Checklist

Standard for Medical Laboratory

Name of hospital .....Name of

Laboratory.....

Name.....Position/

Title.....

DD/MM/YY.....Reision.....

Quality system	Evaluation				Remark
	Y	P	N	NA	
1. Organization and Management					
1. Appointment of a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system.					
2. A quality manual shall describe the quality management system and the structure of the documentation used and shall include or make reference procedures.					
3. Adequate training, specified responsibility, authority, and interrelationships of all personnel.					
4. Laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical record.					
5. Laboratory management shall review the laboratory`s quality management system and all of its medical services at least once every shall be incorporated into a plan that includes goals, objectives and action plan.					
2. Personnel					
6. Laboratory shall be a continuing education program available to staff at all levels.					
7. Policies shall be established which define who may access patient data and who is authorized to enter and change patient results, correct billing or modify computer programs..					
8. Employees shall be trained to quality assurance, prevent or contain the effects of adverse incidents.					
3. Laboratory Equipment					
9. Laboratory shall be furnished with all items of equipment required for the provision of services.					
10. Equipment shall be shown to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.					
11. When equipment is removed from the direct control lf the laboratory or is repaired or serviced, the					

laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.					
12. Laboratory shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It shall also have a documented.					
13. Equipment shall be operated by authorized personnel only.					
14. Laboratory shall have a manual for used and maintenance of equipment.					
15. Laboratory shall have identified of the equipment, reference materials and reagents which affect to the results.					
16. Laboratory shall have a labeled or otherwise coded to indicate the status of calibration or verification ant the date when calibration or reverification.					
17. Whenever equipment is found to be defective, it shall be taken out of service, clearly labeled.					
18. Equipment including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.					
4. External Services and Supplies					
5.1 Accommodation and Environmental Conditions					
19. The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safely of personnel or patient care services.					
20. The laboratory design and environment shall be suitable for the task and separation form office.					
21. The laboratory shall be controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials which affect the analytical results.					
22. Sample shall be storage at suitable condition which is not affect to quality of sample					
23. Work areas shall be clean and well maintained. Measure shall be taken to ensure good housekeeping.					
24. Laboratory shall have procedure for storage and destroy hazard sample and also have a procedure for prevent an environment.					
5.2 Assuring quality of examination procedure					
25. Laboratory shall design internal quality control systems that verify the attainment of the intended quality results.					
26. Laboratory shall have corrective action records where internal quality control out of range.					
27. Laboratory shall participate in as interlaboratory comparisons such as those organized by external quality assessment schemes.					
28. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control					

criteria are not fulfilled.					
29. A programme for calibration of analytical systems shall be designed and performed so as to ensure that results are traceable to SI units. Calibrator and control materials shall be recorded.					
30. Documentation of statements regarding reagents, procedures or the examination system when traceability is provided by supplier or manufacturer.					
31. For those examinations performed using different equipment : there shall be a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals.					
5.3 Pre – analytical process					
32. Specific instructions for the proper collection and handling of primary sample shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection.					
33. Laboratory shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual and in a manner that ensures safety for carrier.					
34. Criteria shall be developed for acceptance or rejection of primary sample.					
35. Laboratory shall have documented for rejection of inappropriate primary sample.					
36. Laboratory shall have a procedure for storage primary sample, if it is not immediately examination.					
5.4 Analytical					
37. If in – house procedures are used, they shall be appropriately validated.					
38. Laboratory shall be reviewed of procedures at least once in twelve months and documented.					
39. Biological reference intervals shall be periodically reviewed.					
40. All procedures shall be documented and be available at the workstation for relevant staff .					
41. Laboratory management in consultation with the requesters shall establish turnaround times for each of examination.					
5.5 Post – analytical Procedures					
42. Authorized personnel shall systematically review the results of examinations, and signature.					
43. Storage of the primary sample shall be in accordance with approved policy.					
44. Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.					
5.6 Reporting					
45. The laboratory shall have a procedure for reporting of					

results including date time. Procedure, and receiver and reported by telephone and facsimile.					
46. Records of actions taken in response to results in the critical intervals shall be maintained.					
47. Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information in possible. The length of time that reported data are retained may vary: however, the reported results shall be retrievable for long as medically relevant or as required by national, regional or local requirements.					
48. The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the results.					
5.7 Amendment of Reports					
49. The laboratory shall have written policies and procedures regarding the alteration reports. When altered, the record must show the time , date and mane of the person responsible for the change.					
6. Document control					
50. All documents relevant to the quality management system shall be uniquely identified.					
51. Quality documents shall be included title, edition or current revision date or revision number of pages, authority for issue and source identification.					
52. The laboratory shall have a procedure for check and review documents and shall have a master list and invalid or obsolete documents are promptly removed from all point of use, or otherwise assured against inadvertent use.					
53. All records shall be legible and stored such b that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements. Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.					
7. Control of Nonconformities					
54. Laboratory shall have a policy and procedure to be implemented when it defects that any aspect of its examination does not conform to its own procedures or the agreed upon requirements of its quality management system.					
55. The Laboratory shall define and implement procedure for release of results in case of nonconformities, including the review of such results. These events shall be recorded.					
8. Internal Audits					
56. The Laboratory shall be conducted an internal audit for quality management system.					
57. The Laboratory shall have recorded results of internal audits.					
58. The Laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and					

carried out within an agreed upon time.					
59. The results of internal audits shall be submitted to laboratory management for review					
9. Continual Improvement					
60. The Laboratory shall be reviewed quality management system every year and planed for next year.					
61. Management review shall take account of follow-up previous management reviews, status of corrective and required preventive action, the outcome of recent internal audits, assessment by external body, outcome of external quality assessment, quality indicators, nonconformities, monitoring of turnaround time, results of continuous improvement processes and evaluation of suppliers.					
62. The laboratory shall be continually reviewed the process of work in the aspect of completeness and accuracy.					
63. The laboratory shall audit result work according to purpose and objective of organization.					
64. In case of mistake which is affect to policies, procedure or quality management system, associated activities shall be evaluated.					
65. The laboratory shall submitted reports from management reviews to laboratory management board.					
66. The laboratory shall development quality system activities between organization and team.					
67. Procedure for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective.					
10. Client Management					
68. The laboratory shall establish and maintain procedures for review of contracts. The review of capability should establish that the laboratory possesses the necessary physical, Personnel and information resources and the laboratory`s personnel have skills and expertise necessary, for the performance of the examination question.					
69. The laboratory shall have a policy and procedures for the resolution of complaints or feedback received from clinicians, patients or other parties.					
70. The laboratory shall be performance the responsible rate for the customer once ayear.					

Remark

Y=Yes P= Partial N=No NA = not applicable

This checklist developed by Medical Technology Association Thailand