SITUATION ANALYSIS OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH LABORATORY ACCREDITATION IN THAILAND

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Abstract. The objective of this study was to analyze the current situation of laboratory accreditation (LA) in Thailand, especially on occupational and environmental health. The study integrated both quantitative and qualitative approaches. The response rate of the quantitative questionnaires was 54.5% (226/415). The majority of the responders was environmental laboratories located outside hospital and did not have proficiency testing. The majority used ISO 9000, ISO/IEC 17025 or ISO/IEC Guide 25, and hospital accreditation (HA) as their quality system. However, only 30 laboratories were currently accredited by one of these systems.

Qualitative research revealed that international standard for laboratory accreditation for both testing laboratory and calibration laboratory was ISO/IEC Guide 25, which has been currently revised to be ISO/IEC 17025. The National Accreditation Council (NAC) has authorized 2 organizations as Accreditation Bodies (ABs) for LA: Thai Industrial Standards Institute, Ministry of Industry, and Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health. Regarding LA in HA, HA considered clinical laboratory as only 1 of 31 items for accreditation. Obtaining HA might satisfy the hospital director and his management team, and hence might actually be one of the obstacles for the hospital to further improve their laboratory quality system and apply for ISO/IEC 17025 which was more technically oriented. On the other hand, HA may be viewed as a good start or even a pre-requisite for laboratories in the hospitals to further improve their quality towards ISO/IEC 17025.

Interviewing the director of NAC and some key men in some large laboratories revealed several major problems of Thailand's LA. Both Thai Industrial Standards Institute and Bureau of Laboratory Quality Standards did not yet obtain Mutual Recognition Agreement (MRA) with other international ABs. Several governmental bodies had their own standards and accreditation systems, and did not accept other bodies' standards and systems. This put a burden to private laboratories because they had to apply and get accredited from several governmental bodies, but still had to apply and get accredited from several governmental bodies. There were only few calibration laboratories, not enough for supporting the calibration required for the equipment in testing laboratories' LA. Purchasing proficiency testing specimens from abroad was very expensive, and often got into troubles with the customs duty procedures.

The authors recommend some strategies and activities to improve laboratory accreditation in Thailand. Improvement in occupational and environmental health laboratories would essentially be beneficial to laboratory accreditation of other areas such as clinical laboratory.

INTRODUCTION

Laboratory service has been one of the essential components of occupational and

environmental health services and systems. In Thailand, most laboratories have internal quality control system but are lack of impartial and systematic external quality control and accreditation (Promptmas and Prijavudhi, 1999; Promptmas *et al*, 1999). It is quite often that physicians, relevant professionals, or even the patients themselves raise questions about the accuracy and reliability of laboratory results (Dorsey, 1989; Peddecord, 1989).

The recently enacted Labor Protection Act of 1998 requires employers to offer their employees annual periodic physical examination and some laboratory tests as biological monitoring for some high risk groups. This will expand the market for private hospitals and laboratories that have been lately suffered some financial difficulties. Competition, both in pricing and in quality, can be expected. Both competition should be considered positive, but competition in pricing inevitably has some tradeoff with quality and may result in lower quality and hence reliability.

Workplace environmental monitoring, which serves as one of primary preventive measures for occupational diseases, also depends on laboratory services to test environmental specimens such as air samples. The issue of quality definitely plays an important role as well. Moreover, some laboratory data may become the basis for court judgement in environmental conflict cases. The issue of laboratory quality and reliability become even more important.

In Thailand, hospital accreditation (HA) has recently drawn more attention. The Ministry of Public Health has a policy to strongly advocate HA, and HA has grown to be an independent and autonomous institute. Some private hospitals also put HA, along with ISO 9000 series, as their means for quality improvement. However, HA (Hospital Accreditation Institute, 2000) concerned laboratory quality as only one of all 31 items and admitted that quality assessment and accreditation for clinical laboratory services was technically difficult and required professional organizations, universities, concerned government and private bodies to jointly establish specifically a laboratory accreditation system. HA standard for clinical laboratory services currently used would be considered a general and temporary framework before establishment of such system. This is obvious that HA project could not cover all the aspects of laboratory accreditation. Moreover, those stand-alone clinical laboratories (outside hospitals) would not be covered in HA. All environmental laboratories would not be covered either.

Thailand Industrial Standards Institute (TISI), Ministry of Industry, has the authority on standards and accreditation for both products and services. Bureau of Laboratory Quality Standards, Department of Medical Laboratories, Ministry of Public Health, has also worked on this area for more than 3 years including monitoring hospitals' laboratory quality, accrediting hospitals which serve to examine and certify workers who go to work abroad, and accrediting laboratories which serve to analyze health products.

The laboratory accreditation system would take a long time to establish and the process must be continual (The College Accreditation Steering Committee, 1990; Hamlin, 1999; Otter and Cooper, 1999), and a research may be used to enhance this system. A good point to start is to analyze the current situation of laboratory quality and accreditation in Thailand, and we would first focus only on occupational and environmental laboratories as the objective of this study.

MATERIALS AND METHODS

This study was performed during June 2000 and May 2001 by integrating both qualitative and quantitative approaches.

Qualitative component

Documents of the current international standard and criteria for laboratory accreditation (Spence and Bering, 1978; Dybkaer *et al*, 1993; Abell and Doemeny, 1991; Timperley, 1991; Hamlin, 1994; Jansen *et al*, 1995; 1997), and of the legislation and related bodies of laboratory accreditation in Thailand were reviewed. HA personnel on clinical laboratory accreditation in HA and 24 key men in the laboratory accreditation system and in 24 large laboratories were interviewed.

Quantitative component

A questionnaire asking about laboratory characteristics, services, and quality system currently used was developed and mailed to the directors of all 415, without sampling, laboratories known of or anticipated to be providing laboratory services on occupational and environmental health. The directors were asked to mail the questionnaires back, and the questionnaires were analyzed.

RESULTS

Qualitative component

Qualitative research revealed that international standard for laboratory accreditation for both testing laboratory and calibration laboratory was ISO/IEC Guide 25, which currently has been revised to be ISO/IEC 17025 (ISO/ IEC, 1999). Thailand has the National Accreditation Council (NAC) authorized and responsible for accreditation. NAC has authorized 2 organizations as Accreditation Bodies (ABs) for LA: Thai Industrial Standards Institute, Ministry of Industry, and Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health. Regarding LA in HA, HA considered clinical laboratory as only 1 out of 31 items for accreditation. The author also interviewed the director of NAC and 24 key men in 24 large laboratories for in-depth information.

Quantitative component

The response rate of the quantitative questionnaires was 54.5% (226/415) although we had followed at least two times.

Table 1 reveals that government and private laboratories had significantly different response rate (p<0.001), 75.5% of government laboratories responded but only 43.4% of private laboratories responded. Laboratories located in hospitals had higher response rate than laboratories not located in hospitals (p<0.001), their response rates were 80.6% and 45.8% respectively. Laboratories located in Bangkok and its vicinity did not have different response rate from laboratories located in other provinces (p=0.17), their response rates were 51.2% and 57.8% respectively. Most organizations had response rate higher than 50%. The private laboratories had only 37.9% response rate despite their largest number of 88. We did not analyze this item by χ^2 test because more than 20% of cells had expected number lower than 5.

Table 2 shows that among 226 laboratories responded, 102 of them (45.1%) were environmental laboratories. Forty-eight laboratories (21.2%) did not perform either occupational or environmental laboratory services and were excluded from further analyses.

Table 3 reveals that 66.4% of the occupational and 80.6% of the occupational and environmental laboratories were governmental, whereas 72.5% of the environmental laboratories were private. Most laboratories (88.9%) located in hospitals were occupational laboratories, while 99% of the environmental and occupational and 71% of the environmental laboratories were not located in hospitals 37.8% of the 49%. Regarding regions, occupational, environmental, and occupational and environmental laboratories located in Bangkok and its vicinity (37.8%, 49.0%, and 29.0% respectively). Most occupational and occupational and environmental laboratories were under the Ministry of Public Health (54.4% and 71.0% respectively). Whereas, most environmental laboratories were private (72.5%).

Table 4 shows that 10 governmental laboratories had doctoral degree personnel (12% out of 82 laboratories) which was higher than (8) private laboratories (8.5% out of 95 laboratories). The largest numbers of laboratories with doctoral degree personnel were in environmental laboratories, both government and private. The majority of laboratories had personnel with bachelor and below bachelor degree.

Table 5 reveals that governmental laboratories had highest mean of below bachelor degree personnel (7.3 per one lab), the second

LABORATORY ACCREDITATION IN THAILAND

Characteristics of laboratories	Response (n=226)		Non-response (n=189)		Total (n	=415)	
	No.	%	No.	%	No.	%	
Category							
Government	108	75.5	35	24.5	143	100	
Private	118	43.4	154	56.6	272	100	
χ^2 tes	t = 42.2	df	=1	p-val	alue < 0.001*		
Whether located in hospital							
Located in hospital	83	80.6	20	19.4	103	100	
Not located in hospital	143	45.8	169	54.2	312	100	
χ^2 tes	est = 36.7 df=1				p-value < 0.001*		
Location of laboratories							
Bangkok and its vicinity	108	51.2	103	48.8	211	100	
Other provinces	118	57.8	86	42.2	204	100	
$\chi^2 t$	est= 1.8	df	=1	p-val	lue = 0.17		
Organization							
Ministry of Public Health	63	84 0	12	26.0	75	100	
Ministry of Science, Technology, and Environment	4	44.4	5	55.6	9	100	
Ministry of University Affairs	20	54.1	17	45.9	37	100	
Ministry of Labor and Social Welfare	1	100.0	0	0	1	100	
Ministry of Interior and Bangkok	9	81.8	2	18.2	11	100	
Metropolitan Administration							
Ministry of Defence	6	85.7	1	14.3	7	100	
Ministry of Agriculture and Co-operation	tives 3	100.0	0	0	3	100	
Private hospitals	32	80.0	8	20.0	40	100	
Private laboratories	88	37.9	144	62.1	232	100	

Table 1 Number, response rate, and p-value (by χ^2 test) comparing response and non-response, by characteristics of the laboratories.

*Statistically significant (p<0.01)

			Table 2	
Туре	of	226	responded	laboratories.

Type of laboratories	No.	%
Occupational health	45	19.9
Environmental health	102	45.1
Both occupational and environmental	31	13.7
Neither occupational or environmental	48	21.2
Total	226	100.0

highest was bachelor (3.8 per one lab). The same was true for private laboratories, which had an average of 8 and 5.3 person per 1 lab respectively. Governmental laboratories had higher mean of master (2.5 per one lab) and doctoral (2.1 per one lab) degree personnel than private lab (1.9 and 1.4 per one lab respectively).

Data on laboratory potentials and testing capability revealed that the item that most occupational and occupational and environ-

General information	Occup	ational	Enviror	nmental	Occupational and environmental		То	tal
	No.	%	No.	%	No.	%	No.	%
Category								
Government	30	66.7	28	27.5	25	80.6	83	46.6
Private	15	33.3	74	72.5	6	19.4	95	53.4
Total	45	100.0	102	100.0	31	100.0	178	100.0
Whether located in hospital								
Located in hospital	40	88.9	1	1	9	29	50	28.1
Not located in hospital	5	11.1	101	99	22	71	128	71.9
Total	45	100.0	102	100	31	100	178	100.0
Location								
Bangkok	17	37.8	50	49.0	9	29.0	76	42.7
Central	12	26.7	35	34.3	7	22.6	54	30.3
North	5	11.1	5	4.9	7	22.6	17	9.6
South	5	11.1	6	5.9	5	6.1	16	9.0
Northeast	6	13.3	6	5.9	3	9.7	15	8.4
Total	45	100.0	102	100.0	31	100.0	178	100.0
Organization								
Ministry of Public Health	25	54.4	6	5.9	22	71.0	53	29.8
Ministry of Science, Technology and Environment	0	0	4	3.9	0	0	4	2.2
Ministry of University Atfairs	3	6.7	10	9.8	1	3.2	14	7.9
Ministy of Labor and Social Welfar	e 0	0	0	0	1	3.2	1	0.6
Ministry of Interior and Bangkok Metropolitan Administration	1	2.2	4	3.9	1	3.2	6	3.4
Ministry of Defence	1	2.2	1	1	0	0	2	1.1
Ministry of Agriculture and Co- operatives	0	0	3	3	0	0	3	1.7
Private hospitals	13	28.9	0	0	1	3.2	14	7.9
Private laboratories	2	4.4	74	72.5	5	16.1	81	45.5
Total	45	100.0	102	100.0	31	100.0	178	100.0

Table 3 Laboratories classified by location and general information.

mental laboratories could serve was blood lead level (23 and 15 lab respectively). Most (51) environmental laboratories could serve for pH testing. The maximum average number of tests per year was 20,000 for formaldehyde, cyanide and phenol.

Table 6 shows that most (112) laboratories served only 1-10 tests, and only 8 laboratories served more than 30 tests. Among these were big laboratories receiving specimens and testing them for smaller laboratories.

Data on current laboratory accreditation

Some laboratories were accredited by other external organizations, based either on ISO/ IEC Guide 25 or ISO/IEC 17025, ISO 9000 series, HA, or by the Department of Medical Sciences.

Table 7 reveals that 26.7% of occupational laboratories were accredited, whereas only 11.9% of environmental laboratories were accredited. Private organization was accredited (21.1%) more than government organization

Personnel education	Occu	Occupational		Environmental		Occupational and environmental		l Total	
	No.	%	No.	%	No.	%	No.	%	
Government	(n=30 lab)		(n=27 lab) ^a		(n=25 lat))	(n=82 lab)		
Doctoral	1	3.3	6	22.2	3	12.0	10	12.0	
Master	12	38.7	17	63.0	15	60.0	44	53.0	
Bachelor	26	86.7	26	96.3	24	96.0	76	92.7	
Below bachelor	21	70.0	17	63.0	17	68.0	55	67.1	
Private	(n=15 lab)		(n=74 lab)		(n=6 lab)	(n=95 lab))	
Doctoral	1	7.1	5	6.8	2	33.3	8	8.5	
Master	5	33.3	27	36.5	3	50.0	35	37.2	
Bachelor	15	100.0	73	98.6	6	100.0	94	98.9	
Below bachelor	15	100.0	60	81.1	5	83.3	80	84.2	

Table 4Laboratories classified by their personnel's educational level.

^aNote: one governmental environmental laboratory did not give information about its personnel.

Education level	Occupational		Environmental ^a		Occupational and environmental		Total	
-	No.	Mean	No.	Mean	No.	Mean	No.	Mean
Governmental laboratories								
Doctoral (n=10 lab)	5	5	10	1.6	6	2	21	2.1
Master (n=44 lab)	19	1.6	67	3.9	25	1.6	111	2.5
Bachelor (n=76 lab)	91	3.4	111	4.3	88	3.7	290	3.8
Below bachelor (n=55 lab)	223	10.1	62	3.6	114	6.7	399	7.3
Private laboratories								
Doctoral (n=8 lab)	1	1	5	1	5	2.5	11	1.4
Master (n=35 lab)	7	1.4	56	2.1	5	1.7	68	1.9
Bachelor (n=94 lab)	148	10.6	297	4.1	51	8.5	496	5.3
Below bachelor (n=80 lab)	145	10.4	441	7.4	53	10.6	639	8.0

Table 5 Mean of educational level of 639 laboratories' personnel.

^aNote: one governmental environmental laboratory did not give information about its personnel.

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Number of type of tests	Occupational		Environmental		Occupational and environmental		Total	
	No.	%	No.	%	No.	%	No.	%
1-10	30	100	59	79.7	23	88.5	112	86.2
11-20	0	0	6	8.1	0	0	6	4.6
21-30	0	0	2	2.7	2	2.7	4	7.7
More than 30	0	0	7	9.5	1	3.8	8	6.2
Total	30	100	74	100.0	26	100.0	130	100.0

Table 6Type of tests served by 130 laboratories.

Note: 48 out of 178 laboratories did not give information on the tests served.

General characteristics	Did not apply for accreditation (n=105)		In the pr appling for a (n=	Obtaining accreditation (n=30)		Total (n=177)	
	No.	%	No.	%	No.	%	No.
Type of laboratories							
Occupational	19	42.2	14	31.1	12	26.7	45
Environmental	73	72.3	16	15.8	12	11.9	101 ^a
Occupational and environmental	13	41.9	12	38.7	6	19.4	31
Categories							
Government	47	57.3	25	30.5	10	12.2	82ª
Private	58	61.1	17	17.9	20	21.1	95
Whether located in hospital							
In hospital	24	48.0	16	32.0	10	20.0	50
Not in hospital	81	63.8	26	20.5	20	15.7	127
Location							
Bangkok	38	50.7	22	29.3	15	20.0	75
Central	37	68.5	11	20.4	6	11.1	54
North	10	58.8	4	23.5	3	17.6	17
South	9	56.3	4	25	3	18.8	16
Northeast	11	73.3	1	6.7	3	20.0	15
Organization							
Ministry of Public Health	28	52.8	17	32.1	8	15.1	53
Ministry of Science, Technology	3	75	1	25.0	0	0	4
and Environment							
Ministry of University Affairs	10	71.4	3	21.4	1	7.1	14
Ministy of Labor and Social Welfare	1	100.0	0	0	0	0	
Ministry of Interior and Bangkok	3	50.0	2	33.3	1	16.7	6
Metropolitan Administration							
Ministry of Defence	1	50.0	1	50.0	0	0	2
Ministry of Agriculture and Co-	1	50.0	1	50.0	0	0	2ª
operatives							
Private hospitals	3	21.4	3	21.4	8	57.1	14
Private laboratories	55	67.9	14	17.3	12	14.8	81

Table 7 Laboratories applied for accreditation.

^aNote: one laboratory did not give information on accreditation.

		Tabl	le	8			
Accredited	laboratories	according	to	the	accreditation	system	used.

Accreditation system	Occuj	Occupational		Environmental		Occupational and environmental		Total	
	No.	%	No.	%	No.	%	No.	%	
ISO/IEC17025/Guide25	2	16.7	4	33.3	4	66.7	10	33.3	
ISO 9000 series	10	83.3	6	50.0	2	33.3	18	60.0	
Others	0	0	2	16.7	0	0	2	6.7	
Total	12	100	12	100	6	100	30	100	

	Being a P	Γ provider	Not being a PT provider			
Type of laboratories	No.	%	No.	%		
Occupational (n=45)						
Government	0	0	30	66.7		
Private	0	0	15	33.3		
Environmental (n=100) ^a						
Government	2	66.7	24	24.7		
Private	1	33.3	73	75.3		
Occupational and environmental (n=3)	0) ^b					
Government	3	100.0	21	77.8		
Private	0	0	6	22.2		
Total (n=175)	6	100.0	169	100.0		

 Table 9

 Laboratories that were Proficiency Testing Providers (PT providers).

Note: atwo laboratories did not give information; bone laboratory did not give information.

Table 10 Laboratories being members of proficiency testing network.

PT member	Occupational		Environmental		Occupational and environmental		Total	
-	No.	%	No.	%	No.	%	No.	%
In Thailand	34	91.9	15	62.5	19	76	68	79.1
Other countries	1	2.7	5	20.8	1	4	7	8.1
Both Thailand and other countries	2	5.4	4	16.7	5	20	11	12.8
Toal	37	100	24	100	25	100	86	100

Note: 92 laboratories did not join any PT network.

(12.2%). Laboratories located in Bangkok and the northeast were most accredited (20%), and the central the least (11.1%). Most private hospitals were accredited (57.1%).

Table 8 reveals that among 30 accredited laboratories, 60% used ISO 9000 series and 33.3% used ISO/IEC 17025/Guide 25. Occupational and environmental laboratories used ISO/IEC17025/Guide 25 (66.7%).

Table 9 shows that there were 6 laboratories serving as Proficiency Testing Providers (meaning that they provided samples for proficiency testing): 2 government and 1 private environmental laboratories and 3 governmental occupational and environmental laboratories. Table 10 reveals that most laboratories (79.1%) were members of some PT network in Thailand, and both Thailand and other countries (12.8%).

DISCUSSION

The response rate of the quantitative questionnaires was only 54.5% despite at least 2 times follow-up. This implied that interest in laboratory accreditation was rather low in Thailand. The majority of the responders was environmental laboratories located outside hospital, and did not have proficiency testing. The majority used ISO 9000, ISO/IEC 17025 or ISO/IEC Guide 25, and HA as their quality system. However, only 30 laboratories were currently accredited by one of these systems. Most occupational and occupational and environmental laboratories were under the Ministry of Public Health, whereas most environmental laboratories were private. The majority of laboratory personnel's educational level bachelor degree or lower. Most laboratories served fewer than 10 types of tests. There were only 6 large laboratories served as proficiency testing providers.

Qualitative research revealed that international standard for laboratory accreditation for both testing laboratory and calibration laboratory was ISO/IEC Guide 25 which currently has been revised to be ISO/IEC 17025. However, ISO 9000 series and HA are currently more popular quality systems applied in Thailand. ISO 900 series and HA may be more easier to accomplish since they are essentially management requirements. Whereas, ISO/IEC 17025 requirements are more technical hence requiring more resources and effort to accomplished.

We recommend that NAC accelerates its ABs to make MRA with other international ABs through International Laboratory Accreditation Cooperation (ILAC, 1994) and Asia Pacific Laboratory Accreditation Cooperation (APLAC, 1998). Both Thai ABs should share their responsibilities over LA activities and make this clear to concerned bodies.

A system to cope with lacking of calibration laboratories should be established through co-operation among National Metrology Institute, Thailand's Metrology Association, Thai Industrial Standards Institute and Bureau of Laboratory Quality Standards. Having enough number of calibration laboratories will help improving the LA for testing laboratories. Proficiency testing (Duckworth, 1988; Hoeltge and Duckworth, 1987) providers should also be supported to be able to produce quality PT specimen in the country and hence reducing imported PT specimen. This can be done in part by supporting those current PT providers to produce more kinds of PT specimen. Improvement in occupational and environmental health laboratories would essentially be beneficial to laboratory accreditation of other areas such as clinical laboratory.

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