Evaluation of Iso 9001:2015 Risk Control in Case of Used Antigen Swab

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ABSTRACT

The number of domestic passengers departing from the Medan Polonia airport was on average as many as hundreds of thousands of passengers per month. Where every passenger is required to carry out a covid antigen examination, one of which is an antigen swab examination. At the end of April 2021, the Police uncovered a case of using a used antigen test kit at Kualanamu Airport. Therefore, the author tries to evaluate and review the antigen swab process in Kualanamu Medan to take technical steps for risk-related assessments at the antigen swab sampling facility. This research design uses a literature study by studying theories and secondary data. Based on data obtained from the Statistics Agency as many as hundreds of thousands of people using domestic flights from Polonia airport. To reduce risk organizations make the existing process risks, namely, the sampling process, specimen examination, data analysis and supervision from the head office, where the probability risk greatly affects the organization. The five steps of improving diagnostic pharmaceutics are considered good in solving the problems at hand, but perhaps the additional implementation of improvements must be carried out more consistently and using risk base thinking and PDCA cycle.

Keywords: *Risk base thinking, PDCA, ISO 9001:2015, Antigen swab*

INTRODUCTION

Health is one of the things that greatly affect humans to carry out their daily activities. Without human health, it will not be productive to live a decent life both economically and in education. Health is a human right and one of the elements of welfare that must be realized following the ideals of the nation contained in the Pancasila and the 1945 Constitution of the Republic of Indonesia. Article 34 paragraph (3) of the 1945 Constitution, as a result of the amendments, states that the state is responsible for the provision of proper health care facilities and public service facilities. [12]

To reduce the number of Covid transmissions in air transportation modes, Coordinating Minister for Maritime Affairs and Investment Luhut Panjaitan requires passengers of all transportation modes to show negative antigen swab results. This obligation is effective from 18 December 2020. [5]

The government has renewed the travel requirements and validity period of the PCR-antigen swab for domestic travelers. This provision will be effective as of April 1, 2021. This latest travel condition is stated in the Circular Letter (SE) of Task Force Number 12 of 2021. This provision replaces the previous SE Number 7 of 2021.

Air transportation travelers are required to show a certificate of negative RT-PCR test results whose samples were taken within 3 X 24 hours before departure or negative rapid antigen test results whose samples were taken a maximum of 2 X 24 hours or negative results of the Genoese C19 test at the airport before departure. [6]

Clinical Laboratory is a health laboratory that carries out clinical specimen examination services to obtain information about individual health, especially to support efforts to diagnose disease, cure disease, and restore health. [10]

At the end of April 2021, the police uncovered a case of using a used antigen test kit at Kualanamu Airport, Deli Serdang, North Sumatra. At least five suspects were arrested by the authorities.

The suspects were arrested after opening the practice of recycling long sticks or cotton buds which are used as a tool to carry out antigen swab tests. The trick, they wash again, clean, and repackage the sticks so they look new. [7]

The President Director of Kimia Farma Diagnostics, Adil Fadhilah Bulqini, emphasized that the actions taken by these individuals were contrary to the Standard Operating Procedure (SOP). [9]

Islam teaches safety and security at work, based on HR. Ibn Majah. Book of Al Ahkam 2340 states that the Prophet Muhammad recommended

لاَ لاَ ارَ "It must not cause harm and must not harm other people"

Risk and danger cannot be separated from every work and human life. The definition of risk is complex and very broad, but broadly speaking, the risk is an opportunity for loss or something that is not expected and has the impact of problems that can affect human life. [4]

ISO 9001:2015 does not direct us to apply risk-based thinking only at the beginning of the design of the quality management system, but we need to apply this thinking periodically during management reviews and determine corrective actions to be taken. This means that top leaders also need to play an active role in encouraging the application of this risk-based thinking for the sake of the continued effectiveness of the quality management system run by the organization.

The management system approach applied in the above problem is based on the Plan-Do-Check-Act (PDCA) concept.

The PDCA concept is an iterative process used by organizations to achieve continuous improvement. This system can be applied to the management system and each of its elements, as follows:

a) Plan/Plan: determine and assess risks, opportunities, and other risks and other opportunities, establish goals and processes needed to deliver results in accordance with organizational policies;

b) Do/Do: implement the process as planned;

c) Check: monitor and measure activities and processes related to the policy, and report the results. [1]

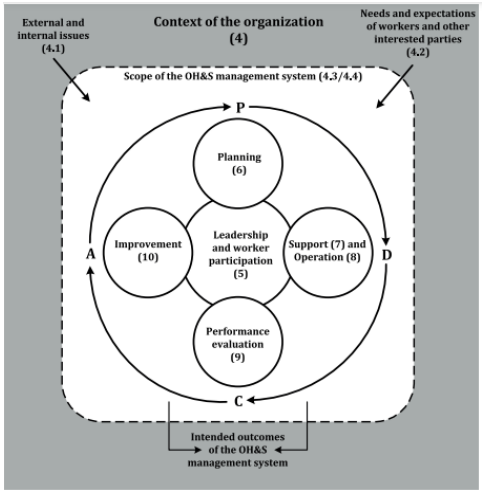

Figure 1. Scope of the OH&S Management System

METHODS

Literature study and ISO 9001:2015 management system approach based on risk-based thinking with the concept of Plan-Do-Check-Act (PDCA).

RESULTS AND DISCUSSIONS

From the flight data, it can be seen that there are almost 100 thousand passengers per month who fly from January to April 2021 at the Polonia airport, the domestic terminal, so it is very worrying for this swab check by using an antigen swab using used ones by washing them.

	Jumlah Penumpang Pesawat di Bandara Utama (Orang)				
	Keberangkatan pada Penerbangan Domestik				
	2021				
Bandara Utama	Januari	Februari	Maret	April	Mei
Polonia	157 614	100 191	122 498	-	-
Soekarno Hatta	507 262	482 132	672 107	-	-
Juanda	189 560	152 366	198 457	-	-
Ngurah Rai	118 962	71 049	116 888	-	-
Hasanudin	163 992	128 429	166 182	-	-

Figure 2. Number of Aircraft Passengers at Main Airport Departures on Domestic Flights

So to reduce the risk that the same will happen in the future, the author will try to make a risk register related to the process that is roughly the root cause or the root of the problem that will or is likely to occur.

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Sseveral things that are in the ISO 9001:2015 standard related to risks, opportunities, and risk-based thinking, as a reference for making risk-based thinking in each activity process such as:

1. “The organization shall establish the processes required for the quality management system and its implementation throughout the organization and shall: address risks and opportunities as determined.” (Item f in clause 4.4.1)
2. “Top management must demonstrate leadership and commitment to the quality management system by promoting the use of a process approach and risk-based thinking.” (Item d in clause 5.1.1)

3. "Top management must demonstrate leadership and commitment to customer focus by ensuring that: risks and opportunities that may affect conformance to products and services and the ability to improve customer satisfaction are identified and addressed." (Item b clause 5.1.2)
4. "When planning a quality management system, organizations must consider issues and requirements and determine risks and opportunities." (Clause 6.1.1)
5. "Organizations must plan: actions to address risks and opportunities." (Item a clause 6.1.2)
6. "The organization shall analyze and evaluate the appropriate data and information arising from monitoring, measurement. The results of the analysis should be used to evaluate: the effectiveness of the actions taken to address risks and opportunities." (Item e clause 9.1.3)
7. "Management reviews should be planned and implemented taking into account: the effectiveness of actions taken to address risks and opportunities." (Item e clause 9.3.2)
8. "When nonconformities occur, including any complaints that arise, the organization shall: update the risks and opportunities identified during planning, if necessary." (Item e clause 10.2.1

So from some of the things above, the authors make a risk register and a matrix related to the core process of taking the antigen swab below:

Table 1. List of risks

Aktifitas (Item Resiko) (1)	Issue (2)	Impact (Dampak) (3)	Severity (Kepar ahan) (4)	Potensial Cause (Penyebab Potensial) (5)	Probability (Kemungk inan) (6)	Risk Priority Number (RPN) (7)	Action Plan (Rencana Tindak Lanjut) (8)
proses pengambilan sampel							
1. penyiapan alat swab	a.kemasan rusak	Terjadinya kesalahan pengukuran	3	(MAN, METHOD, MATERIAL)	1	3	pengecekan alat swab (kemasan, nomer batch , expired, Mengantongi izin edar dari Kementerian Kesehatan Memenuhi rekomendasi WHO Mendapat rekomendasi Badan Pengawas Obat dan Makanan Amerika Serikat (FDA) Direkomendasikan Badan Obat-obatan Eropa (EMA)dll)
	b.slik berubah warna, berbau, bergerigi	Terjadinya kesalahan pengukuran, cross contamination	3	(MAN, METHOD, MATERIAL)	1	3	pengecekan alat swab (kemasan, nomer batch , expired, Mengantongi izin edar dari Kementerian Kesehatan Memenuhi rekomendasi WHO Mendapat rekomendasi Badan Pengawas Obat dan Makanan Amerika Serikat (FDA) Direkomendasikan Badan Obat-obatan Eropa (EMA)dll)

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2. selesai pemeriksaan spesimen							
a. perhitungan alat swab bekas pakai	salah hitung jumlah pemakaian	Terjadinya selisih barang masuk dan keluar	3	(MAN, METHOD, MATERIAL)	1	3	pengecekan alat swab (kemasan, nomer batch , expired, Mengantongi izin edar dari Kementerian Kesehatan Memenuhi rekomendasi WHO Mendapat rekomendasi Badan Pengawas Obat dan Makanan Amerika Serikat (FDA) Direkomendasikan Badan Obat-obatan Eropa (EMA)dll)
b. pengumpulan alat swab sudah pakai	dipakai kembali	tidak dikumpulkan pada tempatnya , dilaporkan jumlah pemakaian dan cross contamination	3	(MAN, METHOD, MATERIAL)	1	3	pelaporan jumlah alat test yang dipakai dan laporan manifest yang disupervsisi
c. pemberian manifest ke pihak yang ditunjuk	pihak yang ditunjuk tidak ada ada ijin	pencemaran lingkungan , cross contamination	3	(MAN, METHOD, MATERIAL)	1	3	pelaporan jumlah alat test yang dipakai dan laporan manifest yang disupervsisi

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3. Supervivisi Kantor pusat							
a. internal Audit	Man (kompetensi,) Methode (prosedur), Machine (alat Test), Material (alat swab)	gap , kepercayaan publik berkurang	3	(MAN, METHOD, MATERIAL)	1	3	jadwal internal audit, auditor no conflict of interset

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4. Proses input data hasil							
a. pembuatan hasil	salah input data	kepercayaan publik berkurang	3	(MAN, METHOD,MACHIN,MATERIAL)	1	3	Kompetensi , prosedur(no urut, nama orng ,dll) , cek bahan yang dipakai
a. pemberian hasil ke pelanggan	salah hasil dan salah orang	kepercayaan publik berkurang	3	(MAN, METHOD,MACHIN,MATERIAL)	1	3	Kompetensi , prosedur(no urut, nama orng ,dll) , cek bahan yang dipakai

Table 2. Risk Matrix

MATRIKS RPN

		PROBABILITY (KEMUNGKINAN)		
		1	2	3
Severity (Keparahan	1	1	2	3
	2	2	4	6
	3	3	6	9

L	LOW
M	MEDIUM
H	HIGH

Table 3. Description of Severity, Probability, and Risk Priority

KETERANGAN FORM IDENTIFIKASI RISK REGISTER

Indikator	Keterangan
Severity (Keparahan) =	1 = berpengaruh kecil terhadap proses 2 = berpangaruh secara parsial terhadap proses 3 = berpangaruh signifikan terhadap organisasi/ organisasi tidak dapat beroperasi (*dilihat dari effect)*
Probability (Kemungkinan) =	1 = jarang terjadi (0-1 kali terjadi dalam setahun) 2 = sering terjadi (2-4 kali terjadi dalam setahun) 3 = hampir selalu terjadi (lebih dari 4 kali terjadi dalam setahun) (*dilihat dari penyebab*)
Risk Priority Number (RPN) = (Severity x Probability)	Low = 1-2 Medium = 3-4 High = 6-9 dan Severity = 3

In Kimia Farma's diagnostic related to the above case, it has carried out 5 steps to improve the changes:

1. Organizational restructuring aimed at improving performance and service
2. Strengthening service and supporting systems prioritizing digital and cashless applications
3. Synergy with stakeholders for comprehensive improvement
4. Internal Monitoring System (SPI) which will be deployed to all regions of Indonesia
5. Placement of quality control officers in every branch manager and KFD outlet

There is no complete internal data related to Diagnostic Pharmacy Chemistry that can be presented by the author, but only from the perspective of risk assessment with the PDCA cycle to reduce risk factors that will arise in the future.

a) Plan / Plan: determine and assess risk, to the input process, the process to output.
risk

CONCLUSIONS AND SUGGESTIONS

The five steps for improving diagnostic pharmaceutical chemistry are considered to be good in solving the problems at hand but perhaps additional and details related to the implementation of improvements must be carried out more consistently and using the PDCA cycle and always include risk-based thinking in all existing processes, namely the 4 M:

1. Man (competency)
2. Method (SOP, work instructions, etc.)
3. Materials (materials for inspection, reagents, test equipment, etc.)
4. Machine (inspection / test tool)

Suggestions to other researchers to be able to complete the existing or future risks and issues in laboratory companies in general and KF diagnostics in particular.

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