CHARACTERISTICS OF INTERNAL AUDITS IN IMPROVEMENT OF QUALITY GOALS IN CALIBRATION LABORATORIES

Karakteristik Audit Internal dalam Perbaikan Sasaran Mutu di Laboratorium Kalibrasi

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Abstract

The Quality Goals and Internal Audits are two important links in the quality management system. These two interrelated points are in many cases surprisingly not considered as they should be. Quality goals aren't often subject to internal audits. Similarly with quality goals scarcely describe the improvement of internal audits as a tool to strengthen the quality management system. The fact, recent audit findings found no more than 11 out of 165 findings in 18 accredited calibration laboratories operated on the basis of ISO/IEC 17025 that relates to quality goals. This paper proves no strong correlation between quality goals and internal audit statistically. The important thing for the improvement of quality goals – internal audits relationship is giving more clarification to clause 4.10 Improvements and add internal audit-based items on the quality goals.

Keywords: calibration laboratory, internal audit, quality goals.

Abstrak

Sasaran Mutu dan Audit Internal merupakan dua bagian penting dalam sistem manajemen mutu. Kedua hal yang berkaitan ini dalam banyak kasus, ternyata tidak dipandang sebagai berkaitan satu sama lain. Sasaran mutu mutu sering tidak menjadi target audit internal. Sama halnya dengan sasaran mutu yang sangat jarang menyinggung peningkatan audit internal sebagai sarana untuk memperkuat sistem manajemen mutu. Fakta penelitian, saat ini temuan audit menunjukkan kurang dari 11 temuan dari 165 temuan pada 18 laboratorium kalibrasi terakreditasi yang cara kerjanya berdasarkan ISO/IEC 17025 yang terkait dengan sasaran mutu. Makalah ini membuktikan tidak cukup kuatnya kaitan antara sasaran mutu dan audit internal secara statistik. Hal yang penting untuk perbaikan hubungan sasaran mutu – audit internal adalah memberikan klarifikasi pada klausul 4.10 Peningkatan, dan menambah butir-butir terkait audit internal pada sasaran mutu.

Kata kunci: laboratorium kalibrasi, audit internal, sasaran mutu.

1. INTRODUCTION

Internal audit is an examination of a matter (work unit, organization, laboratory, etc.) by an expert employed by the same employer. Some consider internal audits as more important compared to external assessments (Arena, 2013; Achua et.al., 2014; Dănescu et.al., 2014; International Atomic Energy Agency, 2009; & Saidin et.al., 2014) from time flexibility, information disclosure, and obviously low cost. External assessments limited to one or a few consecutive days, internal audits might be accomplished in a longer duration depending on the time agreement between the auditor, auditee, and the quality management. Further, as internal auditors recruited from the staff of the same organization

as the auditee, there is no information barrier making the audit flowing smoothly. There are no extra transportation and accommodation costs for the auditors and there may be no professional fee payable to the auditors either. Most people interpret the word 'audit' as the examination of the financial matter. In this paper, however, it refers to quality related to a laboratory especially calibration laboratories. It is therefore, the term 'quality audit' is often used to ascertain the meaning.

It is no secret that all accredited calibration laboratories carry out an internal audit on a regular basis, mostly annually. Besides, it required by the international standard of ISO/IEC 17025 (ISO, 2005), they enjoy benefits in general term mainly because the internal auditors know most problems faced by the auditee and they

contribute to seeking the root cause and solve them using the most effective way.

Internal audits and quality goals look like running without regard to each other. On one hand, it is seldom that internal auditors examine the quality goals and on the other, it is also very rare that the quality goals described the need of the organization about the results of the internal audit. This paper raises the issue of the importance of quality goals, most findings as the result of internal audits, an examination to proof the lack of correlation between quality goals and internal audit, and hence gives advice on efforts to harmonize between the two, based on experiences in both internal audits and external assessments. All description will focus on calibration laboratories only as they located in the center of measurement traceability between the national metrology institute and the industry as the end user.

2. LITERATUR REVIEW

Quality Goals are laboratory targets in maintaining and improving the quality of its calibration service. They derived from the quality policy and consist of certain quality plans. Quality policy wrote in the form of statements where the top management promises to serve the customers to the highest standard (Yoo, 2014). Quality goals provide canalization in which the services aimed to suit the customer needs on the basis of ISO/IEC 17025, and the quality plans put all actions in detail to accomplish the quality goals (Meng & Song, 2011; Moore, 2012; Stevens et.al., 2014; Eagles, 2014; & Plösch et.al., 2010). The high level of the quality policy was usually designed for a longer period of time and therefore wasn't frequently revised, five years or a longer period considered as normal (Steel et.al., 2004 dan Maxim et.al., 2011). Quality plans, on the contrary revised annually to suit the objective of the laboratory from time to time (Bailit, 2007 dan Nord, 2014).

Quality Goals of laboratory in this case is calibration laboratory, it's also renewed annually. It's substance can be group into two parts, i.e. external and internal matters. The former deals with interactions between the laboratory and external bodies for the purpose include recalibration of its measurement standards to external higher level calibration laboratories both domestic or overseas, interlaboratory comparison of certain artifacts with other participant laboratories (usually of the same level) also both domestic or overseas, and recognition of calibration competence by a third-party accreditation (known as pathway) (Ocone

et.al., 2013 & Bassanini, 1998). The interaction between the laboratory and its customers stated on their quality goals offer in low cost, and rapid calibration. Some of them even offer same day calibration service and proactive calibration service by providing shuttle service for the calibrated items. Fail in renewing calibration certificates of the measurement standards before their due time, giving calibration service beyond the accredited calibration scope and providing quality services didn't promised. Those may invite customer complaints.

The second part of the quality goals i.e. internal matters deals with the management within the laboratory itself. It's unlimited to menpowers development both technical and managerial, quality procedures including work instruction to carry out the calibration works, and workplace conditions such as workspace and, ergonomic factor, but the most important ones is environmental physical requirements that make deteriorate calibration results when not fulfilled. These internal matters influence the quality of the service provided and invite customer complaints.

Internal audit should be carried out on all aspects of a laboratory and quality goals are subject to audit as well. On the other hand, as an internal audit supposed to maintain and improve the performance of the laboratory, its perspective should be described in the quality goals. The correlation between quality goals and internal audit in a number of calibration laboratories could be tested using proportion test (one-sided test utilizing statistic):

$$Z = \frac{x / n - \pi_0}{\sqrt{\pi_0(1 - \pi_0) / n}} \quad (1)$$

and $\begin{cases} H_0: \pi = \pi_0 \\ H_1: \pi \neq \pi_0 \end{cases}$

H_0 is accepted when $z < z_{0.5} - \square$

where: x = default value

n = sample size

3. RESEARCH METHODOLOGY

Technique to analyze quality goals - internal audit relationship, data were compiled from 18 accredited calibration laboratories through an assessment scheme. Maintaining their confidentiality, the laboratories are simply named as laboratory A, B, C, etc. These 165 findings were recorded. They grouped into 16 categories as shown in Table 1. The findings divided into two types i.e. service related and quality related findings. The first deals with administrative matters such as mistyping the name of

instruments, persons in charge don't sign the related documents, the absence of personnel evaluation after training and etc., the later concerns technical substance of the procedures

such as the method of estimating measurement uncertainty, the method of the calibration processes themselves, and etc.

Table 1 Category of non-conformance findings in calibration laboratories.

No	Category	Number of Findings	Service related	Quality related
1	Error in quality procedure	34	✓	✓
2	Analyses of correction and measurement uncertainty	24		✓
3	Planning related	20	✓	
4	Malpractices	15	✓	✓
5	Mismanagement problem	11	✓	
6	Legalization matter	11	✓	
7	Quality goals	4 (11)	✓	✓
8	Measuring points	10		✓
9	Expire/due date	7	✓	
10	Accreditation problem	6		✓
11	Retention time	6	✓	
12	Forms matter	4	✓	✓
13	Auditors and their requirements	4		✓
14	Management review related	3	✓	✓
15	Reference value or reference document	3		✓
16	Calibration certificate	3	✓	✓

Note: figures in bracket denote findings related to quality goals but not literally state.

The data unveil four findings strongly related to quality goals. The quality goal targeted 50 calibration orders monthly, the realization gave only two. This was reported in the Management Review but no solution was given. Further there are findings those related to (but not literally state) the quality goals. The interlaboratory comparisons (ILC) for torque-meter calibration and hardness tester calibration haven't yet been carried out. In this case, although it wasn't mentioned, the plan for doing the ILC has to be there in the quality goals. There are seven items in this category. Further, the proportion of findings related to quality goals within each audited laboratory is given in Table 2.

There are only 4 findings dealing with quality goals out of 165 (but the research found 7

findings those related to, but not literally state), this means that it is inevitably important and therefore, should not be neglected in each internal audit scheme. These findings concern mainly with either the structure of documents where the quality goals were kept, or the substance of the quality goals. The four directly related findings to quality goals, three of which constitute quality related findings such as the quality goals do not reflect quality-based target, they are not sufficiently tangible due to unclear targets and they are undocumented so that year per year progress can easily be traced. One of them could be categorized as service related finding. It is only about the number of unit under tests those might be completed within any single working day.

Table 2 Non-conformance findings in individual calibration laboratories.

No	Calibration laboratory	Total Findings	Findings related to quality goals
1	A	7	0
2	B	9	(2)
3	C	9	0
4	D	8	0
5	E	5	0
6	F	8	(1)
7	G	11	1
8	H	7	1

No	Calibration laboratory	Total Findings	Findings related to quality goals
9	I	12	1
10	J	8	0
11	K	6	0
12	L	13	0
13	M	6	(1)
14	N	9	(1)
15	O	9	(1)
16	P	11	1
17	Q	13	(1)
18	R	14	0

Note: figures in bracket denote findings related to, but not literally state, quality goals.

4. RESULT AND DISCUSSION

This research has two ways to study quality goals – internal audit relationship. These are quality goals from point of view of internal audit and vice versa. The former described in Chapter 3. Theoretically, audit findings (including those in quality goal area) are easy to spot referring to certain clauses within the international standard of ISO/IEC 17025. In practice, detailed information should carefully be examined. All the four findings described in Chapter 3 are purely referred to quality goals. If other findings correlating to but do not exactly refer to quality goals are put into account, then the figure increases to 11.

Taking 11 findings (instead of four) into account to demonstrate the most moderate situation and assuming that the proportion of quality-goals-related findings to total number of findings of less than 10 % leads to negligible quality goals – internal audit relationship. Using equation (1) it is obtained that $z = -19,56$. This is much less than the z value from the standard normal list even if significant level α of 0,05 is taken. This strengthens the hypothesis that it is almost no correlation between quality goals and audit internal as it should be.

Further, the absence of quality goal target discussion in the management review should be treated as non-conformity referring to clause 4.15 Management Review instead of the quality goal itself. It is solely because the management review meeting does not cover the discussion on quality goals as it should do. The less audit findings in the quality goal area might be considered as a result of auditor's lack of interest in unveiling subjects relating to quality goals. This might be caused by the lack of clarity about the clauses associated with quality goals. Based on this reason, clause 4.10 Improvements might

be used to accommodate information relating to quality policy, quality goals, and quality plans.

Quality goals research to examine internal audit may not result any interesting point. This is mainly caused by the lack of internal audit targets described in the quality goals. Those mostly expressed in quality goals are the plan for recalibration, interlaboratory comparison, staff recruitment and technical training, calibration scope extension, and lessen customer complaints. Adding the number of internal auditors or improving their competence, enhancing quality procedure especially that relates to internal audit, lessen the percentage of non-conformities to the total number of calibration orders, are among necessary items but very few listed in the quality goals. Internal audit and external assessment experiences show that none of the laboratories reviewed express important items directly related to internal audit goals.

5. CONCLUSION

Many calibration laboratories operate on the basis of ISO/IEC 17025. This can be easily to trace by counting the number of accredited calibration laboratories from the Indonesian National Accreditation Committee (KAN). In February 2016 this figure reaches 168 excluding those under review and temporary suspended. Internal audits and external assessments conducted mostly show non-conformities on the absence of certain procedures, procedures those implemented imperfectly, problems related to measurement uncertainty analyses, lack of clarity on work instructions, and etc. However, almost none of them directly related to the substance of internal audit such as the number and expertise of the internal auditors employed, efforts to minimize customer complaints by introducing better internal audits, and etc. There may be some reviews on quality goals from point

of view of internal audits, but there is obviously a lack of reviews on internal audits from point of view of quality goals. Both laboratories and internal auditors were suggested to take this matter into consideration. Other weaknesses on the implementation of ISO/IEC 17025 are worth to be considered. It has been proven that occur correlation lack between quality goals and internal audit in calibration laboratories. It may be occur on the case for test laboratories and other types of conformity assessment bodies. A similar research based on the method may be applied to other things accordingly.

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