

Health Facilities Safety Assurance Improvement through the Establishment of a Testing and Calibration Institution in Riau Province

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ABSTRACT

One of the important parameters of providing health services to the community is the availability of adequate medical devices. To ensure safety and accuracy, medical devices must be tested and calibrated periodically by the Health Facility Testing Institution (IPFK) which has obtained permission from the Ministry of Health. The island of Sumatra, which is one of the large islands in Indonesia which has many health facilities, currently only consists of one Health Facility Security Center (BPFK). Therefore, to improve safety assurance in health facilities in the Sumatra region, it is necessary to establish new IPFKs that can provide testing and calibration services for medical devices. The purpose of this activity is to establish IPFK in Pekanbaru, Riau to improve the safety of patients and users' assurance of medical devices in health facilities. This activity refers to the procedures established by the Ministry of Health. Some of the activities carried out were developing company deeds, business plans, organizational structure, human resource (HR) needs and infrastructure, recruiting HR, conducting HR training, developing quality assurance documents, developing operational authorization application documents, and applying for operational authorization to the Ministry of Health. The activity was carried out for approximately one year and succeeded in establishing an IPFK that had adequate human resources, infrastructure, and quality documents and obtained an operational permit from the Ministry of Health.

Keywords: testing and calibration, health facilities, medical device

INTRODUCTION

Testing and calibration of medical devices in healthcare institution must be conducted to ensure the safety and usefulness of medical devices. According to UU No. 44 2019 (DPR RI, 2009), testing and calibration of medical devices must be conducted at least once a year by Health Facility Testing Institute (IPFK) which has an operational authorization from the Ministry of Health. Sumatra Island, which is one of the large islands in Indonesia and has many health facilities, currently only consists of one Health Facility Security Agency (BPFK) (Ombudsman Republik Indonesia, 2018). Therefore, it is necessary to establish a new IPFK that can provide testing and calibration services for medical devices. The objective of this activity is to establish an IPFK in Pekanbaru, Riau to improve safety assurance at health facilities in the Sumatra region.

According to Permenkes No.54 (2015), an IPFK must meet the requirements of location, building, equipment, documents, laboratories, and human resources. An IPFK locations must meet the provisions regarding environmental health and safety by complying with the Statement of Environmental Management and Monitoring (SPPL). An IPFK building must be permanent and not attached to the residence and must pay attention to function, security, comfort, and convenience in providing services as well as protection and safety.

Human resources in an IPFK shall at least consist of the head of IPFK, the person in charge of the laboratory, the person in charge of technical quality and service management, implementing staff, and administrative staff. The education qualification that must be possessed by the person in charge of an IPFK is at least Bachelor of Physics, Electrical Engineering, Biomedical Engineering, or Engineering Physics. For the person in charge of technical quality and service management, education requirement is at least Bachelor of Electrical Engineering, Environmental Engineering, Engineering Physics, Physics, Electrical Engineering, Biomedical Engineering,

Mechanical Engineering, Industrial Engineering, or Radiodiagnostics. The education qualification that must be possessed by the technical implementing staff of the Testing and Calibration laboratory are Diploma or Bachelor of Medical Electronics Engineering. All positions are required to have a minimum of 3 (three) years of work experience in their field/according to education; and has a training certificate in the field of Testing and/or Calibration of Medical Devices obtained from accredited training in accordance with the provisions of the legislation.

An IPFK must have measuring instruments or analyzers, test equipment, and calibration equipment in accordance with the type of Testing and/or Calibration of Medical Devices calibrated periodically by the Health Facility Testing Center for class A, class B, or level 2 (two) testing and calibration laboratories. accredited must be well maintained and have instructions for use and maintenance.

Building of an IPFK must have a space at least consisting of a work/laboratory, service room, and management room equipped with safety procedures, environmental monitoring, and sanitation as well as waste disposal.

An IPFK must have a quality document consisting of quality guidelines, quality procedures, worksheets and work methods as determined by the Director General, according to the type of Testing and/or Calibration.

METHODOLOGY

This activity refers to the procedures established by the Ministry of Health. Some of the activities carried out are making company deeds, business plans, organizational structures, human resource needs and infrastructure, recruiting human resources, conducting HR training, making quality documents, making operational permit application documents, and applying for operational permits to the Ministry of Health. Gantt chart of the implementation of the establishment of IPFK can be seen in Table 1.

Table 1. Gantt Chart of Establishment of IPFK in Pekanbaru, Riau

Activity	1	2	3	4	5	6
Making Company Legal	√	√				
Design of human resource needs, infrastructure, and business plans	√	√				
HR Recruitment			√	√		
Procurement of Infrastructure					√	√
HR Training					√	√
Activity	7	8	9	10	11	12
Quality Document Creation	√	√	√	√	√	√
Preparation of Institutional Documents	√	√	√			
Application for Operational Permit to the Ministry of Health				√	√	√

The list of company legal documents developed are company registration from a notary, registration letter from Ministry of Law and Human Rights, Trading Business Permits (SIUP), Company Registration Certificates (TDP), Domicile Certificates, Statements of Capability to Manage and Monitor the Environment (SPPL), Company Commercial Permits, Certificate of Registration, and Certificate of Fiscal. Several legal documents related to the central government are carried out online through the Online Single Submission (OSS) system on the oss.go.id website while documents related to the city government are carried out at the Pekanbaru City Investment and One Stop Integrated Service Office (DPMPTSP).

Human resources, infrastructure, and business plans are very important to be planned as the main document before carrying out the activities of establishing IPFK. To design the needs of human resources, infrastructure, and business plans, several factors that are taken into consideration are all the requirements in Permenkes No.54 of 2015, the SNI ISO 17025:2017 document, and the availability of funding.

To obtain human resources that are in accordance with the needs of the establishment, IPFK opens vacancies as laboratory managers, quality managers, and medical device testing and calibration technicians with the main qualifications being diploma or bachelor graduates in Medical Electronics Engineering, preferably having work experience and certificates for testing and calibration of medical devices. Job vacancies are disseminated through WhatsApp, Facebook, and Instagram groups, especially the electromedical group, as well as job vacancies websites.

Technical and quality training activities for testing and calibration of medical devices were carried out for 7 days in collaboration with the Jakarta Health Facility Security Agency (BPFK) at the IPFK Laboratory as shown in Figure 1. This activity was attended by all HR in IPFK. The training agenda is as follows:

Day 1: Opening and Introduction from the Head of BPFK and Quality Testing and Calibration Training in accordance with ISO 17025:2017;

Day 2: Electrical Safety Test Training;

Day 3: Basic Training on Uncertainty Calculation Analysis of Test Results and Calibration;

Day 4: Technical Testing and Calibration of Sphygmomanometer and Patient Monitor;

Day 5: Technical Testing and Calibration of the ECG Machine and Ventilator;

Day 6: Technical Testing and Calibration of Defibrillators and Electrosurgical Units;

Day 7: Technical Testing and Calibration of Infusion Pumps and Closures.

Next, the preparation of quality documents consisting of quality guidelines, quality procedures, worksheets and work methods is carried out as determined by the Director General, according to the type of Testing and/or Calibration. Quality guidelines and quality procedures are developed referring to the SNI ISO IEC 17025:2017 standard which is adapted to IPFK's internal policies. The working method was developed based on standards from the Ministry of Health, while the worksheet was developed referring to the work method based on guidance from BPFK Jakarta.



Figure 1. Training on Testing and Calibrating Medical Devices with BPFK Jakarta

Then, all documents required for the establishment of IPFK are collected in hardcopy and softcopy. Then the document is prepared to be submitted to the Ministry of Health online. The application for a letter of recommendation from the Pekanbaru City Health Office is done by sending a recommendation letter along with the complete institutional establishment documents in accordance with Permenkes 54 of 2015. The document is then processed by the Pekanbaru City Health Office then a visit is carried out to the laboratory location to verify the files and conformity with the establishment requirements. IPFK.

Next, the recommendation letter from the Pekanbaru Health Office, and all licensing documents were uploaded online through the website <http://perizinan.yankes.kemkes.go.id/perizinan/> on September 19, 2019. The licensing procedure can be seen in Figure 2.



Figure 2. Health Service Licensing Procedures (perizinan.yankes.kemkes.go.id)

The progress of the establishment process can be seen online at the website. The next stage is the visitation conducted by the Ministry of Health team. This visitation was carried out to verify documents and the readiness of human resources, IPFK facilities and infrastructure to test and calibrate medical devices. The visit took the form of presentations, HR interviews, HR competency tests, and verification of infrastructure and quality documents. The visitation activity was carried out for 1 day at the IPFK Laboratory as shown in Figure 3.



Figure 3. Ministry of Health Visitation Team

RESULT

The activity was carried out for approximately one year and succeeded in establishing the IPFK which has 7 types of medical device testing and calibration services, organizational structure, 9 operational HR people who fill positions that meet the requirements and support service implementation, infrastructure facilities that support operational activities, and quality documents. and obtain an operational permit from the Ministry of Health.

Service Type

The IPFK was established with type D qualifications with a list of medical device testing and calibration services provided consisting of a sphygmomanometer, EKG machine, patient monitor, defibrillator, ventilator, electrosurgical unit, and infusion pump. This service has different processing times and rates, which are calculated from the amount of operational costs, investment, maintenance of infrastructure, and the benefits of each service.

Organizational structure

The organizational structure consists of a director, laboratory manager, quality manager, administrative manager, marketing manager, and four technicians. The top director of the IPFK is responsible for carrying out supervision and evaluation of technical operations and laboratory management, so that the effectiveness of understanding and implementing the quality management system according to ISO/IEC 17025 is met and customer satisfaction is achieved.

The quality manager is responsible to the director for ensuring that the quality management system conforms to ISO/IEC 17025 and the scope of sampling, testing and/or calibration activities is communicated, understood, implemented, and maintained by all HR. The laboratory manager is responsible to the director in terms of ensuring all aspects of technical operations and the completeness of the resources needed for the validity of the data from sampling, testing and/or calibration according to customer needs and satisfaction. The administrative manager is responsible to the director for managing the creation and movement of all operational documents in the laboratory and managing laboratory finances. The marketing manager is responsible to the director for managing the IPFK profiles in the form of websites and brochures, then publishing and communicating to customers or health facilities. The technician is responsible to the technical manager for collecting test data and calibration of medical devices in health facilities using a calibrator and filling in the results in a worksheet. The structure can be seen in Figure 4.

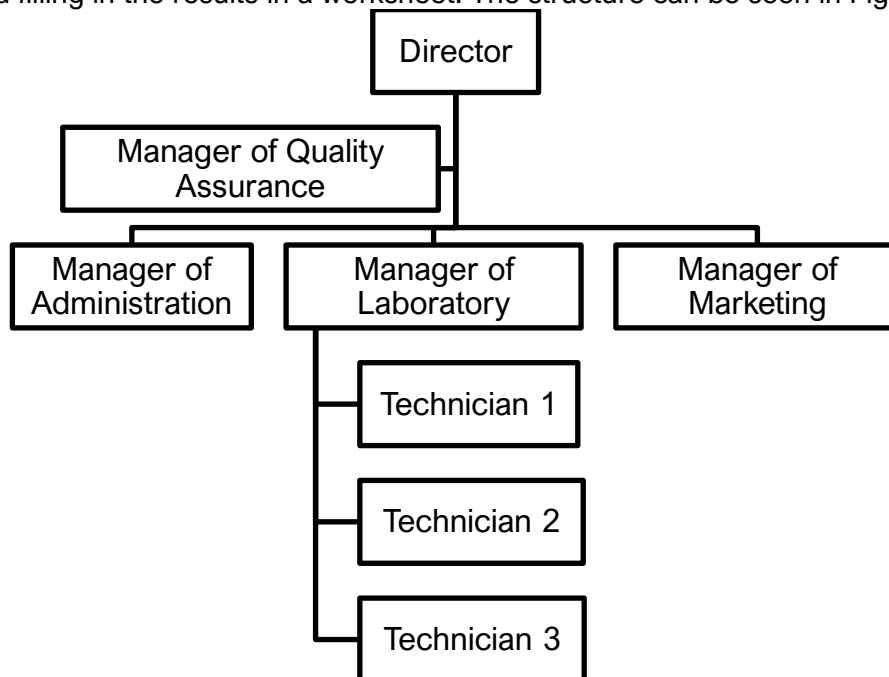


Figure 4. Organizational Structure of the IPFK

Human Resources

The recruited human resources have educational qualifications, work experience, and competencies that are in accordance with the requirements for their position. All human resources involved in testing and calibration activities have certificates of training for testing and calibration of 7 services provided and certificates of quality assurance based on SNI ISO/IEC 17025:2017. The technician implementing the testing and calibration of medical devices also comes from Diploma and Bachelor of Medical Electronics Engineering with work experience in their field and already has a Registration Certificate (STR) and Practice License (SIP) which are managed through professional organizations in their area. Details of HR qualifications can be seen in Table 2.

Table 2. List of Human Resource of the IPFK

Position	Education	Work Experience (Years)	Testing and Calibration Certificate
Director	Bachelor of Electrical Engineer	6	√
Manager of Quality Assurance	Bachelor of Physics	6	√
Manager of Laboratory	Bachelor of Physics	6	√
Manager of Administration	Bachelor of Public Health	2	X
Manager of Marketing	Bachelor of Communication	2	X
Technician 1	Bachelor of Medical Electronics Engineering	1	√
Technician 2	Diploma of Medical Electronics Engineering	1	√
Technician 3	Diploma of Medical Electronics Engineering	1	√

Infrastructure

The type of calibration tool owned by the IPFK is in accordance with the type of service to be performed. The calibrators provided are new and used tools purchased from distributors and other calibration companies. This calibrator has also been tested and calibrated at BPFK Jakarta so that the tool has a calibration certificate and correction value. before the permit document is uploaded to the ministry of health. This calibrator must be tested and calibrated once a year to ensure the validity of the test and calibration results. The list of facilities owned by IPFK can be seen in Table 3.

Table 3. List of the IPFK Equipment

Equipment Name	Merk	Model	Status
Electrical Safety Analyzer	Fluke	612	Calibrated
Defib Analyzer	Fluke	Impulse 4000	Calibrated
NIBP Analyzer	Fluke	Cufflink	Calibrated
Patient Simulator	Fluke	MedSim 300B	Calibrated
Electrosurgical Analyzer (ESU)	Fluke, DNI Nevada	402A	Calibrated
Infusion Device Analyzer	Bio-Tek	IDA-4	Calibrated
Oxygen Analyzer/Anesthesia Machine Analyzer	IMT Medical	PF 300	Calibrated
Pulse Oximeter Tester	DNI, Nevada	Oxitest plus 7	Calibrated

Infrastructure is buildings and rooms owned by IPFK. IPFK already has its own building which is separate from the residence and has an adequate electrical and water installation system. The room consists of a management room, a testing and calibration room, a service room, and a tool storage room. The list of infrastructure or buildings/rooms owned by IPFK can be seen in table 4.

Table 4. List of IPFK Infrastructure

Infrastructure Name	Area (m ²)
Management Room	6x6
Testing and Calibration Laboratory	6x6
Receptionist Room	6x4
Equipment Storage Room	6x2

Laboratory Quality Documents

The test and calibration laboratory quality documents are the main document in carrying out technical testing and calibration. This document has been prepared in accordance with SNI ISO 17025:2017 which consists of quality policy documents, quality procedures, work instructions, and forms/records. The quality document developed has met the general requirements consisting of impartiality and confidentiality, structural requirements, human resources, processes, and management. The working methods and worksheets that have been developed are the sphygmomanometer, EKG machine, patient monitor, defibrillator, ventilator, electrosurgical unit, and infusion pump work method. This method and worksheet consist of objectives, scope, references, measuring instruments used, environmental conditions, test and calibration procedures, performance testing, test times, and calculation and analysis of measurement uncertainty.

Operational Permit

The Operational Permit is issued by the Ministry of Health based on the Decree of the Director General of Health Services regarding the Operational Permit of the Health Facility Testing Institute on January 22, 2020. This operational permit is granted with a class D classification which is valid for 5 years from the date of stipulation and can be extended as long as it meets the requirements. In this operational permit document, it is also explained that the guidance, supervision, and control of the IPFK implementation in stages and periodically is carried out by the Riau Provincial Health Office.

DISCUSSION

Testing and calibration of medical devices is one of the most important things to ensure the security, safety, and usefulness of medical devices in health facilities. Not only in Indonesia, testing and calibration are also the main activities in the implementation of planned preventive maintenance in the world (Badnjevic et al., 2017). Although this activity can be carried out internally in health facilities, most health facilities in the world use an outsourcing system to carry out testing and calibration of medical devices (Smithson & Dickey, 2020). This outsourcing system will be given to Health Facility Testing Institutions (IPFK) which already have permission from the government in their respective countries and are accredited with SNI ISO IEC 17025:2017.

Apart from activities carried out by testing and calibration laboratories, both government and private, various efforts have been made by the community, especially educational institutions to support the implementation of testing and calibration of medical devices in health facilities to ensure security, safety, and benefit. Testing and calibration activities of medical devices have been carried out by (Irawati et al., 2018) at the Pacitan District Health Office, (Fajrin et al., 2019) at Banguntapan II Health Center Yogyakarta, and also (Susana et al., 2020) at the Puskesmas South Kebayoran Lama District and its fostered Village Health Center. It can be concluded that testing and calibration of medical devices is still very much needed through the addition of new IPFK in areas that have not been reached or still have few testing and calibration facilities.

To establish an IPFK, intense coordination with BPFK in the relevant work area is required. Medical device testing and calibration services in the North Sumatra region are under the Medan BPFK. However, because BPFK Medan does not have activities to conduct training for IPFK, testing and calibration training can coordinate with BPFK Jakarta. BPFK Jakarta is quite cooperative in responding to requests for testing and calibration of medical devices. Cooperation with BPFK Jakarta is also carried out through testing and calibration of calibrators owned by IPFK. This collaborative activity is very necessary both in establishing the IPFK as well as in the implementation of testing and calibration. Several educational institutions have also collaborated with IPFK to provide testing and calibration services for medical devices in health facilities. Poltekkes Jakarta II is collaborating with PT Medcalindo to test and calibrate medical devices (Susana et al., 2020).

There are several evaluations that can be used as input in the establishment of IPFK. Some of these evaluations include standards and understanding of the procedures for establishing a

health laboratory which have multiple interpretations that make many changes to activity planning, dependence on external agencies such as the Health Service and the Ministry of Health becomes a challenge in planning and implementing activities, inappropriate timing of incentives and inappropriate implementation of work procedures. calibration technique.

In relation to service planning, the work method of the ministry of health which is the main reference in conducting testing and calibration services for medical devices cannot be accessed. This is quite difficult for IPFK in planning service needs such as training, facilities, and infrastructure or what calibrator tools are needed. The working method of Testing and Calibrating Medical Devices from the Ministry of Health should be published publicly so that the public can learn about the needs needed if they want to provide services per medical device.

Furthermore, there are several evaluations related to the requirements and mechanisms for establishing IPFK. For HR requirements, in the position of technical implementing staff of the Testing and Calibration laboratory, based on information from the BPFK and the Ministry of Health, the qualifications that must be met are at least DIII in Electrical Engineering with STR and SIP. This provision is not stated in the Minister of Health Regulation No. 54 of 2015 so that the planning process for the establishment of IPFK is less able to project the activities that should be carried out. For the establishment procedure, the visitation procedure for the ministry of health team has not been explicitly stated in the Minister of Health. The time interval for uploading the proposal to the visitation of the ministry of health team is 40 working days and the distance between the visitation and the issuance of the announcement of the results and the Decree of the Director General of Health Services is 46 working days so that the total duration of the issuance of an operational permit is 86 days. In the Minister of Health, the duration of the procedure for issuing an operational permit is 33 days starting from the submission of the application for establishment until the issuance of a decree.

The duration of this process is very important considering that the company has to pay HR and other operational expenses while waiting for the licensing process while income from services cannot be done. To anticipate this, IPFK needs to have sufficient financial resources as long as income cannot be obtained or the company has alternative income other than testing and calibration services such as medical device repair services, consultation and training.

Some of these evaluations are input for the ministry of health to improve the quality of policies related to the requirements and mechanisms for establishing IPFK in Indonesia so that more and more the general public or government agencies are interested in establishing IPFK in areas that are still not covered by testing and calibration of medical devices.

Furthermore, after the establishment of IPFK, in order to achieve a management system that is in accordance with SNI ISO 17025:2017, a good computerized and online management system is very important to implement. This IT system will greatly assist the process of carrying out testing and calibration in health facilities. For example, when a technician performs testing and calibration in a health facility, if the completed worksheet has been integrated with the online system, the data will be immediately analyzed by the technical manager. The technical manager does not need to linger in the analysis because the calculation system is already integrated and processed to issue test and calibration results and issue certificates. Studies on the implementation of IT systems have also been conducted at BPFK Surabaya by (Daputra & Oranova, 2011). An IT system using an enterprise architecture model in IPFK has also been developed by (Santoso & Affandi, 2016). Electronic certificates have also been implemented in IPFK so as to speed up the process of granting certificates to health facilities and also make it easier for health facilities to verify the validity of the results on the certificate (Asrori, 2020). It would be even better if the IT system was managed by the Ministry of Health so that the IT system at IPFK could be integrated with the IT system in health facilities as described by (Gurbeta & Badnjević, 2016). Of course, with the development of information technology today, it will help facilitate IPFK in carrying out the process of testing and calibrating medical devices.

CONCLUSION

To increase the assurance of the safety and usefulness of medical devices at Health Facilities in Sumatra, the establishment of the Health Facility Testing Institution (IPFK) has been carried out in Pekanbaru, Riau. The establishment of IPFK follows the procedures determined by the Ministry of Health and has met the requirements of legality, organizational structure, human resources, equipment and buildings, and operational and quality documents. Testing and calibration services that are opened are sphygmomanometer, EKG machine, ventilator, patient monitor, defibrillator, infusion pump, and electrosurgery unit. The implementation of this activity is carried out for 1 year and has been able to operate to serve health facilities in Sumatra. The next stage of this activity is that IPFK will carry out operational testing and calibration of medical devices in accordance with the services provided by referring to the SNI ISO IEC 17025:2017 standard. After 1 year, a comparative test and proficiency test will be conducted to ensure the validity of the results of the testing and calibration activities. After that, IPFK will apply for SNI ISO 17025:2017 accreditation to the National Accreditation Committee (KAN). It is hoped that the results of this activity can be a reference for the public, testing and calibration professions, and business actors to contribute to establishing IPFK, especially in other areas in Indonesia that have health facilities that have not yet obtained access to guarantee the safety and accuracy of medical devices. The results of this activity can also be input for the ministry of health to improve the quality of policies related to the requirements and mechanisms for establishing IPFK in Indonesia so that more and more the public or government agencies are interested in establishing IPFK in areas that are still not covered by testing and calibration of medical devices.

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