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Internal Audit ISO /IEC 17025 : 2008 at Laboratory For Hydrodinamics Technology, BTH - BPPTeknology

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ABSTRACT

While all materials inside International standard ISO/IEC 17025 have an universal value as “generalities” for all laboratory, especially on Technical and Management aspect, other specific terms such as testing process, calibration process and method for estimating any error when scaling could use another method that came from various technical standard. International standard ISO/IEC 17025 is published in 1999 and revised on 2005. Those standards describe various debatable clauses when internal audit is in place, especially when it is used for audit process in Hydrodynamics Laboratory in terms for management quality. Based on various researches, finally it is decided that those standard needs to be revised again and perfected in terms for Quality Internal audit.

Keywords: *ISO/IEC17025; Testing Laboratory; Quality Standard; Management Quality; Hydrodynamics*

1.0. PRELIMINARY

In order to control the quality of work produced must be supported through a system of testing in the form of Quality Control and Collecting data so the quality of work can be controlled in accordance with the expected technical specifications. The iimplementation of Quality Control and Collecting data into benchmarks for the development of quality testing laboratory activities Laboratory for Hydrodinamics, BTH BPPTeknology

Factors that must be met in order that the technical service process can run as expected, among others:

- Adequate infrastructure such as buildings, vehicles etc.
- Laboratory equipment that has been accredited
- Sufficient number of personnel
- Professional human resource capability
- Method of conducting laboratory testing based on SNI
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This is done for the process of improving the performance of human resources BTH BPPTeknology is proportional and professional

Method

Current standards, i.e. SNI ISO / IEC 17025: 2008 is now the most appropriate standard for Hydrodynamics laboratories in BTH. While there are other national hydrodynamics laboratories (such as in the Republic of Korea) that use ISO 9001 as the basis [5], but the benefits of ISO / IEC 17025 which is directly directed to the laboratory encourages the wide implementation of these standards in the laboratory environment of hydrodynamics, as well as the testing laboratories and calibration laboratories in general [2].

As reference for laboratory, ISO / IEC 17025 should provide a clear, meaningful, scientifically correct, well-structured footing ground that is easy to learn, The analysis used in this paper is based on the elements of suitability and usefulness whose explanations are as follows:

A. Usefulness

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Learning the benefits of a material clause or sub-clause by looking at its implementation in the laboratory environment (for both the quality manager, technical manager, supervisor and operator), and their usefulness to the auditor, the assessor or in conducting the conformity inspection of the application of the material. [3]

B. Related Clause.

There are several audit materials that require more in-depth analysis to further refine. so that the implementation of this international standard can be more easily done and the goal is more easily achieved, without causing harm in the form of deviations from the basic purpose of becoming a general requirement of laboratory competence [1]. Therefore, the analysis is focused directly on some substance in ISO / IEC 17025 which is quite often highlighted in the audit or assessment process (herein after referred to as 'audit') especially in BTH BPPTeknologi, as Hydrodynamics laboratory, namely:

1. Clause 5.1 Technical Requirements> General
2. Clause 5.2 Technical Requirements> Personnel
3. Clause 4.10 Management Requirements> Enhancement

The discussion takes place in two perspectives, namely 'laboratory competence' which emphasizes the implementation and influence of the material analyzed for the purposes of the laboratory, and 'audit philosophy' in which the use of related material for the auditor is examined.

2.0 AUDIT PLANNING

The frequency of internal audits within the requirements of ISO 17025 is not explicitly stated how many times a year but the certification body conducts audits every 6 months or 2 times a year. Most organizations plan an internal audit program twice 3 times or even 4 times a year, not infrequently the internal audit conducted just to meet the requirements of ISO 17025 only

In this case the Laboratory for the Hydrodynamic Technology, the internal audit is conducted once in one year. When viewed from the side of the audit objectives, the implementation of the Internal audit is only aimed at surveillance audit, only cannot reach the overall goal of internal audit that is actually measuring the effectiveness of the organization's quality management system, Often the audit results do not have a significant impact on the implementation of quality management systems implemented by the organization [6].

That is, internal audit performed cannot change the performance of the unit being audited. In other words, the internal audit implemented cannot provide an overview of the effectiveness of the quality management system that has been implemented or the extent to which the quality management system is successfully implemented. Therefore, Internal Audit objectives should be improved from surveillance audit to compliance audit That is, internal audit objectives are intended to prepare and see to what extent the application of ISO 17025 procedures In other words, the extent to which ISO principles or procedures are carried out, are consistently undertaken and adhered to Planning objectives Internal audits such as the above (surveillance audit) is not wrong but only meets the minimum requirements and this does not provide much benefit to organizational management [4].

Appropriately, the Internal audit objectives in addition to considering past audit results and the importance of the areas/processes being audited, it would be nice if the purpose of internal audit is more focused on the problem of identifying value-added processes, so that the audit results really have benefits for management.

In order to achieve such a result, the internal audit should be able to:

1. See if the quality objectives of each department have been implemented as planned,
2. Make sure that the problematic process of customer complaint analysis has been corrected,
3. Ensure that new policies or procedures are understood and implemented by all relevant sections,
4. 4.Make sure the readiness to be audited by the customer
5. Considering the above objectives, the preparation of the audit schedule does not necessarily have to be the same way but may vary from department, article in standard, area, or particular process.

3.0 AUDIT PREPARATION

In preparing the Internal audit, an auditor must absolutely read or review all documents related to the area / process to be audited The results of this activity, then formulated and poured in the form of pointers to be checked or can also be a list of audit questions. The auditor does not audit the area / process itself (cross audit) and the time available is generally short, so how can it judge the effectiveness of a system if the auditor does not understand the area being audited?

Documents used as a reference for making such a list of questions can be obtained after a review of the quality manual, quality policy, quality targets and quality procedures and related work instructions. In addition to the above mentioned documents in order to make the audit question more weighted, the following documents and records should also be studied as well as the ISO 17025 standard requirements, business process maps, quality targets, past internal audit results, section performance records (e.g. status of target achievement of sections), status of corrective and preventive actions, customer complaint analysis results, customer satisfaction measurement results.

Thus, in order for the Internal Audit implementation process to succeed according to the objectives to be achieved, the preparation of a mature Internal Audit is the key to more valuable internal audit. But it should be noted also that the success of Internal auditing is also located in the preparation of auditors If at the time of the Internal audit the auditor is not ready, better the implementation of Internal audit is delayed rather than wasting the time auditor and auditee. Auditor readiness is absolutely necessary to support the success and success of the implementation of Internal audits in achieving its objectives to measure the effectiveness of the organization's quality management system.

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4.0 AUDIT IMPLEMENTATION

The implementation Internal audit rarely runs smoothly. But quite the opposite, often resistance auditee is a problem that faces in the implementation of internal audit.

This arises because of differences in perceptions between the auditor and the auditee about the Internal audit itself. There are some circles of auditors who feel proud if the examination resulted in many findings. They assume that indeed an auditor's job is to find the findings of nonconformity, the more the resulting findings mean he is successful in carrying out his duties as an auditor.

On the other hand, in the auditee's eyes an auditor is often regarded as an error seeker. The more findings mean the more mistakes they have made, this condition, if it continues will result in the rise of resistance auditee to Internal audit Furthermore, this condition indicates that there has been auditee uncertainty over the quality management system applied by the management of the organization.

In other words, this condition occurs because of the lack of socialization about what is ISO 17025, the definition of audit and how the role of audit in the application of ISO 17025. The job of an auditor is to collect information / audit evidence to compare with audit criteria whereby the overall result is concluded to assess the effectiveness of the system Furthermore, the task of an auditor in the Internal audit should be able to verify and prove that the auditor

1. See if the quality objectives of each department have been implemented as planned,
2. Ensure that the problematic process of customer complaint analysis has been corrected.
3. Ensure that new policies or procedures are understood and implemented by all relevant sections,
4. Collecting audit evidence is the key word, how much to collect, its nature is random (sampling), and there is no standard, as a reference and depends on the status and importance of the area / process being audited,. but certainly not taking just one sample

The audit preparation discussed above will be helpful in deciding how much audit evidence is needed to support the audit conclusion argument. Regarding the methods used to collect audit evidence generally includes interviews, observation of field activities and reviewing documents. High curiosity, love for details and the ability to search for a process are the "competencies" that are needed by an auditor during audits. This is evident from the questions asked by the auditor during the search or examination. This auditor's search capability will affect the nature of the audit whether the audit is in-depth or limited to the surface Reports of audit findings are often a problem, particularly in the writing of non-conformance descriptions, i.e. incomplete descriptions of problems found, unmet requirements and examples of audit evidence found or worse, auditee undertaking corrective actions based on the description of such nonconformities

Writing this description greatly affects the assessment of the weight of the findings. Will the audit findings affect the effectiveness of the improved quality management system? This is strongly influenced by the auditee's analytical ability to find these nonconformities. The tendency is often the attitude of resistance from the auditee to change. As a result, auditee becomes less or less serious in analyzing the cause of the problem or the action taken is more 'correction' than 'corrective action'. One indicator is always finding the same problem in almost every audit. In the audit report, it is necessary to include an audit cluster that contains an overview of the strengths and weaknesses of the system as well as opportunities for improvement, so the audit report is not just a list of findings of nonconformity.

This is important in order to support the answers to the objectives Internal audits are conducted i.e. the extent to which the principles or procedures of ISO 17025 are implemented, done and consistently followed by the organization of the audited work unit. So it is easy to measure the success rate of the implementation of the quality management system within the work unit being audited.

5.0 AUDIT OBJECTIVES

In many internal audit procedures that have been read by the author, almost never found activities to evaluate the implementation of the audit itself and the evaluation of the auditor, but there are plenty of opportunities to improve both. The goal of this audit is to evaluate the implementation of the program, this can be done by applying the 'Check' and 'Act' steps in the PDCA cycle (Plan, Do, Check, Act). Things that can be evaluated include; the ability of the audit team to implement the audit plan, the suitability of the audit schedule and its realization. consistency between audit teams, audit methods used, 'weighting' of findings, trends of internal audit findings versus external audits and anticipated evolving needs.

While the auditor's evaluation of the competence may include knowledge of the area/process being audited, understanding of standards, communication skills and other 'personal attributes', the easiest way is to spread or distribute the questionnaire or ask the auditee directly The results of the above evaluation are used as input for planning and preparation of subsequent audits including to improve auditor competence.

6.0 AREA OF AUDIT

For the BTH scope, the field areas to be audited are: Management, QA, HR, Marketing, Instruments, Drawings, Ship Models, TT Facilities, BOB Means, Testing and Analysis.

Clause 4.10 Management Requirements>
Enhancement

Clause 4.10 is a material that says "the laboratory shall enhance the effectiveness of the management system in a sustainable way through the use of the quality policy quality objectives, audit results, data analysis, remedial action and preventive measures, and management review ", it appears that the material of this clause is intended to reinforce the parts that are already present in this international standard.

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Clause 5.1 Technical Requirements> General

For auditors, each material is used as a reference in examining quality documents and laboratory activities. The auditor wishes that all quality documents and each laboratory activity correspond to any relevant material. However clause 5.1 cannot be used as a reference, since its editorial does not contain directional elements. The indication of this is very clear, i.e. there has never been a finding of nonconformities referring to sub-clause 5.1.1 or 5.1.2. The conclusion is that sub-clause 5.1.1 and 5.1.2 (so that overall clause 5.1) does not have a high usage.

Clause 5.2 Technical Requirements> Personnel

The placement of 'Personnel' in Core Clause 5 (and not in Core Clause 4) is of course the intention of fulfilling the basic rule of Clause 5 for good evidence in sub-clause 5.2.1 Personnel, 5.2.3 contracting personnel, and 5.2.5 technical personnel

The conclusion is that the sub-clauses accommodate rules that relate directly to physical work as well as selecting testing methods, the need to analyze measurement uncertainties, and make calibration certificates

In this case it is 'personnel directly addressing the physical work of testing or calibrating', as 5.2.1, 5.2.3, and 5.2.5 have good consistency with each other, and have sufficient conformity to be in the zone of the Core Clause 5 Requirements technical. Not all sub-clauses in Clause 5.2, however, have characteristics that correspond to 'technical requirements'. Sub-clause 5.2.2 does not focus on technical personnel. Here only the need for laboratory management to formulate the objectives of education, training, and skills of laboratory personnel may be in the form of training on internal audit, or on quality system documentation for personnel managing laboratory management

This is given in light of the fact that no other sub-clause (including in Core Clause 4) describes training for laboratory management personnel, so this understanding is incorporated into 5.2.2. In sub-clause 5.2.4 is explicitly included 'managerial personnel' elements in addition to technical personnel and core support personnel in the maintenance of the applicable job descriptions. This is confirmed in the note for 5.2.4 in the seventh item "managerial duty". The conclusion is that sub-clause 5.2.2 and 5.2.4 do not fully comply with the core clause 5 which is based on 'technical requirements'.

7.0 CONCLUSION

The Plan-Do-Check-Act concept should be implemented in the internal audit management. In addition, Internal Audit should be viewed as a management tool that can be used to ensure implementation in accordance with planning and to seek improvement opportunities in all aspects of both processes and systems. If in an audit process it is found that the laboratory does not have a training program on internal audit or does not have job descriptions for its managerial personnel, the referred sub-clause may be 5.2.2 or 5.2.4. Though both are based on Clause 5 (Technical Requirements), which are directly related to the physical work of testing or calibrating

In these two sub-clauses there is a combination of the meaning of purpose because it can aim toward the technical personnel (e.g. lack of ability to handle the evaluation of calibration data, corresponding to the domain of Core Clause 5, as well as toward the managerial personnel. The conclusion is that sub-clause 5.2.2 and 5.2.4 do not fully comply with the core clause 5 which is based on 'technical requirements'. If in an audit process it is found that the laboratory does not report the results of the audit in the past year, generally the auditor will refer to clause 4.14 (Internal Audit) or precisely sub-clause 4.14.3 (field of audit activity,

Audit findings and oversight actions performed must be recorded), although may also refer to clause 4.10 (Enhancement). This ambiguous thing will happen for findings in the fields 'summarized' by this clause 4.10 because each item has a profound explanation on the other clause or sub-clause. Therefore, clause 4.10 on this increase becomes less useful both for the laboratory in the preparation of quality documents and in carrying out its quality activities, as well as for the auditor in making a decision on the suitability of the quality in the laboratory he or she audited.

The conclusion is that clause 4.10 poses ambiguity because it may cause a finding of non-conformity to be uniquely correspondent to a particular clause. So the purpose of Internal Audit is not simply to meet the minimum 'standard' requirements, but even higher is to measure the level of effectiveness of the quality management system (ISO 17025) that has been implemented by the organization or to what extent the principles or procedures of ISO 17025 are implemented, consistently obeyed. To achieve these objectives, it is necessary to have high-performing and competent search auditors in the area to be audited.

REFERENCE

1. Badan Standarisasi Nasional. (2008).SNI ISO 9001:2008(E). *Sistem Manajemen Mutu- Persyaratan*:Jakarta.
2. Cameron, J., Graham. (2002). ISO/IEC 17025 – *Enhancing the Competitiveness of Calibration and Testing Laboratories*:.
3. Harsono, A. (2008). *Metode Analisis Akar Masalah dan Solusi, Makara,,* Sosial Humanior volume 12 no 2 pp : 72-81.
4. Hoolihan, Daniel D (1999). *The Evolution of Guide 25 into ISO Standard 17025.*
5. Huber, Ludwig. (2009). *Understanding and Implementing ISO/IEC 17025.*
6. International Organization for Standarization (2008). ISO 9001:2008. *Quality Management System - Requirements*

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