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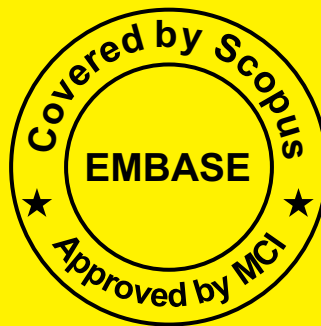
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Exploring the Compliance Test for X-ray in Health Facilities Security of Makassar Region

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ABSTRACT

The initial observation on compliance test for X-ray facilities reported that some of them were failed to meet the obligation of compliance test provided by the Health Facilities Security of Makassar Region or BPFK Makassar. The purpose of this study was to explore the reasons for their failure to fulfill the obligation on X-ray facilities compliance and services. This research employed qualitative methods. The ten informants of 9 primary informants and 1 secondary informant from the X-ray health facilities in Makassar of South Sulawesi Island were interviewed. The result behind the success in their compliance test was mainly due to the presence of the supervision team from the Nuclear Energy Regulatory Agency of Indonesia. Additionally, another factor such as the presence of internal and external supervision also played significant support to be able to fulfill the compliance test for X-ray facilities. At the other side, inadequate funding and lack of understanding about the purpose and obligation of the compliance test were mostly informed by the respondents as the main reasons for their failure to comply with the calibration test of the X-ray facilities. Therefore, external and internal supervision should be strengthened to increase the compliance test among X-ray health facilities in Makassar.

Keywords: *Compliance Test, X-ray, Health Facilities, Nuclear Energy Regulatory Agency*

INTRODUCTION

The Minister of Health of Indonesia Regulation Number. 432/MENKES/SK/IV/2007 on occupational safety and health management for the hospital stipulated that radiation is one of potential physical hazards to be concerned by planning, organizing, implementing, and controlling aiming to cultivate occupational safety and health in the hospital especially in radiology examination.

The ionizing radiation that involves the human body can cause deterministic effects such as skin erythema, cataract, sterility, nausea, diarrhea, fetal death, stochastic effects such as cancer, and hereditary defects.¹ The radiation protection is useful to prevent the deterministic effects and to decrease the probability of stochastic effects among workers.

Meanwhile, the compliance test is an assurance of the X-ray used to prevent unnecessary radiation dose on the patients, the workers and the person who may around. The x-ray machine reliability assurance in Indonesia is regulated by BAPETEN Regulation Number 9/2011 regarding the implementation of the compliance test and the Indonesian Minister of Health Regulation Number 54/2015 on the medical equipment compliance test. According to BAPETEN Regulation Number 9/2011, every health facilities that request a new permit or an extension of the license of X-ray machine is mandated to apply for the compliance test. If a case occurs.²

The services of the compliance test applied by BPFK Makassar include 10 zones in eastern Indonesia: South Sulawesi, West Sulawesi, Central Sulawesi, Southeast Sulawesi, Gorontalo, North Sulawesi, North Maluku, Maluku, Papua, and West Papua. From 2015 to 2017 some 124, 114, 134, and 145 facilities around the Eastern part of Indonesian territory had the compliance test once or twice. The Director General of Health Services of the Ministry of Health Republic Indonesia showed that 315 hospitals under BPFK Makassar's coverage of General Hospitals and Specialty Hospitals had the X-ray

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facilities.³ Unfortunately, many of them did not meet the standard of twice compliance tests annually. According to a theory, the input, the process, and the output in health administration is unique according to who and how to deal with their limitation.⁴

There are some aspects such as health facilities, fund, policy, and feedback that are in need to boost the fulfillment of twice compliance tests for the X-ray facilities annually.

METHOD

This research was qualitative research. The government's X-ray facilities that implement twice tests continuously or called 'S.P.A,' while the private X-ray facilities are called 'S.P.B.' The government health facilities that do not implement the twice tests

periodically are called 'S.P.C,' and the private ones are called 'S.P.D.' The informants consisted of management staff and a technical worker from both sides, the X-ray facilities and the BPFK of Makassar. An in-depth interview was employed to gather data. A total of ten informants from the X-ray health facilities in Makassar of South Sulawesi Island were interviewed, and their responses were re-check using triangulation with the BPFK staff and technical operator.

RESULTS

Data Analysis of BPFK Makassar: According to BPFK Makassar services, the compliance test from 2014 to 2017 increased in term of the number of test participants, besides the decreasing number of health facilities from 124 facilities to 114 from 2014 to 2015. The result of the implementation of the test can be shown in Table 1..

Table 1: A number of health facilities implement the compliance test and calibration in the year of 2014–2018

Province	2014	2015	2016	2017	2018*
North Sulawesi	8	8	8	10	6
South East Sulawesi	9	5	7	12	2
Central Sulawesi	11	7	11	15	8
South Sulawesi	57	51	66	55	17
West Sulawesi	4	4	3	7	0
West Papua	6	1	3	2	1
Papua	7	9	7	9	2
North Maluku	5	4	7	4	4
Maluku	6	2	5	8	2
Gorontalo	6	14	6	9	2
Outside The Working Area of BPFK Makassar	5	9	11	14	4
Total	124	114	134	145	48

*The data until 2018 May

South Sulawesi is a province with the largest number of health facilities in East Indonesia. Almost half or 44.29% implemented the compliance test with BPFK Makassar annually. In 2017, there was an increasing number of compliance test participants up to 70% of X-ray facilities.

Table 2: The number of Health Facilities based on both possession of government and private from year of 2014-2018

Health Facilities	2014	2015	2016	2017	2018*
Central Government	4	4	6	5	4
Province Government	12	11	12	17	3
County/City Government	48	40	56	57	16
Another Minister	2	2	2	3	0
Private Hospitals	28	24	29	30	7
Clinics	24	26	14	24	7
BUMN	1	2	3	0	0
Companies	2	2	4	2	4
TNI/POLRI	3	3	8	7	7
Total	124	114	134	145	48

*The data until 2018 May

In the input, process, and output are shown in figure 1. the X-ray facilities attached to the government showed an increase in compliance test fulfillment, but the private ones didn't show any progress.

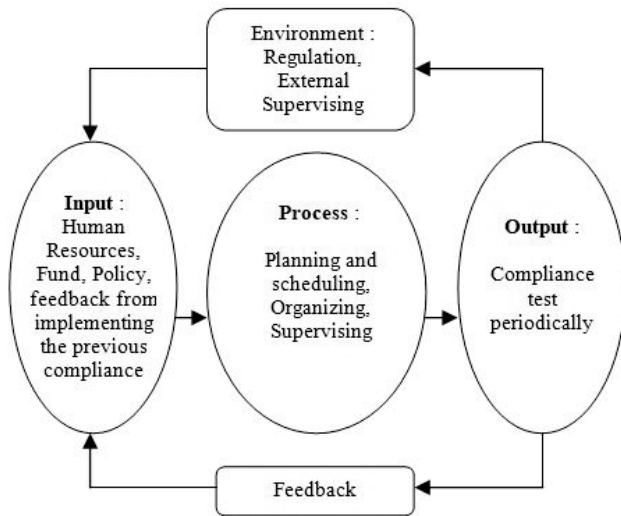


Figure 1: Scheme of the application of the compliance test and calibration with Systems Theory

Interviews Result

Input: All management and staff in ‘SP.A,’ ‘SP.B,’ and ‘SP.C’ knew the latest regulation of the compliance test that should be fulfilled biennial or once every two years along with the extension of the license. Funding was the main reason for failure in the fulfillment of the compliance test.

Subsequently, the standard operating procedure had to be implemented for the X-ray facilities if the facility sought the compliance test and licensed to operate it.

The ‘SP.A,’ ‘SP.B’ and ‘SP.D’ obtained the compliance test with BPFK Makassar. However, ‘SP.C’ had calibrated with private labs in 2017. Financially, one of the respondents said that the cost of medical equipment calibration by BPFK Makassar is too expensive.

Process: Planning for the test was conducted annually. The X-ray Facilities with (‘SP.A’) could not schedule the test because they had no staff to be in charge of the implementation achievement. The ‘SP.B’ code of X-ray facility usually set a reminder on the 90th days before the expiration of the X-ray license.

Staffing had been applied by the management ‘SP.A,’ ‘SP.B,’ and ‘SP.C’ by employing staff for coordinating this implementation of the compliance test and calibration. A radiation protection officer directly involved in the

process of the test. The ‘SP.D’ code for the radiology clinics own by private did not have the coordinator for their compliance test. Therefore, a radiation protection officer should take in charge of compiling the documents of the standard of the permission for the compliance test.

Nuclear Energy Regulatory Agency (BAPETEN) once conducted inspections in all of the research subject. The compliance test related to the accreditation requirements as well as a mean to protect the patient. Subsequently, marketing aspects are also taking advantages of the compliance aspects of the X-ray facilities.

Output: Research subjects ‘SP.A’ and ‘SP.B’ applied the compliance test and calibration periodically, due to human resources awareness on the rules and the benefit of the compliance test. Currently, a significant fund is available to cover the test by BPFK Makassar. However, the calibration was not implemented in ‘SP.C’ due to the insignificant fund, even though ‘SP.C’ was supported by the input system.

The implementation of the calibration periodically could not be applied in ‘SP.D’ due to the lack of understanding the implementation of calibration for every year, but mere applying the compliance test for the standard of the permission for two year.

DISCUSSIONS

Health facilities in two areas such as both West and South Sulawesi could apply the compliance test and calibration due to the close distance with BPFK Makassar. However, health facilities in West Papua could use this test least due to this reason. West Papua is a large area, where most of the regions are wildlife jungle. Technical Unit in Papua could not afford this compliance test, so Papua and West Papua must invite the BPFK testers. According to Weeren (2016), convenience places affected partially.⁵

Input: The supervision from Nuclear Energy Regulatory Agency towards the X-ray facilities and the requirement for a license are the contributor for their implementation of the compliance test. A sanction is enforced according to the Regulation on nuclear energy Number 10/1997.⁶

The compliance test and calibration of the X-ray facility are related to the availability of funding as informed by the respondent. Lack of financing among ‘SP.C’ X-ray facilities was the reason for not being able

to fulfill the compliance test. Although the commitment of the organization presence, without sufficient funding, the compliance test was trying to enforce.⁷ Government Regulation Number 21/2013 stipulated that funding should cover the accommodation, transportation, and daily allowance for the person who conducted the test. However, many X-ray facilities perceived a significant burden to accommodate the compliance test cost.⁸

The BPFK Makassar has the dimension of service quality with top categories and the aspect of services quality with sufficient excellent facilities that put them in a pressure to work harder in convincing and advocating X-ray facilities to obtain the compliance test.

Process: The correct information system can strengthen the importance of the planning, and ensure the preparation run well.⁹ SPB applies the information system through plan ordered in the last year, concerning the limit time of the certificate, so SPB can afford to employ the calibration test punctually.

As BAPETEN Chairman's Regulation No. 4/2013, health facilities utilizing the source of ionizing radiation should have the radiation protection officers. Health facilities had the radiation protection officers even though the officers were not the permanent employees. The test coordinator pointed is to be expected to ease the implementation of the compliance test and calibration periodically. Even though SPC had the test coordinators but the fact of the lack of fund caused not the application of the compliance test and calibration regularly. The role of radiation protection officer is essential, but if their obligations are violated, merely used as the standard of nuclear energy permission, so the sanction will be conducted as mentioned in Regulation Number 10/1997.¹⁰

The most effective supervision is an inspection from BAPETEN. However, it is just limited to the implementation in the compliance test for the permission. People should concern labeling applied by BAPETEN for their common safety. In the calibration implementation, the factor of accreditation assessments done by health facilities becomes the supporting factor of the execution of the compliance test and calibration routinely. SPB also did the internal supervision through the internal audit for every year. This audit is a management step as the supervision effort if disobedience is found in the result of the internal review so that the top management can stop the operational examination permission. The

health facilities supervising the implementation of compliance test and calibration to reduce doses received by the officer, although the addition of radiation doses is also influenced by use inappropriate personal protective equipment.¹¹

Output: The implementation of the compliance test and calibration routinely applied by 'SP.A' and 'SP.B' was affected by the changed input: knowledge and obedience of the human resources towards the regulation of these two tests, the availability of sufficient fund, of procedure, run well, changed the process of planning, staffing, and supervising can increase this implementation.

The application of radiation safety management by applying the quality control of x-ray machine in health facilities should be conducted as it mentioned in its regulations.¹²

CONCLUSIONS

The X-ray facilities without complying with the regulation on compliance test existed in the coverage area of BPFK Makassar.

The inspection by BAPETEN supported the implementation of the compliance test. The requirement to extend the license operation of the X-ray facility contributed to comply with the compliance test.

Source of Funding: Funding also played an essential role in meeting the compliance test mandatory.

Conflict of Interest: The Authors declare no conflict of interest in this article. This research is self funded.

Ethical Clearance: The Ethical Clearance was obtained from the Committee of Ethical Research No. 069/EC/FKM/2018 on 04 June 2018

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