



Comprehensive Dual Certification of ISO 9001:2015 and MS 1900:2014 to SASMEC @IIUM: A Beginning of a Long Journey as *Shariah* Compliant Hospital

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Abstract

SASMEC @IIUM started the operation and offered its service to the public since August 2016 and committed to bring experiences and expertise in providing healthcare services. SASMEC @IIUM has been awarded a dual certification of ISO 9001:2015 and MS 1900:2014 by SIRIM QAS International since December 2020. To become compliant, SASMEC @IIUM underwent stringent evaluation processes before certification to the standard was provided. Obtaining MS 1900:2014 certification officially verifies that SASMEC @IIUM is in compliance with recognized *Shariah* requirements. The scope of SASMEC @IIUM operation, primarily in providing healthcare services are all in accordance with the *Shariah* governance regulations. The objectives of this article are to share our journey to become a *Shariah* Compliant Hospital by highlighting our experience in preparing the requirement, developing the workforce team and other necessary elements to obtain ISO 9001:2015 and MS 1900:2014 certifications.

Keywords: *Shariah* Compliant Hospital, Quality Management System, *Shariah*-Based QMS, SASMEC @IIUM

Abstrak

SASMEC @IIUM telah memulakan operasi dan menawarkan perkhidmatannya kepada orang ramai sejak Ogos 2016 dan komited untuk membawa pengalaman dan kepakaran dalam menyediakan perkhidmatan penjagaan kesihatan. SASMEC @IIUM telah dianugerahkan pensijilan dual ISO 9001:2015 dan MS 1900:2014 oleh SIRIM QAS International sejak Disember 2020. Untuk mematuhi, SASMEC @IIUM menjalani proses penilaian yang ketat kepada standard yang tersedia ada sebelum proses pensijilan. Memperolehi pensijilan MS 1900:2014 secara rasmi mengesahkan bahawa SASMEC @IIUM telah mematuhi keperluan Syariah yang diiktiraf. Skop operasi SASMEC @IIUM, terutamanya dalam menyediakan perkhidmatan penjagaan kesihatan semuanya adalah mengikut peraturan tadbir urus Syariah. Objektif artikel ini adalah untuk berkongsi perjalanan bagi menjadi Hospital Patuh Syariah dengan menekankan pengalaman kami dalam menyediakan keperluan, membangunkan pasukan tenaga kerja dan elemen lain yang diperlukan untuk mendapatkan pensijilan ISO 9001:2015 dan MS 1900:2014.

Kata kunci: Hospital Patuh Syariah, Sistem Pengurusan Kualiti, QMS Berasaskan Syariah, SASMEC @IIUM

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Introduction

Sultan Ahmad Shah Medical Centre @IIUM (SASMEC @IIUM) started the operation and offered its service to the public since August 2016 and committed to bring better experiences and expertise in providing healthcare services. SASMEC @IIUM is proud to be awarded a dual certification of ISO 9001:2015 and MS

1900:2014 by SIRIM QAS International, Malaysia's leading certification body since December 2020. To become compliant, SASMEC @IIUM underwent stringent evaluation processes that included quality management system development, management system documentation review, audit and initial assessment. A thorough review of the management system was conducted before certification to the standard was provided. ISO 9001 is the most widely used and recognized standard for Quality Management Systems internationally. It acknowledges that an organization produces quality products and services, satisfies customers' requirements and organization standards. SASMEC @IIUM has developed and implemented a quality management system in order to improve the overall performance, maintain a high level of quality and patient required services. MS 1900 is a certification for an organization seeking a *Shariah*-based quality management system. The standard specifies requirements for a *Shariah*-compliant quality management system ensuring the incorporation of appropriate and universally accepted values in the quality management process of hospitals. The standard includes halal aspects of delivering products and services. Obtaining MS 1900:2014 certification officially verifies that SASMEC @IIUM is in compliance with recognized *Shariah* requirements. The scope of SASMEC operation, primarily in providing healthcare services are all in accordance with the *Shariah* governance regulations. This paper will highlight our journey and experience in preparing the requirement, developing the workforce team, appropriate workflow and standard operating procedures, monitoring and inspection process and other necessary procedures. Hopefully it will be useful and can encourage other healthcare services to obtain the certification.

Shariah Compliant Hospital Concept

Shariah means "the way" which is Islamic law that governs all aspects of life in Islam, and it is a code of conduct for Muslims. Using the words compliant or compliance is sometimes confusing, as an adjective compliant means is willing to comply or to obey the order by authority and as a noun compliance means an act of complying according to certain accepted standards. In

addition, a hospital is an institution that provides medical and surgical treatment and nursing care for sick or injured people. So, *Shariah* Compliant Hospital (SCH) is a hospital with accessible healthcare services and environment in compliance with the *Shariah* principles or Islamic teaching and deliberate according to *Maqasid Shariah* (Che Ahmad, 2021). It includes Islamic paradigms, values, ethics, and culture of the healthcare professionals (HCPs), other workers and patients. It also incorporates the building design, facilities, medical procedures, and treatment available in the hospital according to Islamic outlook. All existing and useful knowledge and technology used in the hospital are allowed within the Islamic moral and ethical context, through a process called Islamization. The basic guiding paradigms of the hospital consisted of (a) Integration (deriving from *tauhid*), (b) Balance (*tawazun*), (c) Quality work (*ihsan and itqan*) and, (d) Justice (*'adl*) (Kasule, 2011; Wan Su, 2013).

Ibadah Friendly Hospital (IFH) or *Hospital Mesra Ibadah* (HMI) is a service element of *Shariah* Compliant Hospital (SCH) in our Hospital. IFH is an initiative in hospital that practices excellence in service and spiritual care and focuses on the well-being of its clients through the embodiment of the noble values of its employees by producing excellent services, protecting patients' well-being and creating ethical employees. All responsibilities are on performing *Ibadah* and fulfilling the needs as a Muslim which requires HCPs and patients to help each other in performing *Ibadah* and avoiding disobedience (KKM-Unit Hal Ehwal Islam, 2018). In another view, IFH is a concept used in hospital management to ensure the qualities of excellence and pride to employees to be able to cater the well-being of its patients through the adoption and appreciation of worship during and after treatments. IFH aims to create awareness through education on patients and families to always get closer to Allah and to assist Muslim patients in daily worship (Al-Islam Specialist Hospital, 2013).

Muslim Friendly Healthcare (MFH) is the term use in practices of *Shariah* compliance concept to fulfil Muslim patients' needs and is where the healthcare services rendered in the

hospital are in accordance with the *Shariah* principles or Islamic teaching (Md Shariff & Abdul Rahman, 2016). The term of *Shariah* Compliance Hospital (SCH), *Ibadah* Friendly Hospital (IFH) and Muslim Friendly Healthcare (MFH) is interrelated. They have their own scope but overlap. In SASMEC @IIUM, IFH initiative is an element of SCH service (Che Ahmad, 2021). Whereas in public hospitals, IFH includes most of the aspects in line with *Shariah* and emphasis on HCPs and patients' *Ibadah*, moral and value (KKM - Unit Hal Ehwal Islam, 2018).

ISO 9001:2015

ISO 9001 is the most widely used and recognized standard for Quality Management Systems (QMS) internationally. It acknowledged that an organization produces quality products and services that fulfill patients' needs and organization standards. SASMEC @IIUM has developed and implemented a quality management system in order to improve the overall performance, maintain a high level of quality and patient required services. Through QMS, all policies, work procedures and work instructions are documented and reviewed accordingly. All feedback and comments from patients and staff are recorded and improvements are being implemented in order to increase clients' satisfaction (Malaysia Standard, 2015).

MS 1900:2014

MS 1900 is a certification for an organization seeking a *Shariah*-based quality management system. The standard specifies requirements for a *Shariah* compliant quality management system ensuring the incorporation of appropriate and universally accepted values in the quality management process of hospital. The standard includes halal aspects of delivering products and services too. There are four special elements that distinguish this with other standards are the presence of *Shariah* Advisory Committee (SAC), *Shariah* officer (ShO), organization Core Values (CV) and *Shariah* Critical Control Point (SCCP) (Malaysia Standard, 2014).

Planning Process

The idea for SASMEC @IIUM to acquire standard certification by way of SCH was initiated by the first Hospital Director back in 2014 (Zulkifly, 2014). Since then, SASMEC @IIUM management has started to establish its

Department of Quality Assurance in order to hold the responsibilities in executing the process. In the early stage of operation of SASMEC @IIUM, all SOPs were gathered and previewed in order to come out with the best SOPs. Some clinical staff were sent to other healthcare institutions in order to cross check the SOPs. This is to ensure that our SOPs will maintain the quality in our services. The training process will also help SASMEC @IIUM to learn the problems and errors to avoid in the early operation of SASMEC @IIUM prior to the official operation of SASMEC @IIUM in August 2016. The documents were then reviewed and revised to meet the most ideal setting toward facilitating processes and services offered. It took two years to review the processes and procedures before all the documentations are deemed ready in 2019. The effort toward receiving standard certification was continued by the second Hospital Director by highlighting the vision and mission through SASMEC @IIUM Strategic Planning 2019 – 2021 (IIUMMC, 2019). Thus, from the year 2019, the Department of Quality Assurance and Safety (DQAS) has been given the responsibility to outline the planning and coordinate the preparation of SASMEC @IIUM ISO 9001:2015 and MS 1900:2014 certification process. In addition, Department of *Shariah* Compliance (DSC) also was established and responsible to coordinate all *Shariah* compliance matters and services in hospital including the establishment of *Shariah* Critical Control Point (SCCP) in work process at all department /unit/ ward/ clinic (DUWC) (Che Ahmad, 2020).

Preparation and Implementation Process

Due to the non-existent internal expertise in *Shariah*-Based Quality Management Systems, SASMEC @IIUM management has contracted and appointed a consultant to guide and ensure that SASMEC @IIUM documentations are prepared for the certification. Representatives from each department and units have been identified, appointed and trained as the Quality Liaison Officer (QLO) to support the coordination team in completing the relevant documents specific to their work processes. The final documentations were then reviewed by the consultant before being presented to the management of SASMEC @IIUM. A gap

analysis was also attained to overview the parameters required by the ISO 9001:2015 standard. The DQAS had conducted various training and awareness concurrently with the documents preparation to enhance the QMS knowledge and understanding. Discussion with the Office of Knowledge for Change & Advancement (KCI), IIUM which is responsible for quality assurance for university, was obtained to seek advice on the ongoing progression of the certification process. Through the discussion, both parties agreed to attempt the internal audit on 12th until 16th October 2020 and followed by the certification audit by SIRIM on 11th until 13th November 2020.

As required by the ISO 9001:2015 standard, SASMEC @IIUM had successfully conducted their first Management Review Meeting in November 2019 followed by SIRIM Stage 1 (Adequacy) Audit. In November 2020, the hospital underwent the second stage audit for both Quality Management System and *Shariah*-Based Quality Management System concurrently to validate the compliance of SASMEC @IIUM in both certification requirements. In December 2020, SASMEC @IIUM was declared successfully passed the second stage audit by SIRIM and had received both comprehensive ISO 9001:2015 (Quality Management Systems) and MS 1900:2014 (*Shariah*-Based Quality Management System) certification synchronously.

Elements of SASMEC @IIUM Quality Management System

1. Department of Quality Assurance and Safety (DQAS)

DQAS is under the purview of the SASMEC @IIUM Senior Deputy Director (Corporate Affairs) Office. It is headed by a Head of Department who is assisted by two (2) Assistant Director, two (2) Assistant Administrative Officer and three (3) Administrative Assistant in order to run the duty of the department. The department consists of five (5) units including Occupational safety, Health, and Environment Unit, Licensing Unit, Quality Assurance Unit, Risk Management Unit, and Strategic Planning Unit (SASMEC @IIUM, 2021a). Quality

Assurance Unit is the responsible unit that performs the Quality Management System monitoring in SASMEC @IIUM. The unit is accountable to lead and coordinate all quality management activities for the hospital including patient care and relations that include the compliance of ISO 9001:2015 and also monitoring the continual improvement program for the performance of service quality (SASMEC @IIUM, 2021a).

2. Management Representative (MR)

The appointment as Management Representative (MR) is decided to be held by the Senior Deputy Director (Corporate Affairs) who is answerable for DQAS. The responsibilities of MR are to ensure that processes needed for the quality management system are established, implemented and maintained; report to top management on the performance of the QMS and any need for improvement; ensure the promotion of awareness of customer requirements throughout the organization; representing the management during certification and surveillance audits; establish quality management system processes; promote customer requirements; undertake data analysis; and support the continual development of the QMS (Malaysia Standard, 2015).

3. Quality Liaison Officer (QLO)

Quality Liaison Officers (QLO) are appointed to be the representatives from all DUWC (SASMEC @IIUM, 2021c) in order to guarantee the effective management of quality systems at all levels. The duties of QLO are to determine, negotiate and agree on in-house quality procedures, standards and specifications; assess customer requirements and ensure that these are met; coordinate with operating staff to establish procedures, standards, systems and procedures; and act as a contact person for DQAS in change and improvement in performance and quality.

4. Risk Management Committee (RMC)

As to manage the risk of the organization, SASMEC @IIUM has established Risk Management Committee (RMC) that is accounted to ensure that the risk-based management embedded in the operation of SASMEC @IIUM; approve the Risk Register of SASMEC @IIUM; review the risks; and recommend improvement to the SASMEC

@IIUM Risk Management implementation, whenever required (SASMEC @IIUM, 2021c).

5. Shariah Advisory Committee (SAC)

Establishment of SAC has been approved in the Hospital Management Committee (HMC) Meeting No. 1/2018 on 17th January 2018 and nomination of the SAC members has been approved in the University Management Committee (UMC) Meeting No.15/2019 on 16th October 2019. The objectives of the formation of SAC are to provide a comprehensive guidance to the HMC, management of the SASMEC @IIUM and Department of *Shariah* Compliance in settling its duties in matters relating to *Shariah* matters; and advise the management concerning on any *Shariah* issues relating to Islamic procedure or policy (Malaysia Standard, 2014; Yahaya, 2018; Md Shariff et al., 2019; SASMEC @IIUM, 2021e).

SAC shall consist of numerous appointed individuals with relevant qualifications related to *Shariah* matters. The appointment of SAC members depends on the background, experience, position, and qualification. The members of SAC should possess expertise in the field of Islamic jurisprudence (*usul fiqh*), Islamic law and bioethics; medical and managing medical related issues; and relevant experience to advise on *Shariah* related issues (Hamzah et al., 2019).

As the SASMEC @IIUM SAC members, it is consisting of SASMEC @IIUM Hospital Director, who is the chairman for SAC; an IIUM internal expert; a representative of *Jabatan Mufti Negeri Pahang*; a local external expert; an external expert that be nominated by the University; and *Shariah* Officer from Department of *Shariah* Compliance as a secretary for the SAC (SASMEC @IIUM, 2021e).

6. Department of Shariah Compliance (DSC)

The Department of *Shariah* Compliance (DSC) was established in January 2019 in order to coordinate all *Shariah* compliance matters and services in the hospital. The vision of DSC is to become an excellent and reputable department in providing excellence *Shariah* related training and services, and innovative skill development through a well-organized, committed and competent team. The missions of DSC are to coordinate *Shariah* compliance matters and services in SASMEC @IIUM, provide a

preferred *Shariah* monitoring system, establish an excellent Islamic spiritual care service in the region; and become the reputable *Shariah* training centre among university teaching hospital (SASMEC @IIUM, 2021b). DSC is directly reporting to the Hospital Director and headed by a *Shariah* Hospital Coordinator who is currently assisted by an Assistant Director, a *Shariah* Officer, three (3) Assistant Administrative Officer and three (3) Administrative Assistant in order to run the tasks of the department (SASMEC @IIUM, 2021d).

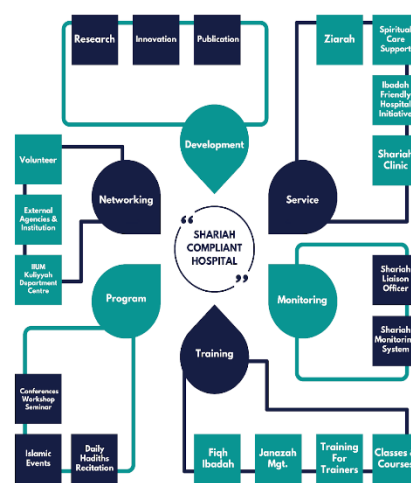


Figure 1: Six Elements of Shari'ah Compliant Hospital

The Scope of Shariah Compliance Workforce

1. **Training** unit leads and coordinates specific on-job training in Medico-Fiqh Ibadah, Janazah management, Islamic spiritual care (INSPIRE) course and trainers training course to equip staff with awareness, knowledge, skills and appropriate values.
2. **Services** unit is responsible for providing a variety of services including Ziyarah, *Shariah* clinic, *Ibadah* Friendly Hospital (IFH) initiatives, Islamic Spiritual Care (INSPIRE) Support and *Janazah* Management to the patients, relatives or staff.
3. **Programs** unit is responsible for organizing and coordinating all the programs related to Islamic affairs and events in the hospital including annual conference, monthly seminars, daily *du'a* and hadiths recitations and special events.

4. **Monitoring & Inspection** unit is responsible to monitor and inspect all activities at DUWC including hospital's kitchen, food stalls and others in order to ensure all the activities are in compliance with *Shariah* by regular monitoring and inspection of the DUWC, implementation of SCCP and SLO matters.
5. **Development** unit is responsible for producing any innovation, publications related to *Shariah* Compliant Hospital such as guidebooks, pamphlets, video and articles; and providing information on websites, archives, media social platforms and others.
6. **Networking** unit is responsible in making strategic collaborations with international and local institutions, hospitals, *kulliyyah* and centres in the university, government and non-government agencies such as *Jabatan Agama Islam Pahang (JAIP)* and *Yayasan Dakwah Islam Malaysia (YADIM)*. It also accountable for engagement with the community and volunteerism (SASMEC @IIUM, 2021b).

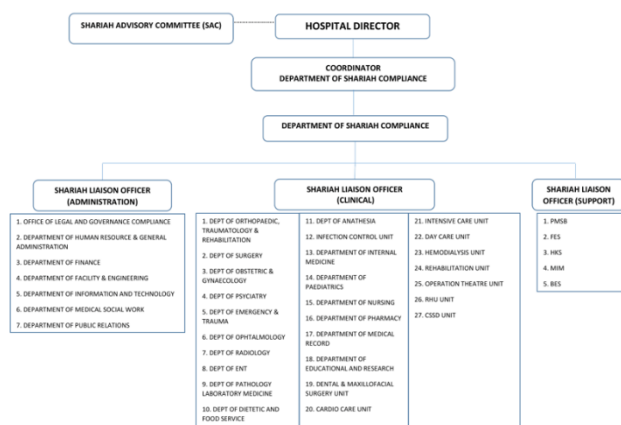


Figure 2: Structure of SASMEC@IIUM Shariah Liaison Officer

7. Shariah Liaison Officer (SLO)

Shariah Liaison Officer (SLO) is selected from and represents all DUWC. The establishment of this appointment was based on a suggestion by the internal audit team from an internal audit exercise on 14th October 2020. The jobs scope for SLO are monitoring the implementation of *Shariah* requirements in all activities of the DUWC; ensuring continuous conformity of *Shariah* requirements at respective DUWC; reporting all *Shariah* matters, any non-

compliance activities and updating *Shariah* matters in SLO meeting; acting as mediator between respective DUWC and DSC; and attending relevant training provided by DSC (Al-Azmi, 2020).

All SLOs are selected based on the nomination by the Head of Department or Coordinator of a Unit. The communication between SLO and DSC is accomplished through coordination meetings that are conducted once a month via various mediums such as physical or virtual meetings. Furthermore, communication between SLO and DSC is also done from time to time through social media groups, email, phone and appointment at a specific time, such as during *Shariah* Clinic at DSC office. All the information and direction from DSC can be disseminated to all SASMEC @IIUM staff through SLO as the mediator and representative of the respected DUWC. On the other hand, all the *Shariah* related issues raised at DUWC can be reported directly to DSC through their SLOs (Al-Azmi, 2020).

8. Shariah Officer (ShO)

One of the key requirements of *Shariah*-based QMS (MS 1900: 2014) certification is the availability of *Shariah* Officer (ShO) in the organization (Hamzah et al., 2019). ShO is a *Shariah* qualified person who is accountable to monitor and ensure that *Shariah* principles are observed and continually practiced in the organization according to the SAC advice (Malaysia Standard, 2014). In the process of document preparation, IIUM has appointed a ShO on 1st August 2019. The main task of SASMEC @IIUM ShO are ensuring continuous conformity of *Shariah* requirements in all activities within SASMEC @IIUM; monitoring the implementation of *Shariah* requirements in all activities of the DUWC; reporting to the SASMEC @IIUM top management on *Shariah* matters including *Shariah* non-compliances; assisting top management of SASMEC @IIUM on validating endorsed Islamic services, products, procedures, and policies of the SASMEC @IIUM with *Shariah* principles; facilitating to fulfill the certification requirements of MS 1900:2014; and responsible as secretary of SASMEC @IIUM *Shariah* Advisory Committee (Che Ahmad, 2020).

9. SASMEC @IIUM Core Values (CV)

Core values (CV) are the shared beliefs, values, norms, systems, processes and approaches that are constructed or exist in an organization that bind the employees to work and interact in order to achieve the missions and goals of an organization. CV provides a common ground, bonding element for members of the entire organization (Malaysia Standard, 2014). In order to fulfill the MS 1900:2014 *Shariah*-Based QMS, a set of values are chosen as SASMEC @IIUM core values and has endorsed during Hospital Management Committee (HMC) Meeting No.3/2018 on 23rd October 2018 and it was officially included in IIUM Medical Centre (later named as Sultan Ahmad Shah Medical Centre @IIUM) Strategic Planning 2019. (IIUMMC, 2019). The SASMEC @IIUM stipulated core values are Responsibility, Excellence, Sincerity, Trust and Unity (RESTU) (Che Ahmad, 2021).

10. *Shariah* Critical Control Points (SCCP)

According to *Shariah*-Based QMS 1900:2014 (Malaysia Standard, 2014), *Shariah* Critical Control Points (SCCP) can be defined as “A point within the organization's activities or processes at which controls can be applied and non-compliance to the principles of *Halal* and *Haram*, and principles of *Mu'amalat* can be prevented and mitigated to ensure compliance to *Shariah* requirements.” The organization is required to identify the *Shariah* critical control points which include establishing a document as evidence for compliance to *Shariah* requirements. (Hamzah et al., 2019; Malaysian Standard, 2014)

In relation to that, a rubric for appraisal matrix of *Shariah* Critical Control Points that formulated based on *Maqasid Shariah* was endorsed by Hospital Management Committee (HMC) Meeting No.3/2020 on 30th November 2020 after it has been presented and recommended by SASMEC @IIUM *Shariah* Advisory Committee (SAC) Meeting No.1/2020 on 26th November 2020. This rubric is used to standardize and guide the staff in formulating their own SCCP at their respective DUWC (Al-Azmi, 2020).

Conclusion

SASMEC @IIUM has just begun a long journey as the *Shariah* Compliant Hospital by successfully receiving a comprehensive dual certification of ISO 9001:2015 and MS 1900:2014. It is a big challenge for the management to maintain the certification as well as the implementation of *Shariah* in all activities at SASMEC @IIUM. Hopefully, this sharing experience will encourage and help other healthcare services to obtain the same certification in the future.

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