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Accreditation of veterinary inspection systems

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Summary
Accreditation of Veterinary Services could be a key factor in facilitating international recognition of certificates. For this to occur, accreditation must be conducted within the international normative framework on compliance evaluation. The EN 45004 standard for inspection bodies is the most appropriate organisational reference. It makes a clear distinction between the technical activity of inspection, and decisions which fall within the competence of public authorities. However, there are few international normative texts describing inspection methods, which is a major obstacle to the development of a widely recognised accreditation system. Organisations that accredit inspection bodies exist in many countries, but there are no agreements on multilateral recognition. This paper describes the accreditation cycle and outlines the possibilities for accrediting networks or individual sites.

Keywords
Accreditation – Inspection – Organisation – Quality – Veterinary Service.

Introduction

As with other economic sectors, Veterinary Services cannot avoid the need to develop a quality management system. More and more new initiatives are being undertaken for various reasons: to improve the services being provided to those who use them; to optimise internal procedures and increase efficiency; to validate any decisions taken, in light of the increasing tendency to test such decisions before the courts; and to restructure a Veterinary Service in accordance with a revision of the legislative and regulatory framework.

In all these cases, this type of approach represents an important investment in human resources, for veterinary inspectors as well as for other technical and administration staff. The recognition of a quality system through accreditation is one way of ensuring that this effort continues to be invested, that progress is maintained, and the gains from this approach conserved.

However, recognising a quality system of accreditation also has far wider implications, which must be taken into account when choosing procedures for such recognition.

Factors in evaluating quality management systems for Veterinary Services

The organisation of a Veterinary Service varies greatly from one country to another. On the one hand, such variation is the result of the different epidemiological situations which each country must deal with; on the other, of the different political and cultural policy choices made by the country concerned. These variations may lead to the following:

– different divisions of responsibility among administrative bodies

– centralising or decentralising the organisation of the Veterinary Service

– increasing or decreasing use of private or public sub-contractors.

Despite the diverse ways in which different Veterinary Services are organised, the certificates issued by these Services for international trade in animals and animal products must all

engender the same level of confidence, no matter which country has issued the certificates. This is the objective of both the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade. Their aim is to limit technical or disease control barriers to international trade by developing a standardised international framework and principles of equivalence for internationally agreed-upon disease control measures. The evaluation and official recognition of the quality systems developed by the Veterinary Service of a particular country will reinforce international confidence in the reliability of veterinary certificates issued by that country.

There are also national reasons for encouraging the official establishment of quality assurance systems within Veterinary Services, quite apart from the motivating effect which such an approach has on staff. These reasons are as follows:

– those who benefit from the inspection service, whether they are food processing companies or farmers, are increasingly committing themselves to quality systems, due to demand from their customers. More and more businesses want to ensure that their management quality system conforms to the International Organization for Standardization (ISO) standard 9001 (13). An increasing number of breeding farms want to follow standards of good practice, by integrating management quality concepts into their approach. These companies and farmers expect the same high standards from those who inspect them. In particular, they want the same inspection principles to be applied throughout the market, so that no artificial distortions or unfair competitive advantages are created.

– recent food crises in industrialised countries have adversely affected consumer confidence in the enforcement of food safety inspections of products of animal origin.

– where the management of animal health risk is still under the control of a national authority, that authority can use this official evaluation of its systems to verify its capability to conduct this responsibility.

Such arguments are not unlike those used to develop quality systems and the international code of ISO 9000 standards in business, i.e. that these standards reinforce both internal and external confidence in the process (14).

These reasons demonstrate that official recognition of quality management systems is particularly applicable to the disease control activities of a Veterinary Service. For this reason, the author will examine only that field of activity. This analysis also shows that the internal systems of self-evaluation which already exist (general inspections, internal audits, etc.) are no longer sufficient to inspire confidence. An independent evaluation of the Veterinary Service conducted by a third party can respond to this double objective, of inspiring both national and international confidence, provided that it is based on widely recognised tools.

Concepts involved in evaluating compliance and their application to Veterinary Services

Different ways of evaluating compliance

The enforcement activities of a Veterinary Service involve evaluating compliance. This assessment of compliance must relate to a product, service, organisation or staff and it is conducted by comparison against a specific standard. The aim is to provide proof to the market that a product, service, organisation or worker meets the specific written requirements applicable to them.

Since the 1980s, an international standardisation framework has been developed to define and organise procedures for evaluating compliance, whether such procedures are conducted by private sector businesses or by public authorities (Table I). Four principal categories exist, as follows:

– self-evaluation by the supplier, where it is the sole responsibility of the supplier to guarantee compliance, and this is done through the supplier making a declaration

– calibration or testing of a product or material, which results in a calibration certificate or test report

– inspection, which results in a report from the inspection service or control authority

– certification, which can be conducted for an organisation (on its quality management system or environmental management) or on products, services or workers.

It is useful to make the distinction between *inspection* of a product or service and *certification* of that same product or service, as the terms are often confused (Table II).

a) Inspection is defined as the examination of a product design, product, service, process or plant, to determine whether it complies with specific requirements or – in the judgement of a professional expert – with more general requirements (EN 45004) (2). Inspection is a direct evaluation of compliance which applies only to the specific item (the product, batch or factory, etc.) being examined. The person who has conducted the examination may then declare that the item complies with the required standard.

b) Certification is the process by which a third party gives a written assurance that a product, process or service conforms to specified requirements (EN 45020) (7). On the basis of an evaluation and monitoring of the product, the process by which it is produced and the organisation which produces it, the

Table I
Survey of standards for compliance evaluation from the European Committee for Standardization/European Committee for Electrotechnical Standardization and the International Organization for Standardization (ISO)/Committee for the Evaluation of Compliance (1, 2, 3, 4, 5, 6, 9, 11, 12, 13)

Domain	Specifications used for evaluating compliance	Specifications for organisations which evaluate compliance (first level evaluation)	Specifications for accreditation bodies in charge of second level evaluations
Laboratories	Analysis or calibration methods (from: ISO 6579 for *Salmonella* research)	ISO 17025: 1999 General requirements for the competence of testing and calibration laboratories	EN 45003 (ISO/IEC Guide 58: 1993) Calibration and testing laboratory accreditation systems – General requirements for operation and recognition
Inspection	Inspection methods (from: regulation on carcass inspection)	EN 45004 (ISO/IEC 17020: 1998) General criteria for the operation of various types of bodies performing inspection	ISO/IEC TR 1710: accreditation body for inspection bodies
Certification	Product or service: normative specifications sheet or standard	EN 45011 (ISO/IEC Guide 65: 1996) General requirements for bodies operating product certification systems	EN 45010 (ISO/IEC Guide 61: 1996) General requirements for assessment and accreditation of certification/registration bodies
	Organisation: quality system: ISO 9001 version 2000	EN 45012 (ISO/IEC Guide 62: 1996) General requirements for bodies operating assessment and certification/registration of quality systems	
	Personnel: standards related to the expertise and working methods of personnel (from: ISO 19011, relevant to auditors and quality and environmental audits)	EN 45013: certifying bodies for personnel	
Self-evaluation and making a declaration		EN 45014 (ISO/IEC Guide 22: 1996) General criteria for supplier's declaration of conformity	

IEC: International Electrotechnical Commission

certifying body declares that the manufacturing process meets the defined requirements. Certification is thus an indirect evaluation of compliance, since it relies not upon the systematic inspection of each batch but on the confidence placed in the continuing ability of the organisation to meet the necessary requirements.

The companies or organisations which conduct compliance evaluations (testing or calibration laboratories, inspection or certification bodies) may undergo a second level of evaluation, through accreditation. Accreditation is defined as the procedure by which an authoritative body formally recognises that a particular body or person is competent to perform specific tasks (EN 45020) (7). Each evaluation is based on a specific standard (Table I).

Unlike certification, which simply states that the item conforms to the specific requirements of the standard, accreditation also evaluates the competence of the entire organisation. This is because evaluating compliance relies upon the ability of the organisation to closely follow defined rules (for methods of analysis and inspection, etc.), but also on the

Table II
Differences between inspection and certification of a product or service (9)

Domain	Product or service inspection	Product or service certification
Nature of the evaluation	Direct evaluation of the compliance of an individual unit: animal, batch, factory	Indirect evaluation of compliance for a line of products, always by a third party
Assurance of compliance	Limited to the inspected unit and to the specific time of the inspection	Certification gives continuing assurance of compliance for the manufactured product
Decision on compliance	Can be made by the person who conducts the inspection	Certification is decided by someone other than the person who conducted the evaluation
Licence and branding of products	Can be included only on the label of the individual product (or batch) inspected	A certificate or licence is given to all products manufactured here for a specified time period. Appropriate labels may be placed on all the products or services which come under this area of certification
Monitoring	Not compulsory	Compulsory, as per the certification schedule

expertise of those who are judging the product, service or organisation under examination. This is why the accreditation process relies upon audits conducted by expert professionals in the field.

For example, a laboratory conducts a compliance evaluation on the basis of analytical performance. These analyses have been conducted according to the required methods described in the standards. The laboratory is evaluated by an accreditation body, which verifies that the laboratory complies with the ISO 17025 standard (12), and that it has a qualified workforce who correctly apply the analytical procedures for which it is accredited. The test report describes in detail the analytical standard used and thus clients can have every confidence in a laboratory which carries the stamp of the accrediting body.

This international standards framework, which is recognised by businesses and authorities in every country, may equally be applied to the evaluation of the disease control activities of a Veterinary Service.

Accreditation principles applied to a Veterinary Service

When using the principles of accreditation to evaluate a Veterinary Service, four issues arise, as follows:

– choosing the type of accreditation which is applicable

– defining the corresponding standards

– choosing the unit to be accredited

– choosing the accreditation body.

The accreditation of a Veterinary Service as an inspection body depends upon defining its disease control activities. By referring to Table II, certain activities are easy to classify as inspection activities. For example, inspecting carcasses at the abattoir clearly corresponds to evaluating a particular unit to determine whether it meets the appropriate health regulations. Other activities come more readily under the heading of certification. For example, the preliminary inspection of a food processing plant, to authorise it to produce and market products of animal origin on the domestic market or for export, can be categorised as certification. However, this approach does raise several problems, as follows:

– where certification includes the power to authorise or withdraw authorisation, it is in effect bringing a government power into the field of accreditation. If accreditation is withdrawn from an organisation for not fulfilling the requirements of the standard, the ability of the accreditation body to use this power may be called into question.

– the certification standards EN 45011 and EN 45012 (5, 6) require the principle of impartiality to be followed by establishing a certification committee in which all the relevant parties (farmers, food-processing businesses, consumers, experts) have equal representation and power concerning certification decisions. This is much more difficult to apply in the case of government organisations (such as a Veterinary Service), where impartiality is ensured indirectly, in most countries, by national representation and political power through the electoral system.

For all these reasons, it is crucial to separate the technical act of evaluation, that is, inspection, from the policy decision taken by the public authorities, whether this decision involves an authorisation, or, in the case of the inspected body being at fault or committing an offence, a penalty. In the example given by the author, the preliminary evaluation of the food processing plant is an act of *inspection*, whereas the decision to authorise the plant (or not) is a power of the State. This approach to accreditation also has the advantage of being applicable to whatever method of organising the Veterinary Service has been adopted by each country: whether inspection is conducted by government services or by decentralised services or whether inspection has been sub-contracted to private inspection bodies.

The choice of appropriate standards, as in the laboratories, involves choosing an organisational standard and one or more technical references for the actual inspection process. In the veterinary context, the organisation standard EN 45004 (or ISO/IEC 17020) (2, 9), which describes the general requirements of the organisational structure and functioning of an inspection body, can be met by following the guidelines given in the *International Animal Health Code* of the OIE (World organisation for animal health) (15) (Table III).

However, unlike standards for methods of analysis, technical standards for methods of inspection are much less developed at international level. Principal guidelines are often described either in the national or supra-national regulations, which define ways of organising veterinary controls, or in specific internal documents within the Veterinary Service of each country. The development and recognition of accreditation for Veterinary Services will also depend on formalising inspection methods. This is an indispensable element of promoting international recognition of the evaluation process by all parties. It is because analytical methods have been internationally standardised and an accreditation system exists for laboratories that both private businesses and public authorities recognise the value of a test report from an accredited laboratory. The standardisation of inspection methods is equally important in ensuring harmonisation of these methods among different countries, which, in turn, is one of the priorities for enforcing the international standardisation framework established by the WTO, in relation to international organisations such as the OIE and the Codex Alimentarius, for facilitating international trade.

The body to be accredited will vary according to the particular Veterinary Service in each country, and depending on the regional organisation of its services (by state, by province, by autonomous body etc.). According to the EN 45004 standard

Table III
Comparison between the guidelines for the evaluation of Veterinary Services described in standard EN 45004 and those given in Chapter 1.3.4 of the OIE (World organisation for animal health) *International animal health code* (2, 15)

Chapter of the EN 45004 standard	Principal corresponding points in Chapter 1.3.4 of the *International animal health code*
4. Administrative requirements	Article 1.3.4.3: Evaluation criteria for the organisational structure of the Veterinary Services Article 1.3.4.6: Evaluation criteria for material resources (1. Financial resources)
5. Independence, impartiality, integrity	Article 1.3.4.3: Evaluation criteria for the organisational structure of the Veterinary Services
6. Confidentiality	
7. Organisation and management	
8. Quality system	Article 1.3.4.4: Evaluation criteria for quality systems Article 1.3.4.10: Performance assessment and audit programmes
9. Personnel	Article 1.3.4.5: Evaluation criteria for human resources
10. Premises and equipment	Article 1.3.4.6: Evaluation criteria for material resources (2. Administrative 3. Technical)
11. Inspection methods and procedures	Article 1.3.4.7: Functional capabilities and legislative support Article 1.3.4.8: Animal health controls Article 1.3.4.9: Veterinary public health controls
12. Handling of samples and items submitted for inspection	
13. Record-keeping	
14. Inspection reports and certificates	
15. Subcontracting	
16. Claims and appeals	
17. Co-operation	Article 1.3.4.11: Participation in OIE activities

(2), the inspection body is a unit or a service provided by a unit and management must make available to this unit everything it needs to implement its inspection policy. This means that the unit must have autonomy of decision-making in terms of human resources and financing. This can occur when the accounting system ensures that the inspection unit remains independent from other veterinary activities. Indeed, a unit which does not have control over its human resources cannot be accredited, since that could lead to depending upon a unit which is suddenly unable to achieve its objectives when certain staff members leave. Inspection units may differ from country to country: accreditation of a network at the national level for organisations which are relatively centralised, as in France; accreditation of regional bodies or locations where supervising bodies are decentralised (for example, the control of animal product markets and catering control by city health services); accreditation of private inspection bodies if some tasks have been subcontracted to these organisations. In any case, only an accredited inspection body can make the decision to subcontract an enforcement task.

Finally, choosing the accreditation body: in most countries, a single accreditation body exists which supervises all accreditation activities: the Comité français d'accréditation (COFRAC) in France, the United Kingdom Accreditation Service, and the Dansk Akkreditering service in Denmark. In some countries, accreditation activities are divided among different bodies. This is the case, for example, in Germany, where the Deutsche Akkreditierungs Rat deals with the accreditation of testing laboratories and certification bodies and the Deutscher Kalibrierdienst is in charge of calibration laboratories. In any case, there can only be one accreditation body in each country for a given domain. Indeed, as this is a second-level evaluation, there cannot be any competition between the accreditation bodies. Most existing accreditation bodies are often found in the private sector, even if their responsibilities are in the public interest. However, it is possible to imagine a government organisation in charge of the accreditation of State services. Nevertheless, this public organisation must also fulfill the conditions imposed on any other accreditation body, as follows:

– to meet the requirements of standard ISO/IEC TR 17010 (11), in particular, the requirements of independence and impartiality when consulting the different parties affected by the accreditation (accredited bodies, clients of accredited bodies, the government, etc.)

– to have sole charge of the relevant field of accreditation, so that there is no competition with any other accrediting bodies in the country

– to be a signatory to any multilateral recognition agreements.

If each country has its own accreditation bodies at its disposal, equivalence can be achieved from one country to another due to multilateral accords which recognise that, through audits and surveillance procedures, all the accreditation bodies which are signatories of these accords work in the same manner. For example, there is the European Co-operation for Accreditation Agreement in Europe and the agreements of the International Accreditation Forum at international level. These agreements already cover the accreditation of testing and calibration laboratories, as well as that of certification bodies. However, agreements in the field of inspection are still in the course of preparation.

Accreditation by a third party, other than a Veterinary Service, is thus possible. However, it must be ensured that:

– on the one hand, the governing functions of the State are not affected by any accreditation which deals only with the quality of the inspection itself (independence, competence of the inspectors, impartiality) and not with any decision taken by the competent authority as a result of this inspection

– on the other hand, the continuity of the service, quantitatively (e.g. the number of inspections) as much as qualitatively, is not called into question by a possible accreditation withdrawal. This eventuality must be anticipated through specific measures (conducting inspections under the supervision of another accredited service, etc.).

The accreditation process for an inspection body: the example of the Comité français d'accréditation

The accreditation process for an inspection body developed at COFRAC is similar to that developed in other countries (8, 10).

Initial accreditation involves four steps, as follows:

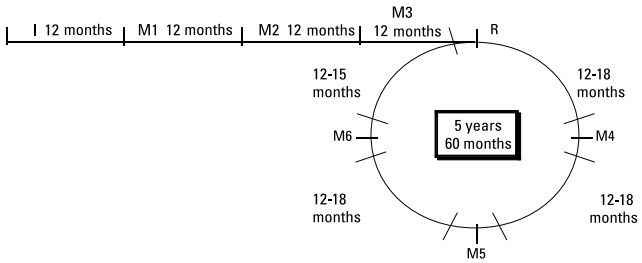
– the first phase, opening the file, involves registering the application of the inspection body and verifying, through a preliminary questionnaire, that the organisation is ready to be audited. The inspection body must specify the field of inspection in which it wants to be accredited: this field may involve all its activities, or one particular domain, chosen according to its level of preparedness and the expectations of its clients or supervisors.

– in the next phase of evaluation, an audit is conducted at the premises of the inspection body. Audits are performed by an audit team, consisting of an audit manager, a quality auditor who is a specialist in standard EN 45004, and one or more technical auditors, who are familiar with the inspection domain or domains being audited. The role of the quality auditor is to ensure that the organisational requirements of the EN 45004 standard are fulfilled, whereas the role of the technical experts is to verify the appropriateness of the work methods used by the inspection body to conduct the inspections for which it wants to be accredited. The presence of two auditors is important because the organisational and technical requirements are very closely linked. For example, a failure in inspection methods can be caused by bad management of human resources at either the training or recruitment stage. The audit report is produced by the audit team.

– after the audit, the decision on whether to accredit is taken by the committee of the inspection section, comprising representatives from inspection bodies, purchasers and clients, government representatives and experts. In reality, this decision is often made by a permanent accreditation committee (*Comité permanent d'accréditation*: CPA), composed of a smaller number of committee members, based on the audit results. The larger committee only takes over the decision if the CPA members cannot come to a consensus. This decision may take the form of recommending accreditation; recommending a waiting period during which further information can be gathered, another audit conducted to verify that issues of non-compliance have been resolved, or a refusal.

– Notification of accreditation is made by the Director of COFRAC, who awards an accreditation certificate.

Following this process, accreditation monitoring requirements can be met by surveillance audits scheduled every 12 to 18 months (Fig. 1). These monitoring audits confirm that non-compliance issues from the previous audit have been resolved and that the system has been adequately maintained, through exploration and analysis of any changes made by the organisation. The renewal audit, conducted four years after initial accreditation, is a complete audit, like the first.



I = Initial accreditation audit
M = Monitoring audit
R = Renewal audit

Fig. 1
Accreditation cycle for inspection bodies at the Comité français d'accréditation, the body which supervises all accreditation activities in France (8)

The inspection body can, at any time, apply for an extension of its accreditation to new areas. An audit process will then be implemented to evaluate the body in these new areas of inspection.

An inspection body which is housed on several sites can apply for an accreditation for each site or an accreditation for the entire network. Accreditation by individual site involves the auditing of and awarding of an accreditation certificate to each site. Accreditation by network is possible if each site is organised in the same way and uses the same procedures. In this case, an audit is conducted on the headquarters of the network, as well as on several sites chosen at random to ensure that the organisation and resources of the network are applied in exactly the same manner throughout. A single certificate is awarded to the entire network. This type of accreditation has the advantage of reducing the costs of accreditation by limiting the number of audits. It reinforces the uniformity of the practices followed throughout the network, as well as promoting the image of the inspection being conducted in the same way by each of the different sites. This approach can be adapted for Veterinary Services which have decentralised services while applying the same arrangements for each. However, any withdrawal of accreditation will involve all the

sites and call into question the quality of inspection throughout the entire network. It is thus an important strategic decision which should be thoroughly investigated before choosing between these two methods of accreditation.

Conclusion

The accreditation of Veterinary Services is a tool which can reinforce confidence in the quality of controls exerted by the Service, as much at national level among consumers and others who benefit from these controls as at international level, where accreditation aids in promoting the recognition of certificates.

This accreditation must be based on the international standardisation framework as defined for the task of evaluating compliance. The EN 45004 standard for inspection is the standard best suited to apply to the diverse range of Veterinary Service organisations throughout the world, as well as to differentiate the task of enforcement from the governmental powers of the State or public authorities who can give assent to, or penalise, the organisation concerned, after the inspection has taken place (2).

However, the accreditation of a Veterinary Service will also require the development of technical standards on the methods of inspection, work which may be included in the priorities defined by the OIE and the Codex Alimentarius. Standards for methods of inspection are important tools for promoting discussion between the inspector and those being inspected on the objectives of the inspection process. International interest in accreditation will be reinforced as soon as a multilateral agreement recognising accreditation in the area of inspection has been signed by existing accreditation bodies.

However, in addition to these general rules, the Veterinary Service of each country should first define its strategy on accreditation, according to its particular situation and priorities. Should the Service choose accreditation by a third party or self-evaluation? Which areas of inspection should be made a priority (exporting of live animals, controls on food products)? Which bodies should be accredited first (the network, regional or local services, subcontractors, etc.)?

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