LAS-Learning

Trainees Instructions

EU Module 26 - Inspector

Development of interactive e-learning modules on specific areas of the Education & Training framework facilitating implementation of DIR 2010/63/EU

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1. Module Description

1.1 Overview

This module - Inspector - aligns with the endorsed EU guidance document on Inspections and Enforcement, covering the EU Education and Training (E&T) Framework Learning Outcomes (LOs) tailored for Inspectors. It targets individuals employed by competent authorities tasked with conducting inspections as outlined in Article 34 of Directive 2010/63/EU to ensure proper inspection procedures are followed. Additionally, the module may benefit a broader audience, including members of Animal Welfare Bodies, by aiding in the review of internal operational processes to proactively identify issues as part of internal quality control procedures and for internal follow-up of formal Competent Authority inspections. While the intended audience is expected to possess an understanding of animal care and use in scientific procedures and the relevant legislation, the varied backgrounds of inspectors should be taken into account. To address potential gaps in knowledge, adequate training and references have been provided.

This module will cover four topics: General Principles, Preparing the inspection, During the inspection, and After the inspection.

If you are visiting the site independently, you should consult the EC Training and Education framework guidance document, which provides an overview of training requirements for individuals with different responsibilities under their relevant national legislation. Additional education and training may be necessary to meet national or institutional requirements.

This document offers suggestions for supporting your training. Each module aligns with the learning outcomes specified by the EU Education & Training framework for laboratory animal science. This module was developed by Ana Isabel Santos and Javier Guillén, experts in laboratory animal science, particularly focusing on laboratory animal welfare, ethics, and regulatory compliance with extensive experience researching, publishing, and training. In addition, an international Reflection Group panel has further refined the content, while Nuno H. Franco managed overall coordination.

Your collaboration and feedback are greatly appreciated, as the module is currently in the testing phase.

1.2 Topics Covered

- General Principles
- Preparing the inspection
- During the inspection
- After the inspection

1.3 Learning Objectives

- Understand the foundational concepts and standards that guide effective inspection processes, ensuring consistency and compliance.
- Develop strategies for thorough pre-inspection planning, including reviewing relevant documents and setting clear objectives.
- Acquire skills to conduct inspections systematically, observe operations accurately, and engage effectively with personnel.
- Learn to document findings comprehensively, communicate results to stakeholders, and implement corrective actions as necessary.

To support your ongoing learning, each module concludes with a curated list of recommended readings and cited references. Whenever possible, these references are linked to facilitate further exploration.

2. Prerequisites and Requirements

No specific prior knowledge is required. However, a basic understanding of searching bibliographic databases and a background in laboratory animal science and/or non-animal methods can be advantageous.

This module is designed to guide you step by step, eliminating the need for prior study.

2.1 Requirements

- Completion of lessons and understanding of learning objectives.
- Participation in knowledge checks and assessments to evaluate understanding.

3.   Grading and Completion

Grading will be based on the successful completion of knowledge checks and assessments provided at the end of each module. Upon finishing all parts of the module, students will receive a certificate of completion.

4. Textbooks and Reading Materials

The **"References and Further Reading"** lesson provides most references and readings. They comprise scientific articles, sections of books, websites, and videos. Clicking on any link will open a new window to download or visualise the additional material. Several links to further resources can also be found in the module contents to better guide the reader.

The additional materials provide more information on specific topics, tools, and resources.

5.   Course Program

The module is organised into six chapters, with lessons and learning objectives as follows:

Chapter	Lesson	Learning objectives
Introduction	1	Get to know the learning objectives
General Principles	2-9	Types and Benefits of Inspections, tested with a quiz and a case study Inspector's Profile and Skills, tested with a quiz and a case study Evaluating Culture of Care, tested with a quiz
Preparing the inspection	10-18	Ethics & the Three Rs, tested with a quiz Procedures and Exceptions Authorisation of Establishments, and Personnel Roles and Responsibilities, tested with a quiz Legal and Associated Aspects for the Inspection Process Evaluation, Authorisation and Reporting of Projects, tested with a quiz Types of Establishments According to Animal Use
During the inspection	19-28	Inspector´s Approach and Effectiveness of Inspections, tested with a quiz Housing, Husbandry and Management Conditions (A) Housing, Husbandry and Management Conditions (B) Animal Welfare and Severity Assessment, tested with a quiz Rehoming, Reuse, Humane Killing, and Management of Surplus Animals Evaluating Training and Competence of Personnel, tested with a quiz Evaluating Compliance and Implementation of the Three Rs in the Authorised Projects
After the inspection	29	Managing the Outcome of the Inspection
Summary and knowledge check	30-32	Module summary List of references and further reading Assess your knowledge

Table 1 - Learning objectives per parts and lessons.

5.1 Progress Tracking

Once you begin working through a module, your progress is tracked, and you can break off and resume your studies at any point. Once the module is completed, the trainee can access any section to refresh their understanding of a topic.

5.2 Module Structure

The module is divided into several parts, and although they were designed to be followed sequentially, they can also be taken iteratively. Please note that a certificate of completion is only issued to learners who complete all module parts.

5.3 In-Depth Explanation Lesson by Lesson

Lesson	Title	LO	Explanation
1	Introduction		
2	Lesson 2.1: Types and Benefits of Inspections	Insp. 47	Image and short introduction Inspections by Competent Authorities (Art.34) with 3 images, 2 flip-cards Announced vs Unannounced Inspections with 6 flip-cards General vs Targeted Inspections Consistency of Inspections with 3 expandable descriptions, 1 image Proactivity of Inspectors Other types of Visit/Evaluation Programmes with 2 expandable descriptions Benefits of Effective Inspections with 1 image, 6 stacked flip-cards
3	Quiz 2.1		Quiz with 5 questions
4	Case Study 2.1		Case Study with 1 question
5	Lesson 2.2: Inspector's Profile and Skills		Image and short introduction Inspector's Profile and Skills with 2 interactive images, 1 image Background, Knowledge & Experience with 1 interactive image Attitude and Personality description The ideal inspector´s Profile and Skills with 1 diagram
6	Quiz 2.2		Quiz with 6 questions
7	Case Study 2.2		Case Study with 5 questions
8	Lesson 2.3: Evaluating Culture of Care	Insp. 44, 45	Image and short introduction Culture of Care in Legislation with 2 images What is a Culture of Care? with a list, 1 image, 1 diagram Communication strategies with list, 3 tabs The Role of the Inspector Performance indicators - examples with list
9	Quiz 2.3		Quiz with 8 questions

10	Lesson 3.1: Ethics & 3Rs	Insp. 1, 2	Three Rs in Legislation with 2 images, 1 list Ethics and 3Rs with 3 images Evaluation Implementation of 3Rs (AWB) with list Examples Identification Ethical Questions with 1 image Identification Ethical Questions (e.g.) with 1 diagram 3Rs alternatives with 1 interactive quiz Other sources with links
11	Quiz 3.1		Quiz with 6 questions
12	Lesson 3.2: Procedures and Exceptions	Insp. 3, 4 Insp. 5	Purpose of Procedures – Directive with 1 image Basic Research - Examples with 7 images, 1 carousel with 5 examples Exceptions to Purpose-bred Animals Potential Reasons and Examples of Legal Exceptions on Purpose-bred Animals
13	Lesson 3.3: Authorisation of Establishments, and Personnel Roles and Responsibility	Insp. 6 Insp. 7 Insp. 26	Image and short introduction Authorisation of Establishments with 1 stack of flip-cards Requirements for Establishments with 1 image Essential: Internal Communication with 1 interactive diagram
14	Case Study 3.3		Case Study with 3 questions
15	Lesson 3.4: Legal and Associated Aspects for the Inspection Process	Insp. 9 Insp. 10 Insp. 13 Insp. 14	Image and short introduction Authorisation of Establishments Control of Member State Inspections with list, 2 flip-cards The importance of the Records with list The importance of Risk Analysis with a list Applying Risk Analysis (1) with expanding text blocks Applying Risk Analysis (2) with expanding text blocks Applying Risk Analysis (3) with expanding text blocks with images Applying Risk Analysis (4) with list Applying Risk Analysis (5) with list
16	Lesson 3.5: Evaluation, Authorisation and Reporting of Projects	Insp. 16 Insp. 40 Insp. 42	Image and short introduction Authorisation of Projects with 1 diagram Non-Technical Summaries (NTS) with 1 image Authorisation of Projects with 1 image Harm-Benefit Analysis with 1 list, 1 image Authorisation of Projects with 1 image, 1 list Authorisation of Projects with 1 image Selecting Projects for Inspection with lists
17	Quiz 3.5		Quiz with 8 questions
18	Lesson 3.6: Types of	Insp. 24 Insp. 27	Image and short introduction

	Establishments According to Animal Use		Academia - Structure with list Academia - Research with list, 1 diagram Public Research/Foundations/Nonprofit with list Pharmaceutical Companies with 1 diagram Contract Research Organisations (CRO) description with 1 diagram Biotechs Hospitals Surgical Training Centres Breeders Suppliers with diagram
19	Lesson 4.1: Inspector´s Approach and Effectiveness of Inspections	Insp. 11 Insp. 12	Image and short introduction Neutrality and Probity Identifying and Avoiding Conflicts of Interest Fluid communication with the key staff during the planning of the inspection Fluid communication with the key staff during the inspection Fluid communication with the establishment key staff after the inspection to report back on the observations noted Keeping abreast of the developments in the field of animal experimentation with 3 flip-cards Effectiveness of Inspections with 1 diagram, 3 flip-cards
20	Quiz 4.1		Quiz with 9 questions
21	Lesson 4.2: Housing, Husbandry and Management Conditions (A)	Insp. 28 Insp. 34 Insp. 35	Requirements for installations and equipment with 1 Image Rodents with list Other (large) species with list Farm settings – Agricultural research with list Aquatics with list Non-human primates (NHP) with list Biosafety with 2 flip-cards Health and Safety with a list Housing Conditions – Annex III with list Space requirements – Annex III with list Social Housing with list Environmental Enrichment Programme with list Environmental Conditions with 2 flip-cards with a list Husbandry Practices – Food and Water with list Impact on Science and Animal Welfare with a list Special Considerations with the list
22	Lesson 4.3: Housing,	Insp. 17 Insp. 19	Marking/Identification with image All Species

	Husbandry and Management Conditions (B)	Insp. 32 Insp. 36	Dogs, Cats and Non-human Primates Basic Concepts Barriers with 3 flip-cards, 3 diagrams Barriers/Species/Studies Health Monitoring with 2 flip-cards, list of questions In Directive 2010/63/EU with 1 image In other EU legislation with 1 image General Aspects Legalities in Practice with list General comments with 1 image Inspecting… with 1 list Nonpharmaceutical drugs (NPD)… with 1 list Use by Researchers
23	Lesson 4.4: Animal Welfare and Severity Assessment	Insp. 19, 20, 21 Insp. 22	Severity of Procedures with 1 image, 5 flip-cards Prospective – Actual - Cumulative with 2 tabs Classification - Prospective with list Practical Evaluation Actual Severity with list Practical Evaluation Actual Severity / Welfare with list, 1 image Inspecting with 1 list
24	Quiz 4.4		Quiz with 5 questions
25	Lesson 4.5: Rehoming, Reuse, Humane Killing, and Management of Surplus Animals	Insp. 8 Insp. 18 Insp. 23 Insp. 30 Insp. 31	Setting free & Rehoming with 2 images Rehoming: Programme Aspects with list Setting Free: Programme Aspects with list Setting free & Rehoming: Inspecting with the list Reuse with image Main conditions for reuse summarised text Telling apart Use from Reuse with 2 flip-cards Reuse vs Continued Use with 2 images Killing of Animals with 1 image Breeding colonies: Minimising Surplus Animals, Scenario, Strategies, Inspecting with lists Sharing of Organs and Tissues with 1 image Examples with 3 images and links
26	Lesson 4.6: Evaluating Training and Competence of Personnel	Insp. 37, 39 Insp. 38	Training and Competence with 2 images Initial considerations Exceptions Modular System – Learning Outcomes with 1 image Examples Modules with list Supervision and Assessment with a list Training, Competence and CPD: Records with expandable text blocks Training and Competence: Inspecting with a list
27	Quiz 4.6		Quiz with 4 questions

28	Lesson 4.7: Evaluating Compliance and Implementation of the 3Rs in the Authorised Projects	Insp. 41 Insp. 43, 46	3Rs Compliance & Implementation in Projects with 2 images Sources of Information on the 3Rs with links Experimental Design and Reporting with list, 2 images Follow up and Inspection with 1 image Project Non compliance? with list
29	Lesson 5.1: Managing the Outcome of the Inspection	Insp. 15 Insp. 25	Reporting of Inspections with 1 image To the Competent Authority with the list To Establishment with 4 flip-cards, list, expandable text blocks To and From the Establishment with the list To Establishment, How and When? description Penalties with 1 image
30	Summary		Module summary
31	References and Further Reading		References for additional materials
32	Knowledge-check		Assesses progress and knowledge acquired during the module

Table 2 - Explanation lesson by lesson.

6.   Target Audience

This module is intended for (bio)medical researchers, participants in laboratory animal science courses, university students, biology/medical teachers, animal welfare body members, regulators, and anyone interested in learning more about animal research ethics and the principles of Replacement, Reduction, and Refinement of animal use for scientific and educational purposes.