care has been taken to preserve the above materials. School Leaving Certificate and other related documents of student in Originals are stored properly for valid proof of birth date & caste of student.

Other purchased materials like Papers/Writing pads/Xerox papers/other stationeries which are needed by the college for day to day teaching activities are stored in proper cupboards/racks and duly labeled for identification purposes.

8.5.5 Post-delivery activities

SSAM always meet requirements for post-delivery activities associated with the services.

In determining the extent of post-delivery activities that are required, the SSAM has always considered:

- a) Statutory and regulatory requirements.
- b) The potential undesired consequences associated with its services;
- c) The nature, use and intended lifetime of its services.
- d) Students' requirements
- e) Students' feedback.

8.5.6 Control of changes

The SSAM always reviews and Controls Changes for production or service provision to the extent necessary to ensure continuing conformity with requirements. The changes may be in syllabus of the studies or guidelines by MUHS.

The SSAM has always retained documented information describing the results of the review of changes the person(s) authorizing the change, and any necessary actions arising from review.

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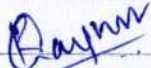

8.6 Release of products and services

The SSAM implement planned *arrangements*, at appropriate stages to verify that the product and service requirements have been met.

The release of products and services to the customer should not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and as applicable by the customer SSAM should retain documented information on the release of products and services The documented information should include

- a) Evidence of conformity with the acceptance criteria
- b) Traceability to the person(s) authorizing the release.

Product release is done by quality control in the form of clearance given on Job card, Inspection Report & check list for panel before dispatch.

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8.7 Control of nonconforming outputs

The SSAM shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The SSAM shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This should also apply to nonconforming products and services detected after delivery of products, during or after provision of services.

The SSAM should deal with nonconforming products in one or more of the following ways:

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the Parents as customer;
- d) Obtaining authorization for acceptance under concession;

Conformity to the requirement shall be verified when nonconforming outputs are corrected.

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SECTION: 9.0 PERFORMANCE EVALUATIONS

9.1 Monitoring, measurement, analysis and evaluation Applicable to all retain the documented information as evidence of the results.

Departments.

9.1.1 General

SSAM should determine:

- a) What needs to be monitored and measured
- b) The methods for monitoring and measurement, analysis and evaluation needed to ensure valid results
- c) When the monitoring and measuring should be performed
- d) When the results from monitoring and measurements should be analyzed and evaluated.

SSAM should evaluate the performance and the effectiveness of QMS.

9.1.2 Customer Satisfaction

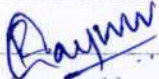
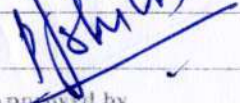
SSAM should monitor customer perception of the degree with respect to programme outcome course set by NCISM/MUHS to which their needs & expectations are fulfilled. SSAM should determine the methods for obtaining, monitoring and reviewing this information.

9.1.3. Analysis and evaluation

SSAM analyses and evaluate appropriate data and information arising from monitoring and measurement.

The result of analysis should be used to evaluate:

- a) Conformity to products and services
- b) The degree of customer satisfaction through matrix based on feedback, business growth, new business, recommendation etc.
- c) Performance and effectiveness of QMS
- d) If planning has been done effectively by comparing planned v/s actual process/product results
- e) Effectiveness of actions taken to address risks and opportunities.
- f) Performance of external providers based on criteria for quality, delivery and competitive rates.
- g) Need for improvements to the QMS.

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9.2 Internal audit

9.2.1 SSAM Should conduct internal audits at planned intervals i.e. every year to provide information on whether the QMS

Conforms to:

a) SSAM's own requirements for its QMS The requirements of this international standard is effectively implemented and maintained.

b) Is effectively implemented and maintained it can be based on Audit criteria. Audit Plan is made as per format F/MR/04 showing clause responsibility matrix dept wise, Audit & MR months planned as per frequency of once a year for the next 2 years. Audit methodology to be adapted by trained auditors is also mentioned along with list of trained auditors the same is approved by system coordinator.

9.2.2 The SSAM shall:

- a. Plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which should take in to consideration the importance of the processes concerned, changes affecting the SSAM, and the results of previous audits;
- b. Define the audit criteria and scope of audit
- c. Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process
- d. Ensure that the results of audits are reported to relevant management.
- e. Take appropriate correction and corrective actions without undue delay.
- f. Retain documented information as evidence of the implementation of the audit program and the audit results. Ref. ISO 9001:2015 for guidance.

Audit schedule to be released by system coordinator as per format F/MR/05

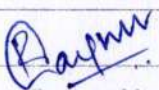

Audit observations will be recorded in the dept wise for all the departments as per plan, check list format & In case of non conformity NCR format F/MR/061 Will be used.

9.3 Management review

9.3.1 General

The SSAM Principal reviews the SSAM QMS at every year as per IA. MRM plan to ensure its continuing suitability and conducts the Management Review to judge the performance of the Quality Management System once in year. It is to be ensured its continuing, suitability, adequacy, effectiveness and alignment with strategic direction of SSAM.

Management review is conducted in the format SSAM/MRM/F/01

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9.3.2 Management Review Inputs

Management review is planned and carried out taking in to consideration:

- a) Status of actions from previous management reviews
 - b) Changes in external and internal issues that are relevant to QMS
 - c) Information on the performance and effectiveness of the QMS including
 - 1) Customer satisfaction and feedback from relevant interested parties
 - 2) The extent to which quality objectives have been met
 - 3) Process performance and conformity to products and services
 - 4) Nonconformities and corrective action.
 - 5) Monitoring and measurements results.
 - 6) Audit results.
 - 7) The performance of external providers
 - d) The adequacy of resources.
 - e) The effectiveness of actions taken to address risks and opportunities.6.1
 - f) Opportunities for improvement.

9.3.3. Management Review Outputs

The outputs of the management review should include decisions and actions related:

- a) Opportunities for improvement
- b) Any need for changes to the QMS
- c) Resource needs.

SSAM retains documented information as evidence of the results of Management reviews.

Management review will be conducted & recorded in the format F/MR/07.

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SECTION: 10.0 Improvement

10.1 General

SSAM should determine and select opportunities for improvement and implement any necessary action to meet customer requirements and enhance customer satisfaction.

These should include:

- a) Improving products and services to meet requirements as well as to address future needs and expectations.
- b) Correcting, preventing or reducing undesired effects.
- c) Improving the performance and effectiveness of QMS.
(Examples of improvement can include: correction, corrective action, continual improvement, breakthrough change, innovation and reorganization.)

10.2 Nonconformity and corrective action

10.2.1 When nonconformity occurs including any arising from complaints the SSAM shall:

- a) React to the non conformity and as applicable :
 - 1) Take action to control and correct it
 - 2) Deal with the consequences
- b) Evaluate the need for action to eliminate the cause(s) of nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) Reviewing and analyzing the nonconformity
 - 2) Determining the causes of the nonconformity;
 - 3) Determining if similar nonconformities exists, or could potentially occur;
- c) Implement any action needed.
- d) Review the effectiveness of any corrective action taken.
- e) Update risks and opportunities determined during planning, if necessary
- f) Make changes to the QMS if necessary


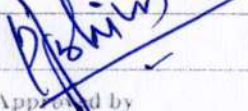
Corrective actions should be appropriate to the effects of the nonconformities encountered.

10.2.2 SSAM shall retain documented information as evidence of:

- a) The nature of the nonconformities and any subsequent actions taken.
- b) The results of any corrective action

10.3 Continual Improvement

The SSAM shall continually improve the suitability, adequacy and effectiveness of the QMS
The SSAM should consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that should be addressed as part of continual improvement.

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