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Lower frequency of certain nonconformities against ISO/IEC 17025 after many year accreditation

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ABSTRACT

Background: It is predictable that the laboratories with many years of accreditation should get lower amount of nonconformities than those of the new ones. The objectives of the study are to find the differences in characteristics and nonconformities among ISO/IEC 17025 accredited laboratories undergoing on-site assessment in 2015 and verify the above prediction.

Materials and methods: A cross-sectional study of the characteristics and the nonconformities from 2015 assessment of 134 laboratories were compared between the laboratories with 6 or more years or at least 3 cycles of accreditation and the ones with shorter accreditation year. Statistical analyses were done by using Stata-intercooled version 6.

Results: There were 1,459 total nonconformities, 572 (39%) were those against management requirements and 887 (61%) were those from technical ones. Longer and new accredited laboratories shared similar basic characteristics. Longer accredited laboratories got lower total nonconformities (mean±SD; 9.1±4.8 vs 12.7±9.0: t-test=2.89, p=0.003), and lower technical nonconformities (mean±SD; 5.0±3.1 vs 8.3±6.9: t-test=3.57, p<0.001). The proportion of longer accredited laboratories was lower on nonconformities against clause 5.6 Measurement traceability (14/87 vs 28/67, Chi square=5.060, p=0.024) and the ones against clause 5.9 Assuring quality of test results (27/67 vs 44/67, Chi-square=6.450, p=0.011) than those of the new accredited laboratories.

Conclusion: This study demonstrated that many year accreditations may enable the accredited laboratories to comply with the requirements more effectively. Lower proportions of the longer accredited laboratories had lower certain nonconformities on clause 5.6 Measurement traceability and 5.9 Assuring quality of test results.

Introduction

The Bureau of Laboratory Quality Standards, BLQS, is an accreditation body for accreditation of medical and public health laboratories complying with the requirements of the International Organization for Standardization, ISO 15189 and ISO/IEC 17025 after getting Mutual Recognition Arrangement from Asian Pacific Laboratory Accreditation Co-operation, APLAC MRA and from International Laboratory Accreditation Co-operation, ILAC MRA, for testing since 2002 and 2003, respectively.[1] In 2015, BLQS has accredited 134 laboratories, with ISO/IEC 17025:2005,[2] 14 are initial accreditations and 120 are reassessment ones. Total numbers of nonconformities and specific clause deviations are so diverse and questionable on how different among these accredited laboratories. A report on trends of nonconformities from BLQS has showed irregular patterns of the distribution of such nonconformities during 2008-2011, with highest frequencies of nonconformities against clause 5.4, Test and calibration methods and method validation.[3] A similar report from Hong Kong Accreditation Service in 2012 has illustrated the frequencies of nonconformities against the requirement of ISO 15189. Interestingly, 27 medical

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laboratories have showed statistically reduction of nonconformities from 13.5 nonconformities per laboratory at the initial assessment to 6.6 nonconformities per laboratory at the reassessment.[4] A previous report in 2015 also has demonstrated the factors affecting correction time among ISO/IEC 17025 accredited laboratories in the public health sectors. By using multiple logistic regression, the report reveals that a longer correction time statistically related to the type of laboratory services in microbiology with chemistry, the presence of nonconformities against clause 4.2 the management system and the presence of nonconformities against technical requirement especially clause 5.4 Test and calibration methods and method validation, with adjusted odd ratio of 3.35-7.58.[5] The objectives of the study are to find the differences in characteristics and nonconformities among ISO/IEC 17025 accredited laboratories undergoing on-site assessment in 2015 and verify whether there are some differences in characteristics and certain nonconformities among accredited laboratories with longer accreditation of 6 years or at, least 3 cycles of accreditation, comparing to those of the shorter accreditation.

Materials and methods

A cross-sectional study of basic characteristics and the nonconformities against the requirements of ISO/IEC 17025:2005 from the latest assessment of 134 laboratories in 2015 were summarized. The mean accreditation of 6 years or three cycles of accreditation was applied to equally classify the laboratories as 67 older ones with accreditation of 6 years or more and 67 newer ones with accreditation of less than 6 years. Out of 134 assessed laboratories, 14 were initial accreditations while the remaining laboratories were reassessed or extension assessed. Stata- intercooled version 6 was used for calculation of normality, mean, Standard deviation (SD), Kruskal Wallis test where all sets of the data cannot be normal distribution,[6] t-test for mean difference and *p*-values.

Results

1. Characteristic properties of 134 ISO/IEC 17025 accredited laboratories. Majorities were the private laboratories. Four of five facilities located in provincial areas outside Bangkok, the capital of Thailand. More than half (61%) served food testing, using chemistry and microbiology. They offered testing scope of 38 tests, with wide range of the scope from only 1 test to 631 tests. They got accreditation for 0- 16 years; with mean of 6 years or 3 cycles of 2 years accreditation. The average 6 year accreditation was applied to classify the laboratories into 2 equal groups of 67 laboratories. Out of 67 new ones, 14 (21%) are those of initial accredited laboratories in 2015. Details of characteristics were illustrated in Table 1. Comparison of characteristics and numbers of nonconformities between the longer accreditation laboratories with those of the shorter ones were illustrated in table 2.

Table 1 Characteristics of 134 accredited laboratories.

Characteristics	Number	Percentage
Sector		
- Governmental	40	29.85
- Private	94	70.15
Location		
- Bangkok	30	22.39
- Other places	104	77.61
Laboratory services		
- Foods	82	61.19
- Others	52	38.81
Assessment		
- Initial	14	10.45
- Reassessment, and others	120	89.55
Scope (test menu)		
- ≥38	102	76.12
- <38	32	23.88
Years of accreditation		
- ≥6	67	50.00
- <6	67	50.00
Service objective		
- Self quality check	78	58.21
- Public service	56	41.79

2. Total 1462 nonconformities were against 575 management requirements (39%) and 887 technical ones (61%). The distribution of these nonconformities, numbered as the specific clauses of ISO/IEC 17025:2005 [2] were illustrated in table 3. The top 3 nonconformities related to management were 4.3 Document control (150,10%), 4.1 The organization (94,6%) and 4.13 Control of records (59,4%). For those of 887 technical nonconformities, the top 3 frequently cited were 5.4 Validation of the methods (315,22%), 5.5 Equipment (153,11%) and 5.9 Assuring quality of results (106,7%). Table 4 showed that the longer accreditation laboratories had lower mean of total nonconformities (mean±SD; 9.1±4.8 vs 12.7±9.0: t-test=2.89, p=0.003) and technical nonconformities (mean±SD; 5.0±3.1 vs 8.3±6.9: t-test=3.57, p<0.001) than those of the new laboratories.

Table 2 Comparison of characteristics and numbers of nonconformities between the longer accreditation laboratories with those of the shorter accreditation, new laboratories, 67 laboratories each. The proportional differences were tested by Kruskal Wallis to avoid non-normal distribution of certain data set and presented the test results as Chi-square, *denotes significant difference when p<0.05

Characteristics (number)	Longer accreditation	New	Chi-square	*p* value
Sector				
Governmental (40)	21	19		
- Private (94)	46	48	0.106	0.745
Location				
- Bangkok (30)	51	53		
- Other place (104)	16	14	0.128	0.721
Testing services				
- Foods (82)	39	43		
- Others (52)	28	24	0.374	0.541
Assessment				
- Initial (14)	14	0		
- Others (120)	53	67	11.638	<0.001*
Scope (test menu)				
- ≥ 38 (102)	63	39		
- < 38 (32)	4	28	17.04	<0.001*
Service objective				
- Self quality check (78)	44	34		
- Public service (56)	23	33	2.284	0.131
Characteristics (mean±SD)	**Longer accreditation**	**New**	**t-test**	**(*p* value)**
1. Years of accreditation (6±3.7)	9.2±2.2	3.1±2.1	16.42	<0.001 *
2. Scope (38.0±79.2)	64.0±104.4	12.1±19.3	4.00	<0.001*
3. Correction days (112.1±71.5)	106.5±72.8	117.6±70.3	0.90	0.371
4. Nonconformities (10.9±7.4)	9.1±4.8	12.7±9.0	2.89	0.005*
5. NC management (4.3±3.5)	4.1±3.0	4.5±3.9	0.58	0.561
6. NC technical (6.6±5.6)	5.0±3.1	8.3±6.9	3.57	<0.001*

3. Factors that might associate to years of accreditation were illustrated in table 4 for qualitative data, table 5 for continuous data and table 4 for various nonconformities, NC, against the specific clauses of the requirements of ISO/IEC 17025:2005. Significantly lower proportions of the longer accreditation laboratories were observed among these factors; total nonconformities, technical nonconformities, as showed above. NC against clause 5.6 Measurement traceability (14 vs 28, Chi square=5.060, p=0.024) and NC against clause 5.9 Assuring quality of test results (27 vs 44, Chi-square=6.450, p=0.011)

Table 3 Distribution of nonconformities against specific requirements of ISO/IEC 17025:2005, present in number and percentage of each relevant clause.

Clause 4	Brief description	Number	%
4.1	Organization	94	6.4
4.2	Management system	36	2.5
4.3	Document control	150	10.3
4.4	Review of contracts	18	1.2
4.5	Subcontracting	5	0.3
4.6	Purchasing services	56	3.8
4.7	Customer services	20	1.4
4.8	Complaints	8	0.5
4.9	Control of NC works	26	1.8
4.10	Improvement	13	0.9
4.11	Corrective action	18	1.2
4.12	Preventive action	15	1.0
4.13	Control of records	59	4.0
4.14	Internal audits	28	1.9
4.15	Management reviews	29	2.0
Total	Management	575	39.3
Mean		38.8	
Clause 5	**Brief description**	**Number**	**%**
5.1	General	3	0.2
5.2	Personnel	76	5.2
5.3	Accommodation/environment	60	4.1
5.4	Calibration/validation	315	21.5
5.5	Equipment	153	10.5
5.6	Measurement traceability	56	3.8
5.7	Sampling	5	0.3
5.8	Handling test and calibrators	56	3.8
5.9	Assuring quality of results	106	7.3
5.10	Reporting of results	57	3.9
Total	Technical	887	60.7
Mean		88.7	
Grand total	Management & technical	1462	100.0

Table 4 Proportions of accredited laboratories by nonconformities against reference clause of ISO/IEC 17025, comparing between the longer accreditation laboratories and the new laboratories, 67 laboratories each. The proportional differences were tested by Kuskal Wallis to avoid non-normal distribution of certain data set and presented the test results as Chi-square, *denotes significant difference when $p<0.05$

Reference clause	Longer accreditation	New	Chi-square	*p* value
4.1 Organization				
- Absent, 72	33	39		
- Present, 61	34	27	0.965	0.326
4.2 Management system				
- Absent, 106	51	55		
- Present, 28	16	12	0.538	0.463
4.3 Document control				
- Absent, 41	22	19		
- Present, 93	45	48	0.235	0.628
4.4 Review of requests				
- Absent, 116	59	57		
- Present, 18	8	10	0.191	0.662
4.5 Subcontracting				
- Absent, 129	66	63		
- Present, 5	1	4	1.392	0.238
4.6 External services and supplies				
- Absent, 85	40	45		
- Present, 49	27	22	0.599	0.439
4.7 Service to customer				
- Absent, 115	57	58		
- Present, 19	10	9	0.046	0.831
4.8 Complaints				
- Absent, 126	62	64		
- Present, 8	5	3	0.396	0.529
4.9 Control of NC testing				
- Absent, 112	52	60		
- Present, 22	15	7	2.591	0.108
4.10 Improvement				
- Absent, 121	60	61		
- Present, 13	7	6	0.063	0.801
4.11 Corrective action				
- Absent, 116	57	59		
- Present, 18	10	8	0.191	0.662
4.12 Preventive action				
- Absent, 119	59	60		
- Present, 15	8	7	0.056	0.813
4.13 Control of records				
- Absent, 86	47	39		
- Present, 48	20	28	1.547	0.214
4.14 Internal audits				
- Absent, 107	53	54		
- Present, 27	14	13	0.035	0.853

Table 4 Proportions of accredited laboratories by nonconformities against reference clause of ISO/IEC 17025, comparing between the longer accreditation laboratories and the new laboratories, 67 laboratories each. The proportional differences were tested by Kuskal Wallis to avoid non-normal distribution of certain data set and presented the test results as Chi-square, *denotes significant difference when $p<0.05$. (continues)

Reference clause	Longer accreditation	New	Chi-square	*p* value
4.15 Management reviews				
- Absent, 108	55	53		
- Present, 26	12	14	0.142	0.706
5.1 General				
- Absent, 131	66	65		
- Present, 3	1	2	0.254	0.614
5.2 Personnel				
- Absent, 78	43	35		
- Present, 56	24	32	1.462	0.227
5.3 Accommodation and environments				
- Absent, 93	49	44		
- Present, 41	18	23	0.654	0.419
5.4 Test methods and validation				
- Absent, 23	16	7		
- Present, 111	51	60	3.165	0.075
5.5 Equipment				
- Absent, 57	31	26		
- Present, 77	36	41	0.568	0.451
5.6 Measurement traceability				
- Absent, 92	53	39		
- Present, 42	14	28	5.060	0.024
5.7 Sampling				
- Absent, 129	63	66		
- Present, 5	4	1	1.392	0.238
5.8 Handling test and calibration items				
- Absent, 78	90	44		
- Present, 56	20	24	0.403	0.526
5.9 Assuring quality of the test				
- Absent, 63	40	23		
- Present, 71	27	44	6.445	0.011
5.10 Reporting the results				
- Absent, 84	41	43		
- Present, 50	26	24	0.095	0.758

Discussion

Accreditation years are one among indicators for experiences in quality improvement of the laboratories. According to ISO/IEC 17011:2004 clause 7.11.2, the accreditation body shall establish procedures and plans for on-sites assessments at sufficient close intervals to monitor the continued fulfillment by the accredited laboratories to comply the requirements.[7] BLQS has the policy on reassessment for every 2 years after successful initial accreditation, in order to monitor the continued fulfillment by the accredited laboratories. All basic characteristics of the experienced ones and the new ones are not different statistically, except for the number of service scope which just confirms that the longer accreditation are more competence. In this report, the mean accreditation time of 6 years or 3 cycles of 2 year accreditation can classify the

laboratories into 2 equal groups of 67 laboratories; some comparisons are feasible for a cross-sectional study. A report from Hong Kong[4] used different year of ISO 15189 accredited medical laboratories and got a strong evidence that lower nonconformities were observed after a number of reassessments. However, a laboratory always faces with changes and new challenges that are certainly affect to the quality management system in each year, thus, such comparison on different years are less valid. Another report[5] uses the correction times as the output variable and finds that some factors related to a longer correction time are nonconformities against clause 4.2 management system and nonconformities against the technical requirements. A previous report[6] reveals that certain nonconformities: the design for safety, safety procedures, personnel responsibilities and safe work practices relate to higher total number of nonconformities in the safety assessment of medical laboratories using ISO 15190 as audit criteria. This report demonstrates how many year accreditation help quality improvement as evidently decreasing nonconformities are observed among those of the longer accredited laboratories.

Conclusions

This study demonstrated that the new laboratories with less than 6 year accreditation had higher chance to get more total nonconformities, especially on the technical requirements clause 5.6 traceability and 5.9 Assuring quality of test results. Such nonconformities need experiences to resolve and improve. Many years of accreditation will help laboratories to comply with each requirement of the standards after many visits from the assessors.

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