

# Toward Global Harmonization of Training and Certification of Specialists in Laboratory Animal Veterinary Medicine

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Laboratory animal medicine (LAM) is a corner stone of animal-based research and has been a veterinary specialty for over 60 y. Today 5 Colleges of LAM (American, European, Japanese, Korean, and Indian) that certify specialists (Diplomates) in LAM are members of the International Association of Colleges of LAM (IACLAM). Goals of IACLAM are to support the development of new Colleges of LAM, to harmonize expectations for the knowledge and skills of newly certified LAM Diplomate, and to harmonize the standards (best practices) for training and examination of candidates among the member Colleges. IACLAM recently conducted an in-depth review and comparison of oversight, training, credentialing, and examination standards in the 5 Colleges as part of an initiative to create a framework for harmonization and consistency for these activities across the 5 Colleges. The process has led to an agreement on recommendations for knowledge and skill requirements for a newly certified Diplomate, as described by each College in a detailed role delineation document (RDD). The RDD is based on task analyses of the work responsibilities of laboratory animal veterinary Diplomates. This agreement is an important step toward the goal of global harmonization of LAM Diplomate training. Further efforts are planned for areas such as training, research, publication, and examination. This paper describes the role and content of the RDD and lists the differences and similarities among the RDDs of 5 Colleges of LAM.

**Abbreviations:** ACLAM, American College of Laboratory Animal Medicine; ECLAM, European College of Laboratory Animal Medicine; IACLAM, International Association of Colleges of Laboratory Animal Medicine; ICLAM, Indian College of Laboratory Animal Medicine; JCLAM, Japanese College of Laboratory Animal Medicine; KCLAM, Korean College of Laboratory Animal Medicine; LAM, Laboratory Animal Medicine; RDD, Role Delineation Document

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Laboratory animal medicine (LAM) is a corner stone in animal-based research and has been a veterinary specialty for over 60 yrs. Today it reflects the international nature of biomedical research and science. In 2005, the International Association of Colleges of LAM (IACLAM) was founded to help LAM colleagues communicate, exchange information and resources, and to define and harmonize the roles of LAM veterinary Diplomates globally.<sup>17</sup> IACLAM's goals are to promote improved animal welfare policies and standards worldwide and to use resource sharing to enable development of the LAM specialty in countries or regions in which it does not yet formally exist.

Today IACLAM represents over 1600 LAM Diplomates from the 4 original Colleges [the American (ACLAM 1320), the European (ECLAM 104), the Japanese (JCLAM 188) and the Korean College of LAM (KCLAM 50)] to the scientific community, government bodies, and public. The Indian College of LAM (ICLAM) was developed in 2019 and 2020 and then admitted to IACLAM in December 2020. IACLAM is intending to investigate the roles and responsibilities of the LAM veterinary Diplomate and establish recommendations on required training and skill sets that will benefit animal welfare and scientific quality. The specialty is very broad and encompasses specific knowledge of several animal species that are not always part of the curriculum presented during veterinary education (for example, nonhuman primates, rodents and zebrafish). Challenging areas facing LAM Diplomates are transportation, housing and care, ethical use in research, health management, adoption and euthanasia of research animals, to mention a few. Recently, a taskforce initiated and sponsored by IACLAM published a systematic review on the welfare impact of carbon dioxide euthanasia in mice and rats.<sup>16</sup>

In 2018, an IACLAM task force reviewed the training and certification requirements of the member Colleges. The goal was to promote harmonization of expectations and requirements

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of Diplomates in the initial 4 Colleges. Diplomate is a title that refers to a veterinarian who is certified in a veterinary specialty area, in this case in the field of laboratory animal medicine. A questionnaire was compiled for an in-depth review and comparison of oversight, training, credentialing, and examination standards in the different Colleges (Supplement 1). The survey resulted in an agreement in April 2020 by the 4 Colleges and ICLAM on recommendations for minimal knowledge and skills that are required by a newly certified Diplomate. This is an important first step toward global harmonization of training of a LAM Diplomate. This agreement and the current manuscript describe the required knowledge and skills contained in the role delineation document (RDD) of the Colleges and can provide a model for newly formed Colleges when setting up standards for training.

### Role Delineation Document (RDD)

The purpose of the RDD is to describe the tasks that must be competently performed by the Diplomate and to identify the minimal knowledge and skills necessary for performing those duties. The RDD is used to plan resident training programs and can aid residents preparing to take a certifying examination. The exam content correlates with the content of the RDD as part of quality assurance, and the RDD must be revised regularly to

ensure that it truly reflects current duties and skills required of the LAM Diplomate. These duties and skills will change over time as biomedical science using animals and societal expectations regarding animal use evolve. In 1997 ACLAM was the first College to develop an RDD.<sup>2</sup> In 2017, ECLAM developed a similar document that defines so called learning modules and serves the same purpose as an RDD.<sup>5</sup> JCLAM,<sup>12</sup> KCLAM<sup>13</sup> and ICLAM,<sup>10</sup> developed their RDDs in 2020, using the ACLAM RDD as a template.

Because biomedical research is a global enterprise, and IACLAM strives to optimize animal welfare and high consistency and quality of research, the RDDs should reflect the similarities of the Colleges. The RDDs of ACLAM, JCLAM, KCLAM, and ICLAM are structured in the same manner, with 6 domains of tasks and knowledge (Figure 1). The tasks are divided into those required at certification and those usually performed after LAM Diplomate certification. Knowledge needed at certification is divided into what is usually learned during basic veterinary training and what is learned after veterinary school (for example, during residency). Tasks that are performed after certification are learned on the job or through continuing education and recertification.

ECLAM's document has 6 modules that describe tasks, knowledge, and skills. Despite its different format, the ECLAM

<b>Role delineation domains and tasks of ACLAM, JCLAM, KCLAM, and ICLAM</b>	<b>ECLAM learning modules</b>	<b>Differences between domain and module</b>
Management of Spontaneous and Experimental Induced Diseases (prevent, control, diagnose and treat disease or condition)	Surveillance of health status; prevention, detection, treatment and control of disease and disaster planning for outbreaks	Domain specifies anatomy, physiology, parasitology, microbiology, pathology, pharmacology, epidemiology and behavior as part of knowledge requirement
Management of Pain and Distress (recognize and minimize pain and distress, administration of anesthesia, euthanize)	Advice on anesthesia, analgesia, surgery, perioperative care and alleviation of pain and distress  Assess the wellbeing of animals and assign severity classification	Modules specify animal welfare, training of animals, suffering, severity, cumulative severity, reuse and rehoming
Research (Facilitate or provide research support, advise and consult with investigators, design and conduct research)	Advice on study related matters of animal health and welfare, animal models, experimental design, the 3Rs and severity assessment	Domain includes conducting research and scientific writing, knowledge on gnotobiotics, information resources, genomics, metabolomics and proteomics
Animal Care (Develop animal husbandry programs, provide management/oversight of animal husbandry programs and LA facilities)	Provision of advice regarding animal husbandry, housing and care	Domain includes developing and management of animal husbandry programs and management of facilities, quality assurance, pest control, environmental effects and monitoring and genetic monitoring Module includes "culture of care" <sup>14</sup>
Regulatory Responsibilities (Attending Veterinarian responsibilities, advocate for humane animal care and use, advice occupational health and safety programs, provide hazard advice, serve on/advice IACUC, review protocols)	Advice and veterinary services regarding transport, import and export of animals  Regulations, Ethics, Training and Facility Design	Domain specifies national regulations whereas Module specifies European legislation. Both include Good Laboratory Practice, Occupational Health and Safety program, AAALAC <sup>1</sup> and disaster planning. Domain includes Controlled Substances Act, Live Animals Regulations (IATA), CITES, <sup>6</sup> Recombinant DNA Guidelines, Occupational Health and Safety legislation and international laws. Specifies research ethics. Module includes the Animal Health Law <sup>7</sup>
Education (train personnel in animal care and use, maintain current knowledge and continued competence in LAM)		Domain specifies organizations pro- and anti-animal-based research and history of animal research

\*Some parts of the description have been left out in the compilation. Full descriptions can be found at the Colleges' websites<sup>2,5,10,12,13</sup>

**Figure 1.** Domains and modules with tasks, knowledge, and skills tested by the LAM colleges in the examination.

Topic	Skills required at time of certification	Knowledge required
<b>Management of spontaneous and experimentally induced diseases and conditions</b>	Prevent spontaneous or unintended disease or condition	Diagnostic procedures (conduct of a physical examination; clinical pathology; species-specific behavioral assessment; serologic, cytologic, and molecular diagnostic tests and proper sampling techniques)
	Control spontaneous or unintended disease or condition	Surgical techniques associated with diagnostic and therapeutic surgeries
	Diagnose disease or condition as appropriate	Anatomy with emphasis on features which have significance with regard to clinical medicine or experimental medicine
	Treat disease or condition as appropriate	Parasitology with emphasis on parasitic diseases that can become established in a colony and zoonotic parasitic diseases
		Nutrition with emphasis on effects of deficiency or toxicity
		Physiology with emphasis on normative data and characteristics, metabolic differences or metabolism of induced disease, reproductive physiology, and clinically significant physiologic features
		Immunology
		Microbiology with emphasis on organisms of clinical significance; subclinical infections that cause physiologic, biochemical, and/or immunologic alterations; zoonotic disease organisms; organisms used experimentally to induce infection and unintended infections; and sampling and culture techniques for such organisms
		Anatomic pathology including pathogenesis of significant naturally occurring and experimentally induced diseases; typical gross and histopathologic lesions; and pertinent anatomic pathology techniques
		Pharmacology with emphasis on drugs used to treat spontaneous or induced disease, and drugs used to induce disease
		Epidemiology including species-specific susceptibility to induced disease
		Preventive medicine
		Genetics with emphasis on control and treatment of naturally occurring and experimentally induced disease, predisposition to disease, and modes of inheritance
	<b>Management of pain and distress</b>	Recognize pain and/or distress
Minimize or eliminate pain and/or distress		Effects of pain and distress on normative physiology and on research studies
Administration of anesthesia		Critical and postprocedural care techniques
Euthanasia		Assessment of pain and distress
		Causes of pain
		Causes of distress
		Patient monitoring
		Pharmacological interventions for pain and distress and their effects on physiology, including age and species differences for such interventions, and depth and duration of analgesia provided by such interventions
		Nonpharmacological interventions for pain and distress and their effects on physiology, including age and species differences for such interventions
		Euthanasia
<b>Research</b>	Facilitate or provide research support	Genetic modification/engineering technology including application of molecular biology techniques
	Advise and consult with investigators on matters related to their animal research	Animal models including normative biology relevant to the research

	Design and conduct research	Biomethodology techniques
		Genetics and nomenclature
		Research methods and equipment
		Characterization of animal models
		Gnotobiotics
		Experimental surgical techniques and instrumentation
		Principles of experimental design and statistics including scientific method
		Information resources
		Scientific writing
		Replacement, reduction and refinement techniques
		Effective methods of communicating research-related concerns
		Aseptic requirements for performing surgery
		Genomics, metabolomics, and proteomics
<b>Animal care</b>	Develop animal husbandry programs	Pathogen-free barriers, maintenance of pathogen-free colonies via sentinel use and surveillance programs
	Manage or provide indirect management/oversight of animal husbandry programs	Environmental enrichment, species-appropriate behavioral and psychosocial needs including creation and maintenance of appropriate social pairs or groups
	Manage or provide indirect management/oversight of laboratory animal facilities	Quality assurance techniques for animal care-related equipment and supplies
		Methods of sterilization, sanitation and decontamination
		Animal procurement considerations
		Breeding colony management
		Animal identification systems
		Pest control management
		Species-specific husbandry
		Containment facilities
		Environmental causes of physiologic alterations in animals and their effects on research
		Environmental monitoring
		Watering and feeding
<b>Regulatory responsibilities</b>	Perform direct or delegated Attending Veterinarian responsibilities	Laws, regulations, policies and standards
	Advocate for humane care and use of animals	Role and function of the IACUC
	Provide advice to occupational health and safety programs	Protocol review
	Provide advice on biologic, chemical and radiation hazards in an animal research program	
	Serve as a member of an IACUC	
	Review protocols and provide advice to investigators and the IACUC	
<b>Education</b>	Train personnel in animal care and use	Educational resources
	Maintain current knowledge and continued competence in laboratory animal medicine	Certification programs
		Societal issues involving use of animals

**Figure 2.** Minimal knowledge and skills required of an LAM diplomate at the time of certification, as agreed on by the IACLAM member colleges.

document is consistent with the RDDs of the other Colleges with respect to the knowledge and skills required at the time of certification. The differences are outlined in Figure 1. The most detailed of the RDDs is that of ACLAM, which provides examples of domain knowledge. All LAM Colleges, through their RDDs, agree that all diplomates should have the minimal knowledge and skills outlined in Figure 2. All RDDs specify tasks and knowledge that are predominantly acquired during graduate veterinary training and residency training.

The RDDs of ACLAM, ECLAM (learning modules), JCLAM, KCLAM, and ICLAM differ in terms of whether some knowledge is acquired during veterinary or residency training. An example of these differences is found under the topic “Management of spontaneous and experimentally induced disease and conditions.” JCLAM and KCLAM expect that the knowledge of anatomy, physiology, parasitology, microbiology, subclinical infections, zoonotic disease, organisms used experimentally to induce infection and unintended infections, anatomic pathol-

ogy, and pharmacology would be acquired during veterinary training, whereas ACLAM, ECLAM, and ICLAM expect that this knowledge should be acquired by the time of certification (for example, during residency training). These differences can be attributed to the different curricula of veterinary training programs in various countries. All 5 Colleges require newly certified LAM Diplomates to be fully cognizant of all laws, regulations and guidelines applicable to the specific College. Knowledge of international law would be acquired after certification. Despite the differences in when individuals might gain the knowledge, the expertise expected of a newly certified LAM Diplomate is harmonized across all 5 Colleges. The performance standards and training outcomes for the specialty of LAM are largely aligned through the certification examination and relevant training programs.

All IACLAM Colleges specify which animal species are most important for their Diplomates in terms of knowledge and skills, defining them as primary or secondary. ACLAM, ECLAM, and ICLAM also list species of tertiary importance. Candidates are expected to have the most in-depth knowledge of primary species, followed by secondary and tertiary species, and examinations are weighted as such. The importance is based on the numbers of animals of each species that are used in research in the particular regions covered under each College. The primary species are very similar across the Colleges. A comparison of species important to each College has been constructed (Supplement 2). All 5 Colleges agree that the mouse, rat, and rabbit are of primary importance; all but ICLAM define macaques as a primary species (ICLAM views macaques as a secondary species), and ICLAM considers guinea pigs primary, whereas the other 4 Colleges view guinea pigs as a secondary species. All 5 Colleges agree that goats, sheep, Syrian hamsters, and zebrafish are secondary species. All Colleges, with the exception of ICLAM, view pigs as a secondary species (ICLAM views pigs as a tertiary species). JCLAM gives special importance to some specific species such as Japanese killifish (medaka), carp, and Japanese quail. ACLAM, ECLAM, and ICLAM consider reptiles as a tertiary species, but JCLAM and KCLAM do not include them at all.

## Discussion

The content of the colleges' RDDs shows the breadth and depth of skills and knowledge that a LAM Diplomate must acquire during training. This broad knowledge is necessary for a LAM Diplomate to participate as an integral part of the research team and contribute to achieving the 3Rs (Replacement, Reduction, and Refinement) of animal research and to the quality of science.<sup>4,17</sup> The 5 IACLAM Colleges agree on the skills and knowledge needed for a LAM Diplomate, which is in part due to the fact that biomedical research is a truly international enterprise. Because ACLAM was the first LAM College to establish an RDD, other Colleges somewhat naturally used ACLAM's RDD as guidance document and as a template for training. A likely reason for ECLAM's document being the least similar (in form more than in content) is the European Directive on the use of animals in research.<sup>8</sup> The Directive has a strong emphasis on the 3Rs and animal welfare, which are the backbones of ECLAM's learning modules (RDD). Apart from ECLAM, the RDDs of other Colleges are primarily focused on the other components of LAM.

National or regional differences in veterinary education and the rules of relevant governing bodies influence the structure of the RDD. The largest differences in RDDs are found in the requirements for knowledge of regulations, although some

agree that a Diplomate should be aware of regulations and laws governing laboratory animal use in other countries or regions. Another difference is that JCLAM, KCLAM, and ICLAM expect more knowledge to be gained in veterinary school; these knowledge areas include anatomy, pharmacology, and parasitology related to laboratory animal species, and pathology related to experimentally induced disease. Certain differences, such as which animal species are considered secondary, are due to cultural and geographical differences. For example, carp and Japanese quail are not commonly used in animal research outside of Japan; however, they are an important species for certification in Japan. Another difference is that ECLAM's document states that the LAM Diplomate must "not only know a vast amount of facts, but also be able to make an analysis, create a synthesis and to evaluate, reason and argue for a solution in different situations and circumstances", that is, to have a high level of critical thinking skills.<sup>3</sup> ECLAM further refers to 3 other sources for information of knowledge and skills: a European position paper on training in LAM,<sup>15</sup> an expert working group document on education and training<sup>9</sup> and a dossier of competencies for Laboratory Animal Science and Medicine programs by the nonprofit association Veterinary Continuous Education in Europe.<sup>18</sup>

**Challenges ahead.** The agreement on minimally required skills and knowledge in a LAM Diplomate is the first step toward harmonization of LAM Colleges. IACLAM's strategic plan of 2020 specifies the target of harmonization of publication requirements, alternatives to residency requirements, residency training program requirements, and exam methodology over the next few years.

Harmonization of performance standards for certification and the creation of guidelines could improve consistency in the application of knowledge and skills needed to become a Diplomate in LAM, regardless of the country in which the College exists. This improvement would allow an LAM Diplomate to be a stronger member of the research team who is better able to contribute to the welfare and care of laboratory animals worldwide. Further areas for finding common ground relate to residency training, publication requirements and exam structure. The Colleges are not independent educational entities but are governed by national or regional veterinary Diplomate boards, such as the AVMA, the European Board of Veterinary Specialization, the Japanese Society of Veterinary Science, the Korean Veterinary Medical Association and the Indian Laboratory Animal Scientists' Association. Member Colleges differ in further areas such as residency training, alternatives-to-residency training, publications, and examination methodology; these differences make mutual recognition of College Diplomates difficult. However, ECLAM and JCLAM allow Diplomates of all IACLAM Colleges to become members without an additional qualifying exam. Apart from national or regional legislation and specialist board requirements, the largest obstacle for movement of LAM Diplomates across cultures and between countries would be language, although English is considered to be the international language in science.

IACLAM's goal is not to standardize training and certification, but to harmonize recommendations as a means of supporting optimal and consistent welfare of research animals and high quality research globally. Standardization and harmonization have 2 quite different definitions. The main difference between them lies in the degree of adherence to an agreed-upon standard. Harmonization aims to reduce the variation in a standard, while standardization often aims to eliminate any variation. Standardization is often a formula that describes the best or

required way of doing something. It is “the distilled wisdom of people with expertise in their subject matter who knows the needs of an organization they represent...”<sup>11</sup>. Various regulatory bodies such as USDA and the FDA rely on strict adherence to engineering standards and regulations. Harmonization relies on achieving a performance standard through the judicious use of sound professional judgement despite variation in the processes used to adhere to or conform with a guideline or standard. IACLAM aims to harmonize training and veterinary skills and knowledge with the goal of global recognition of LAM Diplomates. Recommendations for harmonization help to guide Colleges of LAM, and one of IACLAM’s goals is to aid LAM Colleges in this pursuit. IACLAM allows representatives of Colleges that aspire to become members to participate in meetings as non-voting observers. Becoming a full member of IACLAM is further advanced through associate membership.

## Conclusion

The agreement of 5 major Colleges of LAM in the USA, Europe, Japan, Korea, and India on the minimal knowledge and skills expected of newly certified Diplomates of LAM is a significant accomplishment. This achievement is the cornerstone for future efforts to harmonize formal residency training, alternative-to-residency requirements, research and subsequent publication expectations, recertification, and examination methodology for Colleges of LAM.

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## Supplemental Materials

**Figure S1.** IACLAM member colleges questionnaire.

**Figure S2.** Comparison of species of species importance to each college.

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