SECTION 1.1.

INTRODUCTORY CHAPTERS

CHAPTER 1.1.1.

MANAGEMENT OF VETERINARY DIAGNOSTIC LABORATORIES

INTRODUCTION

Reliable laboratory services can be delivered only by specialised facilities that are appropriately constructed and managed to provide the operating environment where the complex interaction of qualified staff, infrastructure and scientific methods can be coordinated to deliver specialised outputs consistently and safely. This chapter describes components of governance and management of veterinary laboratories that are necessary for the effective delivery of a diagnostic service, highlighting the critical elements that should be established as minimum requirements. Subsequent chapters set more specific standards for managing biological risks associated with laboratory facilities and for the range of aspects to be addressed to ensure confidence in laboratory test results.

The essential prerequisite for effective laboratory management is a clear understanding of the outputs required by the managing jurisdiction. National governments should support laboratory systems by developing a national laboratory policy based on the definition of the categories of laboratory test results required for effective implementation of the national animal health policy, including tests in support of international trade. Such clarity regarding national animal health requirements for laboratory services will guide the formation of national strategic planning for the delivery of these services. A clear statement of expectations of the laboratory service will guide governance and resourcing arrangements.

Further to these considerations, this chapter specifies components of diagnostic service management and delivery including the key support services that are considered essential. In addition to making provision for the scientific and technical aspects of the laboratory activities, the laboratory management system must address biorisk management and quality assurance. Laboratory management must also understand and meet the national and international regulatory requirements governing diagnostic laboratory operations. The outputs from a veterinary laboratory must be based on sound science, and mechanisms must be in place to prevent corrupt practices and inappropriate political influences.

A. GENERAL CONSIDERATIONS

1. Introduction

Laboratories fulfil an essential role in the delivery of veterinary services. Without the data and information supplied by veterinary laboratories, animal disease detection, control and prevention would be significantly weakened (Edwards & Jeggo, 2012). Veterinary laboratories are also a valuable resource to increase national laboratory capacity during major human health events such as pandemics.

Chapter 1.1.6 *Validation of diagnostic assays for infectious diseases of terrestrial animals* lists the usual purposes for which laboratory testing is conducted, which include demonstration of freedom from infection in defined animal populations, certification of freedom from infection in individual animals or products for trade/movement purposes,

contributions to the elimination of infection from defined populations, confirmation of diagnosis of suspect or clinical cases, estimation of prevalence of infection or exposure to facilitate risk analysis, and determination of the immune status of individual animals or populations.

These roles can be provided by governments (public sector laboratories), by industry (private sector laboratories), by universities (university laboratories) or by other organisations. Combinations of such providers in a complex matrix of services create challenges in the management and expectations of service delivery.

The governance of public sector veterinary laboratories will vary from country to country according to their public sector processes. This chapter sets out the general principles of governance and management for all types of veterinary laboratories that should ensure that Veterinary Services have access to reliable, trustworthy laboratory services, data and advice. The governance framework should ensure strong and effective delivery of services in a manner that is politically accountable, transparent, ethical, forward-looking and fair to staff and customers.

2. Accountability and oversight

A veterinary laboratory is held accountable for a range of issues apart from the delivery of basic diagnostic services. These may include health and safety, biosecurity, animal welfare and ethics, environmental contamination, genetic manipulations and quality assurance. It is essential that processes are established for the management and reporting of these issues and that individual staff are held accountable for their formally delegated responsibilities. As part of the process, it is critical to recognise and manage the resource implications, as failure to deliver to these accountabilities can bring the laboratory service into disrepute, detracting from the credibility of national animal health services.

There must be a clearly communicated and effective process by which the laboratory management is assessed and held accountable for delivery of all aspects of service delivery and accountability. This may be through a formally constituted governing body or through line management by the veterinary services or other qualified arm of government. Where a governing board is appointed, an independent chairman should be selected who understands both the political and the scientific environments in which the laboratory operates. The governing board should advise the laboratory director[1] on how to meet the expectations of the customers and owners of the laboratory, but should also represent the laboratory's interests by ensuring that these customers and owners have realistic expectations of the laboratory's capability and capacity, both in normal day-to-day operation and during outbreaks.

Whatever the governance structure, those responsible must ensure that the managers and scientific staff of the laboratory can operate in a scientifically sound environment and are free from inappropriate political influences. This includes the publication of the results of scientific research. A zero-tolerance approach to corruption at all levels must be in place.

A laboratory should have a medium-term strategic plan and a more detailed business plan for the year ahead, including financial and resource management. The director of the laboratory is ultimately responsible for ensuring the management of the laboratory according to these plans and obtaining appropriate governance agreement. The laboratory should also prepare an annual report for approval through the established oversight processes.

The governing body must not become involved with the operational management of the laboratory, which must remain firmly in the hands of the director and the management team.

It is important to review regularly the overall laboratory objectives and agreed deliverables with government to ensure transparency in meeting of expectations. Staff should be kept informed on such deliverables, understand priorities and not feel unduly threatened by the need to ensure financial security for the laboratory. There may be competing pressures with regards to the activities that need to be undertaken, and the director should continually provide leadership and guidance to staff on these issues.

3. Executive management

It is essential that operational activities in the laboratory are conducted under the authority of a single individual who is given an appropriate title, e.g. director or chief executive. The director (or equivalent) should be fully

1 The term "director" is used generically in this chapter to refer to the senior responsible person in the laboratory. Local terminology may vary, and this role is further discussed in Section A.3 of this chapter.

accountable for the delivery of outputs from the laboratory and for the deployment of resources within the institution. As the core role of the laboratory is to participate in the diagnosis of animal disease and disease control programmes, the director should ideally be a qualified veterinarian and also have personal experience of working in a laboratory environment. Where the director does not have a veterinary qualification, a senior deputy should be appointed in the role of veterinary director. The key attributes of the director are to have an understanding of the operating environment of laboratory work, to be fully aware of the end-user requirements so that the outputs are relevant, trustworthy and timely and to demonstrate leadership qualities that will motivate the laboratory staff to deliver their best and to the required quality standard, both during normal operations and in outbreaks.

The director should be supported by a senior management team whose members will lead specific aspects of the work of the laboratory. The size of this team, and the scope of their individual responsibilities, will depend on the size of the laboratory, but it will typically involve leaders of different scientific disciplines (e.g. pathology, bacteriology, virology) as well as business leaders with expertise in human resources (HR), finance, procurement, engineering, information technology (IT) and communication. At least one of the senior team should be designated deputy director; the deputy will work closely with and in support of the director and fulfil the director's responsibilities in his or her absence.

4. Infrastructure

Laboratories are highly specialised facilities with very particular requirements in terms of buildings, services and operational environments. Although some smaller laboratories can operate within an adapted general-purpose building, it is highly recommended that veterinary laboratories are housed in purpose-built units, designed with considerable input from scientific staff, along with architects, environmental experts, safety advisers and others in the design team. The structure and functions of the laboratory must comply with all relevant national regulations and international standards, such as for biocontainment, biosafety and environmental impact. Local issues must also be taken into account, such as the likelihood of extreme conditions (high or low temperatures, earthquakes, hurricanes, floods) and the reliability of water and electricity supplies.

National authorities must recognise that laboratories, whilst very expensive to build, are equally expensive to operate and maintain. It is absolutely essential that an adequate, ongoing budget be allocated for annual operating costs (see section on finance below). Factors to support include the IT data support requirements (including future-proofing), utility costs and waste management. Likewise, as technologies and legislative requirements change, budgetary commitments to equipment and laboratory upgrades should be planned well in advance.

5. Human resources

A veterinary laboratory, like any organisation employing staff, must have a clear, transparent HR policy that is seen to treat all individuals fairly. Appropriate procedures should be in place to determine remuneration, performance management, appraisal and promotion, leading to incentivisation and reduced risk of departure of well-trained staff. A robust mechanism for addressing poor performance is also essential; it should provide clear and fair procedures for dismissal, in extreme circumstances. Veterinary laboratories employ an unusually high proportion of specialised staff, and this can cause difficulties where work patterns change as new technologies are introduced. HR policies should include training and retraining programmes to ensure that all staff are developed to their full potential and contribute to a flexible work force. It is prudent to encourage staff, particularly new entrants, to move around different sections of the laboratory as part of their development. This breadth of experience ensures increased resilience in outbreaks, and also builds tolerance, as staff develop an appreciation of the challenges of different disciplines – and they also make better leaders.

6. Compliance

6.1. Health and safety

Veterinary laboratories are hazardous environments. Most hazards fall into three main categories: biological, chemical and physical. There are biological risks from handling dangerous pathogens, including infectious zoonotic agents (i.e. those that may infect humans), recombinant forms of infectious agents, viral vectors, biologicals introduced into experimental animals and allergens from handling animals. Hazardous chemicals can result in exposure during use, if misused or mishandled, or through inappropriate storage. Appropriate personal protective equipment must be used to protect personnel from exposure to toxic, carcinogenic or otherwise hazardous chemicals. Risks from physical hazards can include ergonomic issues associated with manual tasks, handling sharps, poor housekeeping, ionising

radiation, ultraviolet radiation, fire, high-pressure steam, liquid nitrogen, solid CO_2 vessels and animals (bites, kicks and other trauma to staff). Health and safety (H&S) must comply with the applicable national H&S legislation where such exists and be managed in a transparent and documented manner. The laboratory must have policies and procedures in place to assess all risks to staff (and visitors) and to mitigate those risks to acceptable levels. Risk assessments should be performed by the individuals most familiar with the specific characteristics of the pathogens being considered for use, the equipment and procedures to be employed, animal models that may be used and the containment equipment and facilities available.

It is the responsibility of the laboratory senior management to ensure the development and adoption of H&S policies and procedures. Training of new and existing personnel is key to avoiding accidents. Appointment of an H&S professional should be a serious consideration for larger laboratories, and this should be supported by an appropriate, dedicated H&S budget. The role of the H&S professional must be clearly defined and documented, and all personnel (including visitors) should understand that the presence of an H&S professional does not mean that they are any less responsible for carrying out their work in a safe and responsible manner, in compliance with agreed protocols. The H&S professional must have the full support of laboratory senior management. Personnel should be advised of special hazards, required to read and have easy access to the laboratory safety or operations manual, follow standard practices and procedures and participate in regular training.

A H&S committee should be established consisting of representatives from both staff and management of the laboratory. A requirement for such committee structures and operations is usually included in national legislation, and the laboratory managers must be fully conversant with these defined processes, including the appointment of H&S representatives, actions and reporting procedures for all H&S incidents, H&S training requirements and the minimum laboratory infrastructures and processes to meet these requirements. For larger facilities that may also carry out additional activities, including research, a biological safety officer, a chemical safety officer and a more formal institutional biosafety committee, with external representation, may also be of benefit in assessing and managing additional biosafety risks. Such a committee should also apply oversight and guidance on dual use research of concern[2].

6.2. Biosafety and biosecurity

In addition to health and safety issues, veterinary laboratories have a responsibility to contain pathogens and to prevent unauthorised access to reduce the risk of their accidental or deliberate release that might threaten neighbouring human or animal populations, or the environment. Standards on biorisk management are given in Chapter 1.1.4 *Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities* and in the WHO[3] Laboratory Biosafety Manual (WHO, 2020). All veterinary laboratories should comply with the relevant standards in these documents and also adhere to national standards and regulations. In many countries there is a national compliance monitoring authority for biosecurity or biocontainment. This authority will inspect the laboratory on a regular basis. The laboratory managers must understand the regulations and ensure that sufficient resources are available to ensure compliance. For laboratories undertaking investigations of new and emerging diseases or pathogens, the potential zoonotic risk to staff and the general population should also be subject to a risk assessment and appropriate mitigation measures put in place where potential risks are identified. Brass *et al.* 2017 provide a useful summary of methodologies used to assess risks posed by novel pathogens, as well as covering the fundamentals of laboratory biosafety and biosecurity.

Whilst minimum legal requirements exist, individual laboratories should examine their processes and procedures to determine where elements of biosecurity risk may arise and how best these should be managed on a local basis. A biorisk manual that contains standard operating procedures (SOPs) for all activities should be maintained, with version control. Such SOPs should highlight biosecurity controls, training should be provided, and it is recommended that local procedures are put in place to manage non-compliance. This is a matter of good laboratory practice, regardless of the legislative background.

2 WOAH Guidelines for responsible conduct in veterinary research: https://www.woah.org/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/BTR/A_GUIDELINES_VETERINARY_RESEARCH.pdf

3 WHO: World Health Organization

Laboratory biorisk management should specifically recognise the potential for bioterrorist threats including the concept of the insider threat (e.g. the bioterrorist threat posed by a staff member or visiting scientist). When working with high consequence pathogens, a process should be developed by which this threat can be managed. Physical security measures and an annual staff threat appraisal would be a minimum requirement in such circumstances and security screening of staff may also be considered. In addition, measures must be in place to control access by visiting scientists and to ensure their supervision when working with this class of pathogens.

Where required by regulation or organisational policy, written confidentiality agreements should be in place for appropriate personnel including staff, visiting scientists, contractors and others, to prevent any confidential information being released inappropriately.

6.3. Animal welfare

Veterinary laboratories must ensure their activities comply with animal welfare standards (Section 7 of the *Terrestrial Animal Health Code*, particularly Chapter 7.8 *Use of animals in research and education*). It is also essential to understand fully the national legislation governing the ethical use of animals and put in place processes to ensure compliance. An institutional animal ethics committee, with external representation, is recommended.

6.4. Gene regulation

Many laboratories now use modified genes or gene products in their activities. Compliance with national regulations governing their use must be ensured including establishment of systems in the laboratory to monitor and ensure such compliance. International obligations concerning ethical behaviours in genetic manipulation in the context of Dual Use Research of Concern (DURC)[4] also apply (WOAH, 2019). Particular attention should be given to experiments that might fall into the category or "Gain of Function", where the host specificity or virulence of a pathogen might be altered.

6.5. Environment

Laboratory waste may create concerns of environmental pollution. The risk of environmental damage from carcass disposal and disposal of other biological material is an issue that requires specific attention. Understanding and managing, as far as possible, any potential negative impacts of the laboratory on the surrounding environment is important and may be subject to national and local regulations. Certification of compliance with standard ISO[5] 14001:2015 *Environmental Management Systems* (ISO, 2015) should be a target for laboratory managers. The laboratory should not be established in an inappropriate environment such as close to other facilities that may impact on the safety of the laboratory.

B. SCIENTIFIC SERVICES

1. Diagnostic service delivery

The national Veterinary Services must be very clear in specifying the purposes for which laboratory capability is required, and hence the test methods and technologies to be supported. The defined purposes will include the list of diseases or infectious agent groups in scope, the nature of the government programmes to be supported in terms of the purposes of testing outlined in chapter 1.1.6, the likely scheduling and volume of submissions, and the required turnaround time for test reports. The cost implications must be identified and agreed. These discussions should be recorded in a service level agreement or similar documentation.

A key component of the delivery of scientific services is the routine monitoring, calibration and maintenance of scientific equipment. This is a real challenge in terms of both the resources to maintain the process and the availability of trained engineers and calibration equipment. Managing these processes should be a priority for

4 DURC: https://www.who.int/csr/durc/en/
5 ISO: International Organization for Standardization

resource allocation as test results generated on unmaintained and uncalibrated equipment cannot be trusted to be accurate.

Provision should also be made for the laboratory services that will be required in a disease emergency. The laboratory maximum (surge) capacity for processing samples should be defined as well as a plan for scale-up of operations. This may include a diversion of resources from lower priority tasks. Capacity may be disease-specific and test turnaround times are also an important element in this specification.

All countries should support WOAH designated Reference Centres through submission of specimens, isolates of infectious agents and other information of potential regional or international significance. It is only through receipt of such submissions that the Reference Centres can fulfil their WOAH mandated role on behalf of the international community. Involvement with the designated Reference Centres is necessary for international public good.

In turn, national veterinary laboratories with special expertise in particular areas may seek recognition from international bodies such as WOAH, FAO[6] or WHO as reference laboratories or collaborating centres. This is encouraged, as it facilitates the harmonisation of laboratory procedures worldwide, and strongly supports the work of WOAH and other international organisations. Funding for reference laboratory status needs to be allocated from national sources, and this should be part of the national planning with the Veterinary Services.

Many veterinary laboratories carry out work for a range of different customers. As well as meeting the needs of Veterinary Services, the laboratory may conduct contract work for national or international parties, provide diagnostic and surveillance procedures for private veterinarians, veterinary organisations or livestock industries, test food or environmental samples for food safety or other public health reasons, perform regulatory testing of veterinary medicinal products, and carry out contract testing for the private sector, e.g. for pharmaceutical companies. It is the responsibility of the laboratory director and management team to ensure that a balanced approach is taken in the allocation of resources in order to deliver this complex array of services. There should be clear recognition of priorities to facilitate dealing with unexpected events such as disease emergencies.

In some countries, laboratory services are delivered through a number of laboratories, rather than through a single laboratory. In such cases, it is essential that the laboratories form a network, sharing best practice and information on testing, such that the Competent Authority has assurance that the same result is obtained, wherever testing is performed.

2. Quality assurance

Veterinary laboratories must be managed under a quality assurance system as specified in Chapter 1.1.5 *Quality management in veterinary testing laboratories* and should preferably be accredited to an international standard such as ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* (ISO, 2017). The laboratory should ensure that all of its procedures, not just those concerning the laboratory bench but also those for supporting documentation and computer records, are robust, reliable and repeatable.

The quality standards require that diagnostic tests used in the laboratory should be validated as fit for purpose. The international standard for validation of diagnostic tests is established by WOAH and is set out in chapter 1.1.6. Validation is not a once-for-all-time procedure but requires continual monitoring and refinement as the test is used. Laboratories should strive at all times to use tests that have reached at least stage 3 on the WOAH validation pathway (chapter 1.1.6) and to continue refining the validation data as explained in the text.

3. Research

Laboratories are likely to engage in research, such as development or adoption of new tests or test methods, or pathogenesis or epidemiological studies of infections important in the particular country. It is essential to manage effectively the balance between research and diagnostic service delivery and the potential for competition for resources, including staff time. Many laboratories undertake research aimed at disease awareness, preparedness and mitigation, and to inform policy in “peacetime”, with the research space configured and scientists trained and deployed to disease investigation and surge capacity diagnostic functions during outbreaks. Furthermore, such capability can provide for investigation of new and emerging diseases, or variants of known disease. Publication of

6 FAO: Food and Agriculture Organization of the United Nations

emerging disease threats, novel methods of detection and sharing of protocols with Reference Laboratories is encouraged.

4. Information and data for disease surveillance

Diagnostic laboratories may play a critical role in providing laboratory information and data to support routine disease surveillance activities and hence the claim of disease status in the country, which is essential to maintaining domestic and international trade. Apart from using fit-for-purpose surveillance tests as detailed in the relevant disease and quality management chapters of this *Terrestrial Manual*, laboratories should endeavour to ensure the compatibility of relevant information and data with that used in their central or national animal health systems if available or applicable.

C. SUPPORT SERVICES

1. Internal governance: policies and procedures

To ensure adequate standards of laboratory management across the spectrum of roles and responsibilities as identified in this chapter the responsible authority for the laboratory must ensure that laboratory management has adequate arrangements in place to deliver the required outcomes. These arrangements will include clearly defined policies and procedures supported by a management structure that is adequately resourced for implementation, audit and review. In many areas of activity, national legislation may provide the overarching standards to which laboratories must work and it is essential that compliance is seen to be mandatory, for the welfare of staff, the protection of the environment and the reputation of the laboratory.

Laboratory management should agree and document its policies for all aspects of operational activities. The processes by which such policies are implemented should also be documented in the form of clear procedures that are communicated to all staff who are involved in the particular activity. This approach has been introduced in some laboratories through the development of a quality assurance system, and is also applicable to other aspects of laboratory activity. The responsibilities of designated staff for oversight and implementation of policies and procedures should be included in the documentation and communicated clearly to all staff on the laboratory site.

2. Information management

Modern laboratories are increasingly dependent on computerised systems to manage their data. This can include an all-encompassing laboratory information management system (LIMS), bespoke systems for controlling individual laboratory equipment, and sophisticated analytical systems for use by specialised information scientists in disciplines such as molecular biology, informatics, epidemiology, risk analysis and statistics. A system that monitors location and quantities of high consequence pathogens is also common in high containment laboratories. There will also be office support systems for word processing, finance, HR and bibliographic databases. Systems for internal and external communications such as websites and email services will be needed. As with other elements of the laboratory's activities, it is essential that the computer systems are managed by competent professionals and that the scientific staff are consulted in specifying the services they require. Measures must be in place to protect the integrity of the data, for archiving and retrieval, and for privacy protection of personal or sensitive items. It is important that the laboratory clearly determines its needs and procures the necessary resources, either through a service contract with an IT support company or through the direct employment of IT professionals, so as to provide adequate support in this essential area.

3. Finance

The budget is an integral part of the annual laboratory business plan and will set a basis for negotiation with customers and funders. The director should be personally accountable for delivering the work programme of the laboratory within budget, while individual managers of projects or activities should be set delegated delivery and financial targets. For any but the smallest of laboratories, the director should be supported in this area by one or more finance professionals.

Laboratory management should identify all costs and their allocation to the appropriate area of activity, so that the total cost of delivering any particular service can be identified. The operating costs should include directly attributable items (such as reagents and equipment), staff time per procedure, administration (booking in samples,

generating reports), capital equipment (the cost of which may need to be spread across multiple activities or projects) and an appropriate proportion of overhead costs (covering such items as management, buildings, utilities, IT services, safety and quality procedures, and storage and archiving of samples and records).

Cost control is an essential part of laboratory management. Continual efforts should be made to improve efficiency without compromising on quality. It is to be expected that customers will seek to minimise the costs to them of the services received; however; it is also important that the Veterinary Services or other laboratory customers recognise the complexity of the expenses in running a laboratory.

For many laboratories revenue generation through the sale of services and products is an important component of their finances. There may be political or regulatory constraints that determine whether such activities can make a profit, break even or be subsidised from the government allocated funds, but in all cases where the laboratory recovers costs from submitters, the laboratory should have a transparent pricing policy.

An important aspect of financial management is procurement of equipment, laboratory supplies and services. It is likely that there will be government regulations with which the actual procurement processes must comply. However it is important that the scientific staff of the laboratory should prepare detailed specifications of their requirements, whether for reagent supplies, equipment, or external provision of services. If the specification is well prepared, then the procurement process should be able to secure appropriate supplies of the product at the required quality. Clear rules must be in place to prevent undue pressure or bribery being applied to procurement officers by suppliers. This risk must be monitored closely by the senior management of the laboratory and, if necessary, by the governing body.

4. Engineering and maintenance

A modern veterinary laboratory requires substantial and adequate engineering maintenance and support. It is possible to outsource many of these maintenance requirements, but in many cases an in-house capability may better serve the need. Familiarity of engineering staff with the biological impacts and risks associated with the systems is also important to ensure maintenance and repairs can be conducted safely. Most laboratories have site-specific needs and requirements that are best met with a reasonable complement of engineering and trade skills on site, with staff who are familiar with local needs and issues. A robust reliability programme helps to identify critical points of failure and ensure planned, preventive maintenance of these elements. Sufficient stocks of spare parts and supply lines should also be in place, supported by a stock management system, to ensure continuity. Maintenance schedules affecting laboratories should be carefully programmed in consultation with laboratory users to ensure continuity of operations as far as practicable. Laboratory management should regularly review how best to supply these support services.

5. Communications

Good communications that result in transparency of decision making and operations are vital to the success of a laboratory enterprise. This includes internal communications within the laboratory, ensuring that all staff are aware of the current priorities and how these impact on their work individually, as well as the wider activities of the laboratory and how their efforts contribute to the whole. It is essential that senior management is visible and has a system for communicating with staff throughout the laboratory and that this process genuinely works both ways. Senior managers must make efforts to be aware of the concerns and aspirations of their staff.

Externally, the director and management team must be effective advocates for the laboratory and represent it in meetings with Veterinary Services and other government officials, with scientists from other institutions, nationally and abroad, or with the wider public, including the media. It follows that the director and senior managers should be trained to interact with the media. This is a major priority particularly during a disease emergency, when effective communications with laboratory stakeholders is essential.

The key outputs from a veterinary laboratory are the scientific results and interpretation stemming from its analytical and investigational activities. These must be communicated to the customers or end-users in a clear, unambiguous and meaningful manner. Laboratory reports should include, where appropriate, indications of the level of uncertainty in the results, whether further results are still pending, and how to raise queries or clarifications or request further work. For their part, customers should be encouraged to provide as much additional relevant information as possible, when submitting samples, as this can greatly aid laboratory investigation and the interpretation of results.

A public information policy and procedures should provide a mechanism for individuals and outside bodies to ask about specific activities in the laboratory. Communications support staff should be involved in ensuring that the laboratory's customers are kept informed about the work of the laboratory, its successes and any constraints on future work. Laboratories may provide an internet website or other IT-based strategies to assist with such communications. The management team should also ensure that procedures are in place to ensure compliance with obligatory reporting and notification requirements.

Scientific staff should be encouraged and supported to attend conferences and present papers, while the production of a steady stream of good-quality written papers in refereed journals is vital to the success of a laboratory institution. Importantly, this does not apply only to the research scientists; those working in diagnostic and surveillance work can also play an important role.

D. CONCLUSIONS

Good governance and management of a veterinary diagnostic laboratory are essential for the safe, sustainable and effective delivery of a diagnostic service. This chapter identifies the range of issues to be addressed if laboratories are to meet international standards. Many aspects of the delivery of laboratory services are now highly regulated by national authorities, and laboratory managers must be familiar with these regulations and have compliance processes in place. Key elements of staff safety, biocontainment, biosecurity, quality assurance, animal welfare and environmental management are vital components of operating such facilities. The governance and management of these aspects are as important as the delivery of the actual diagnostic service.

A well managed laboratory will further ensure that the general provisions specified in the remaining chapters of Part 1 of this *Terrestrial Manual* are met as well as the specific standards for the diagnostic testing for specific disease agents as outlined in Part 2. A key component in providing customer assurance is conforming with the WOAH quality standard (chapter 1.1.5) supported by accreditation to quality standards such as ISO 17025. Accreditation is an important achievement of which laboratory staff can be proud, and implies that underlying compliance issues have been addressed.

Fundamental to the effective delivery of diagnostic services is the operation and maintenance of the facility and the scientific equipment. Allocation of adequate ongoing resources to this area is vital.

A successful veterinary diagnostic laboratory will have a highly trained, motivated workforce, with respect and support given to all individuals including both the frontline scientific staff and the important support teams providing vital services in areas such as finance, HR, safety, quality, procurement, engineering, IT and communications.

The achievement of all the above, and delivery of a respected and reliable service, requires a management system with checks and balances and effective review. This will include mechanisms to ensure political accountability, transparency, responsiveness, and coherent planning to ensure sustainability. A structure that includes an oversight process is strongly advocated to assist both financial management and strategic approaches to the delivery of all aspects of the laboratory's activities.

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NB: FIRST ADOPTED IN 2015. MOST RECENT UPDATES ADOPTED IN 2021.