



Quality Systems and Animal Welfare in Research

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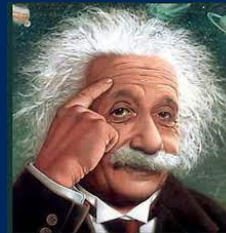
Agenda

- Quality and Animal Welfare Frameworks
- Available Quality Systems in Practice
- Comparison

Quality ...why?



- Health status
- Genetics
- Environment



- Experimental procedures
- Husbandry procedures
- Personnel competence





Quality and Animal Welfare?

Ethics: The Principles of the 3Rs

- Replacement
- Reduction
- Refinement

The Principles of Humane Experimental Technique 1959



WMS Russel and RL Burch

Legislation examples

- Directive 2010/63/EU (European Union)
- AWA... (US)
- Russia? In progress...



Quality and Animal Welfare?



Happy animals make good science

Trevor Poole

Universities Federation for Animal Welfare, 8 Hamilton Close, Potters Bar, Hertfordshire EN6 3QD, UK

Laboratory Animals (1997) 31, 116–124

- **Experimental design**: right species, appropriate numbers (reduction), both sexes... reproducibility, translatability
- **Healthy animals**: no interference with results
- Appropriate **environment** for species (micro and macro)
- Defined experimental and husbandry **procedures**
- Trained and competent **personnel**
- ...



Quality Systems

- Internal practices: institutional systems, legal requirements
- ISO (9001:2015)
- GLP
- AAALAC International
- Other (EQIPD, GMP...)



Quality Accreditation/Certification...why?

“customer” satisfaction

- Animal

- Law



- Buyer of a product or service

- Funding sources

- Society

- Researcher



ISO

- Specifications to ensure that materials, products, processes and services are fit for their purpose
- Quality management systems: covered in the ISO 9000 family of standards (ISO 9001:2008; 9001:2015)

ISO 9001:2015 clauses

- Scope
- Normative References
- Terms and Definitions
- Context of the Organisation
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement



ISO 9001 in practice, in animal research

- Description of standard operating procedures (SOP)
- Personnel, training
- Equipment/facilities maintenance
- Self-evaluation and continuous improvement
- **Animal welfare:** legal/self imposed requirements
- Quality Assurance Unit: working body
- External evaluation (no specialization in animal Research/welfare)

Check you do what
you say you do



GLP key elements

- management/personnel
- QAU
- facilities
- equipment, reactives
- experimental system
- test substance
- procedures (SOP)
- conduction of study (protocol) (study director)
- report
- records (traceability) (confidentiality)





GLP & Animal facilities

- Space requirements
- Environmental control: T^a, humidity, ventilation...
- Quarantine
- Food storage area
- Washing area
- Necropsy room



GLP in practice, in animal research

- Description of standard operating procedures(SOP)
 - Personnel, training
 - Equipment/facilities maintenance
 - Self-evaluation and continuous improvement
 - Authority of Study Director
 - **Animal welfare:** legal/self imposed requirements
 - Quality Assurance Unit: working body
 - External evaluation (no specialization in animal Research/welfare)
- Check you do what you say you do; extra level of paperwork



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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 58

Good Laboratory Practice for Nonclinical Laboratory Studies; Proposed Rule



“For example, we propose that the study director must defer to the attending veterinarian when decisions regarding animal welfare arise, particularly when animals are in pain or distress.”



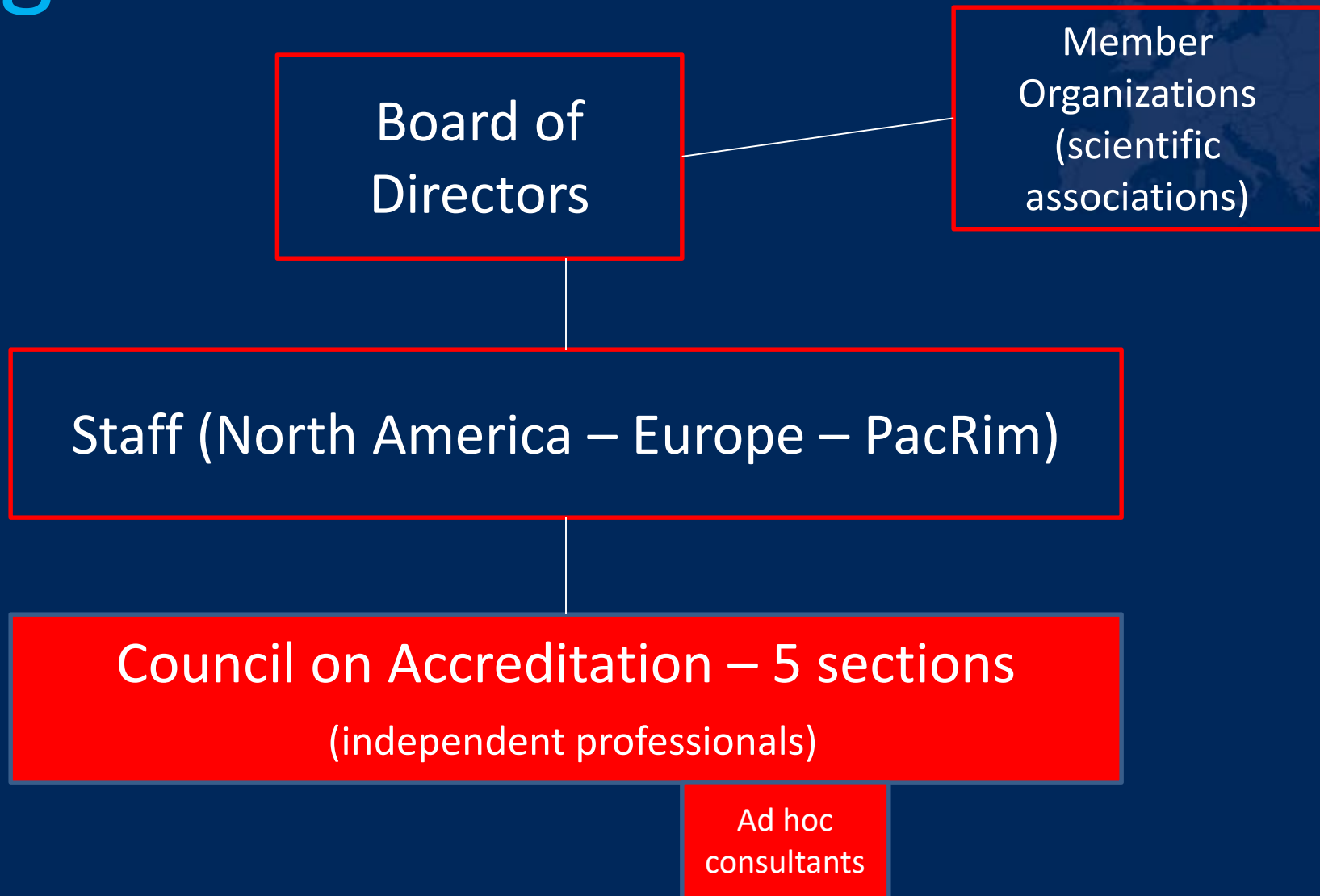
AAALAC International

AAALAC International is a **voluntary** accrediting organization that **enhances the quality of research**, testing and education by promoting **humane and responsible research animal care and use** through provision of advice and independent assessments to participating institutions and accreditation of those that meet or exceed applicable standards.

2021: over 1000 accredited
institutional animal care and use programs
in 50 countries



Organisation

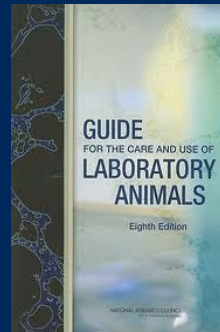




Concept of Program

AAALAC accredits research animal care and use Programmes

“...means the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve the humane care and use of animals in the laboratory and throughout the institution.”







AAALAC

- It represents quality
 - Self evaluation: challenge tradition
 - Engagement in a continuous improvement process
 - External evaluation: confidential peer review
- Promotes team building at the institution
 - OHS, Maintenance, Animal Services, QAU, ERP, Management



AAALAC

- Improvement in animal welfare (promotion of 3R)
- Pride in the work place (animal care people)
- Promotes scientific validity
- Demonstrates accountability
- Facilitates funding (specially from NIH)
- It provides assurance in a global market place

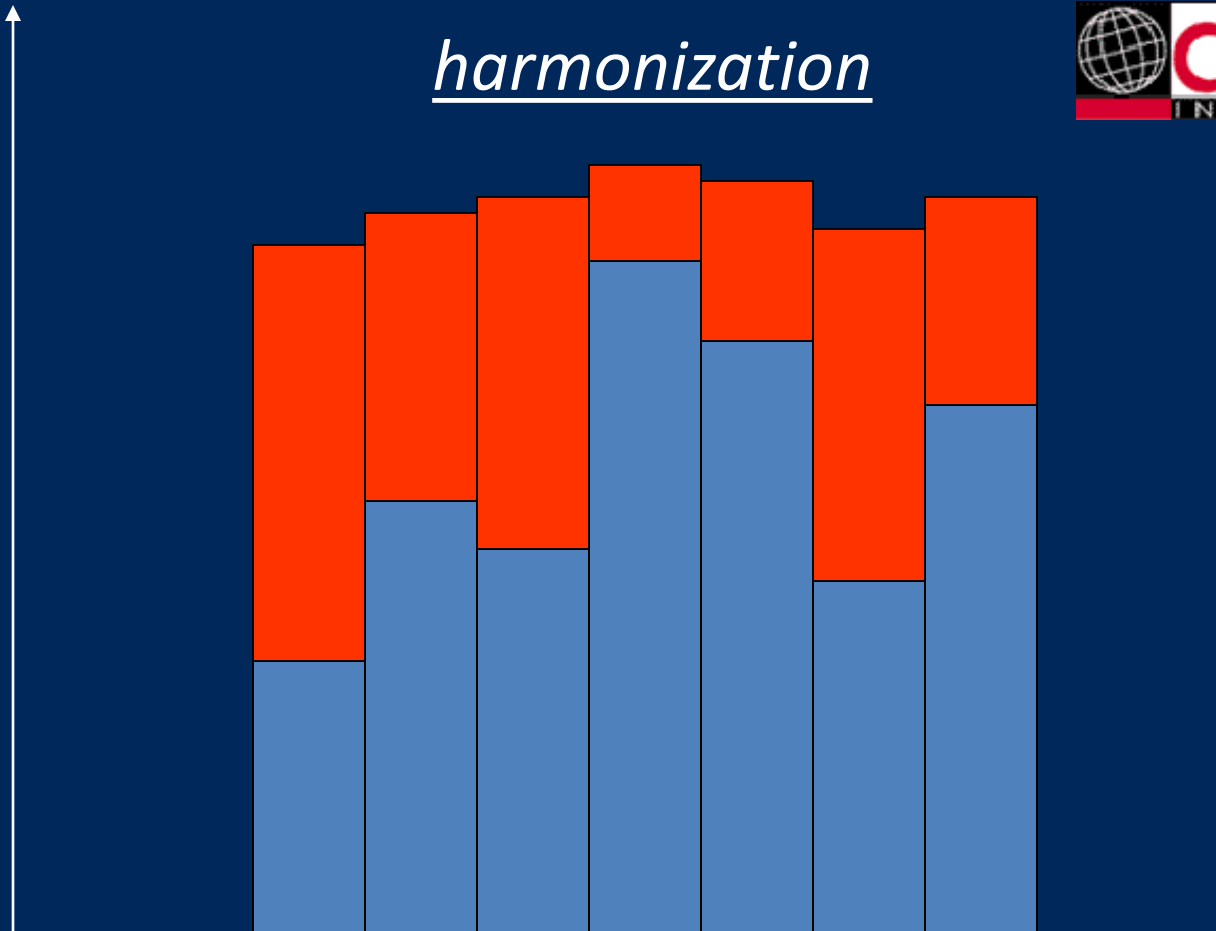
Check if what you do
is good for animals



Quality level

International accreditation

harmonization



countries

Legal requirements...



Similarities - Differences

- voluntary (AAALAC,ISO) vs mandatory (GLP)
- institutional interest, management support (all)
- **level of focus on animal welfare (AAALAC > ISO, GLP)**
- resources needed, QAU... (GLP > ISO > AAALAC)
- international recognition (depending on the field)
- specialization of inspectors/site visitors (AAALAC > ISO, GLP)
- confidentiality (all)
- **can be combined!**

Check you do what you say you do (ISO, GLP) vs check if what you do is good for animals and therefore, for Science (AAALAC)

Thanks

