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SPECIAL ARTICLE

The Pathology Laboratory Act 2007 explained

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Abstract

The past century has seen tremendous changes in the scope and practice of pathology laboratories in tandem with the development of the medical services in Malaysia. Major progress was made in the areas of training and specialization of pathologists and laboratory technical staff. Today the pathology laboratory services have entered the International arena, and are propelled along the wave of globalization. Many new challenges have emerged as have new players in the field. Landmark developments over the past decade include the establishment of national quality assurance programmes, the mushrooming of private pathology laboratories, the establishment of a National Accreditation Standard for medical testing laboratories based on ISO 15189, and the passing of the Pathology Laboratory Act in Parliament in mid-2007.

The Pathology Laboratory Act 2007 seeks to ensure that the pathology laboratory is accountable to the public, meets required standards of practice, participates in Quality Assurance programmes, is run by qualified staff, complies with safety requirements and is subject to continuous audit. The Act is applicable to all private laboratories (stand alone or hospital) and laboratories in statutory bodies (Universities, foundations). It is not applicable to public laboratories (established and operated by the government) and side-room laboratories established in clinics of registered medical or dental practitioners for their own patients (tests as in the First and Second Schedules respectively). Tests of the Third Schedule (home test blood glucose, urine glucose, urine pregnancy test) are also exempted. The Act has 13 Parts and provides for control of the pathology laboratory through approval (to establish and maintain) and licensing (to operate or provide). The approval or license may only be issued to a sole proprietor, partnership or body corporate, and then only if the entity includes a registered medical practitioner. Details of personnel qualifications and laboratory practices are left to be specified by the Director-General of Health, providing for a formal recognition process and room for revision as pathology practices evolve. Encompassed in the responsibilities of the licensee is the requirement that samples are received and results issued through, and management vested in, a registered medical or dental practitioner. This effectively prohibits "walk-ins" to the laboratory and indiscriminate public screening. The requirement for a person-in-charge in accordance with class and speciality of laboratory ensures that the laboratory is under the charge of the pathology profession. Examined carefully, the requirements of the Act are similar to laboratory accreditation, but are backed by legislation. Many of these details will be spelt out in the *Regulations*, and these in turn are likely to fall back on National professional guidelines, as accreditation does. Although not at first obvious, enforcement of the Act is based on self-regulation by pathology laboratory professionals. Sincere professional input is thus required to embrace its philosophy, ensure rational and transparent enforcement of legislation, and develop National guidelines for good pathology practices upon which enforcement may be based.

Keyword: Pathology act, regulations, practice guidelines, laboratory legislation, accreditation

INTRODUCTION

A brief history of the pathology laboratory services in Malaysia

Western-style medicine was introduced to Peninsular Malaya in the 16th Century by the Portuguese (1511), Dutch (1640) and British (1766) and to East Malaysia in the 19th Century (Sarawak 1841, Sabah 1846). The earliest pathology laboratories were developed within hospitals towards the end of the 19th Century, and

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offered only simple tests carried out by junior laboratory technicians.[1] A few state hospitals offered a wider range of biochemistry tests and bacteriological investigations but histopathology, cytology and serology services were poorly-developed or non-existent. The establishment of the Institute for Medical Research (IMR) in 1900 was a landmark event. Branches of the IMR dominated the pathology scene over the next 50 years, making a mark in medical research, training of scientific and technical personnel and providing the bulk of the diagnostic laboratory services for the country.[1]

With national independence in August 1957, the health services took on strategic development along formulated five-year plans. The post-independence era saw the mushrooming of pathology laboratories linked to Ministry of Health (MOH) hospitals (other than the IMR) throughout the country. The establishment of Medical Schools and their respective Departments of Pathology at the University of Malaya (UM) in 1964, Universiti Kebangsaan Malaysia (UKM) in 1973 and Universiti Sains Malaysia (USM) in 1979, saw the emergence of University Pathology laboratories with both academic and service functions.[2] There were no private laboratories until about 1960. Before that, private medical practitioners were dependent on the IMR or government laboratories. However, by 1980, several private laboratory chains and private hospitals with in-house pathologists had emerged.

Evolution of the laboratory services

The past century has seen tremendous changes in the scope and practice of pathology laboratories in tandem with the development of the medical services in Malaysia. Major progress was made in the areas of training and specialization of pathologists and laboratory technical staff.[3] Although earlier laboratories tended to be under the charge of a "general pathologist", by 1990, provisions were made for mono-discipline pathologists in all major MOH hospitals.[2] Many earlier pathologists were trained through the DCP and MRCPath programmes in the United Kingdom, but this was recognized as expensive and the pace lagging behind national human resource needs. To meet national needs, Master of Pathology (MPath) programmes, which are professional pathology training programmes structured along the MRCPath system, were established in the UM (1973), UKM (1988) and USM (1992). Universiti Putra Malaysia (UPM) and Universiti Technologi Malaysia (UiTM) are also in the process of formalizing MPath programmes. The current MPath programmes are full-time, structured, programmes of four-years duration aimed at training mono-discipline specialist pathologists, assessed through conjoint examinations controlled by an Inter-University Pathology Committee.

In 1994, of the about 120 medically-qualified pathologists working in Malaysia, only about 10% were in private practice.[2] With a breakthrough development in 1994 between the MOH and Universities to utilize MOH pathology laboratories as training ground, it was possible to step-up the training of pathologists. By 2007, there were about 300 medically-qualified pathologists and 150 pathology trainees in the country. Currently there are more than 200 private laboratories and more than 40 pathologists in private practice. With a population of more than 25 million, it is recognized that the pathologist: population ratio of 1:90,000 is still short of international standards. A ratio of 1:75,000 is probably achievable by 2010.

A changing market and playing field

It was estimated that about 240 million pathology laboratory tests were performed in the country in 2006. Of these, 46% were conducted in the MOH, 10% in University hospitals and 44% in private laboratories.[4] Today the pathology laboratory services have entered the International arena, and are propelled along the wave of globalization. Many new challenges have emerged as have new players in the field.

Landmark developments over the past decade include the establishment of "national" quality assurance programmes in the MOH and the Laboratory Quality Assurance Scheme (LABQAS) programme jointly run by the College of Pathologists of the Academy of Medicine of Malaysia (CPath-AMM) and the Malaysian Institute of Medical Laboratory Scientists (MIMLS), the establishment of a National Accreditation Standard for medical testing laboratories based on ISO 15189 (2004), the development of Guidelines for Good Laboratory Practices by CPath-AMM in 2005,[5] and the passing of the Pathology Laboratory Act in Parliament in mid-2007. All these ground-breaking developments are linked. Driven by public expectation for quality and accountability, they are, in principle, based on peer-assessment, self-regulation among professionals and cooperation between stakeholders.

THE PATHOLOGY LABORATORY ACT MALAYSIA

The idea for legislative regulation of pathology laboratories was first proposed by the Malaysian Society of Pathologists (the predecessor of CPath-AMM) in a Memorandum to the MOH in 1983. The acceptance of this idea and the drafting of the Bill took a chequered course over 24 long years (Table 1). Along the way, there were several consultations with stakeholders and issues raised in the public domain (Table 2).

TABLE 1: Landmark events leading to the Pathology Laboratory Act 2007

1983:	Memorandum to MOH by Malaysian Society of Pathologists pointing out need for legislative control of laboratories
1984:	Survey by MOH on Private Pathology Labs justified the need for regulation
1984:	Drafting activities started
1987:	First draft completed but objections to legislation raised
1989:	Reversal of objections
1992:	Submission by Malaysian Pharmaceutical Society to be exempted from Pathology Lab Act for performance of screening and monitoring tests
1994:	MSOP survey on aspects of Pathology Laboratories to be regulated: • Qualification of personnel, environment & safety, quality (EQA); restrictions to public screening, etc
1994:	Second draft approved by AG Department
1997:	Consultation with Professional bodies
1997:	Issues raised • Walk-in testing • Grandfather's clause for existing laboratories
1998:	Bill redrafted to be in line with Private Healthcare Facilities and Services Act
2000:	Third draft entitled "Pathology Laboratory Facilities and Services Bill"
2000:	Consultation with Professional bodies
2002:	Fourth draft entitled "Pathology Laboratory Bill" approved by Minister of Health
2003:	First draft of Path Lab regulations approved by Minister of Health
2004:	Public consultation
2004-2006:	Fine-tuning of draft Bill
2007:	Pathology Laboratory Bill tabled and passed in Parliament

TABLE 2: Increasing public awareness of the Pathology Bill

Annual dialogues with Minister of Health

Consultations with relevant professional bodies and public (1997; 2000; 2004)
- Malaysian Association of Private Medical Laboratories
- Malaysian Institute of Medical Laboratory Scientists (MIMLS)
- Malaysian Society of Clinical Biochemists
- Malaysian Medical Association
- Federation of Private Medical Practitioners Association Malaysia
- Others

Issues raised in the media (2001-2006)
- MMA wants labs to conform to fee schedule
- Discrepancies in test results from different labs
- Controversies over "Walk-ins"
- Abuse of screening tests; test vouchers; etc
- Support for Pathology Act: "Why the delay?"

In principle, the Pathology Laboratory Act 2007 seeks to ensure that the pathology laboratory is accountable to the public, meets required standards of practice, participates in QA programmes, is run by qualified staff, complies with safety requirements and is subject to continuous audit. The requirements are similar to laboratory accreditation, but is backed by legislation rather than based on volunteerism. The Act provides for the regulation and control of pathology laboratories through 13 parts. The following commentary is best read together with a copy of the Act.[6]

Part I: Preliminary – definitions and applications

This part provides for the interpretation of the Act by defining the various personnel and entities mentioned in the Act, such as pathologist, medical laboratory technologist, scientific officer, registered medical practitioner, Director-General, premises, body corporate, pathology laboratory, pathology services, class and speciality, licence, licensee, person-in-charge, record, etc.

What laboratories are regulated?
Pathology services are defined as "any services in the analysis and examination of samples of human tissue or fluid or any other product of the human body or for assessing any change in the physiological state of human beings for the purposes of preventing, diagnosing or treating diseases in human beings." By this definition, the Act is empowered to regulate all mainstream pathology laboratories that conduct diagnostic, screening and monitoring tests, as well as therapeutic drug monitoring (TDM) and point-of-care testing (POCT). Excluded by definition are forensic, research and infertility (handling of gametes) laboratories and those involved in product testing (manufacturing laboratories).

Note that by definition, the term "body corporate" includes not only bodies incorporated under the Companies Act 1965 but also statutory bodies. When read together with Part XIII, it is clear that the Act regulates through extension of the powers of the Director-General of Health (DG) beyond the MOH to all private pathology laboratories (whether stand alone or hospital-based) and those in statutory bodies such as University hospitals and foundations. It is important to note that the Act is not applicable to MOH laboratories, which is logical since the DG already has jurisdiction over those laboratories. Also exempted are laboratories in clinics of registered medical practitioners conducting First Schedule tests and of registered dental practitioners conducting Second Schedule tests. These Schedules spell out limited simple tests, and are only applicable to the clinic's own patients. Also generally exempted are 3 tests listed in the Third Schedule (home test blood glucose, urine glucose, urine pregnancy test), which patients are today able to conduct on themselves using over-the-counter kits. While the various exemptions may lead to some contention, it is clear that they were granted to reduce "hardship" on patients in situations when testing does not require a great deal of expertise and can be well-monitored by their attending doctors.

The definitions also provide for various "class and speciality" of pathology laboratories, recognizing that there should be different requirements according to complexity (e.g. whether there is interpretation of test results or not) and speciality (e.g. Anatomical pathology, Haematology, Medical microbiology and Chemical pathology). Clearly, these will have to be more clearly specified in the *Regulations*.

Who can work in the pathology laboratory?
By definition, the pathologist has to be medically-qualified and possess qualifications, training and experience in pathology approved by the DG. By this definition, it will no longer be possible for persons qualified otherwise to be employed and designated as "pathologists." The same concept applies for scientists and medical laboratory technologists. The Act thus protects the public by requiring professionals working in the laboratory to be competent for their jobs. Gone the days when anyone can be deemed qualified according to business convenience. By requiring the qualifications of various personnel to be "approved by the DG" provides for a formal recognition process, allowing room for input by relevant professional bodies and revision from time to time.

Part II: Control of the Pathology Laboratory

This Part provides for the control of the pathology laboratory through the processes of approval and licensing. An *approval* is granted to establish or maintain a laboratory (i.e. permission to build) whereas a *licence* is granted to operate or provide a laboratory (i.e. permission to start the business). A licence cannot be granted without a prior approval. This two-step process avoids the disastrous situation whereby a laboratory may

be built (at great cost) and then is not granted a licence because of unacceptable shortcomings.

The main issue in Part II is the requirement that the approval or licence may be issued to a sole proprietor, partnership or body corporate only if a registered medical practitioner is included. This has been a point of contention among non-medically qualified pathology managers. However, it is a valid requirement since the pathology laboratory is not just any science laboratory but is an important component of the medical "business." Resting the control of the pathology laboratory with the medical practitioner is a move to ensure that accountability of the pathology services is commensurate with other medical practices, that practices conform to the Code of professional conduct of the medical profession, and that pathology practices are subject to the ethical requirements of the Medical Act.

But why not be even more stringent and require the licensee to be a pathologist? That would be ideal, and would almost certainly be the case for sole proprietors or partnerships. However, it would be impractical to require that the pathologist be on the board of directors of all corporate bodies that provide pathology services.

Part III: Approval to establish or maintain a pathology laboratory

Part III of the Act spells out the procedures to obtain an approval to establish and maintain a pathology laboratory. Basically, the application for an approval is made to the DG. The Act provides for matters to be considered before an approval is granted (e.g. class and speciality of laboratory, need for services in geographical areas) and for reasons where an approval may not be granted (e.g. unsuitable capability, fraud, conviction, bankruptcy). An approval is valid for only 3 years. A separate approval is required for each laboratory not physically, administratively or organisationally linked. The class and speciality of pathology laboratory approved shall also be specified.

Part IV: Licence to operate or provide a pathology laboratory

Part IV spells out the procedures relating to licensing of a pathology laboratory. The application for a licence shall be made (to the DG) before the expiry of the approval (i.e. 3 years). A licence is granted only after the laboratory has been inspected by authorized government officers and ascertained to conform to construction, design and operational requirements. A separate licence is required for each pathology laboratory. The licence shall specify the class and speciality of the pathology laboratory. It is valid for 3 years and shall be displayed in the laboratory premises. The Act also provides the procedures for modification (e.g. change class and speciality) and renewal of the licence.

Requirements similar to laboratory accreditation

Basically, Part III and Part IV complement each other. The crucial aspects to be considered for establishment of a Pathology laboratory are (1) appropriateness of laboratory design and manpower, (2) organisational make-up, (3) qualification and experience of staff, and (4) the need for pathology services in the location. It is noteworthy that the quality and competence requirements are similar to those of laboratory accreditation (MS ISO 15189). Because of that, questions have been raised as to why the Act has not just simply required that laboratories have to be accredited before they can be licensed. Although the concept may be good for existing laboratories, it would not be possible to impose such a requirement on a new laboratory. A proposed new laboratory would not yet be operational and thus would not be in the position to seek accreditation. Because of that, the two-step approval and licensing process is the more practical one.

Part V: Responsibilities of licensee or person in charge

Part V may be considered the meat of the Act. The Act holds the licensee ultimately responsible for the organizational set-up of the lab. The licensee has to ensure that laboratory health professionals are registered under the laws regulating those professions, that they possess qualifications and experience as approved by the DG, and that laboratory policies comply with the codes of professional conduct governing those professions. These reflect the sentiments that tests must be conducted by appropriate, legitimate and competent personnel, and that business considerations should not contravene professional ethics.

No walk-ins

Whether pathology laboratories should be allowed to conduct tests upon the request of

any member of the public (i.e. walk-ins) has been a contentious issue during the drafting stages of the Act and also during Parliamentary debate. Although there have been arguments for the positive empowerment of the public to test (and even treat) themselves, there are abundant nightmarish stories of self-requested testing that have led so many into the paranoid, confused and expensive maze of chasing the meaning of an "abnormal" test result. In the end, it was felt that the public is better protected by restricting walk-ins and self-testing. This is achieved by requiring that samples be received and results issued through, registered medical or dental practitioners (who are in a better position to decide what tests to request and what action to take on the results, in the light of the clinical findings of their patients). This requirement also aims to prevent exploitation of the public by unjustified and unrestricted screening, an activity that has been hugely profitable for laboratories but places them at the questionable side of professional ethics. The requirement that the licensee takes responsibility for ensuring that management of patients rests with registered medical or dental practitioners is also a clear recognition that the pathology laboratory is an integral part of the medical services, and not just an analytical laboratory. Note that this requirement will also restrict conducting tests upon the request of non-medically qualified persons such as a bomoh or sinseh.

There are, of course, loopholes. An errant laboratory may employ its own medical doctor to order tests for the public who walk-in, or set up its own "clinic" to order tests and receive results, or have a "kick-back" arrangement with a medical practitioner to order tests and receive results. How the restriction will affect health tourism also has to be considered. This is an area where the *Regulations* will have to spell out details very carefully.

Person in charge

The Act requires the licensee to appoint a suitably qualified *person in charge* to manage the lab and supervise the various categories of staff employed. A licensee (e.g. a sole proprietor) who is suitably qualified may also serve as person in charge. Note that while a licensee may hold more than one licence, there has to be a different person in charge for each laboratory. This is a recognition that the person in charge is crucial for the actual control and running of the laboratory, in contrast to the licensee who is responsible for the organizational set-up and policies of the laboratory. The person in charge is regarded as the most important *key personnel* of the laboratory and thus has to have specific qualifications and training related to the pathology laboratory services as specified by the DG (to be detailed in the *Regulations*). These qualifications are expected to be similar to that of "laboratory director" in the accreditation setting. The MS ISO 15189 accreditation requirements for laboratory director are related to the scope of services of the laboratory. For specialized laboratories which issue test results with clinical interpretation (e.g. histopathology reports), the laboratory director has to be a pathologist with at least 5 years of working experience in a pathology laboratory. For laboratories that issue only test results (data) without clinical interpretations, the laboratory director may also be a medical practitioner with at least 3 years of pathology laboratory working experience or a scientist with at least 5 years of pathology laboratory working experience.

Other responsibilities of licensee

Part V also spells out other responsibilities of the licensee, including (1) inspection of the laboratory, (2) establishing and maintaining methods, equipment, materials, disposal, (3) safety, (4) establishing a grievance mechanism, (5) incident reporting to the DG, and (6) ensuring appropriate records are kept.

Part VI: Suspension or revocation of approval or licence

The DG is empowered to cease the establishment or operation of a pathology laboratory through suspension or revocation of an approval or licence. The reasons for suspension or revocation are spelt out (e.g. fraud, fail to comply with the law, illegal activities, etc).

Part VII: Closure of Pathology Laboratory

Part VII provides for closure of the pathology laboratory by order of the DG when it poses a grave danger to the public, implying situations such as contamination of the environment by harmful substances from the laboratory. In contrast to cessation, closure may be temporary (until the danger is over).

This Part also provides for closure of the laboratory on the licensee's own volition, for whatever reason.

Part VIII: General provisions related to approval or licence

The Act empowers the DG to vary terms and conditions of an approval or licence. It allows the DG to assess the operation of the laboratory, impose restrictions on the use of its premises and prohibit extensions and alterations. While this may appear draconian at first glance, the sentiments are to allow the DG to intervene when a pathology laboratory is developing along lines that are against public interest.

Part VIII also provides for transfer of an approval or licence from the holder to another, a practical matter of little contention.

It also provides for a register of approved and licensed pathology laboratories to be kept and maintained by the DG, for the benefit of public information. As a public document, the register is open for public inspection and search.

Part IX: Quality of Pathology Laboratory

Part IX emphasizes the importance of quality of services, by requiring the licensed laboratory to engage in quality assurance programmes and activities. These programmes may be prescribed in the *Regulations*, but is unlikely to be stringently prescribed until a National External Quality Assurance Scheme is in place.

Apart from quality assurance programmes, the DG may also give directives on quality and standards if he thinks it necessary. This applies to situations where a laboratory is found to be operating in a substandard manner in relation to methodology, equipment or sample handling.

Part X: Pathology Laboratory Advisory Committee

There is provision for a Pathology Laboratory Advisory Committee, in recognition of good governance, transparency and social consciousness. Membership and duties may be prescribed in the *Regulations*. However, these are unlikely to be stringently prescribed because of the wide variation in scope of pathology laboratories. Small laboratories may find it a hardship to support a large and complex Committee.

Part XI: Managed Care Organisation

The regulation of pathology laboratories in relation to Managed Care Organisations (MCOs) is similar to that of the Private Healthcare Facilities and Services Act, which was passed at a time when there was a great deal of concern over ethical flaws resulting from the infringement of MCOs into medical decisions. In gist, any contract or arrangement with MCOs must not contravene the Codes of Professional Conduct of Healthcare Professionals (including the medical profession) and any provisions of the Pathology Laboratory Act.

Part XII: Enforcement

Part XII empowers enforcement of the Act and its *Regulations*. The DG is authorized to appoint enforcement officers and empower them to act on his behalf. Appointed enforcement officers may enter and inspect the pathology laboratory premises, have the power to search the premises and seize records or samples, have the power to seal the laboratory, shall be given access to laboratory data and can require cooperation of relevant persons in the discharge of their duties. While seemingly draconian, such wording is not unusual in a legislative setting. Without such empowerment of enforcement officers it would be possible to implement the Act.

Compounding of offences

The DG may compound any offence prescribed to be compoundable (to be detailed in the *Regulations*). This allows swift imposition of punitive action for offences without having to go through a long-drawn court procedure.

Part XIII: Miscellaneous

Part XIII provides for various seemingly unrelated issues which nevertheless have to be addressed to ensure that the Act can be implemented and enforceable. The main ones are discussed here.

Non-application of the Act

The Act is not applicable to public pathology laboratories (e.g. MOH laboratories) established by the Government, laboratories in clinics of registered medical practitioners for their own patients (only for tests listed in the First Schedule), laboratories in clinics of registered dental practitioners for their own patients (only for tests listed in Second Schedule), and tests in the Third Schedule (home test blood glucose, urine glucose and urine pregnancy test). The rationale for these exemptions have already been mentioned earlier in this paper.

Power of the Minister to make Regulations
The Minister of Health is empowered to make *Regulations* to give effect to the Act. As long as there is no contradiction to the Act, the *Regulations* may prescribe all the details related to any aspect of the Act not already spelt out. The rationale of leaving such details (e.g. class and speciality, qualifications of personnel, standards, procedures) to the *Regulations* is to allow revisions to be made as the pathology services evolve without having to take the long-drawn path back to Parliament for amendments to the Act. This is an important provision so that advances in pathology laboratory practices may not be curbed by archaic legislation. Also there is room for dialogue among all stakeholders, professionals and public alike, to fine-tune legislative control so that there is a level playing field for all.

The Minister also has the power to prescribe fee schedules (*Regulations*), social or welfare contributions (*Regulations*) and to amend schedules (in the *Gazette*).

Appeals
Since the Act grants extensive powers to the DG, it is good balance to see the provision for any aggrieved person to appeal to the Minister of Health against the decisions of the DG.

Transition
There is provision for a transitional period of 6 months (from the date of commencement of the Act) for any existing pathology laboratories to apply to the DG for a licence. Pending the decision of the DG, such a laboratory shall be allowed to operate without a licence. Once a licence has been granted by the DG, the laboratory shall have another 6 months to comply with any terms and conditions (if any) imposed.

Since the Act cannot take effect without the *Regulations*, existing pathology laboratories need not take action until the *Regulations* are issued. After the *Regulations* are issued, there would be, at minimum, 6 months for all laboratories to comply with the requirements of the Act. In practical terms, the period is more likely to be a year (or even longer), as it will take a while for enforcement officers to inspect the many existing laboratories.

The provision of a transitional period has laid to rest the arguments for a grandfather's clause to exempt all existing pathology laboratories from the requirements of the Act. Such an exemption would legitimize any existing substandard laboratories and defeat the purpose of the Act. As it stands, all laboratories (other than those specified in Part XIII) will have to apply for a licence and all will eventually have to comply with the Act.

Offences

Those reading the Act for the first time may be rather taken aback that there is so little written that specifically stipulates how the pathology services should be run. After all, is not the Act meant to ensure that the pathology laboratory meets required standards of practice? Instead, what are covered in great detail are the punitive actions that will be imposed on the person who contravenes each section or clause of the Act. This is the nature of legislation, and if you examine it closely, there is great wisdom in it. To specify too many details in the Act itself would effectively fossilize pathology practice. As mentioned before, it is better to spell out the details in the *Regulations* so that they can be revised in line with the evolution of the pathology services.

However, there is no ambiguity on accountability. Contravention of the Act (and the *Regulations*) would be an offence. Depending on the seriousness of the offence, various fines or imprisonment terms may be imposed. This is very similar to the Private Healthcare Facilities and Services Act, although the severity of the punitive action imposed under the Pathology Laboratory Act is proportionately lower.

The importance of the *Regulations*

It can be seen that the implementation of the Act will depend heavily on the *Regulations*. The *Regulations* interpret the Act in the light of current peer and public expectation of quality pathology practice. As laboratory accreditation is now well accepted internationally as a mark of quality, it is very likely that the *Regulations* for the Pathology Laboratory Act will stipulate requirements very similar to those for accreditation (i.e. ISO 15189). This, in particular, would apply to criteria for the various classes and specialities of laboratories, the organization and management system of the laboratory, the qualification and experience of the person-in-charge, the qualification and competence of pathologists, scientific and technical staff engaged to conduct tests, and the standards of laboratory practice.

The *Regulations* will also have to address procedures to be taken in the application,

granting, modification and renewal of approvals and licences, the inspection of laboratories, the issuance of directives, the collection of fees, appeals, action to be taken against offences, etc. Numerous forms have to be created and schedules drawn. Hence there is a tremendous amount of work to be put in to draft the *Regulations*, but much of this would have been done while the Pathology Bill was being drafted. I believe that the *Regulations* are near completion.

To ensure smooth implementation of the Act, the final stages of regulation drafting should involve consultative sessions with stakeholders, and the testing of the procedures on volunteer laboratories.

Can the Act fulfill objectives?

What the public expects of a pathology Laboratory is that it performs relevant and useful tests and issues results that can be trusted. This means that the results should be accurate, consistent and reliable, and be performed and interpreted by qualified persons. To be relevant and useful in medical practice, test results should also be timely and affordable. The laboratory also should not pose any danger to the public.

What the laboratory wants is to pursue a satisfying professional service with appropriate recognition as an essential partner in the medical and healthcare services. In so providing the service, it looks forward to a viable, thriving business with good returns for investments in man and machine. It looks to a level playing field with fair competition and a fair market.

There is no disagreement that all parties would not like to see the existence or persistence of substandard laboratories. We are well aware that unsafe practices and wrong diagnoses pose a danger to patients and the public. Laboratories that do not fulfill minimal requirements profit by exploitation and undermine the integrity of the pathology profession.

In the quest for quality, several approaches have been developed. Proficiency testing through inter-laboratory comparisons (e.g. external quality assurance schemes), is an essential activity of the quality laboratory. However, the performance of laboratories at such schemes is confidential and usually no punitive action can be taken even when a laboratory consistently falls below standard.

Accreditation is another universally accepted approach to ensure quality and competence. In countries where healthcare financing and insurance is well established, reimbursement of testing fees may only be made to accredited laboratories. In Malaysia where healthcare financing schemes are not well-established, seeking of accreditation is entirely voluntary, and largely driven by competitive edge. Failure to comply can at most result in withdrawal of accreditation status. The accreditation body cannot close the laboratory.

Considering the present state of development of the pathology laboratory services in Malaysia, legislation is the most powerful tool to ensure quality in laboratories. The Act has the backing of the law, empowered by parliament. It can prevent a substandard laboratory from being established and can close down existing substandard laboratories. Non-compliance is dealt with through fines and even imprisonment, not just loss of (accreditation) status.

Differences between accreditation and legislation

While there are many similarities between accreditation and legislative requirements, it is noteworthy that the Act holds the licensee accountable for the laboratory, whereas accreditation holds the laboratory director (person in charge) responsible. The Act is more focused on processes: applications, approvals, enforcements, punishments, etc. Control of actual laboratory practices are made through the *Regulations*. In contrast, accreditation standards are more directly focused on laboratory practices. Details are prescribed in supportive documents (e.g. Specific criteria for accreditation, and the Specific technical requirements for each scope) which are revised regularly.

The importance of peer-review and consensus guidelines

Whether considering proficiency testing, accreditation or legislation, peer-review is the key influencing success. Proficiency testing is basically a comparison against peer performance. Accreditation standards are determined by peers and assessment is by peers. For rational and transparent enforcement of legislation, there has to be peer input in drafting of the *Regulations*, and major peer involvement in enforcement.

Finally, all three approaches towards establishment of quality in pathology laboratories require reference to National guidelines and norms for good laboratory practice. These in turn have to be developed through peer

participation and consensus. Recognising this, the *College of Pathologists, Academy of Medicine Malaysia* developed 6 Professional Practice Guidelines by April 2005, in order to support both accreditation and legislation. These were (1) retention of pathology records and materials,[7] (2) minimum qualification, training and experience of professional personnel working in a pathology laboratory,[8] (3) laboratory construction and design,[9] (4) maintenance and operation of equipment in a pathology laboratory,[10] (5) safe laboratory practice,[11] and (6) sample management.[12] A seventh guideline, that on manpower norms, is being developed.

National Professional Guidelines may thus be regarded the hidden power behind both accreditation and legislation. They provide the true basis of self-regulation and peer-review, and recognize that the future of pathology testing depends on participation and cooperation among all stakeholders.

THE FUTURE

Pathology and laboratory medicine is a rapidly changing field where new technology and scientific advances are introduced into medical practice. Any approach to control of the pathology laboratories (whether proficiency testing, accreditation or legislation) has to allow for evolution of technology and scientific concepts, without compromising minimal standards and without losing sight of the patient care and ethical responsibilities of the laboratory. This must be the guiding principle as stakeholders now sit to finalise the *Regulations* to the Pathology Laboratory Act. This will not be an easy task, and while a lot of ground has been covered, a recent forum (Regulatory issues in laboratory medicine, Petaling Jaya, 16 January 2008) has raised a number of issues that need to be clarified, including:

(1) Whether Ministry of Defence pathology laboratories should be regulated, considering that these are currently not directly under the jurisdiction of the DG of Health
(2) How loopholes in the Act may be closed to prevent "walk-in" testing
(3) How, while curbing indiscriminate and exploitative public screening, may screening related to legitimate health tourism be regulated

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