

Ethical Principles for Teaching, Research, Consultancy, Knowledge Exchange and Related Activities

Contents

1.0	Context of principles.....	3
2.0	General ethical principles.....	3
3.0	Ethical principles for work with human participants.....	5
4.0	Ethical principles for work using animals.....	10
5.0	Ethical principles for work with micro-organisms.....	13
6.0	Principles relating to genetic modification (GM)	14
7.0	Ethical principles for work with chemicals.....	16
8.0	Ethical principles for work with radiation	16
9.0	Ethical principles for work in the environment	17
10.0	Ethical principles relating to art.....	18
11.0	Ethical principles for work with military weapons.....	18
12.0	Guiding principles for self-experimentation	19
13.0	Guiding principles internet mediated research.....	20
14.0	Ethical principles for autonomous and intelligent systems (A/IS)	21

1.0 Context of principles

1.1 The principles listed below are intended to protect human, animal and other living subjects as well as the environment in all activities carried out in the University.

2.0 General ethical principles

2.1 The University expects staff and students to adhere to the law and to be aware of the ways in which it affects their work. They should be aware of all relevant University policies and practices , including those relating to [Data Protection](#) and [Freedom of Information](#). Work, particularly in the areas of Health, Science and Engineering, has health and safety implications. All such work must comply with the University's [Health and Safety policies and practices](#) including a full Risk Assessment. Researchers[†] should be aware of and adhere to the University's Code of Conduct for Research, while staff involved in Income Generating Activities (IGA) should adhere to University policy documents relating to contract work, financial management, investment and purchasing, including the current embargo on accepting funding from the tobacco industry.

2.2 Members of the University should consider the implications of their work in relation to:

- Respect for autonomy, which means respect for an individual's capacity for self-determination, bearing in mind specific needs and vulnerabilities of individuals;
- Non-maleficence, which means avoidance of harm and potential harm, bearing in mind the specific vulnerabilities of those affected;
- Beneficence, which means, wherever possible, promoting benefit;

[†] Footnote: "Research" in this document is defined as a systematic investigation into a topic involving original data or original thought applied to existing information. It therefore covers some work within the teaching programme as well as some commercial work and non-academic research carried out by administrative staff. "Researchers" is defined as any member of staff, student or other worker at the University who is carrying out the research.

- Justice, which means the fair and appropriate treatment of those affected by the work.

2.3 Members of the University should be aware of and address any ethical issues relating to their work. Staff should be aware that the University has adopted ethical principles for teaching, research, income-generating activities and other work, and established an ethics procedure to ensure that the ethical guidelines are adhered to. Additionally, ensuring the principles of the **Global Code of Conduct in Resource Poor Setting** for any research being conducted in low and lower-middle income countries as defined by the World Bank are applied. The way by which this is done will vary depending on the nature of the work, but they should consult with their appropriate Ethics Review Panel where ethical issues have been identified, and all such research, income-generating and teaching activities should be approved by an Ethics Review Panel. Students may not initially be aware of the University's ethical principles, but by the time they work on their final year dissertation/project they should be aware of them and of the role of School/Faculty and central ethics processes in overseeing such work.

2.4 The University will make reasonable adjustments whenever possible to enable individual staff or students to carry out their work without compromising their ethical principles.

Conflicts of Interest

2.5 The conduct of research must be fair, honest and transparent. Researchers should consider any conflicts of interest (personal, professional, economic and political) between the researcher, funder/s, and/or participants and the wider community. Researchers should identify and inform the relevant stakeholders if there are any conflicts of interest which may harm participants, the researchers and the wider community, and which may influence or bias the research process and research findings.

Encryption

- 2.6 When sensitive data is likely to be held on multiple and inaccessible backups encryption may be the only effective means of complying with an agreement to delete data. By deleting the encryption key, the encrypted copies remain on the backups but are irreversibly encrypted (and hence effectively deleted).
- 2.7 The following sections outline ethical principles and guidelines for work in areas which raise particular ethical issues.

3.0 Ethical principles for work with human participants[‡]

- 3.1 Researchers should consider the ethical implications of their work in all circumstances. In doing so, they should strive to consider the viewpoints of all who may be affected by the work: participants, colleagues, members of the public, potential end-users, funding agencies and the researchers themselves. They should also be aware of any additional ethical guidelines relevant to their area of work and of any requirements for ethical approval external to the University.

Consent

- 3.2 Participants should give their informed consent before any research is undertaken. The researcher should make every effort to provide sufficient information about the purpose and methods of the study and make participants aware of any aspects of the research that might reasonably be expected to influence willingness to participate. This information should include details of the form in which the results of the study will be made available to them after taking part, i.e. whether they will be able to obtain individual results, or only a summary of the results of the study. If individual results are to be made available, this should be done cautiously, in a manner that takes account of

[‡] Footnote: Whilst this section relates primarily to research, other activities which raise similar issues should be considered and addressed in like manner.

any potential distress that may be caused (e.g. if the research relates to health problems or other sensitive issues). Potential participants should also be provided with details of how long the study will last, whether, and for how long, some or all the information they provide may be stored for potential future research. If future research might occur, they should also be informed as to whether, or in what circumstances, they will be approached for consent and whether further ethical approval will be sought prior to its commencement. Researchers should also bear in mind their own qualifications or competence to give advice on the relevant issues and should refer participants to appropriate sources of professional advice when necessary. If the nature of the research is such that fully informed consent is not possible, additional safeguards are required to protect the welfare; dignity and privacy of participants (see sections 3.5, 3.12 and 3.13).

- 3.3 Consent may be written or verbal, and must be well-informed, voluntary and specific. Whichever form of consent is used, a record should be kept for audit purposes.
- 3.4 In research with infants and children under the age of 16, informed consent should normally be obtained from their parents, defined as those holding "parental responsibility" for the child, including any other carer or local authority as specified in the Children Act 1989. Young people aged between 16 and 18, while not legally fully adult, are usually presumed to be competent to give consent. Children under 16 may be considered competent to give consent if they have sufficient intelligence and understanding of the proposed research (sometimes referred to as "Gillick Competence"). Whether or not parental consent is a legal necessity, however, it is considered good practice to involve parents as much as possible unless it is not in the child's best interests to do so. Whether or not parental consent is being obtained, researchers should remember that children of all ages have the right to be informed, to express an opinion, and to influence any decisions about their participation in research, and that this process should be facilitated in a way that is appropriate for the age and understanding of the child. Reliance on the consent of a head teacher acting "in loco parentis" should be reserved for the least contentious or intrusive studies, or those that are indistinguishable from normal school activities. It should not be relied upon where

there is the possibility of a child being identified from the study results, or where the study is personal or relates to sensitive issues. Even when head teacher consent is being obtained, it is still considered good practice to advise the parents of the fact that the study is being undertaken, and to offer the option of withdrawal.

- 3.5 Where informed consent cannot be obtained from adults with impairments in understanding or communication, or if the research involves those in vulnerable situations or dependent relationships (e.g. the elderly in care), then special care should be exercised. Researchers should consult with, and obtain assent from, those well-placed to appreciate the participants' likely reactions, such as family members, professional carers, charitable organizations, other experts in the relevant field, or a supervising authority (e.g. Official Solicitor or The Court of Protection). Only in trials of pharmaceutical products can consent for an adult's participation legally be obtained from another person, referred to as their 'legal representative'.
- 3.6 It is important for researchers to realise that they may sometimes be in a position of authority over participants who may, for example, be students, employees, clients or prisoners. They should not use this authority to pressurise individuals to participate in research.
- 3.7 Where research is carried out in a country other than the UK the researcher should generally follow the basic principles outlined here but should consider variations as may apply in that country.
- 3.8 Volunteers may be paid for their inconvenience and time, but such payment should not be so large as to induce them to risk harm beyond that which they risk without payment in their normal lifestyle.

Withholding Information or Misleading of Participants

- 3.9 Withholding information from or misleading of participants is unacceptable except

where this form an essential part of the research. It is the responsibility of the researchers to determine whether alternative procedures are available. Participants in such research should be provided with additional information as soon as possible. They should then be asked to confirm their consent, and if they do not do so they should be removed from the study sample and their data destroyed. All Ethics Review Panels should pay attention to such research which should be avoided whenever possible. If, in the Ethics Review Panel's judgement, the participants are likely to object after debriefing, then the research should not be approved.

Feedback to Participants

- 3.10 In studies where participants are aware that they have taken part in an investigation, once the data has been collected the researchers should provide participants with sufficient information at an appropriate level to enable them to understand the nature of the research. The researchers should, where possible, discuss with participants their experience of the research to monitor any unforeseen negative effects or misconceptions.

Withdrawal from the Research

- 3.11 At the beginning of the investigation, researchers should make clear to participants that they have the right not to participate or to withdraw from the research at any time during data collection, irrespective of whether payment has been offered. Researchers should check throughout the investigation that the participants are not showing signs of distress and are still willing to continue. Procedures should be in place to provide care and support for participants if they do show signs of distress. Participants have the right, following their experience of research or debriefing, to withdraw their consent, and require that their own data be destroyed. Where destruction of data is not possible participants should have been informed of this and given their consent at the outset.

Confidentiality and anonymity

- 3.12 Subject to the requirements of the Data Protection and Freedom of Information Acts, all information collected about a participant during an investigation is confidential

unless otherwise agreed in advance. If confidentiality cannot be guaranteed for any reason, participants must be warned of this in advance and should consent explicitly to the release of their information. Audio, video, photographic and other recordings can only be made with the express consent of those being recorded (except for recordings of public behaviour) as to both the making of the recording and subsequent uses of it. In open group discussion, such as used in focus groups, participants should be asked to agree to maintain the confidentiality of any information provided by others during the discussions.

- 3.13 Data on (or samples from) human participants should be coded or fully anonymised as soon as possible. Any codes linking names to data should be stored in a secure manner in a separate location from the coded data. When it is unnecessary to preserve the link between people's names and the data (or samples), the names should be removed from the data (or samples). Additionally, during the design of a study, researchers should always consider whether, even if people's names are not included, data might contain information from which others could deduce the identity of at least some of the participants. Should there be the potential for such identification, participants should be warned of this and consent in advance. Otherwise information which might lead to identification should either be removed or stored in a secure manner and (where appropriate) encrypted (see 2.6).

Consideration of Participants

- 3.14 Researchers have a primary responsibility to protect participants from any unnecessary harm arising from the investigation. They should always comply with the Risk Assessment and Health and Safety procedures of the University (see 2.1).

Observational Research

- 3.15 Studies based upon observation must respect the privacy and psychological well-being of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in situations where those observed would

expect to be observed by strangers. Additionally, account should be taken of local cultural values.

Medical Research with Humans and Clinical Trials

3.16 Medical Research requires additional considerations; researchers should consult appropriate references (e.g. World Medical Association Declaration of Helsinki, 2000; Directive 2001/20/EC of the European Parliament and of the Council, 4 April 2001; The Medicines for Human use (Clinical Trials) Regulations 2004; Medical Research Council guidelines on <http://www.mrc.ac.uk>).

Teaching and Research using Human Tissue Samples

3.17 Human material may be used in both teaching and research, e.g. preserved organs which may be normal or pathological, tissues for biochemical analysis or slides prepared from tissues for microscopical examination. Any use of such material must comply with the Human Tissue Act 2004 and should follow Medical Research Council Operational and Ethical Guidelines, 2005. Advice must be sought from the Persons Designate of your Faculty, before any human tissue is brought onto UCLan premises. Detail of the Persons Designates for the Faculties can be found on the [ethics intranet page](#) (staff access only) or by contacting EthicsInfo@uclan.ac.uk.

4.0 Ethical principles for work using animals

General

4.1 Much academic work on animals uses animals living freely in natural or modified environments or in captivity and is designed to further our knowledge and understanding of their biology without harming them in any way. At the other extreme, some research on animals involves suffering or loss of life. Animals that are kept in confinement on University premises are normally species that have been bred for many generations in captivity e.g. mice, rats, farm animals. Primates and other species that

require extensive and diverse environmental conditions to lead healthy lives will not be kept on University premises. Caging conditions and husbandry practices must meet the latest recommended requirements for keeping animals (see current Universities Federation for Animal Welfare (UFAW) handbook).

Animal Welfare and Ethics Review Body

4.2 Researchers should adhere to The Animals (Scientific Procedures) Act 1986, Amendment Regulations 2012 (incorporating changes brought in by the European Directive 2010/63/EU), which controls any scientific procedure applied to a protected animal[§] that may cause pain, suffering, distress or lasting harm and meet all Home Office standards. All proposed studies need approval by the University's Animal Welfare and Ethics Review Body (AWERB), an advisory body established and appointed under the terms of the Act. AWERB carries out a local ethical review process on proposals for any scientific procedures on an animal (whether protected or not), including domestic animals and invertebrates, both in the field and in captivity. It also examines and submits draft licences and certificates required under the Act for work with protected animals to the Home Office. Please contact AWERB via email to EthicsInfo@uclan.ac.uk.

Reduction, Refinement and Replacement

4.3 The Home Office requires that work with protected animals is directed by a set of principles based on Reduction, Refinement and Replacement of their use, known as the 3R's. These guiding principles aim to minimise animal use and suffering without compromising scientific progress (Reduction means minimisation of number of animals used; Refinement means modifying procedures to minimise pain and distress; Replacement means using non-animal models in place of animals). Where suffering or loss of life may occur, animals are only used when the value of the work outweighs this suffering. Suffering is generally understood to relate to the degree of development of the nervous system, therefore if a research project is proposed involving many animals,

[§] Footnote: A protected animal is defined in the Act as a vertebrate animal (other than humans) or an octopus.

or if some degree of suffering is likely, then animals with simple nervous systems are used whenever possible (e.g. invertebrates rather than vertebrates).

- 4.4 All experimental work should seek where possible to avoid the use of animals, and the proposal must advance sound scientific reasons for their use, explaining why no realistic alternative exists. All studies must take full account of the welfare of animals.
- 4.5 In teaching, physiological principles are demonstrated as far as possible by using invertebrate rather than higher vertebrate preparations.
- 4.6 Animals which have been killed for food but will be used for other purposes (e.g. forensic, physiological, biochemical, biological, ecological) should be considered by the appropriate Ethics Review Panel not by AWERB, but the guidance on Reduction, Refinement and Replacement (4.3) should still apply.

References

Animals (Scientific Procedures) Act, 1986, Amendment Regulations 2012
<https://www.gov.uk/guidance/research-and-testing-using-animals>

UFAW, Selection and Use of Replacement Methods in Animal Experimentation,
1998, ISBN 0 900767 98 7

UFAW Handbook on the Care and Management of Laboratory and Other
Research Animals, 8th edition, April 2010, edited by Robert Hubrecht and James
Kirkwood., Published by Wiley-Blackwell.

5.0 Ethical principles for work with micro-organisms

Background

5.1 Microbiology is the study of small (micro-) organisms including viruses, bacteria, protozoa, algae, fungi, yeasts and moulds. These are ubiquitous in nature and while some are harmful pathogens causing diseases such as meningitis and influenza, others are beneficial e.g. in recycling nutrients in the soil or can be used to human benefit e.g. production of vaccines or of antibiotics.

Health and Safety

5.2 Work with micro-organisms on University premises should comply with relevant regulations and should only be carried out in laboratories with containment measures appropriate for the organisms likely to be encountered. The risk of escape of micro-organisms to the environment should be minimal.

Health and safety risks in microbiological work should be minimised e.g. by using attenuated or disabled laboratory strains of pathogens or by choice of culture media or experimental design to minimise the chances of culturing undesirable pathogens.

Special care should be given to ensure safe working practice for at-risk groups such as pregnant women or those who are immunologically compromised.

References

Health and Safety at Work Act, 1974

Report of Advisory Committee on Dangerous Pathogens, 2003

Food Safety Act, 1990

Control of Substances Hazardous to Health Regulations, 1999

Ethical issues

- 5.3 The degree of risk accepted in work with micro-organisms should be balanced and justified by the actual or potential benefits (e.g. to humankind, to other animals, or to the environment).

6.0 Principles relating to genetic modification (GM)

Background

- 6.1 Advances in molecular biology over the last 30 years, have resulted in the development of a wide variety of techniques, which are often grouped together and referred to as genetic modification. GM techniques have been applied to a wide range of micro-organisms, plants and animals, resulting in increased scientific understanding, as well as allowing the commercial production of enzymes, complex therapeutic agents and genetically modified crops. Some recent research has attempted to correct genetic disorders in humans by a process called gene therapy e.g. severe combined immunodeficiency and type A haemophilia.

Definitions

- 6.2 Genetic Modification (GM) is the alteration of the genetic material of an organism (either DNA or RNA) by use of a variety of techniques that do not occur in nature such that the modification can be replicated and/or transferred to other cells or organisms. Typically, GM involves the removal of DNA, its manipulation outside the cell and its reinsertion into the same or another organism. The aim of GM is often to introduce a new or altered characteristic to the target organism.
- 6.3 Genetically Modified Organisms (GMOs) are the organisms which have been genetically modified. GMOs may be plants, animals or (most commonly) micro-organisms. If the GMO is a micro-organism it is often called a genetically modified micro-organism (GMM).

Health and Safety

- 6.4 GM work should comply with the Health & Safety Commission's contained use** regulations and should only be carried out in registered laboratories, animal houses, plant growth facilities (including growth rooms in buildings and suitable glasshouses) and large-scale production facilities on industrial sites.
- 6.5 Wherever possible GM work should use micro-organisms that have been disabled with mutations preventing their growth outside the controlled environment of a laboratory test tube. Where GMMs that are not disabled and still capable of growth outside the laboratory are used, extra control measures should be in place before the work can commence.
- 6.6 Risk assessments and containment measures should comply with GMO(CU) (2000) and GMO(CU) Amendment (2005).
- 6.7 The University is a registered site (GM 239) and currently has two laboratories which operate at Containment Level 1 (the lowest of four Levels). All proposed GM work should be approved by the Genetic Modification Safety Committee (GMSC).

Ethical Issues

- 6.8 The degree of risk accepted in GM work should be balanced and justified by the actual or potential benefits (e.g. to humankind, to other animals, or to the environment).

References

** Footnote: 'Contained use' means that control measures are in place to minimise the chances of contact between GMOs and humans and/or the environment.

Genetically Modified Organisms (Contained Use) Regulations (GMO[CU]), Health & Safety Commission, 2000. Genetically Modified Organisms (Contained Use) Regulations (GMO[CU] Amendment), Health & Safety Commission, 2005.

7.0 Ethical principles for work with chemicals

7.1 All work using chemicals should comply with University health and safety regulations, procedures and practices, and appropriate disposal methods should be employed. This does not necessarily mean that no harm will be caused by an aspect of chemical work, e.g. particular chemicals may have high toxicity, they may be carcinogenic, mutagenic or teratogenic, or be so resistant to degradation that they will persist in the environment for a very long time. In all such cases the risk of any harmful effects should be weighed against the benefits of doing the work.

8.0 Ethical principles for work with radiation

8.1 All forms of ionising radiation have the potential to damage living cells, and some radioactive materials will continue to emit radiation for hundreds, thousands or millions of years. The basic framework for radiological protection has been developed by the International Commission for Radiological Protection and the International Atomic Energy Agency which advocate an approach based on three principles, justification, optimisation and dose limitation.

8.2 All work at the University involving radiation should comply with University health and safety regulations, procedures and practices, and the risk of any harmful effects should be justified by weighing them against the benefits of doing the work.

9.0 Ethical principles for work in the environment

General

- 9.1 Work in the environment includes traditional fieldwork in geography and biology, but also all other work carried out in natural or human-made environments which focus on the environment and/or the people who live and work there. Thus, it also covers archaeology, conservation and environmental management (including agriculture, forestry, and waste management).

All environmental work should comply with relevant University Health & Safety policies and procedures including those relating to fieldwork and to hazardous equipment (e.g. in forestry).

Ethical Issues

- 9.2 The main ethical issues in environmental work relate to the interaction between people and the environment:

- 9.3 *Biodiversity and Conservation.* Researchers should aim to disrupt the natural environment as little as possible except where alterations to the environment can be justified (e.g. to reduce pollution, to grow more food or to enhance biodiversity).

Studies of rare animals and plants protected by law must have the prior approval of the appropriate organization (e.g. in England this is Natural England). Collection of non-pest species that are not protected by law should only occur if it can be established that collection poses no threat to the population. Collection and study of animals should be approved by AWERB (see Section 4).

- 9.4 *Landownership.* Whilst extensive areas of the UK and other countries form open landscapes, legislation related to landownership and property rights should be

complied with. Access to private land as well as the removal of material should always be agreed with the landowner prior to entry.

9.5 *People*. Ethical guidelines relating to work with people are given in Section 3.

9.6 *Archaeological Remains and Artefacts*. Artefacts found on excavation remain the property of the landowner. Human remains will always be treated with respect. Excavation and study of human remains should follow the guidelines established for the British Archaeological Jobs Resource (available at <http://www.bajr.org/documents/HumanRemainsGuide.pdf>).

References

Wildlife & Countryside Act, 1981, amended 1984

Countryside & Rights of Way Act, 2000

10.0 Ethical principles relating to art

10.1 Art will sometimes have a legitimate aim to challenge, shock, or even offend. In such cases consideration should be given as to whether precautions are needed to avoid access by those who might not be a suitable audience - for example, by warning notices or age restrictions.

11.0 Ethical principles for work with military weapons

11.1 Research and consultancy work related to military weapons and the Defence Industry may raise ethical issues that conflict with the ethical principles of non-maleficence and beneficence (see 2.2 above). The appropriate University Senior Management Team member (normally the Executive Dean) should be involved in the evaluation of such proposals.

12.0 Guiding principles for self-experimentation

12.1 Self-experimentation in research is a data-driven approach in which the experimenter conducts the experiment on themselves, using a single case, i.e. $n=1$, where the experimenter is also the subject.

Approval for self-experimentation is required following normal University process for ethical approval. When applying for approval to undertake self-experimentation, a proposal should address the following questions:

Q1. Is there a conflict of interest in the proposal?

Q2. Is there a mechanism by which the experiment can be observed by a peer researcher?

Q3. Is there a mechanism by which the results are confirmed by a peer researcher?

Q4. Are there any restrictions imposed by any future publisher which would suggest the results could not be disseminated?

Q5. Is there any potential harm to the experimenter or others who are involved?

Q6. Is there a legitimate reason for the study?

Prior to submitting their application for ethical approval, the researcher must identify the journals they intend to publish their results in and address the author guidelines regarding self-experimentation. All safeguards must be in place to mitigate any risks to the participant and data.

13.0 Guiding principles internet mediated research

13.1 Research involving the use of online surveys, questionnaires, social media, data processing, data analysis and storage etc. In addition to completing your application for ethical approval you should consult with your supervisor.

Internet-mediated research is research involving online activities to acquire data on participants, e.g. social networks, web-based surveys, video communications. When applying for approval to undertake internet mediated research, a proposal should consider the following points:

- Identity and location of participants.
- Inability to accurately locate participants, restricting the ability of researchers to intervene should participants disclose intentions to cause harm to themselves or others, or harmful behaviour viewed on Skype.
- Consent ensuring parents are involved in research involving children as would happen in face to face research.
- Assessing mental capacity of participants.
- Anonymity and compliance with data protection laws as IP addresses can be collected.
- The provision of online support links and organisations.
- Indemnity arrangements for the researchers.

13.2 Additional information regarding internet mediated research can be found in the UCLan document [Internet Mediated Research](#)

14.0 Ethical principles for autonomous and intelligent systems (A/IS)

14.1 Research involving autonomous and intelligent systems (A/IS) should be conducted in accordance with professional and legal requirements. All research, including research which does not directly involve human participants, should consider the wellbeing, rights and dignity of humans. Any research involving the creation or testing of A/IS should be conducted in accordance with the ethical principles of the IEEE Ethically Aligned Design (IEEE, 2019) guidance document, as outlined below:

- *Human Rights* - A/IS shall be created and operated to respect, promote, and protect internationally recognised human rights.
- *Well-being* - A/IS creators shall adopt increased human well-being as a primary success criterion for development.
- *Data Agency* - A/IS creators shall empower individuals with the ability to access and securely share their data, to maintain people's capacity to have control over their identity.
- *Effectiveness* - A/IS creators and operators shall provide evidence of the effectiveness and fitness for purpose of A/IS.
- *Transparency* - The basis of a particular A/IS decision should always be discoverable. The term "transparency" in the context of A/IS also addresses the concepts of traceability, explainability, and interpretability.
- *Accountability* - A/IS shall be created and operated to provide an unambiguous rationale for all decisions made. People and institutions responsible for the design and production of A/IS need clarity around the manufacture and deployment of these systems to establish responsibility and accountability, and to avoid potential harm.
- *Awareness of Misuse* - A/IS creators shall guard against all potential misuses and risks of A/IS in operation.
- *Competence* - A/IS creators shall specify and operators shall adhere to the knowledge and skill required for safe and effective operation.