Exploring the potential of conformity assessment techniques to support ethics assessment

Deliverable 7.2

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ABSTRACT

This report explores (in consultation with stakeholders) whether conformity assessment, and specifically certification, could be helpful in facilitating and improving the use and quality of ethics assessment in research and innovation (R& I). The report studies conformity assessment including certification, certification and ethics, ISO standards on certification, stakeholder views on conformity assessment and certification, and how certification is regulated at the EU-level. It explores how (and what types of) conformity assessment could be used to support the application of the *SATORI CEN Workshop Agreement (CWA) on ethics assessment for research and innovation* and presents some tools to facilitate its use, e.g., self-assessment and declaration of conformity (process and templates); a self-declaration of conformity publication platform; self-assessment and declaration review; benchmarking for maturity; peer-review; and a peer-review publication platform.

EXECUTIVE SUMMARY

This report explores whether conformity assessment, and specifically certification, could be helpful in facilitating and improving the use and quality of ethics assessment in research and innovation (R&I). It explores how various tools of conformity assessment could be used to support the application of the *SATORI CEN Workshop Agreement (CWA)* on *Ethics assessment for research and innovation*[1].

The structure of the report is as follows. First, it outlines the scope and methodology (Chapter 2). Second, it briefly examines conformity assessment in general (Chapter 3). Third, it looks at certification (as required by the SATORI project description of work) (Chapter 4). Fourth, it looks at the relationship between ethics and certification (Chapter 5). Case studies in ISO certification standards follow (Chapter 6). Next, it presents stakeholder (including research ethics committees and national ethics committees) views on conformity assessment and certification (Chapter 7). After this, it examines the regulation of certification in Europe (Chapter 8). Finally, the report explores how (and what types) conformity assessment could be used to support the SATORI CEN Workshop Agreement (Chapter 9) and presents some tools to facilitate the use of the SATORI CWA Parts 1 & 2 (Chapter 10).

Conformity assessment and certification

Conformity assessment can help organisations build trust, develop and foster compatibility with a variety of standards across organisations. Certification is third-party conformity assessment. For some industries, certification is a legal and/or contractual requirement. Its advantages are that it provides a means of demonstrating compliance, building trust and confidence, gaining reputational and financial advantages. There are many benefits (perceived and actual) of standards, certification, and accreditation. However, they vary and depend on the nature of the standard, certification or accreditation, their underlying criteria, and at whom they are targeted.

Case studies on ISO certification standards

This report studies specific ISO certification standards some of which specifically address ethical aspects, e.g., anti-bribery management, food safety, environmental responsibility, and social responsibility. Our study revealed various challenges facing the use of such standards, such as: misinterpretation of the certification requirements; underestimation of the efforts and resources required; costs (training, audit fees, audits); overdevelopment of the quality system; excessive documentation and control; apparent erosion of the perceived benefits over time; lack of support (e.g., from management) and resources available for SMEs; lack of guidelines on how to accomplish the 'continuous improvement' elements of a standard. These are all relevant to consider in the development of any certification standard for ethics assessment. Critical success factors include: market and legal incentives; consumer demand for use of certification; widespread support, use and adoption of the scheme; sustainability; and internationalisation.

Stakeholder views on conformity assessment and certification

The overall conclusion by the stakeholders with whom we engaged was that certification might not be effective for ethics assessment; standardisation is more relevant. Stakeholders at the SATORI Delft workshop strongly discouraged the presumed obvious link between standardisation process of ethics assessment and the certification process. Participants felt the certification discussion was premature and should not be further developed in the SATORI project. Several interviewed research ethics committee

[1] SATORI, *CEN Workshop Agreement Ethics assessment for research and innovation*, CWA SATORI-1:2016. http://satoriproject.eu/publications/satori-mutual-learning-workshops-portal/ [Note, these are the public consultation drafts; the final version of the CWA will be presented in mid-2017 and will be available on the SATORI website.]

and national ethics committee members thought conformity assessment and certification could benefit 'ethics assessment procedures', by improving **transparency, credibility, confidence, reliability,** and **consistency** of the ethics review process. But it is essential that conformity assessment is carried out in a way that **simplifies procedures, and reduces (not increases) bureaucracy**. A conformity assessment and certification system should **allow for differential approaches in different cases, ranging from a simple and fast exercise to detailed and time-consuming process** depending on the specific situation and needs (levels of risk). In line with this, the proposals in this report aim to support a flexible and adaptable use of conformity assessment.

Regulation of certification in Europe

The report looks at some key examples of legislation that govern, support or encourage certification[2] at the EU-level and derives some useful insights for SATORI. Overall, there is no single overarching framework for the regulation of certification in the EU. The key aspects for the legislative instruments we analysed (i.e. nature, criteria and conditions, certification procedure, revocation and withdrawal, measures to boost public trust and confidence, and harmonisation) provide an insight into how these are covered, their similarities and sectoral divergences. In some cases, the law is highly prescriptive, in other cases, it is flexible.

Enhancing ethics assessment through conformity assessment

This report explores how (and what types) conformity assessment could be used to support the SATORI CWA Parts 1 and 2.[3] Most conformity assessment techniques could be used to check, evaluate, or assess adherence to the SATORI CWA specifications, either exclusively, or in combination with others, depending on what is to be assessed, the context, and the specific characteristics to be assessed.

This report assesses specifically how self-declaration of conformity, peer review (or peer assessment), certification, and accreditation might play out in relation to Parts 1 and 2 of the CWA informed by the study's literature review and the stakeholder engagement. The assessment considers potential target(s) of evaluation, target stakeholder, conformity issuer, relying party (i.e. a natural or legal person that relies upon the conformity assessment results), how would it play out, benefits, risks, challenges, and business case.

Conforming to the SATORI CWA: tools to assist organisations

The report explores various tools to assist organisations in conforming with the SATORI CWA. These include self-assessment and declaration of conformity (process and templates), a self-declaration of conformity publication platform, self-assessment and declaration review, benchmarking for maturity, peer-review, and a peer-review publication platform.

Final conclusions

The report shows some ways in which conformity assessment could play out in relation to Parts 1 and 2 of the SATORI CWA. However, as highlighted by our stakeholders, some of these (e.g., certification) may be premature and even counter-productive. Their ability to be successfully implemented and have an impact depends on three key things:

- **policy and legal frameworks** that support the development and implementation of such schemes, whether at the EU or national level;

[2] In line with the SATORI Description of Work specification.

[3] Part 1 of the SATORI CWA outlines recommendations for the composition, role, functioning and procedures of ethics assessors (i.e., research ethics committees, institutional review boards, ethical review committees). It aims to help organisations strengthen and/or improve ethics assessment of research and innovation projects. Part 2 of the CWA provides researchers with guidance for carrying out ethical impact assessments (i.e., the process of judging the ethical impacts of research and innovation activities, outcomes, and technologies).

- **incentives and subsidies** to undertake conformity assessment activities, and
- **usefulness and ability** of conformity assessment techniques to deliver their goals vis-a-vis improving the quality of ethics assessment and ethical impact assessment.

Based on the analysis in the report, we can see that **even the least rigorous form of conformity assessment (self-assessment) can contribute to meeting the needs (enhancing the quality of ethics assessment, user friendliness, awareness, mutual learning) and countering the challenges (window dressing, resource burdens, fragmentation, etc.) faced in ethics assessment**. The tools presented in this report represent a good starting point, but how the SATORI CWA has been formulated and will be finalised (i.e., its text and discussions) limits their scope.[4] As part of future work, the demand for these tools, their usefulness and further development needs to be further assessed with stakeholders.

Conformity assessment could be a beneficial tool to leverage in enhancing ethics assessment activities. Different approaches might have value and serve the goals of improving the quality of ethics assessment or ethical impact assessment. But, their uptake and success depends on the demand, push for, and incentives (e.g., legal mandates, funding and/or procurement requirements) to use such tools**.**

One challenge in the uptake of conformity assessment for the SATORI CWA is the rigour of the specifications. In its current form, the SATORI CWA represents a voluntary consensus agreement on ethics assessment by a variety of ethics stakeholders. Therefore, it represents an amalgamation of various ethical cultures and practices, and is flexible to take these into account. The CWA was purposefully framed to be flexible enough for adaptation in different contexts. Hence, its specifications are not unduly rigorous; these might pose a challenge for those seeking to adopt conformity assessment techniques to support its implementation. We do not see an easy solution due to local, national, and regional differences in the ethics environment; in any event, full harmonisation in ethics assessment may be neither possible nor desirable.

Another challenge is the amount of time and effort required to undertake conformity assessment activities. Simply carrying out conformity assessment activities is not the end goal; it is also important to communicate the results via a certification mark or listing e.g., an ethics committee might be on a register of EU ethics committees qualified to assess EU research projects. Monitoring will also be essential to ensure compliance with the conformity assessment requirements on an ongoing basis.

[4] As of date of submission of this report (28 February 2017), the SATORI CWA is in the process of being finalised.

GLOSSARY

Accreditation	The formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards (ISO).
CEN Workshop Agreement (CWA)	A CEN Workshop Agreement (CWA) is a document published by CEN in at least one of the CEN three official languages. It is an agreement developed and approved in a CEN Workshop; the latter is open to the direct participation of anyone with an interest in the development of the agreement. There is no geographical limit on participation; hence, participants may be from outside Europe. The development of a CWA is fast and flexible, on average between 10-12 months (CEN).[5]
Certification	A written assurance (a certificate) that the product, service, or system in question meets specific requirements (ISO[6]).
Certification standard	A standard that contains requirements that can be used for certification purposes.
Conformity assessment	Demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled (ISO/IEC 17000). In this case, its purpose is to help ensure that ethical policies, procedures, professionals, deliver on their promises. Certification is one of the methods of demonstrating conformity.
Ethics assessment	Institutionalised assessment, evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria (SATORI D1.1, 2015[7]/CWA 2016).
Ethical impact assessment	A process of determining and addressing the ethical impacts of research and innovation activities, outcomes, and technologies typically in consultation with stakeholders (Adapted from the SATORI CWA Part 2[8]).
Stakeholders	Stakeholders are individuals, groups or organisations who have an interest in an R&I activity because it may affect them, or who can influence the R&I activity (SATORI D1.1[9]).

[5] CEN, "CWA - CEN Workshop Agreement". http://www.cen.eu/work/products/cwa/pages/default.aspx
[6] International Organization for Standardization.
[7] Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright and Kush Wadhwa, *SATORI Deliverable D1.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, June 2015, p.28.
[8] Note, this was adapted from Wright, D., "A framework for the ethical impact assessment of information technology", *Ethics and Information Technology*, Vol. 13, 2011, pp. 199–226. http://doi.org/10.1007/s10676-010-9242-6
[9] Shelley-Egan, op. cit., 2015.

1. Introduction (overview and rationale)

The need for different governance solutions for ethics assessment calls for the exploration of the feasibility of using conformity assessment, specifically certification, to support the goals of strengthening and improving ethics assessment. This report explores whether conformity assessment, and specifically certification, could be helpful in facilitating and improving the use and quality of ethics assessment in research and innovation (R& I).

The structure of the report is as follows. First, it outlines the scope and methodology. Second, it briefly examines conformity assessment in general. Third, it looks at certification (as required by the SATORI project description of work). Fourth, it looks at the relationship between ethics and certification. Case studies in ISO certification standards follow. Next, it presents stakeholder (including research ethics committees and national ethics committees) views on conformity assessment and certification. After this, it examines the regulation of certification in Europe. Finally, it examines which, and how, conformity assessment tools could be employed to support the SATORI CEN Workshop Agreement (CWA) Parts 1 and 2.

2. Scope and methodology

The main objective of this report (in line with the SATORI project description of work, work package 7) is to examine and assess the feasibility of conformity assessment, more specifically certification, (relying primarily on ISO standards[10]) for ethics assessment. This report aims to show what support exists amongst ethics stakeholders (individuals and organisations involved in ethics assessment for R&I) for such certification, and what could be done if deemed necessary to certify ethics assessment procedures and/or ethics assessment professionals. As was subsequently recommended by the SATORI stakeholders and Advisory Board, this report while fulfilling this remit, does not present a certification model for ethics assessment in R&I. Instead, it shows how conformity assessment more generally could support ethics assessment and particularly, how it could progress the goals of the SATORI CEN Workshop Agreement (CWA) proposals.

The key research methods used in the preparation of this deliverable include:

- literature and website reviews, including analysis of ISO documents, technical papers, and academic literature on standardisation and certification,
- consultation of relevant stakeholders through structured interviews and workshops.

The literature review for this report included a scan of ISO documents e.g., guidance, standards, technical papers. We also scanned some academic and industry coverage of the ISO standards that were selected for detailed study.

Interviews

The partners interviewed a variety of stakeholders' face to face, via phone, and Skype. These included standards and certification bodies, research ethics committees, and national ethics committees. The purpose of these interviews was to get stakeholder views on certification in general, conformity assessment, and the feasibility of certification for ethics assessment.

[10] In line with the SATORI Description of Work (DoW).

Interviews were conducted for specific purposes and have fed into the deliverable as indicated in specific sections.

The WP7 team developed an interview guide (Annex 3) for determining the views, particularly of research ethics committees (RECs) and national ethics committees (NECs) on conformity assessment, and the feasibility of certification for ethics assessment. The interview guide was developed in an iterative fashion in WP7, reviewed and revised in discussions between the Netherlands Standardization Institute, Danish Standards, and Trilateral Research. The interview questions were discussed with RECs and NECs. Some respondents sent in written responses (due to constraints relating to availability for phone interviews). Invitations were issued to RECs and NECs in June 2016. The interview consultations closed in August 2016. We summarised the interviews. Sections 7.2 and 7.3 document the details of the interviews and the results.

Discussions in SATORI workshops

The SATORI consortium specifically discussed certification for ethics assessment with participants (internal and external stakeholders) in a dedicated session at the SATORI workshop on "A European Framework for Ethics Assessment", at NEN, Delft, Netherlands, on 18 February 2016. Annex 5 contains the full report of the workshop. The SATORI consortium, its Advisory Board, and external stakeholders' feedback and results from the SATORI meeting in Copenhagen (30 May-1 June 2016) also informed, and set the direction of this report.

3. Conformity assessment in general

Conformity assessment "is the term given to different techniques that ensure a product, process, service, management system, person or organisation fulfils specified requirements".[11] Too often it is only equated with certification, but is much broader. ISO outlines the following benefits of conformity assessment:

- It provides consumers and other stakeholders with added confidence.
- It gives your company a competitive edge.
- It helps regulators ensure that health, safety, or environmental conditions are met.[12]

Conformity assessment can help organisations build trust, develop and foster compatibility with a variety of standards across organisations. It is internationally recognised and has been usefully leveraged to protect not only the interests of consumers, and the environment, but even human rights[13].

There are three main types of conformity assessment: first-party, second-party, and third-party. In first-party conformity assessment, the manufacturer or supplier declares on his own responsibility that tests and other assessment activities needed to show that a product is conformant, have been carried out.[14] The company carries out typical conformity assessment

[11] ISO, "Conformity Assessment techniques and schemes". http://www.iso.org/sites/cascoregulators/01_1_conformity-assessment-techniques.html
[12] ISO, "What is conformity assessment". http://www.iso.org/iso/home/about/conformity-assessment.htm
[13] E.g. ISO 14155:2011 specifies general requirements intended to protect the rights, safety, and well-being of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and principal investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.
[14] International Electrotechnical Commission (IEC), "Types of conformity assessment", 2017. http://www.iec.ch/conformity/what/ca_types.htm

activities, including testing and inspection, in-house and then delivers an SDoC (Supplier's Declaration of Conformity).[15] This type of conformity assessment is only deemed acceptable for low risk products (due to lack of independent oversight), but on the positive side it is flexible, less cost and resource intensive[16] and any changes necessary might be easier to make[17]. A person or an organisation with a user interest in the object being assessed e.g., the purchaser (government or major manufacturer) performs second-party conformity assessment.[18] Such organisations set up and maintain their own conformity assessment procedures and test facilities for products or services they procure. It is a kind of review by stakeholders using expertise in the field. The European Commission H2020 ethics review process can be compared to this. Second-party assessment is not as commonly used as third-party assessment. Third-party conformity assessment is performed by a person or body that is independent of the seller and the buyer, and is an independently-provided unbiased assurance of the safety of products and processes.[19] The incentives for third-party conformity assessment are market demand and legislative mandates. Third-party conformity assessment is more demanding and costlier than other types of conformity assessment; but on the other hand, is an extremely good trust and confidence generating means.

Techniques of conformity assessment include: assessment, auditing, calibration, evaluation, examination, inspection and testing, or combinations of such techniques. The table below explains these further:

ISO
ASSESSMENT Determining whether an organisation fulfils requirements related to its technical competence. An example is the assessment of conformity assessment bodies (e.g., laboratories, inspection bodies and certification bodies) to ensure that the results that they produce can be relied upon. Assessments are carried out during accreditation and peer assessment.
AUDIT Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. Audit criteria are contained in policies, procedures and requirements adopted by an organisation and may include applicable laws and regulations, policies, procedures, standards, management system requirements, contractual requirements, or industry/business sector codes of conduct.
EVALUATION Process of gathering evidence about whether a product, process or service meets specified requirements. It is also sometimes used in the context of person certification.
EXAMINATION A mechanism that measures a candidate's competence by one or more means, such as written, oral, practical, and observational, as defined in the certification scheme.

[15] International Electrotechnical Commission, "Types of conformity assessment", 2017. http://www.iec.ch/conformity/what/ca_types.htm

[16] Note, however that the use of supplier's declaration of conformity does imply costs in terms of administration i.e. higher costs for market surveillance. http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_117312.pdf

[17] World Trade Organisation, "Supplier's Declaration of Conformity: A Case Study in Implementation", Information Technology Agreement Industry Symposium, Geneva, 16 July 1999. https://www.wto.org/english/tratop_e/inftec_e/gall.doc

[18] International Electrotechnical Commission, "Types of conformity assessment", 2017. http://www.iec.ch/conformity/what/ca_types.htm

[19] International Electrotechnical Commission, "Types of conformity assessment", 2017. http://www.iec.ch/conformity/what/ca_types.htm

ISO
INSPECTION Closely aligned with testing activities and certification activities (and particularly product certification); or may be stand-alone activity. One of the key aspects of inspection is that the determination of conformity with specific requirements is made based on professional judgment of the inspection bodies' personnel. Inspection could include: visual examination of physical items; measurement or testing of physical items; examination of specification documents such as design drawings; comparison of the findings with the requirements of specification documents or with generally accepted good practice in the field; and drawing up a report on the results of the inspection.
TESTING Determination of one or more characteristics of an object of conformity assessment, according to a procedure. Typically applies to materials, products, or processes.
COMBINATION OF TECHNIQUES Different types of techniques may be used depending on what type of product, process, or system is to be assessed, the methods and characteristics to be assessed.

Table 1: Techniques of conformity assessment

The results of conformity assessment are different claims of conformity such as self-declaration of conformity, certification, and accreditation. A self-declaration of conformity refers to a formal declaration by an entity that it, its product, or service, conforms with the requirements of the applicable legislation and/or requirements based on an assessment or test performed by the entity itself.[20] Accreditation is the "the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards"[21]. United Kingdom Accreditation Service (UKAS) states, "accreditation delivers confidence in certificates and conformity statements. It underpins the quality of results by ensuring their traceability, comparability, validity and commutability".[22] Accreditation is carried out by international or national accreditation bodies. Since the SATORI scope of work primarily called for an examination of how certification could support ethics assessment, we next look at certification in a bit more detail.

4. Certification

The ISO defines certification as "the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements".[23] Certification is third-party conformity assessment. For some industries, certification is a legal and/or contractual requirement. Certification has its advantages i.e., it provides a means of demonstrating compliance, building trust and confidence, gaining reputational and financial advantages. The ISO develops international standards, but is not involved in their certification, and does not issue certificates (issued by certification bodies).

Objectives and types of certification

There are some general objectives of certification; however, specific objectives depend on the type of certification. There can be different types of certification activity; the CASCO[24]

[20] Adapted from: http://www.iso.org/sites/cascoregulators/01_2_conformity-assessment-claims.html
[21] ISO, "Certification". http://www.iso.org/iso/home/standards/certification.htm
[22] UKAS, "About accreditation". https://www.ukas.com/about/about-accreditation/
[23] ISO, "What is conformity assessment?". http://www.iso.org/iso/home/about/conformity-assessment.htm
[24] CASCO is the ISO committee that works on issues relating to conformity assessment. It develops policy and publishes standards related to conformity assessment, but does not perform conformity assessment activities. http://www.iso.org/iso/Casco

document lists three types of certification activity: product certification, management system certification and personnel certification.[25] This does not exclude other types of certification.

Product certification is "a comprehensive activity in both developed and developing countries and has a much longer history than management systems certification. It is also perhaps the most visible form of certification".[26] The CASCO document suggests the two basic drivers for product certification "are the provision of information to assist consumers of products and services to make better-informed choices on products, and to assist suppliers of certified products to achieve market acceptance".[27] Examples include CE marking[28], and keymark certification[29].

Personnel certification "recognises the competence of individuals to fulfil specific requirements".[30] Often the lack of specific qualifications being available through other means, such as formal qualifications from educational or professional institutes, drives the need for such certification. The relevant ISO/CASCO standard for personnel certification bodies is ISO/ IEC 17024*, Conformity assessment – General requirements for bodies operating certification of persons.*[31] This International Standard aims at achieving and promoting a globally accepted benchmark for organisations operating certification of persons. The process involves assessment and periodic re-assessments of the competence of certified persons. Examples include: auditor certification, certification of information security professionals.

Management systems certification seeks to provide assurance that an organisation has effectively implemented a system for the management of relevant aspects of its activities in line with its policy. A management system describes the set of procedures an organisation needs to follow to meet its objectives.[32] ISO management system standards provide a model to follow when setting up and operating a management system. Like all ISO standards, they are the result of international, expert consensus and therefore offer the benefit of global management experience and good practice. CASCO outlines "A significant feature of management system certification is that the standards affected by this form of conformity assessment are produced, not only by ISO, but by many consortia and companies. For example, many major retail organisations and groups have developed management system criteria, against which they expect compliance by all their suppliers. (Some of these are a combination of management system and product certification requirements)."[33] Examples: ISO 9001[34] certification; ISO/IEC 27001 for information security management systems[35]; ISO 14000 environmental management[36].

[25] ISO, UNIDO, *Building Trust, The Conformity Assessment Toolbox*, ISO, Switzerland, 2010-02/3 000 (hereinfater, *the CASCO document*). http://www.iso.org/iso/casco_building-trust.pdf
[26] ISO & UNIDO, op. cit., 2010.
[27] ISO & UNIDO, op. cit., 2010, p.76.
[28] European Commission, "CE marking". https://ec.europa.eu/growth/single-market/ce-marking_en
[29] European Committee for Standardization (CEN), "Keymark". https://www.cen.eu/news/brochures/brochures/Keymark.pdf
[30] ISO & UNIDO, op. cit., 2010.
[31] https://www.iso.org/obp/ui/#iso:std:iso-iec:17024:ed-2:v1:en
[32] http://www.iso.org/iso/home/standards/management-standards.htm
[33] ISO & UNIDO, op. cit., 2010, p. 76.
[34] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=62085
[35] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=54534
[36] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=34676

Typical certification process

The following diagram illustrates a typical certification process.

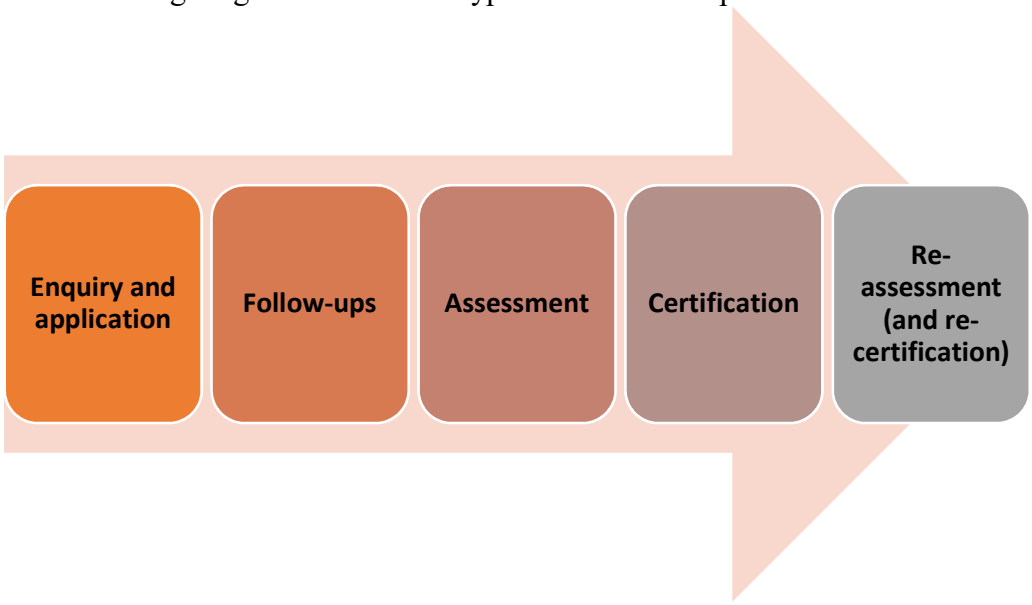

Fig 1: Typical certification process

As seen above, a typical certification process follows certain key steps. The certification body is responsible for overseeing the process (the specific conditions for certification may be based on a technical, industry standard, or legal mandate; sometimes it might even be entirely determined by the certification body itself).

5. Ethics and certification

Based on a literature review and online search, the SATORI report on *Standards, certification and accreditation organisations*[37], identified a number of different types of standards, certification and accreditation organisations (particularly outside the formalised standardisation system) that are relevant to SATORI since they directly or indirectly cover ethical aspects in some of their activities.[38] Examples of the certification activity covered by these organisations include: quality assurance for higher education; accreditation; social responsibility certification; manging ethical risk in supply chains; certification of quality and protections for human research; ethical product certification; accreditation of organisations using animals in research, teaching or testing; certification of ethical business practices; accreditation of organisations conducting clinical trials; accreditation of research ethics committees against agreed standards; self-accreditation covering requirements for undertaking primary research.

The SATORI report concluded that there are many benefits of standards, certification, and accreditation. However, they vary and depend on the nature of the standard, certification or accreditation, their underlying criteria, and at whom they are targeted.
The report concludes,

[37] See Rodrigues, Rowena, "Ethics assessment and Guidance in Different Types of Organisations: Standards, certification and accreditation organisations", Annex 3.i *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, Deliverable 1.1, June 2015. http://satoriproject.eu/media/3.i-Standards-certification-and-accr-orgs.pdf
[38] Ibid.

Standards not only create benchmarks for the sector or organisations that they apply to or subscribe to them, but can be used to gain greater trust and credibility. They can have a direct and beneficial impact on society. Standards such as the ISO 26000[39] provide guidance to businesses and organisations as to how they can operate in a socially responsible manner. It also facilitates their actual actions to meet this objective ultimately contributing to positive societal outcomes. Certification provides organisations a means of determining (whether through self- or third party certification) whether and to what extent they comply with ethical standards, rules, and regulations (depending on what the criteria are). This creates compliance and reputational advantages.[40]

6. Case studies on ISO certification standards

The ISO has thousands of standards written in a way that enables organisations, products, services, or persons to become certified in the content of the standards (henceforth called certification standards). As stated before, these include management system certification, product certification and personnel certification standards. Some of these specifically address ethical aspects, e.g., anti-bribery management, food safety, environmental responsibility, and social responsibility.

The SATORI work package 7 team (The Netherlands Standardization Institute, Danish Standards, and Trilateral Research) trawled through many ISO certification standards[41], and had several internal discussions on which standards were apt for study in SATORI; it was not feasible to analyse all ISO certification standards. In conjunction with SATORI *Task 7.1 General Study of Standardising Operating Procedures*, we selected the standards listed below for further study. The standards were selected because of their type; many of these standards have some ethics or ethics-related elements, e.g., social responsibility, food safety, environmental responsibility, quality management, and were thought to therefore hold inspiration for SATORI and any future developments related to certification of ethics assessment. The list includes suggestions made by the standards and certification bodies we interviewed as part of this work.

1. ISO 9001:2015 Quality management systems – Requirements
2. ISO 14001:2015 Environmental management systems -- Requirements with guidance for use
3. ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes
4. ISO/TS 16949:2009 Quality management systems -- Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations
5. ISO/IEC 17021-1:2015 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
6. ISO 17024: 2012 Conformity assessment – General requirements for bodies operating certification of persons
7. ISO/IEC 17067:2013 Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes

[39] Note, however, that ISO 26000 is not used for certification.
[40] Rodrigues, op. cit., 2015.
[41] E.g., those listed at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=54998&published=on&includesc=true

8. ISO/IEC 20000-2:2012 Information technology – Service management – Part 2: Guidance on the application of service management systems
9. ISO 22000:2005 Food safety management systems – Requirements for any organization in the food chain
10. ISO 22222:2005 Personal financial planning -- Requirements for personal financial planners
11. ISO 22301:2012 Societal security – Business continuity management systems – Requirements
12. ISO/IEC 27001:2013 Information technology – Security techniques – Information security management systems – Requirements
13. ISO 45001 Occupational health and safety management systems – Requirements (based on OHSAS 18001)
14. DS 49001 Social responsibility management systems – requirements
15. ISO 50001:2011 – Energy Management System

The SATORI team presented the above list to stakeholders at the SATORI workshop in Delft on 18 February 2016 and welcomed further recommendations (no further suggestions were received).

Analysis of the results of the study of selected standards

The table in Annex 1 presents the detailed results of the study of the select certification standards. It presents a short introduction, their key features, scope and application, obstacles, and challenges (identified based on review of media and academic literature) and success factors & impact (of certification).

The analysed standards cover a variety of topics: quality management, personal financial planning, conformity assessment, environmental management, medical devices, automotive production, information technology, social responsibility, food safety, occupational health, societal security, and energy. The analysis represents all three categories of certification: product certification, personnel certification, and management systems certification.

Comparison of key features

There are many general features common to the various ISO certification standards considered here, that are important to highlight. We focus on four such features: certification process requirements, continuous improvement, plan-do-check-act (PDCA) cycle, and policy development.

One key feature of the ISO standards under consideration are standard requirements for the certification process. This feature is central to the ISO standards because it offers clear conditions and requirements for certification. For example, ISO 17024: 2012 provides requirements for the certification of persons; ISO/IEC 17021-1:2015 provides certification requirements for various kinds of management systems; and 17067:2013 deals with product certification. Another advantageous feature of ISO certification standards is that they can enable mechanisms for continuous improvement of the various processes being implemented. Such mechanisms ensure that certification supports growth for the organisation. Continuous improvement is a key feature of ISO/TS 16949:2009 for the automotive industry, with emphasis on defect prevention and the reduction of waste in the supply chain. We also see continuous improvement as a feature of ISO 22301:2012 for business management systems as

a way of protecting against and reducing the likelihood of disruptive incidents. The goal of continuous improvement can also be seen in ISO 50001: 2011 which involves reviews of how policies work to continually improve energy management.

Another key feature found in ISO standards is the adoption of the well-known Shewhart[42] or Deming[43] plan-do-check-act (PDCA) cycle. The cyclical nature of this management strategy is an effective way to promote ongoing improvement and to guard against undesirable outcomes, such as products that are of poor quality. This cycle is a key feature of ISO 9001:2015 used in conjunction with risk-based thinking for quality management systems in organisations. The PDCA cycle is also a main feature of ISO/IEC 20000 for service management systems in information technology. The PDCA approach was taken up by SATORI and recommended as good way to help ethics assessors plan their ethics assessment processes and interactions better, ensure quality by enabling them to ensure processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on.[44]

Another feature of analysed ISO certification standards is their support to good organisational policy development. Certification need not apply only to pre-established policy, but can also promote prudent development of new policy. We see this benefit of certification put into place, for example, in DS 49001 that specifically supports organisations develop and maintain good social responsibility policies. Policy development is also a key feature of ISO 50001:2011 which promotes the development of more efficient energy policy.

Comparison of scope and application

The analysed ISO certification standards possess a range of scopes and applications. Some of the standards under consideration are extremely generic and can be applied to organisations of nearly any kind. The set of standards with broad application include: ISO 9001:2015 for quality management in any organisation; ISO 14001: 2015 which covers environmental management for any organisation and can be used in whole or in part to improve environmental management; DS 49001 is dedicated to social responsibility management systems in any organisation and can be adapted to different geographic, cultural and social conditions; ISO 45001 for occupational health and safety management in any organisation; ISO 22301 for business continuity management in any organisation; and ISO/IEC 17067:2013 for any organisation interested in product certification.

We considered some ISO certification standards that are not entirely generic, yet not tied to a specific industry, or type of organisation. Such certification standards include ISO/IEC 17021-1:2015 dedicated to conformity assessment in any organisation performing audit and certification for quality and ISO 17024: 2012 which provides conformity assessment for any organisation involved with the certification of persons.

Finally, some of the analysed ISO certification standards are dedicated to specific industries or areas. These standards are also intended to be as broadly applicable as possible, given the constraint of their focus on specific areas. Such standards include ISO 22222:2005 which covers conformity assessment for all personal financial planners, ISO 13485:2003 for all medical devices regardless of size or kind, ISO/TS 16949: 2009 for quality management in the

[42] Shewhart, W. A., *Statistical Method from the Viewpoint of Quality Control*, Dover, 1939.
[43] Deming, W. E., *Out of the Crisis*, MIT Center for Advanced Engineering Study, 1986.
[44] SATORI, "Ethics assessment for research and innovation — Part 1: Ethics assessment unit", CEN Workshop Agreement, CWA SATORI-1:2016.

production of consumer-specified automotive parts, ISO 22000: 2005 for food safety management in any aspect of the food chain, and ISO 50001: 2011 for continual improvement of energy management. Both ISO/IEC 27001:2013 and ISO/IEC 20000-2: 2012 are dedicated to information technology, with the former dedicated to IT security in any organisation and the latter dedicated as support for any organisation seeking to meet the requirements of ISO/IEC 20000-1.

Obstacles and challenges

Our analysis of the selected ISO, IEC and DS standards provided a good insight into the obstacles and challenges faced by, or relevant to the analysed certification standards.[45] One, was the misinterpretation of the requirements underlying the certification[46]. Another key challenge is the underestimation of the efforts and resources required in certification, costs (training, audit fees, audits) required for implementation and certification. Other challenges include: overdevelopment of the quality system; excessive documentation and control; apparent erosion of the perceived benefits over time; lack of support (e.g., from management) and resources available for SMEs; and lack of guidelines on how to accomplish the 'continuous improvement' elements of a standard. These are all relevant to consider in the development of any certification standard for ethics assessment.

Success factors

The analysis of the certification standards highlights the following key success factors for the analysed certification standards.

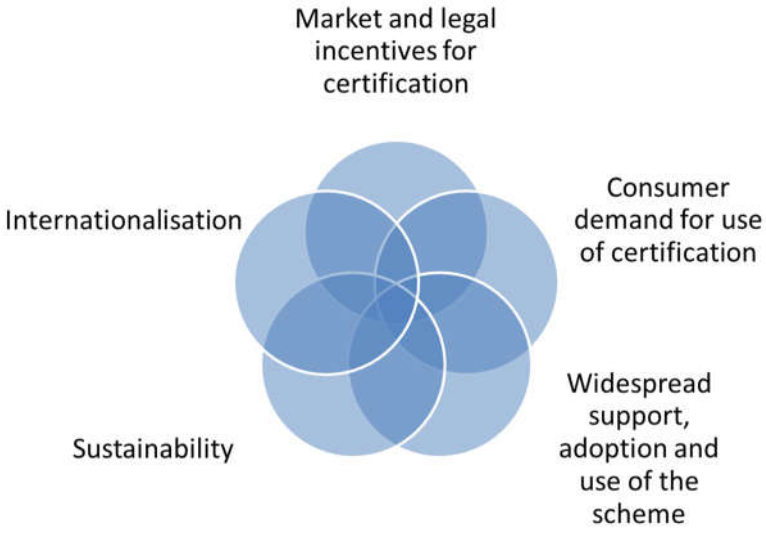

Fig 2: Some success factors of ISO certification standards

One of the industry stakeholders contacted during the Task 7.2 engagement exercises, suggests,

> In general, the success factors for certifiable standards are down to basic economics. Economists would call certifications for a particular market "rents". Answering why such rents can successfully be charged means looking from the points of view of the

[45] Specific details are available in Annex 1.
[46] Highlighted, for instance, in case of ISO 9000 standards clauses. See Moatazed-Keivani, R., A. Ghanbari-Parsa, & S. Kagaya, "ISO 9000 standards: perceptions and experiences in the UK construction industry", *Construction Management and Economics*, 17, 1999, pp. 107-119. This problem could be attributed to lack of training.

> stakeholders: the providers of service, the receivers of service, the certifiers. For the three relationships between these three stakeholders asking and scoring "does a certification solve a real problem for at least one party" and "is it economically viable to solve that problem" will allow the adding up of a future-facing score indicating potential success.[47]

Another key success factor is trust. As the CRISP project[48] report on security standards and certification in Europe, states, "For a certification system to be successful, it is important that stakeholders trust in the certification system as well as the requirements that are being certified.[49] This is also one of the conclusions of the EU privacy seals project report on *Challenges and Possible Scope of an EU Privacy Seal Scheme* which states "A certifier must be independent (financially and resources), capable of engendering trust from members and successfully able to implement and enforce the scheme".[50] Future certification efforts, if implemented to support ethics assessment in R&I should take these success factors into account.

7. Stakeholder views on conformity assessment and certification

This section summarises the results of the SATORI Delft workshop group discussion session on certification for ethics assessment held on 18 February 2016, and the views expressed by the REC and NECs in the interviews carried out from June to August 2016.

7.1. Summary of results of the SATORI Delft workshop (February 2016)

This section summarises the key results of the Delft workshop group discussion session on certification. Five groups deliberated on the following topics: is certification useful; actors and measures; certifying ethics professionals; certification of ethics assessment procedures; and certification support measures. Annex 5 contains further details.

Usefulness of certification for ethics assessment

The usefulness of certification might be seen in two different options of "areas of certification": research misconduct, and ethical assessment of implications of research in the future. Only for the first category, certification might be useful at all, i.e. procedures dealing with research integrity lean well to certification. The most promising venues for certification: certification of ethical assessment procedures, and certification of training. The possible target groups for certification include: funding agencies, and journals. However, from the point of view of a funding agency, the added value of certification is limited. Certification might lead to additional bureaucratic procedure. The open questions that remain are: how does certification relates to existing regulation and legislation? Who would manage the certification scheme and

[47] Email communication dated 26/11/2015. Name anonymised on request.
[48] http://crispproject.eu/. CRISP (Evaluation and Certification Schemes for Security Products) is a three-year project (April 2014 – March 2017) that aims to facilitate a harmonised playing field for the European security industry by developing an innovative evaluation and certification methodology for the CRISP certification scheme for security systems.
[49] Wurster, Dr. Simone, et al, *Deliverable D 2.1: Report on security standards and certification in Europe - A historical/evolutionary perspective*, 30 August 2014. http://crispproject.eu/wp-content/uploads/2014/10/CRISP_Deliverable_2-1_Sec_Standards_Certification_Europe-Compressed.pdf
[50] De Hert, Paul, Vagelis Papakonstantinou, Rowena Rodrigues, David Barnard-Wills, David Wright, Luca Remotti, Tonia Damvakeraki, *Challenges and Possible Scope of an EU Privacy Seal Scheme, Final Report Study Deliverable 3.4*, EU Privacy Seals Project, European Commission, 2014, p. 104.

issue the certification? The overall conclusion was that certification might not be very effective for ethics assessment; there is more use for standardisation, than for certification.

Actors in, and measures of certification

The key organisations that were seen to play a key role in certification of ethics assessment were: funding organisations (provide funding incentives); governments (create policy and legal incentives), standardisation agencies and certification bodies (to clear a path for certification); associations of research ethics committees (to use and benefit from certification), and civil society organisations (for consultation).

Any proposed certification scheme for ethics assessment should be modelled on successful existing examples. But, we need to consider the novelty in ethics assessment certification. It is also important to consider incentives and subsidies for certification. At the EU level, relations should be established between existing ethics certification bodies to ensure harmonisation.

Several points were made about what needs to be put in place and ensured to support certification of ethics assessment in the EU. Certification should be rigorous not symbolic in compliance and auditing. There should be appropriate procedures, governance, and legislation (hard law, soft law, sectoral agreements) to support it (there is a need to be 'motivated' about certification). Other incentives include sanctions for non-compliance (greater than mere recall of certification). There is a need for professionals for certification and quality assurance. Other points highlighted were: scale ratings and metrics in compliance; capacity building; major/secondary compliance; training of auditors; creating certifying agencies or checking if existing bodies would be willing to take this on; a standard (as an underlying mechanism) and accreditation body and training for accreditors, and expertise within standard organisations and expertise in auditors.

Certifying ethics professionals

Participants made the following comments about whether certification of ethics assessment professionals was beneficial. One, professionals might benefit from having the certification: from the self-development perspective or if there is a legal incentive to get one; it may be good for their CVs (better career prospects) and improving marketability. Two, industry might benefit from an enhancement of quality.

The obstacles and challenges include: difficulty in determining who are ethics assessment professionals – are they ethics assessors? There are differences in country approaches i.e. criteria might need to be developed at the national level. Who will be the bodies offering certification? Certification may be relevant for some disciplines not others - differences in disciplines might pose a problem. Certification may perpetuate the tick-box mentality. Further, how will the certificates be monitored? Another view expressed was that they did not see clear added value and how it would relate to already existing schemes. Such certification might not work without a clear legal framework.

Certification of ethics assessment procedures

The workshop discussion identified several c*hallenges or obstacles in certifying ethics assessment procedures.* In some technological fields, it is hard to standardise non-institutionalised things. Another challenge was the lack of demand and support for such

certification (the latter is questionable). Country-based differences might also pose a problem. Medical research ethics committees do not need to be certified. I.e. in all countries, that participated in the discussion i.e. Denmark, Germany, Netherlands, Poland, MRECs comply with legal requirements. Legislation plus accreditation might be better.

There was some agreement that standardisation is important in countries, in Europe. Especially for research ethics committees there is a demand and need for standardisation of procedures. There is a need for standardisation of procedures on handling ethical misconduct.

Certification support measures

The kinds of training and courses that would be needed for certification of ethics assessment procedures depends on what would be the subject of certification (i.e. product, process, or procedures). It must be achievable. Delivery must meet transparency requirements, and be relevant to a wide range of stakeholders from regulatory authorities to patient groups, civil society organisations, academics, industry.

The discussion also revolved around *who could be accredited* to offer certification of ethics assessment procedures. RECs and people within their own organisation have conflict of interest so independent organisations should offer this service. Therefore, we need suitably qualified and experienced assessors independent of who they are going to assess (either third party or within an institution).

Critical comments and conclusions

Participants made several other general critical comments during the workshop which are important to consider. One was that we really need to determine whether we need a certifiable standard or not and what will be the subject. There was a strong discouragement of the presumed obvious link between standardisation process of ethics assessment and the certification process. Participants felt the certification discussion **was premature and should not be further developed in the SATORI project**. However, participants felt that researcher guidance for ethics self-assessment might be a good alternative to certification.[51] SATORI could try to come up with an ethics footprint, such as QALY[52] in health, or CO2 (carbon) footprint in environment. If a certification scheme is developed for ethics assessment, there will be a need to ensure buy-in by organisations to the certification scheme. There might be a possibility of self-certification but only supported by strong enforcement mechanisms. Certification should not be window dressing.

7.2. Views of interviewed research ethics committees

For this section of the deliverable, we contacted 23 research ethics committees (from countries such as Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Serbia,

[51] Note, the subsequent iterations (post-Delft) of the SATORI CWA and Framework address this.
[52] The quality-adjusted life year (QALY) is a "measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health". National Institute of Health and Care Excellence (NICE). https://www.nice.org.uk/glossary?letter=q

Slovenia, Spain, Sweden, Switzerland, UK) to invite representatives to interviews on the topic of certification standards for research ethics. Five representatives of different RECs from Austria, Latvia, Portugal, Slovenia, and the UK (names and organisations anonymised on request) agreed to interview with us. We sent the interview questions (Annex 3) to the interviewees in advance and obtained informed consent from all of interviewees (template in Annex 4). We should point out upfront that the distinction between RECs and NECs in our investigation is not a straightforward one. That is, there were many individuals interviewed who have contributed both to RECs and NECs. We keep the distinction here only as a useful approximation.

The interviews consisted of three parts: conformity assessment and ethics in general, certification of ethics assessment procedures, and certification of ethics professionals. Here we will focus on each part in turn.

Views on conformity assessment and ethics in general

The initial question was a general one about which of the following could most benefit from conformity assessment: (a) ethical products, technologies, systems, or services, (b) ethics assessment procedures, (c) ethics professionals, or (d) ethical organisations. In replying to this question, three of the five interviewees indicated that ethics assessment procedures would most benefit. After giving this answer, one interviewee elaborated that transparent standards across organisations are necessary, but that there must be an allowance for some decisions to be made locally. Another interviewee chose option (a), but suggested that all the categories would benefit.

All interviewees thought that conformity of ethics assessment procedures in research and innovation is necessary, or at least that it is important. Two cited transparency as a main feature that conformity of ethics assessment ought to support. Others cited harmony across the procedures in different countries, as well as the goal of protecting the interests of stakeholders and well-being of research participants. One interviewee cited public accountability as something that conformity in ethics assessment procedures might ensure.

The interviewees offered a range of responses for the different challenges that conformity of ethics assessment may face. Such challenges include: a lack of knowledge in the individuals carrying out ethics assessment, conflicts of interest in those individuals, a general distrust of legal regulations in some countries (in areas such as Eastern Europe), unwillingness of lay volunteers to undergo additional training, and the challenge that such assessment would have to be carried out at level of generality that might not be useful. An interviewee with a background in the social sciences pointed out that cultural differences may be important to consider. For example, written consent may not be appropriate in spoken-word cultures. Similarly, in some cultures it may be more appropriate to seek consent from elders or from the "community of care" rather than from individuals.

Views on certification of ethics assessment procedures

The second part of the interview covered certification of ethics assessment procedures. For the most part, the interviewees were not aware of any existing certification for ethics assessment.

One exception was an interviewee from Austria who suggested that ethical assessment there does have "Ethikkommissionen,"[53] which are like a certification process at the national level.

Four of the five interviewees supported certification of ethics assessment procedures, citing the need for standards as the main motivation. One of those four added the qualification that certification of ethics assessment must take local traditions and problems into consideration. These four interviewees offered many advantages for certification, including transparency, credibility, reliability, and consistency. One interviewee did not support certification for ethics assessment, suggesting that the current methods within the university are sufficient. The five interviewees offered a range of different responses on the question of possible challenges for certification of ethics assessment. The challenges mentioned include competing interests, lack of qualified trainers, the problem of the context-sensitivity of ethical decision-making, and the concern that many will view the certification process as an extra, and unwanted, layer of bureaucracy. Four of the five interviewees thought that regulations would have to be put into place to ensure that organisations go through the certification process. Two interviewees pointed out disadvantages of regulations, such as instances when regulations can disrupt workflow in a costly manner, and worries about a loss of freedom in conducting scientific research.

Three of the five interviewees suggested that training and accreditation for certification of ethics assessment should be carried out at the national level, by a National Ministry of Health, for example. Other suggestions were that universities could offer training (as many currently do) and that an EU umbrella organisation, such as European Network of Research Ethics Committees (EUREC)[54], may be best suited for training and accreditation purposes.

Views on certification of ethics professionals

In addition to questions about the certification of ethics assessment procedures, the interviewees were also asked a series of questions about the certification of ethics professionals. They were split on the issue of whether ethics professionals should be certified. Two interviewees approved of certification, with one of those adding that some ethics professionals currently lack specific qualifications in their educational background. Reasons against certification of ethics professionals included the claim that requiring certification may dissuade individuals from volunteering their time and the claim that certifying individuals may give too much power to some people. One interviewee acknowledged that ethics professionals should be qualified, but added that experience, such as experience sitting on ethics committees, would be superior to formal training. The interviewees were not able to indicate specific examples of certification for ethics professionals, with one exception who noted the Compliance Certification Board (CCB).[55]

The interviewees suggested many different possible obstacles and problems for certifying ethics professionals. Two of the interviewees expressed concern that certification of individuals may give too much power or status to those who are certified, creating an undesirable "two-class system" in which view of the uncertified are not taken seriously. Other obstacles highlighted were potential for disagreement among stakeholders (e.g., in proposals of ethics committees and government ministries), and a lack of will and/or time to carry out certification. A noteworthy concern was that training cannot replace experience. An individual may go

[53] http://www.ethikkommissionen.at/
[54] http://www.eurecnet.org/index.html
[55] http://www.compliancecertification.org/CCEP/CertifiedComplianceEthicsProfessional.aspx

through training for certification by just "ticking the boxes" without really gaining the skills and knowledge required.

On the issue of gaps in the certification process and on what might be needed to establish an effective certification of professionals, the interviewees gave various responses that reflected their replies to previous questions. For example, there were concerns about the selection process itself including individuals with little experience as well as concerns about the creation of a "two-class system." Other themes here were a lack of knowledge in ethics and a lack of high-level (e.g. European level) norms and rules. Another point is that existing gaps exist because there may lack an open and transparent process determining who becomes certified and who does not.

7.3. **Views of interviewed national ethics committees**

People interviewed were representatives of NECs across Europe (Italy, Finland, Denmark, UK), mainly dealing with healthcare and bioethics issues.[56] These four organisations were selected for the interviews, from a total of ten considered as candidates (these organisations had participated in interviews in SATORI WP1 so were familiar with the project). The structured interviews were carried out by phone, one was conducted in person. A synthesis report of the each of the interviews was prepared based on the transcript of the meeting. Besides the distribution of documentation of the project by email, a brief introduction to both the SATORI project and the interview guidelines were provided at the start of the interview.

The interviewees found the guidelines quite clear, though some additional explanation was required with respect to the concept of "ethics assessment professionals" (mainly due to the general scepticism about this topic, which then reflected in the discussion). Despite the limited number of people interviewed, detailed information was collected and quite homogeneous results emerged, likely fulfilling the original scope of the analysis.

Interviewees mainly focused on the discussion regarding conformity assessment[57] of ethics assessment procedures and ethics assessment professionals, and not much on ethics assessment of products and technologies. This was most likely due to the background of the interviewees, most of them had expertise in the research and development area (rather than on product development).

The analysis showed that interviewees share similar views on most of the themes discussed, and therefore results are presented (unless controversial opinions were identified).

Views on conformity assessment and ethics in general

Regarding conformity assessment of ethics assessment procedures, the interviewees identified both pros and cons, and areas of potential interest.

[56] Names anonymised upon request.

[57] The interview guideline defined this as follows: Conformity assessment refers to demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled. Its purpose is to help ensure that policies, procedures, professionals deliver on their promises. Certification is one of the methods of demonstrating conformity (others are testing, inspection and declarations of conformity) and the intent here is to specifically gauge stakeholder views.

According to the interviewees, positive aspects include improving consistency and confidence on ethics assessment and support harmonisation of ethics assessment procedures; challenges include the risk of too formal and bureaucratic procedures, and transformation of the evaluation process into a mere tick-box exercise (checking compliance against a pre-set of rules and criteria), instead of qualitative evaluation of the specific cases (as stated by the interviewees: "taking away the attention from the individuals involved"). The interviewees underlined the risk that any conformity system for ethics assessment, if not properly designed, could have a negative impact on basic principles and approaches of ethics assessment. Ethics assessment is based on human judgment, and often it needs to be done on a case-by-case basis, and this could conflict with too strict and formal conformity assessment procedures.

The interviewees identified possible ways to implement conformity assessment, with suggestions on how to ensure different levels of certification and harmonisation depending on the situation and level of risks. Regarding ethics assessment of products and technologies, one of the interviewees suggested an approach based on the responsible research and innovation (RRI) concept, as a systematic approach capable of ensuring a certain degree of uniformity. The interviewee pointed out that improper use (unethical behaviour) at the level of applications and products, should be dealt with by the law (conformity assessment is not appropriate in these cases).

In the case of conformity assessment of ethics assessment professionals, though some possible advantages have been underlined, most of the interviewees where sceptical about scope and feasibility.

At the general level, a major defining factor in the discussion on conformity assessment is whether there a reference regulatory framework for ethics assessment exists. The law generally sets principles and requirements for the activities of national ethics committees, and the same applies to ethics assessment procedures in certain fields (e.g., medical and biomedical field). A certain degree of conformity is therefore implicit in the rules governing NECs, and thus in the opinions of interviewees the interest in conformity assessment for national ethics committees is limited.

In the case of other types of assessment (e.g., ethics committees within a research organisation, or active in less regulated areas[58]) the need for, and interest in conformity assessment could be more prominent. In the case of private organisations carrying out ethics assessment (e.g., providing ethics assessment as a service to other organisations), conformity assessment becomes essential, and it should also be accompanied by an appropriate accreditation system.

Overall, experts agreed that conformity assessment could provide advantages, but on the other hand they also pointed out that too formalised procedures could be detrimental to ethics assessment, carrying a risk of changing the nature of the ethics evaluation process.

Views on certification of ethics assessment procedures

Within NECs, ethics assessment procedures are relatively well established, based on the experience and long tradition of these bodies, and therefore definition of standardised protocols for their work seems a feasible option. The final scope of conformity assessment should be the improvement of the quality of the ethics assessment processes.

[58] Interviewees were mainly active in the biomedical and healthcare areas.

The way ethics assessment of research projects is carried out, and the minimum requirements for ethics assessment (e.g. protocols, key questions to address) are seen by experts as good candidates for standardisation. Conformity assessment could then aim to evaluate whether and how these protocols are applied.

All interviewees recognised that conformity assessment could be a way to:

- Improve consistency and assure correctness of ethics assessment, help do things more systematically, and thus facilitate both the application and ethics review process
- Improve understanding and communicate the ethics evaluation process
- Improve transparency, confidence, and trust in ethics assessment (from the point of view of people involved in ethics assessment procedures as well as people using the product)[59]
- Support harmonisation of ethics assessment. For example, a single evaluation from a certified ethics committee might be trusted and accepted by another ethics committee, thus enhancing the ethical review system within different committees in a country, or across countries.

The type and characteristics of projects, review processes, experts involved in ethics assessment are generally very broad. Ethics assessment is characterised by diversity, and based on in-depth evaluation and human judgment, and often performed on a case-by case basis. Therefore, if such procedures become too formal and standardised it could be difficult to deal with differences in context, situations, issues that are part of the ethical evaluation work. Experts agreed that conformity assessment carries a risk of reducing the flexibility and adaptability of the ethics assessment process, and fostering standard procedures that do not fit with specific situations, and local conditions.

Another challenge is also evident; to define and evaluate conformity, there is a need for objective, measurable parameters. Ethics assessment is too broad to identify these parameters at a general level, and therefore, to define effective criteria, conformity assessment should focus on specific clusters/areas (e.g., in terms of applications, use, issues).
As one of the interviewed experts pointed out:

> Ethical evaluation is based on discussion of different groups and human judgement. You have to assume that in an exercise with human judgement you might have different outcomes and that you need to be able to explain the different outcomes. Human judgement implies that outcomes might not be simple, and that you could achieve non-predictable answer. At the same time, you need to ensure a degree of consistency (and uniformity) in outcomes of those different decisions. You need to be confident that is a reasonable and rigorous assessment (e.g. avoiding arbitrary decision from individuals that are not accountable).[60]

Other risks include increasing complexity, costs, and bureaucracy of ethics assessment procedures. A key challenge identified by most of the experts would be to find the resources to carry out conformity assessment.

It is essential that conformity assessment is carried out in a way that simplifies procedures, and reduces (not increases) bureaucracy. A conformity assessment and certification system should allow for differential approaches in diverse cases, ranging from a simple and fast exercise to

[59] As an example, one of the interviewees mentioned the CE marking on quality and safety.
[60] Name anonymised on request. Interview carried out on 31 August 2016 by AIRI.

very detailed and time consuming processes, depending on the specific situation and needs (levels of risk). It should be integrated as a component of existing processes (e.g. such as the safety and quality process in research, or product development).

As an alternative to setting up a formal conformity assessment systems, some interviewees suggested other ways to ensure consistency, quality, and harmonisation of procedures in the work of ethics committees. For example, a good networking system, connecting all ethics committees (that are working on a specific area, topic, etc.) and providing the opportunity for sharing of resource and documents, common education and professional training, regular meetings amongst members to discuss criteria and objectives of ethics assessment, could work well to this end. A system ensuring continuous exchange of information and practices amongst ethics assessors, could reduce differences in the way ethics assessment is carried out, the quality of work of ethics committees, and could act as an "informal" conformity assessment. Examples of this approach can be found in the activities of local and national committees in Denmark and Finland.

Incentives for conformity assessment of ethics assessment procedures

All interviewees agreed that ethics committees are generally overloaded with procedures, and that conformity assessment should not become an additional burden.

A clear motivation will be needed to ensure effective implementation of any conformity assessment system. Simplification of procedures, harmonisation, increase of transparency and trust in the work of ethics committees, and the other benefits previously underlined, could support conformity assessment. However, incentives should be put in place to address the most relevant challenges, particularly, the costs and resources needed for conformity assessment.

A specific regulation (e.g. an EU Directive or a national law), would ensure consistency and would provide the possibility for setting out specific requirements and monitoring how conformity assessment is implemented in ethics committees (e.g. some interviewees gave the example of the legislation on clinical trials). However, it would imply a significant, maybe unfeasible, political exercise (in particular, across countries). As already said, the risk would be to reduce the flexibility of ethics assessment, and make conformity assessment a bureaucratic burden. A benefit would be that if a certified ethics committee approves a project, then it would be valid in the whole country, or in all countries in Europe.

One interviewee warns against applying a complex and bureaucratic system in all circumstances. It should be a system able to adapt to different levels of activities.

Experts underlined that in any case such system should ensure that a wide range of people and stakeholders are consulted and involved at all stages, in both developing and operating the system (the regulatory system, and the related conformity assessment, and certification procedures).
Interviewees mentioned examples of conformity assessment of ethics assessment procedures:

- In the Netherlands, the Central Committee on Research Involving Human Subjects (CCMO)[61].

[61] http://www.ccmo.nl/en/tasks-of-the-ccmo

- In UK, the centralised Research Ethics Committee system in the healthcare and clinical area (NHS)[62]
- In the pharmaceutical sector, ethics assessment is routinely carried out on specifically identified ethical issues and ethical procedures, such as the way experiments with humans and animals are carried out, safety of products, patients care. These are requirements set by the law, so conformity is somehow implicit.

Regarding the UK system, it has been underlined that it requires different levels of assessment and oversight (less or more complex), depending on the level of risks or ethical concerns involved.

A differentiated approach depending on the level of risks is an essential aspect of any conformity assessment system.

Training and courses for certification of ethics assessment procedures

Organisations providing training should be independent, and trusted by ethics committees and their members. They should also have in-depth competences of the issues at stake, and update their competences and knowledge continuously. Good candidates to define training requirements and provide training could be national association or a central coordinating office of national ethics committees and/or research ethics committees.

All interviewees agreed that people involved in conformity assessment of ethics assessment need to have a common basic understanding of the mechanisms, systems and principles involved in ethics assessment. Training is an essential aspect to develop a trustable (and transparent) certification system.

Accreditation system for certification of ethics assessment procedures

Whenever the law sets out the requirements for the work of ethics committees (e.g., as in the case of NECs), most of interviewees viewed accreditation as not essential.

Where there are ethics committees that are not subject to specific regulation (e.g., an ethics committee in a research organisation active in unregulated areas, organisations providing ethics assessment as a service to other organisations, etc.), it could become important to have conformity assessment tools and an accreditation system in place.

To work properly, the accreditation system must be based on the principles of independence, and absence of conflict of interest. Professional groups and organisations involved (with a good reputation amongst stakeholders) should support it. Good potential candidates to organise and carry out accreditation could be government ministries, EU agencies and competent authorities, existing certification bodies, and private accreditation organisations already active in other areas.

However, considering resources available, most of interviewees underlined that it would be quite difficult to require NECs to support, with their own funding, an accreditation system for conformity assessment of ethics assessment.

[62] See Health Research Authority - http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/ and the Clinical Ethics Network - http://www.ukcen.net/main/about

Views on certification of ethics professionals

Most interviewees were sceptical and could not see any value in certification of ethics professionals.

Interviewees highlighted that a key issue was how to define an 'ethics professional'. Ethics committees compose of permanent staff of the committee, and invited members. All of them are people with different expertise and backgrounds (e.g. philosophy, law, social science, life science, etc.); each provide their views in the evaluation process. Besides staff and experts, participants in the evaluation process often include lay people. It is therefore quite difficult to identify and characterise an ethics professional through any specific training or disciplines background. Considering the variety of disciplines involved, the challenge in certification is the description of what aspects would be essential to qualify as an 'ethics professional'.

Discussion within an ethics committee is based on the combination of different disciplines and expertise, including legal, philosophical, medical, ethical points of views. It is the merging of the different expertise of members that supports the evaluation process. Therefore, it would not be relevant to have a certification system only for the staff of an ethics committee (i.e. those that might be classified as "ethics professionals"), considering their impact in the evaluation process is limited (they provide just one view).

An interviewee said that in their country, ethics and ethics judgment is a citizen issue, and not a "professional" issue.

An interviewee suggested that certification could be beneficial for the curriculum vitae of a person employed in an ethics committee. Other interviewees noted that a system of certification of ethics professionals should be regulated by the law, and in any case, it would be a complex and lengthy process.

8. Regulation of certification in Europe

This section briefly explores the regulation of certification in Europe, based on desk research (legislative databases e.g. EUR-LEX, and searches using key words such as certification, conformity assessment, accreditation) into the various ways in which certification is currently regulated in the EU. As there is no single overarching framework for the regulation of certification, this research looked at some key examples of legislation that govern, support or encourage certification at the EU-level and tries to derive some useful insights for SATORI.

A scan of EUR-Lex using keywords threw up 62207 results on 'certification', 16988 results on 'conformity assessment', and 2061 results on 'ethical certification'.[63] A search for 'conformity assessment ethics' threw up 1822 searches. Since this is the key focus of SATORI, we looked at some examples that came up within this latter search to draw some conclusions about the regulation of certification in Europe. These legislative instruments analysed were: Regulation 1025/2012 on European standardisation[64]; Regulation (EC) 66/2010 on the EU Ecolabel

[63] Scan carried out in November 2016.

[64] European Parliament and the Council, Regulation (EU) no 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council.

(which lays down rules for the establishment and application of the voluntary EU Ecolabel scheme); Regulation (EC) No 1060/2009 on credit rating agencies[65]; Directive 2007/59/EC on the certification of train drivers; the New Legislative Framework instruments – i.e. Regulation No 765/2008 setting out the requirements for accreditation and the market surveillance of products[66], Decision No 768/2008/EC on a common framework for the marketing of products[67], and Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country[68]; and Regulation (EU) 2016/679 – the General Data Protection Regulation or GDPR[69]). We examine these legal instruments under the following categories: nature; criteria and conditions; certification procedure; revocation and withdrawal; measures to boost public trust and confidence; and harmonisation.

Nature

The most broad of the select legal instruments is the Standardisation Regulation (not specifically focussed on certification), "establishes rules with regard to the cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation".[70] The other legal instruments are more topic (data protection, train driver certification, accreditation of CABs), sector (product marketing) or field-specific (environment), offering details (in a particular context) about who may apply for certification, and the conditions (or requirements) for obtaining certification. Some of the legal instruments support a mandatory type of certification e.g. Regulation No 765/2008 and the CE Marking, while others such as the GDPR encourage or deal with certification that is of a 'voluntary' nature. This shows us that regulation either addresses certification at a general or more specific level depending on the objective to be met.

Criteria and conditions for certification

The legal instruments studied here cover various types of criteria. The Standardisation Regulation offers criteria on requirements for the identification of ICT technical specifications[71], and criteria for determining European stakeholder organisations eligible for union financing for standardisation activities[72]. The Ecolabel Regulation specifies general requirements for EU Ecolabel criteria (i.e. their basis, how they shall be determined, what they

[65] Amended by Regulation (EU) No 462/2013 of the European Parliament and of the Council of 21 May 2013 amending Regulation (EC) No 1060/2009 on credit rating agencies, *OJ L* 146, 31.5.2013, p. 1–33.
[66] European Parliament and the Council, Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, *OJ L* 218, 13.8.2008, p. 30–47.
[67] *OJ L* 218, 13.8.2008, p. 82–128
[68] *OJ L* 218, 13.8.2008, p. 21–29.
[69] European Parliament and the Council, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJ L* 119, 4.5.2016, p. 1–88.
[70] Article 1.
[71] Annex II.
[72] Annex III.

should include, feasibility exploration provision, when the label shall not be awarded, and derogation).

Akin to the Ecolabel Regulation, Directive 2007/59/EC on the accreditation of train drivers establishes a list of requirements for obtaining a licence which are set out in Articles 10-13 of the Regulation and include: age, education, physical fitness, psychological fitness, professional competence, and passing examinations.

The Regulation on credit rating agencies covers certification for credit rating agencies. It lays down specific criteria for assessing the compliance of a credit rating agency with its duties in terms of internal organisation, operational arrangements, rules on employees, presentation of credit ratings and disclosure.

Decision No 768/2008/EC defines a 'conformity assessment body' as one "that performs conformity assessment activities including calibration, testing, certification and inspection". It deals with the EC declaration of conformity, outlines rules and conditions for affixing the CE marking, lays down requirements relating to notifying authorities, requirements relating to notified bodies etc.

Regulation 765/2008 lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities and provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security. When considering SATORI recommendations for granting accreditation for ethics committees and ethics professionals, Regulation 765/2008 may be an important document to consult. It lays down the general principles of the CE marking.

The GDPR calls for the establishment of certification mechanisms and data protection seals and marks to be encouraged to allow data subjects to quickly assess the level of data protection of relevant products and services. It has specific provisions devoted to certification (Article 42-43 etc.). It specifies the nature of certification (voluntary), who shall provide it, duration etc. It provides the criteria for accreditation of certification bodies.

This analysis reveals the analysed regulations outline criteria and conditions for certification to varying degrees – some are more prescriptive, others less so. They cover the list of requirements, exclusions, criteria for conformity assessment and/or certification bodies, etc.

Certification procedure

Regulation 1025/2012 on European standardisation does not lay down any specific conformity assessment or certification procedures. The EU Ecolabel Regulation specifies the procedure for the award of the EU Ecolabel (application to competent bodies, checks by the notification to applicant, registration post verifications, conclusion of contract with operator, placement of the EU Ecolabel), conditions of its use, and market surveillance and control of the use of the EU Ecolabel.

Regulation (EC) No 1060/2009 on credit rating agencies also specifies the procedure i.e. this involves application for certification by the credit rating agency to the Committee of European Securities Regulators (CESR), transmission by CESR of the application to the competent

authorities of all Member States, inviting them to consider becoming a member of the relevant college, notification of acceptance by competent authorities that have decided to become members of the college, drawing up by CESR and publication on its website of the list of the competent authorities that are members of the college, selection of a facilitator in accordance with set criteria, examination of the application for certification, notification and publications of the certification decision.

Under Directive 2007/59/EC which lays down the procedures for obtaining the licence and the certificates for train drivers operating locomotives and trains on the railway system in the Community, licence applications must be lodged with the competent authority by the candidate driver or any entity on his behalf. The competent authority issues the licence as soon as possible and no later than one month after receiving all the necessary documents.

Regulation No 765/2008 setting out the requirements for accreditation and the market surveillance of products[73] sets out the CE marking procedure: it states that the manufacturer is responsible for affixing it, thus ensuring that the requirements are complied with. Penalties, including criminal penalties, are in place in the case of unauthorised use of the marking. Decision No 768/2008/EC contains a range of conformity assessment procedures from which the legislator can select as appropriate. It also lays down rules for CE marking. Regulation (EC) 764/2008 lays down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.

The GDPR prescribes that certification bodies (which have an appropriate level of expertise in relation to data protection) or competent supervisory authorities can issue certification, based on approved criteria, to data controllers or processors.

The comparative analysis of the certification procedures outlined in the analysed regulations shows that in some cases procedure too (based on sectoral practice) is either specified or left to be elaborated by competent authorities.

Revocation and certification withdrawal conditions

Regulation 66/2010 on the use of the Ecolabel establishes revocation conditions through a contract between the competent body and each operator. This contract will include provisions for withdrawal of the Ecolabel. Directive 2007/59/EC on the certification of train drivers covers revocation conditions by specifying that drivers must undergo periodic checks to ensure that they comply with requirements. Regulation No 1060/2009 on credit rating agencies sets forth measures, such as withdrawal of registration or the suspension of use, that may be put into place in case of a breach of the obligations. For the more general regulations, such as Regulation 765/2008 and Regulation 768/2008, the revocation conditions are left largely in the hands of the Member States. In the GDPR, certification can be withdrawn, as applicable, by the certification bodies referred to in Article 43 or by the competent supervisory authority where the requirements for the certification are not or are no longer met.

The comparative analysis here shows that again revocation and withdrawal of certification is highly variable – sometimes strictly specified in law or covered in contractual terms, depending on what is being certified.

[73] European Parliament and the Council, Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, *OJ L* 218, 13.8.2008, p. 30–47.

Measures to boost public trust and confidence

The regulations that we considered, for the most part, include measures for boosting public trust and confidence in the accreditations. The most common method for boosting public trust is in the forms of official publications or registers. For example, Directive 2007/59/EC calls for the competent authority to publish and update a register of persons who have been accredited. Regulation No 765/2008 calls for a list of national accreditation bodies to be compiled, updated, and made publicly available. The General Data Protection Regulation states that the European Data Protection Board shall collate all certification mechanisms and data protection seals in a register and shall make them publicly available by any appropriate means. Regulation No 1025/2012 increases public trust by stipulating that public authorities must be included in the standardization process.

Of the regulations considered, Regulation No 66/2010 dedicates the most effort to raising public trust, which is to be expected given the nature of the regulation. It specifies that both Member States and the Commission should agree on an action plan to promote the EU Ecolabel by "awareness-raising action and information and public education campaigns for consumers, producers, manufacturers, wholesalers, service providers, public purchasers, traders, retailers and the general public."[74]

Measures to boost public trust and confidence are extremely important. However, the above analysis shows boosting public trust does not appear to be a primary concern, though some good measures are evident.

Harmonisation

Nearly all the regulations explicitly call for some form of harmonisation, although their methods of implementation vary, depending on the focus of each. Regulation No 66/2010 specifies that future legislation shall guarantee harmonisation, while Regulation No 1060/2009 lays down the harmonised conditions in the regulation itself. Community harmonisation (Regulation No 765/2008) is another method that is used. Regulation 1025/2012 calls for the Commission to publish harmonised standard. The issue of harmonisation is perhaps most important for Directive 2007/59/EC, which has harmonisation as one of its main goals to facilitate train drivers moving from one railway undertaking to another. The analysis shows harmonisation is important and has significant value in many contexts. But one must note the difference between harmonisation by a EU Regulation and harmonisation via a Directive which affects the impact of such harmonisation. Regulations are directly applicable and enforceable; Directives must be transposed by Member States into national law.

9. Enhancing ethics assessment through the use of conformity assessment

This section explores how (and what types of) conformity assessment could be used to support the SATORI CEN Workshop Agreement (CWA) *Ethics assessment for research and innovation*[75]. The CWA has two parts. Part 1 of the SATORI CWA outlines recommendations for the composition, role, functioning and procedures of ethics assessors (i.e. research ethics

[74] *OJ L* 27, 30.1.2010, p. 1–19

[75] SATORI CEN draft, *Ethics assessment for research and innovation*, 2016. http://satoriproject.eu/publications/satori-mutual-learning-workshops-portal/ [Note, these are the public consultation drafts; the final version of the CWA will be presented in mid-2017]

committees, institutional review boards, ethical review committees). It aims to help organisations strengthen and/or improve ethics assessment of research and innovation projects. Part 2 of the CWA provides researchers with guidance for carrying out ethical impact assessments (i.e. the process of determining and addressing the ethical impacts of research and innovation activities, outcomes, and technologies).

A CWA is a reference document and conformity with it is entirely voluntary; a CWA does not have the status of a European Standard and entails no obligation at national level.[76] However, if deemed apt, the CEN and the committee responsible for the standard could grant the SATORI CWA the status of a recognised standard for ethics assessment and ethical impact assessment.

How would the three types of conformity assessment apply to the SATORI CWA? All three types of conformity assessment might have some value depending on: expectations, demands for, existing regulation, and the added value of their use to boost ethics assessment procedures or ethical impact assessment processes and results.

	CWA Part I (Recommendations for ethics committees)	CWA Part II (Ethical Impact assessment)
First party	✓	✓
Second party	✓	✓
Third party	✓	✓

Table 2: Mapping conformity assessment types to CWA Parts 1 and 2

However, as our stakeholders pointed out some types might be more relevant than others, and further it also depends on the context (local, national, regional), other existing oversight mechanisms, incentives for its use, etc.

As each types of conformity assessment may use one or more different types of techniques, the following table plots the relevance of these various conformity assessment techniques to the SATORI CWA Parts 1 and 2.

	CWA Part I (Recommendations for ethics committees)	CWA Part II (Ethical Impact assessment)
Assessment	✓	✓
Auditing	✓	✓
Evaluation	✓	✓
Examination	✓	✓
Inspection		✓
Testing	✓	✓
Combinations of techniques	✓	✓

Table 2: Relevance of conformity assessment techniques to SATORI CWA Parts 1 and 2

Most conformity assessment techniques could be used to check, evaluate, or assess adherence to the SATORI CWA specifications, either exclusively, or in combination with others,

[76] http://www.cen.eu/work/products/cwa/pages/default.aspx

depending on what is to be assessed, the context, and the specific characteristics to be assessed. The reason that inspection is not marked for the CWA Part 1 is because we see a possible resistance from ethics committees to this technique; it might be counter-productive due to its dependence on the professional judgment of the inspectors or inspection team (unless there is a common agreed or legislative requirement). As the ISO suggests "the competence of inspection bodies is highly dependent on the knowledge, experience, and interpretive skills of the inspection bodies' personnel".[77]

At this stage, it would be premature to be too prescriptive. It should be up to the policy makers, associations of RECs and RECs (as users of the ethics assessment process) to determine (in consultation with standards and conformity assessment agencies) the best path forward – i.e. what single technique or combination of techniques would present the best means of assessing their conformity with Part 1 of the SATORI CWA.

9.1. Conformity assessment: Part 1 CWA

This section assesses specifically how self-declaration of conformity, peer review (or peer assessment), certification, and accreditation might play out in relation to Part 1 of the CWA (which outlines recommendations for the composition, role, functioning and procedures of ethics assessors). These are some preliminary ideas informed by the literature review and the stakeholder engagement carried out in the project. The tables consider: Potential target(s) of evaluation, target stakeholder, conformity issuer/certifier/accreditor, relying party (i.e. a natural or legal person that relies upon the conformity assessment results), how would it play out, benefits, risks, challenges, and business case.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
Potential target(s) of evaluation (from CWA Part 1)	Ethics assessment/review processes & procedures, implementation, quality, competence of members, continual improvement.	Ethics assessment/review processes & procedures, implementation, quality, competence of members, continual improvement.	-Ethics assessment/review processes & procedures, implementation, quality, competence of members, continual improvement. -Certification of competence of members of ethics committees.	Certification bodies that perform an audit on ethics committees and institutional review boards.
Target stakeholder	Ethics committees, institutional review boards, researchers.	Ethics committees, institutional review boards, peer-review board.	Ethics committees, institutional review boards, Certification bodies.	Certification bodies that assess ethics committees.

[77] ISO, "Conformity assessment techniques – Inspection". http://www.iso.org/sites/cascoregulators/documents/Conformity%20assessment%20techniques%20-%20Inspection.pdf

	Self-declaration of conformity	Peer-review	Certification	Accreditation
Conformity issuer/certifier/ accreditor	Ethics committees, institutional review boards	Peer-review board	Certification bodies	National or EU accreditation body.
Relying party	The organisation where the ethics committee is constituted (e.g., university); international research funders; publishers; society.	The organisation where the ethics committee is constituted (e.g., university); research funders; publishers; society.	The organisation where the ethics committee is constituted (e.g., university); research funders, publishers; society.	The organisation where the ethics committee is constituted (e.g., university); research funders, publishers; society.
How would it play out	An ethics committee would perform an assessment of itself and then declare that it complies/conforms to the guidelines set out in SATORI CWA Part 1. Stakeholders, (e.g. research funders especially regional ones e.g. EU or international) would be able to evaluate that the REC follows a EU minimum model.	A group of peers (peer-review body, could be ad-hoc) will review the self-assessment, and possibly check additional information (e.g. through interviews). Stakeholders, and most notably research funders especially regional (e.g. EC or international) would be able to evaluate the conclusions of peers about committee's performance.	Independent certifying bodies would (using one or more of the conformity assessment techniques outlined above) assess and declare (a) that the quality of ethics assessment/review processes & procedures meet the SATORI requirements, or (b) that an ethics committee has the competencies to perform ethics review. Stakeholders can review the independent certificate.	An accreditation body independently evaluates the technical and organisational capacity of the certification body that performs the audit of the ethics committee or institutional review board against the SATORI CWA specifications. Stakeholders will be assured that the certification bodies that perform the audit are of a certain quality.
Benefits	Improve ethics assessment policies and procedures. Enable regional and international funders make decisions about REC quality. Promote good practice. Transparency.	Improve ethics assessment policies and procedures, though input from peers. Enable regional and international funders make decisions about REC quality. Promote good practice though input from peers.	Improve suitability, adequacy, credibility, consistency, and effectiveness of ethics assessment policies and procedures. Transparency. Trust.	Trust. Stakeholders will be assured that the certification bodies that perform the audit are of a certain quality.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
		Transparency.		
Risks	Sole responsibility of the organisation making the declaration.	If the process is not well managed, relationships may suffer.	Resistance from ethics committees to open themselves up to scrutiny. Increase in bureaucracy.	Resistance from ethics committees to open themselves up to scrutiny. Increase in bureaucracy.
Challenges	Some costs. Resource (time and human) burdens. Lack of incentives to self-declare.	Some costs. Resource (time and human) burdens. Lack of incentive to get a peer-review, Lack of peers to conduct review.	Costs. Resource (time and human) burdens. Lack of incentives to obtain a certificate.	Costs. Resource (time and human) burdens. Lack of incentives for certification body to get accredited.
Business case	Most accessible tool. If intrinsic motivations drive ethics assessment, this is the most feasible tool. The number of implementations ("demand") depends on the presence of incentives to promote and enforce. Funders can request a self-assessment be carried out to guarantee a high quality of ethics assessment. Also, research organisations could establish it to promote transparency and inform researchers about existing procedures. It could form part of an organisation's CSR policy to foster transparency in relation to research	There is a good tool, if (in line with arguments mentioned under "self-assessment,") ethics committees want to learn and improve from peers. Number of implementations ("demand") depends on the presence of incentives to promote and enforce.	In addition to the reasons mentioned under "self-assessment," this is the best option if an independent and rigorous check is desired. There might be a business case to establish such certification at the EU level given the increase in collaborative, pan-EU research projects. It may also be required in cases where there are doubts about the quality of ethics committee procedures and processes in a country. The number of implementations ("demand") depends on the presence of incentives to promote and enforce.	In addition to the previous mentioned reasons under business case, if it is desired that the certification bodies are reviewed for their independence and expertise.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
	subjects and/or other stakeholders.			

Table 3: Connecting SATORI CWA Part 1 to SDoC, peer review, certification, and accreditation

9.2. Conformity assessment: Part 2 CWA

The following table looks specifically at how self-declaration of conformity, peer-review, certification, and accreditation might play out in relation to Part 2 (ethical impact assessment) of the SATORI CWA.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
Potential target(s) of evaluation (CWA Part 2)	EIA of a R&I project.	EIA of a R&I project.	EIA of a R&I project.	Certification bodies or agencies certifying EIA of projects.
Target stakeholder	Researchers, innovators, stakeholders of the research project or innovation under scrutiny.	Ethical impact assessors, researchers, innovators, stakeholders of the research project or innovation under scrutiny.	Organisations (or researchers/innovators or ethical impact assessors within) carrying out EIA and which want their research projects to be certified for EIA.	Ethical impact assessor (or the organisations carrying out EIA or providing such services).
Conformity issuer/certifier/ accreditor	Ethical impact assessor. (researcher, innovator, ethical impact assessment specialist)	Peers of ethical impact assessors. (researcher, innovator, EIA specialist)	Certification bodies	National or EU accreditation body.
Relying party	Funding agencies. Innovation procurers. Publishers e.g. journals.	Funding agencies. Innovation procurers. Publishers e.g. journals.	Funding agencies. Innovation procurers. Publishers e.g. journals.	Funding agencies. Innovation procurers. Publishers e.g. journals.
How it would play out	Individuals, departments, bodies, or organisations carrying out an EIA after using one or more conformity assessment techniques would declare that it met the SATORI CWA Part 2 specifications	Peers of individuals, departments, bodies, or organisations carrying out an EIA after using one or more conformity assessment techniques would declare that it met the	Independent certifiers would (using one or more of the conformity assessment techniques outlined above) assess and declare (a) the EIA was compliant with the SATOI CWA, (b) ethical impact assessors/consultants (or the organisations carrying out EIA or providing such	An accreditation body would independently evaluate the technical and organisational capacity of the EIA certifier against the SATORI CWA specifications.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
	(and maintain the documentation to prove it).	SATORI CWA Part 2 specifications (and maintain the documentation to prove it)	services) had the technical and organisational capacity to perform this task.	
Benefits	Improvement in EIA processes. Flexibility, transparency for stakeholders.	Improvement in EIA processes. Flexibility, transparency for stakeholders.	As increasing numbers of organisations offer EIA services, certification would give those certified a competitive and reputational advantage.	Improved operational efficiency in EIA certifiers. Improved credibility of the assessments.
Risks	Ethicswashing.[78] False or misleading declarations (liabilities must be prescribed) Might be unreliable, inadequate, or unsuited for high risk research and innovation projects.	The independence of peers and anonymity of the researcher (competition or scientific viewpoints). There is a risk of conflict of interest if reviewers are connected to government and funding bodies – i.e. two key R&I players. Commercial sensitivity of a project.	Lack for field-specific competence with the certification bodies.	The setting up of an accreditation system might be costly and therefore hinder innovation.
Challenges	Monitoring mechanisms. For the declaration to be truly meaningful the person making the declaration should be someone who has the authority to commit the resources required to ensure that the	Finding available peers for the project, independence (anonymity).	Cost of certification. Certification bodies must be willing to train their staff to certify against this standard ("based on demand for this certificate).	High cost and difficulty of obtaining recognised accreditation.

[78] Refers here (in line with the concept of 'greenwashing') to the spin in which ethics marketing and public relations is deceptively used to promote the perception that an organisation's research and innovation are ethical, ethics-friendly, or ethics-compliant.

	Self-declaration of conformity	Peer-review	Certification	Accreditation
	EIA process is properly completed.			
Business case	More cost savings implied. Demonstration of good practice as part of CSR policy of an organisation. Greater opportunity for public debate on research & innovation.	Learning though peer-review. Demonstration of good practice as part of CSR policy of an organisation. Greater opportunity for public debate on research & innovation.	Would bring overall benefit to entities (e.g., research funders) having to rely on the quality of EIAs. It promotes good decision making and supports positive social and environmental impacts. Public acceptance of an innovation.	Would promote a system based on trust, transparency, and competence.

Table 4: Connecting SATORI CWA Part 2 to SDoC, peer review, certification, and accreditation

Thus, we see from the exercises above that there are some ways in which conformity assessment could play out in relation to Parts 1 and 2 of the SATORI CWA. However, as highlighted by our stakeholders, some (e.g., certification) might be premature and even counter-productive. Their ability to be successfully implemented and have an impact depends on three key things: **policy and legal frameworks** that support the development and implementation of such schemes, whether at the EU or national level, **incentives, and subsidies** to undertake conformity assessment activities, and **usefulness and ability** of conformity assessment techniques to deliver their goals vis-a-vis improving the quality of ethics assessment and ethical impact assessment.

10. Conforming to the SATORI CWA: tools to assist organisations

The proposals in Section 10.1 and 10.2 are broad and of general nature. We need something practical that can facilitate the use of the SATORI CWA and the organisations that decide to use it in their application, and to facilitate the sharing of good practice, in relation to first and second party conformity assessment. This section presents tools to facilitate the use of the SATORI CWA Parts 1 & 2.

10.1. Self-assessment and declaration of conformity: process and templates

The objective of the self-assessment would be to check compliance with SATORI CWA Parts 1 & 2. An organisation (ethics or ethical impact assessor) would self-assess and evaluate its results based on SATORI CWA Parts 1 and/or 2. Based on this, the organisation can establish and sign a self-declaration and ensure it is published with references to supporting information.

In line with *NPR 9026 (EN) Guidance on self declaration NEN-ISO 26000*[79], there would be five steps in this process:

1. Preparation,
2. Carrying out of the assessment,
3. Reviewing results,
4. Publishing the self-declaration, and
5. Determining the need for re-assessment.

Preparation involves determining the competencies needed to carry out an adequate self-assessment and to evaluate and review the results. It also includes establishing the scope of the self-declaration. *Carrying out assessment* includes carrying out an internal assessment and filling out the forms in the Annexes (Annex 6 for Part 1, Annex 7 for Part 2). Next, the results are *evaluated and reviewed* internally (preferably by one or several persons who was or were not involved in the assessment) with SATORI CWA Part 1 and/or 2. Based on the evaluation of the results, the organisation reviews whether there are sufficient grounds for the self-declaration. Annex 8 contains a standard format for the self-declaration. When establishing and signing the self-declaration, the organisation should also determine the validity period. *Publishing the self-declaration* involves publishing or communication of the self-declaration itself (this could be on the organisation's own website or on a common platform or registry). In the final step, *determining need for re-assessment,* the organisation should repeat the process described in this code of practice to ensure the self-declaration is up to date in line with the validity period determined by the organisation.

10.2. Self-declaration of conformity publication platform

To foster transparency and openness, organisations that carry out the SATORI CWA Part 1 or 2 self-assessments should publish their declarations of conformity (in a central EC/national or local registry). To facilitate this at the EU level, and given the importance of ethics in cross-border research, the European Commission could consider creating a registry of ethics committee declarations of conformity (and any supporting reports) and ethical impact assessment reports. For the credibility of the self-assessment, it is important the published report includes all relevant proof that an ethics committee or research project complies with the standard.

A report based on the aforementioned self-assessment review questionnaire would be advisable. Before publication on the publication platform, the report should be reviewed by an independent organisation for transparency by checking whether the review questionnaire is filled out completely (NB: the independent reviewer will not review the content of the questions as this is too subjective and will require additional information. It is up to stakeholders to question the quality of the content of the responses). Commercial sensitivity may be a concern in some sectors; it is possible for applicants and sponsors to submit a request to defer or perform a redacted publication.

The publication platform can function as a resource for those commissioning research, and other stakeholders, on ethical (impact) assessment practices of an individual organisation or

[79] NEN, Nederlandse praktijkrichtlijn NPR 9026 (EN) Guidance on self declaration NEN-ISO 26000, Handleiding zelfverklaring NEN-ISO 26000, ICS 03.100.01; 03.120.20, November 2011.

project. The platform will also be a place for organisations to highlight good practice and/or function as a mutual learning portal.

10.3. Self-assessment and declaration review

The results of the self-declaration of conformity should be reviewed using the following three steps:

i. **Review of the quality of the assessment**: review the answers provided in the self-assessment exercise. Are the answers correct, complete, relevant or need to be updated and/or revised?
ii. **Review each assessment question in comparison with the SATORI CWA**: i.e. review whether the organisation really applies the recommendations of SATORI CWA Parts 1 and/or 2, are there any (important) deviations, and if there are, what they mean for the organisation and its stakeholders.
iii. **Final evaluation:** does the organisation that wants to declare that it applies the SATORI CWA Parts 1 and/or 2, properly substantiate this?

10.4. Benchmarking for maturity

As the SATORI CWA outlines, continuous improvement is critical to maintain the quality of ethics assessment.[80] Organisations should engage in benchmarking to help assess the maturity, strengths and weaknesses in their ethics assessment or ethical impact assessment.

In line with the views of Andersen & Pettersen[81], we view benchmarking in a broad manner: a process to compare, evaluate processes against comparable good processes, and learn from these to achieve improvements. In this case, benchmarking is proposed: (a) to help analyse an organisation's REC composition, ethics assessment procedure, or ethical impact assessment processes against the SATORI CWA and/or other established good practice (*as ethics assessment is very contextual and conditional to national requirements and conditions*), (b) to determine the improvements that are needed in an organisation's ethics assessment procedures or ethical impact assessment processes, and (c) to use this information to improve the efficiency and impact of ethics assessment and ethical impact assessment. The following steps of a benchmarking process are a useful guide:

1. **Determine internal processes to be benchmarked and objectives of the exercise**. *[In this case, it would be either the ethics assessment processes and procedures, or the ethical impact assessment process carried out by the organisation, its teams, or individual researchers]*
2. **Determine the parameters** *[critical success factors extracted from the relevant part of the SATORI CWA and/or other organisational or industry good practice]*.
3. Collect information *[about the ethics committee, ethics assessment procedures or ethical impact assessment processes, and their performance using internal and external sources]*.
4. **Determine current performance, identify gaps, and relevant future trends** *[How do the identified processes map against the critical success factors; are there*

[80] SATORI, "Ethics assessment for research and innovation — Part 1: Ethics assessment unit", CEN draft Date: 2016-08, CWA SATORI-1:2016, Secretariat: NEN.
[81] Andersen, Bjorn, and Per-Gutte Pettersen, *The Benchmarking Handbook: Step-by-step instructions,* Chapman & Hall, London, 1996, p.4.

issues or challenges that adversely affect ethics assessment or ethical impact assessment?].

5. **Communicate the results** *[to the ethics committee chair, senior management and other employees or persons who must make improvements; present the methodology, findings, and strategies for improvements]*
6. **Achieve consensus on revised goals** *[determine the changes needed, impact within the organisation and outside, management and organisational commitment]*
7. **Develop an action plan** *[with clear steps and responsibilities for implementation]*.
8. **Implement procedures and monitor results** *[this includes collecting data on new levels of performance; using problem-solving teams to investigate problems; and adjusting the improvement process if goals are not being met]*
9. **Update/re-calibrate benchmarks** *[benchmarks are re-evaluated and updated, based on the most recent performance information]*

This presents another guidance tool for organisations using or that will use SATORI CWA Parts 1 and/or 2 to discover whether ethics assessment or ethical impact assessment best performance is being achieved. However, this type of exercise does have its limitations (it won't solve all the problems or challenges that arise and may not consider the all underlying factors that makes certain form of ethics assessment or ethical impact assessment succeed or fail). The way to avoid the limitations of this approach is to seek out other state of the art ethics assessment and/or ethical impact assessment improvements, and by re-examining presumed assumptions about ethics assessment and/or ethical impact assessment.

10.5. Peer-review

During a peer-review assessment, colleagues in the field will assess whether an ethics committee or a project's ethical impact assessment complies with the SATORI CWA. Based on the information provided by an ethics committee (the template in Annex 6 or can be used for this purpose), peers will assess the quality of the committees' ethics assessment processes and procedures. Based on the information provided by an ethical impact assessor (using the template in Annex 7), peers can assess the quality of an ethical impact of an R&I project. As part of the peer-review process, additional information could also be gathered using various means (e.g., interviews, meetings etc.).

As peers have expert knowledge of the field, the advantage will be that they quickly understand the context of the committee or project. Also, researchers are already familiar with peer-reviews, this might make it easier to implement. An independent organisation could also organise the peer-review process to manage the practical work, bring in other relevant expertise and, if needed, facilitate an anonymous reviewing process.

10.6. Peer-review publication platform

As proposed for the self-declaration of conformity, the peer assessment results should be published on a publication platform. This will not only be a good resource for funders or commissioning organisations, but also help organisations who want to learn from peer good practices.

11. Conclusion and recommendations

There are many benefits of standards and conformity assessment; however, they vary and depend on the nature of the standards and conformity assessment, their underlying criteria, and at whom they are targeted. The analysis of selected ISO, IEC and DS standards provided a good insight into the obstacles and challenges faced by, or relevant to, the analysed certification standards, including:

- misinterpretation of the requirements underlying the certification;
- underestimation of the efforts and resources required in certification,
- costs of implementation and certification;
- overdevelopment of the system;
- excessive documentation and control;
- apparent erosion of the perceived benefits over time;
- lack of support (e.g., from management) and resources available for SMEs; and,
- lack of guidelines on how to accomplish the 'continuous improvement' elements of a standard.

These are all relevant to consider in the development (and implementation) of a certification standard or conformity assessment scheme for ethics assessment in R & I. Critical success factors would include:

- market (sector) and legal incentives,
- demand for the use of conformity assessment (and validation of this),
- internationalisation, sustainability, and
- wide support for the adoption and use of the scheme.

Overall, SATORI stakeholders at the Delft workshop strongly discouraged the presumed obvious link between the standardisation process of ethics assessment and the certification process. Participants felt the certification discussion **was premature and should not be further developed in the SATORI project**. However, participants felt that researcher guidance for ethics self-assessment might be a good alternative to certification. This expectation was reflected in the subsequent drafts of the SATORI CWA and the Framework. However, the SATORI CWA Part 1 also notably recommends third party evaluation and accreditation to demonstrate the quality of an ethics committee's work (while this currently does not exist).[82]

Several interviewed RECs and NECs thought conformity assessment and certification could provide benefits to 'ethics assessment procedures', including improvements in **transparency, credibility/confidence, reliability,** and **consistency** of the ethics review process. This is true in areas where requirements for the work of ethics committees is not clearly established or regulated by national or international laws. When a regulatory framework is in place (e.g. for NECs in the healthcare and the biomedical field) a certain degree of conformity in the work of ethics committees is implicit.

Conformity assessment and certification could also be beneficial to increase the level of **harmonisation** of the work of ethics committees within and across countries. However, this

[82] SATORI, "Ethics assessment for research and innovation — Part 1: Ethics assessment unit", CEN draft Date: 2016-08, CWA SATORI-1:2016, Secretariat: NEN, p 17.

would be challenging due to local and national differences in ethics cultures and practices, and the context-sensitivity of ethical decision-making.

Interviewees also pointed out that highly formalised procedures could be detrimental to ethics assessment, carrying a **risk of changing the nature of the ethics evaluation process** (reducing flexibility, making it more bureaucratic and transforming it into a mere tick-box exercise).

It is essential that conformity assessment is carried out in a way to **simplify procedures, and to reduce (not increases) bureaucracy**. A conformity assessment and certification system should **allow for differential approaches in diverse cases, ranging from a simple and fast exercise to detailed and time-consuming processes**, depending on the specific situation, and the needs (levels of risk). The proposals in this report aim to support a flexible and adaptable use of conformity assessment.

Given the limited resources available to NECs and RECs, the issue of resources and costs for establishing and maintain conformity assessment (including certification and accreditation procedures) needs to be carefully considered. As shown by experience in some countries, good networking between ethics committees, resource sharing, training that fosters continuous mutual learning would be good alternative means to foster good practice, and provide an "informal" conformity assessment of the work of ethics committees.

Certification of ethics professionals might have its pros and cons. One the one hand, it could be helpful to have a system in place to qualify people for working in ethics committees; on the other hand, practical experience in being a part of and working in an ethics committees is viewed as superior to formal training. Interviewees pointed out that it is quite difficult to identify and characterise an ethics professional through any specific training or disciplines background. Ethics committees compose of people with different expertise and backgrounds, as well as people expected not to have specific qualifications (lay people). Overall, interviewees were sceptical about scope and feasibility of certification of ethics assessment professionals.

The legislative analysis showed is no single overarching framework for the regulation of certification in the EU. The key aspects examined (nature, criteria and conditions, certification procedure, revocation and withdrawal, measures to boost public trust and confidence, and harmonisation) provide an insight into how these are covered, similarities and sectoral divergences. In some cases, the law is very prescriptive, in others very flexible depending what is being certified, the sectoral needs etc. For ethics assessment, there is no straightforward path to having a single regulatory framework. As the SATORI report on *International differences in ethical standards and in the interpretation of legal frameworks* highlights,

> Efforts to harmonise ethics assessment across the European Union or across the world need to take into account the significant differences in institutions, values, legal frameworks and cultural practices that exist between different countries and regions. These differences do not automatically imply that no harmonisation is possible (to say so would also preclude the existence of international laws and standards), but they may imply that not every element in ethics assessment can be harmonised, and that there should be flexibility in the formulation and interpretation of international standards.[83]

[83] Brey, P. et al, *International differences in ethical standards and in the interpretation of legal frameworks*, SATORI Deliverable D3.2, 2015. http://satoriproject.eu/media/D3.2-Int-differences-in-ethical-standards.pdf

In the final part of the report, we presented how conformity assessment could be used to support the SATORI CWA Parts 1 and 2. Most conformity assessment techniques could be used to check, evaluate, or assess adherence to the SATORI CWA specifications, either exclusively, or in combination with others, depending on what is to be assessed, the context, and the specific characteristics to be assessed. Policy makers, associations of RECs, and RECs (as users of the ethics assessment process) should determine (in consultation with standards and conformity assessment bodies) the best path forward i.e. what conformity assessment techniques might best suit their needs and contexts, and bring them maximum benefit.

The exercises in Section 10 show some ways in which conformity assessment could play out in relation to Parts 1 and 2 of the SATORI CWA. However, as highlighted by our stakeholders, some of these (e.g. certification) may be premature and even counter-productive. Their ability to be successfully implemented and have an impact depends on three key things:

- **policy and legal frameworks** that support the development and implementation of such schemes, whether at the EU or national level;
- **incentives and subsidies** to undertake conformity assessment activities, and
- **usefulness and ability** of conformity assessment techniques to deliver their goals vis-a-vis improving the quality of ethics assessment and ethical impact assessment.

As stakeholders largely thought third party conformity assessment (i.e. certification) was premature and even counter-productive for ethics assessment, the report specifically explored and presented some concrete tools for first-party (self-declaration of conformity) and second-party assessment (peer-review) that would support organisations in using the SATORI CWA: self-assessment and declaration of conformity: process and templates; self-declaration of conformity publication platform, self-assessment and declaration review: process, benchmarking, peer-review; peer-review publication platform. Already, we can see that even the least rigorous form of conformity assessment (self-assessment) can contribute to meeting the needs (enhancing the quality of ethics assessment, user friendliness, awareness, mutual learning) and countering the challenges (window dressing, resource burdens, fragmentation etc.) faced in ethics assessment.

Conformity assessment could be a beneficial tool to leverage in enhancing ethics assessment activities. Different approaches might have value and serve the goals of improving the quality of ethics assessment or ethical impact assessment. But, their uptake and success depends on the demand, push for, and incentives (e.g. legal mandates, funding and/or procurement requirements) to use such tools. One challenge in the uptake of conformity assessment for the SATORI CWA is the rigour of the specifications. As developed, the SATORI CWA represents a voluntary consensus agreement on ethics assessment by a variety of ethics stakeholders. Therefore, it represents an amalgamation of various ethical cultures and practices, and is flexible to take these into account. The CWA was purposefully framed to be flexible enough for adaptation in different contexts. Hence, its specifications are not unduly rigorous; these might pose a challenge for those seeking to adopt conformity assessment techniques to support its implementation. We do not see an easy solution due to local, national, and regional differences in the ethics environment; in any event, full harmonisation in ethics assessment may be neither possible nor desirable. Another challenge is the amount of time and effort required to undertake conformity assessment activities. Simply carrying out conformity assessment activities is not the end goal, it is also important to communicate the results via a certification mark or listing e.g. an ethics committee might be on a register of EU ethics

committees that are qualified to assess EU research projects. Monitoring will also be essential to ensure compliance with the conformity assessment requirements on an ongoing basis.

The work presented in this report sets the ground for future work on conformity assessment of ethics assessment. The tools presented in this report (Annexes 6, 7, 8) have a limited scope – i.e. limited by how the SATORI CWA has been formulated (in discussion with stakeholders), its contents, and how will be finalised (i.e. its text and discussions). Nevertheless, they can be used by organisations that decide to use the SATORI CWA to improve their ethics assessment or ethical impact assessment practices.

As part of future work, the demand for conformity assessment tools to support ethics assessment needs to be further assessed with stakeholders on a more wider scale. Future work should also involve a review of the tools (and their usefulness, changes needed e.g. via implementation of a good ratings system, developing online versions).

Annexes

Annex 1 Table on certification standards

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
ISO 9001:2015 Quality management systems -- Requirements	Specifies requirements for a quality management system.	Employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. The process approach enables an organisation to plan its processes and their interactions	All the requirements of ISO 9001:2015 are generic, and intended to be applicable to any organisation, regardless of its type, size, or the products and services it provides.	Revised rather recently. Obstacles to ISO 9001:2008: insufficient management support and commitment, unrealistic expectations, availability of funds and resources, training of employees, change management.[84] Kim identifies the following barriers to certification[85]: misinterpretation of the requirements; over-development of the quality system; excessive documentation and control; and underestimation of	Over one million ISO 9001-certified organisations worldwide. Introduced in 1987, ISO 9001 has been revised four times to date. ISO 9001:2015 – is the first major revision since 2000. Paris suggests "the biggest problem facing any implementation of ISO 9001:2015 will be the certification body auditors" …and predicts "the US will fall below 10,000 certificates — that's only four digits — around the 2018 time frame".[86] **ISO survey 2014[87]:** Total certificates issued worldwide: 1,138,155 Total certificates issued in Europe: 483710

[84] See Corbett, C., "Global diffusion of ISO 9000 certification through supply chains", Working paper, University of California, Los Angeles, CA, 2005; Sampaio, Paulo, Pedro Saraiva, and António Guimarães Rodrigues, "ISO 9001 certification research: questions, answers and approaches", *International Journal of Quality & Reliability Management*, Vol. 26 (1), 2009, pp. 38-58; Manders, Basak, "Implementation and Impact of ISO 9001", No. EPS-2014-337-LIS, Erasmus Research Institute of Management (ERIM), 2015; Bruce, Ken, and Rakesh Gupta, "Global Financial Planning Education Standards", *Journal of Modern Accounting and Auditing,* Vol. 7 (11), 2011, pp. 1169.
[85] Kim, Y., "ISO - making companies competitive", *Quality in Manufacturing*, November-December 1994, p. 26.
[86] Paris, Christopher, "Users: Certification Body Auditors Remain Biggest Obstacle to ISO 9001:2015", 11 Nov 2015. http://www.oxebridge.com/emma/users-certification-body-auditors-remain-biggest-obstacle-to-iso-90012015/
[87] ISO, *ISO Survey 2014*. http://www.iso.org/iso/iso-survey

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
				the efforts and resources needed in certification. Apparent erosion of ISO 9001 perceived benefits over time.	
ISO 22222:2005 Personal financial planning -- Requirements for personal financial planners	Defines the personal financial planning process and specifies ethical behaviour, competences, and experience requirements for personal financial planners.	Describes and addresses the various methods of conformity assessment and specifies requirements applying to each of them. Individuals claiming conformity with the standard can self-declare against the requirements of BS ISO 22222 or alternatively, independent third-party certification can be sought.	Is applicable to all personal financial planners regardless of their employment status.	Some writers suggest "For as informative ISO 22222:2005 is as standard, it largely sits on a shelf and at best is a reference point for curriculum writers and others with an interest in financial planning."[88]	ISO certification is not an easy option. ISO 22222:2005 "has not been adopted in the US or Australia or the other affiliate member organizations of the FPSB".[89]

[88] Bruce, Ken, and Rakesh Gupta, "Global Financial Planning Education Standards", *Journal of Modern Accounting and Auditing,* Vol. 7 (11), 2011
[89] Ibid.

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems	Contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems.	Describes inter alia the principles on which credible certification is based.	Specifies requirements for bodies providing audit and certification of management systems. It gives generic requirements for such bodies performing audit and certification in the field of quality, the environment, and other types of management systems.	ISO/IEC 17021-1 2015 was published on 8th June 2015. ISO/IEC 17021-1 2015 replaces ISO 17021: 2011 and resulted in the need for Certification Bodies (CBs) to implement changes within their management systems and processes.	Not covered by the ISO survey.
ISO 14001:2015 Environmental management systems (EMS) -- Requirements with guidance for use	Specifies the requirements for an EMS that an organisation can use to enhance its environmental performance.	Provides organisations with a framework to protect the environment and respond to changing environmental conditions in balance with socio-economic needs. It specifies requirements that	Is applicable to any organisation, regardless of size, type, and nature, and applies to the environmental aspects of its activities,	Zutshi & Sohal underline the following obstacles in implementing ISO 14001[90]: Costs (training, auditor fees, audits) required in addition to implementation and certification of EMS and its maintenance; Lack of support and resources	ISO survey 2014: Total certificates issued worldwide: 324148 Total certificates issued in Europe: 123849 King et al "obtained evidence that organizations certify with ISO 14001 to reduce information asymmetries with supply chain partners", and found that

[90] Zutshi, A., & A. S. Sohal, "Environmental management system adoption by Australian organisations: part 1 reasons, benefits and impediments", *Technovation,* 24, 2004, pp. 335-357.

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
		enable an organization to achieve the intended outcomes it sets for its EMS.	products and services that the organisation determines it can either control or influence considering a life cycle perspective. ISO 14001:2015 does not state specific environmental performance criteria. It can be used in whole or in part to systematically improve environmental management.	available for SMEs; unclear guidelines for EMS implementation for organisations with mobile workforce, such as the construction sector; Lack of set guidelines for setting of objectives and targets and extent of involvement of employees, suppliers and other stakeholders; Lack of guidelines on how to accomplish 'continuous improvement element of the standard; Interpretation of terms present within the standard".	"suppliers were more likely to certify when ongoing vertical relations increased the need among potential buyers to monitor supplier behaviour", "that certification provided information about the existence of an environmental management system and subsequent performance improvement but it did not indicate superior performance" and concluded that "certification provides buyers with information about an ongoing supplier's performance improvement efforts".[91]
ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for	Specifies requirements for a quality management system where an organization	Includes some requirements for medical devices and excludes some of the requirements of ISO 9001 that are not	All requirements of ISO 13485:2003 are specific to organizations providing	One presentation on the Standard states "certification in Europe, for example, does not mean your ISO 13485 certification is valid in	ISO survey 2014: Total certificates issued worldwide: 27,791 Total certificates issued in Europe: 12,983

[91] King, Andrew A., Michael J. Lenox, and Ann Terlaak, "The strategic use of decentralized institutions: Exploring certification with the ISO 14001 management standard", *Academy of Management Journal,* Vol. 48 (6), 2005, pp. 1091-1106.

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
regulatory purposes (Revised by: ISO 13485:2016)	needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.	appropriate as regulatory requirements.	medical devices, regardless of the type or size of the organisation.	other markets such as Canada or Japan. Many countries impose their own additional QMS requirements on top of those outlined in the standard. You must meet those additional requirements – on top of ISO 13485 – to be certified to sell in those markets".[92]	This is one of the most widely used quality system standards in medical device manufacturing and compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements. The standard was adopted by CEN as EN ISO 13485:2003/AC: 2007 and is harmonized with respect to the European medical device Directives 93/42/EEC, 90/385/EEC and 98/79/EC. ISO 13485 is now considered to be inline standard and requirement for medical devices even with the Global Harmonization Task Force Guidelines (GHTF).
ISO/TS 16949:2009 Quality management systems -- Particular requirements for the application of ISO 9001:2008 for automotive production and	In conjunction with ISO 9001:2008, defines the quality management system requirements for the design and development, production and,	The goal of this technical specification is the development of a quality management system that provides for continual improvement, emphasising defect prevention and the reduction of variation	Applicable to sites of the organisation where customer-specified parts, for production and/or service, are manufactured. Can be applied throughout the	Requirement for internal audit of product is deemed unnecessary with no added value.[93]	ISO survey 2014: Total certificates issued worldwide: 57950 Total certificates issued in Europe: 11848

[92] "Overview presentation of ISO 13485", Workshop on Accreditation of Bodies Certifying Medical Devices Kiev, 17 - 18 November 2014. http://ec.europa.eu/enlargement/taiex/dyn/create_speech.jsp?speechID=33663&key=f1c2077c25eabab373594aa37322102a

[93] The Quality Forum Online, "What changes do you expect for ISO/TS 16949:2016?" 31 July 2015. http://www.qualityforumonline.com/forum/index.php?threads/what-changes-do-you-expect-for-iso-ts-16949-2016.14/

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
relevant service part organizations	when relevant, installation and service of automotive-related products.	and waste in the supply chain.	automotive supply chain.		
ISO/IEC 27001:2013 Information technology – Security techniques – Information security management systems – Requirements	Specifies the organization for establishing, implementing, maintaining, and continually improving an information security management system within the context of the organization.	Includes requirements for the assessment and treatment of information security risks tailored to the needs of the organization.	The requirements set out in ISO/IEC 27001:2013 are generic and are intended to be applicable to all organizations, regardless of type, size or nature.	This standard appears to have been well-received. One main challenge seems to be mapping controls from the 2005 standard to the 2013 standard in accordance with Annex A of the new standard.[94]	Internationally recognized best practice framework ISO survey 2014: Total certificates issued worldwide: 23972 Total certificates issued in Europe: 8710
DS 49001 Social responsibility management systems – requirements	Provides organisations with elements of an efficient social responsibility management system, which can be integrated with	Specifies requirements for a social responsibility management system so that organisations can develop and implement a policy and objectives, which are based on respect for	Applies to all types and sizes of organisations and may be adapted to different geographic, cultural, and social conditions.	National approach. Created for the national market. One commentator highlights two obstacles: it was "developed by organisations that belong to the actor type 'market'" and "is not publicly	National approach but DS 49001 standard has been translated to German and is available for the German market. The German version of the DS 49001 standard was introduced in September 2011 and includes 135 requirements of all three topics of Sustainable Development.

[94] Watkins, Steve, "Converting to ISO27001:2013 – a quick overview". 25 November 2013. http://www.iso270012013.info/news-articles/resources/converting-to-iso27001-2013-a-quick-overview-for-t.aspx

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
	other management organization and which help organisations meet their social responsibility objectives.	international norms of behaviour. At the same time, Danish legal requirements have been taken into account, and guidance is given for how organisations can go beyond the fulfilment of legal requirements.		available" (comparing this with other social responsibility standards).[95] Danish Standards experts suggest there are three main challenges: 1. Many companies chose to work with UN Global Compact instead –it's been there longer than the standard; 2. The market demand is low – i.e. if your customers do not consider it to be of great importance, why get certified? 3. Lack of knowledge of the standard –too few organisations know that the standard exists.[96]	Danish Standards confirmed via email of 15/6/2016 that around 20 companies are certified to this Standard.
ISO 22000:2005 Food safety management systems – Requirements for	Specifies requirements for a food safety management system where an	Can be applied independently of other management system standards. Its implementation can	Applicable to all organizations, regardless of size, which are involved in any	"ISO 22000:2005 was having problems in defining prerequisite programs (PRPs) because, set specifications were not	ISO survey 2014: Total certificates issued worldwide: 30500 Total certificates issues in Europe: 10654

[95] Gdaniec, D. E., *Comparison of different certifiable and non-certifiable Corporate Social Responsibility standards in the European telecommunications industry*, 45 ECTS Master Thesis, 2012. http://dspace.library.uu.nl/bitstream/handle/1874/254773/Masterthesis_Gdaniec.pdf?sequence=1

[96] Danish Standards, email communication to Trilateral Research Ltd, 15 June 2016.

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
any organization in the food chain	organization in the food chain needs to demonstrate its ability to control food safety hazards to ensure that food is safe at the time of human consumption.	be aligned or integrated with existing related management system requirements, while organizations may utilise existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard.	aspect of the food chain and want to implement systems that consistently provide safe products.	adequate to define PRPs and GMP was implemented through PRPs. However, specifications given on PRPs were not satisfactory where additional guidelines were issued to rectify issues. In addition, supplier evaluation and selection were not prominent while traceability was introduced in a separate standard later; which should have included into system at the beginning."[97]	
ISO 45001 *Occupational health and safety management systems* – Requirements (based on OHSAS 18001)	Aims to help an organisation to manage their OH&S risks and improve their OH&S performance	Specifies requirements for an occupational health and safety (OH&S) management system, with guidance for its use, to enable an organization to proactively improve	Intended for use by *any* organization, regardless of its size or the nature of its work, and can be integrated into other health and safety	Still in development – not determinable. (Expected publication October 2016)	Still in development – not determinable.

[97] Lokunarangodage C.V.K et al, "Review of ISO 22000:2005, Structural Synchronization and Ability to Deliver Food Safety with Suggestions for Improvements", *Journal of Tea Science Research*, 2015, Vol.5, No.12. See also Food Quality Management Consultancy (FQMSC), "Incredible failure of ISO 22000:2005", 2 March 2014. http://fqmsc.blogspot.de/2014/03/incredible-failure-of-iso-220002005.html

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
		its OH&S performance in preventing injury and ill-health.	programmes such as worker wellness and wellbeing. It also addresses many, if not all, legal requirements in this area. Not intended to be a legally binding document, it is a management tool for voluntary use by organizations.		
ISO/IEC 20000-2:2012 Information technology – Service management – Part 2: Guidance on the application of service management systems	Offers guidance for implementing a Service Management System (SMS) based on ISO/IEC 20000-1. Provides examples through references to	Promotes a 'Plan-Do-Check-Act' (PDCA) methodology. Does not add any additional requirements beyond ISO/IEC 20000-1.	Support for all SMS seeking to meet the requirements of ISO/IEC 20000-1. Does not include specific recommendations for any project or tool.	The standard is non-specific. "To achieve wide and comprehensive coverage, the standard addresses only the generically valid core elements of the service management processes; it can never describe the full set of processes/procedures that an individual service	"ISO/IEC 2000 is an international IT standard that allows companies to demonstrate excellence and prove best practice in IT management. The standard ensures companies can achieve evidence-based benchmarks to continuously improve their delivery of IT services"[99] 823 ISO/IEC 20000 certified organisations worldwide.[100]

[99] APM Group, "ISO/IEC 20000". http://www.isoiec20000certification.com
[100] APM Group, "ISO/IEC 20000". http://www.isoiec20000certification.com/home/ISOCertifiedOrganizations/ISOCountryListings.aspx

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
	other parts of ISO/IEC 2000 and other relevant standards.			provider will require to deliver effective and efficient, customer-focused services."[98]	
ISO 17024: 2012 Conformity assessment – General requirements for bodies operating certification of persons	Contains principles and requirements for a body certifying persons against specific requirements, and includes the development and maintenance of a certification scheme for persons.	In addition to other things, specifies certification process requirements, management system requirements and principles for certification bodies for persons and their certification activities.	Can be used as a criteria document for accreditation or peer evaluation or designation by governmental authorities, scheme owners and others.	An ANSI document identifies the following barriers to implementing ISO 17024: assessor difficulties in evaluating requirements; limited experience of assessors, examination validity; surveillance and recertification criteria; training independence and impartiality of the scheme committee etc.[101]	Globally accepted benchmark for organisations operating certification of persons. The processes of the ECQA (European Certification and Qualification Association) are mapped onto the ISO 17024 international standard for the certification of persons.[102]
ISO 22301:2012 Societal security – Business continuity management	This International Standard specifies requirements for	Specifies requirements to plan, establish, implement, operate, monitor, review, maintain and	Requirements specified in ISO 22301:2012 are generic and intended to be	One organisation states it "found the biggest challenge to certification to ISO 22301 was the requirement to look at our	ISO survey 2014: Total certificates issued worldwide: 1757 Total certificates issues in Europe:

[98] Van Haren Publishing, "ISO/IEC 20000 for IT Service Management – in 3 minutes", 12 August 2012. http://www.vanharen.net/blog/it-management/isoiec-20000-in-3-minutes/

[101] Swift, Roy A., "ISO/IEC 17024 Increasing the Quality of the Workforce", American National Standards Institute (ANSI), 26 September 2007. http://www.inmetro.gov.br/noticias/eventos/certificacao_pessoas/ANSI.pdf

[102] European Certification and Qualification Association (ECQA), ECQA White Paper: Europe wide Industry Certification Using Standard Procedures based on ISO 17024, May 2013. http://www.ecqa.org/fileadmin/documents/ECQA_Guide/Chapter_1_-_ECQA_Architecture_Version5.pdf

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
systems – Requirements	setting up and managing an effective Business Continuity Management System (BCMS)	continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise.	applicable to all organizations, or parts thereof, regardless of type, size and nature of the organization. The extent of application of these requirements depends on the organisation's operating environment and complexity.	BCMS from an independent position and critically access the differences between ISO 22301 and BS 25999".[103]	593
ISO 50001:2011 – Energy Management System	ISO 50001 establishes a framework for industrial plants; commercial, institutional, or governmental facilities; or entire organizations to manage energy	Provides a framework of requirements for organisations to: develop a policy for more efficient use of energy; fix targets and objectives to meet the policy; use data to better understand and make decisions about energy use; measure	Certification to ISO 50001 is possible but not obligatory. Some organisations decide to implement the standard solely for the benefits it provides. Others decide to get certified to	Voluntary nature. One article states, "Some organizations may be reluctant to implement ISO 50001 due to "audit fatigue." Because some organisations already have multiple certifications—ISO 9001, ISO 14001 and OHSAS 18001 (a British standard for occupational health & safety)—the	ISO survey 2014: Total certificates issued worldwide: 6,778 Total certificates issues in Europe: 5,526 According to the ISO, "ISO 50001 adoption is gathering pace around the world" and several organizations "are already reporting significant benefits and

[103] *MacLeod, Andrew, "Experiences during certification to ISO 22301:2012", Continuity Briefing, 3 August 2012. http://www.continuitycentral.com/feature1001.html*

Standard	Introduction	Key features	Scope and application	Obstacles and challenges [identified based on media and academic reviews]	Success factors & impact [of certification]
		the results; review how well the policy works, and continually improve energy management.	it, to show external parties they have implemented an energy management system.	thought of yet another audit, and all the documentation and data recording that go with it, is not attractive".[104]	energy cost savings from their early ISO 50001 implementation".[105]
ISO/IEC 17067:2013 Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes	Describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.	Outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.	Intended for use by all with an interest in product certification, and especially by certification scheme owners.	A document by *Accredia* outlines the following criticism: related costs mean it's not easy to start with voluntary product certification schemes, if there are no external influences, e.g. from the buyers or retailers and/or from the market.[106]	Undeterminable.

[104] LeonardoEnergy, "Energy Management", 23 December 2014. http://help.leonardo-energy.org/hc/en-us/articles/202097901-How-does-ISO-50001-differ-from-ISO-9001-and-ISO-14000-If-my-company-is-certified-to-an-existing-ISO-management-standard-what-are-the-consequences-or-benefits-for-ISO-50001-certification-

[105] Lambert, Garry, "Energy management - Early ISO 50001 adopters report major gains", *ISO News*, 12 July, 2011. http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1618

[106] Musa, Alberto, Francesco Santini, "Voluntary product certification. What is working well, what is failing and why?", *Accredia*, 27 June 2013. http://www.accredia.it/UploadDocs/4074_Workshop_UE___27_06_2013___4___Voluntary_product_certification___Musa_Santini___ACCREDIA.pdf. The document discusses voluntary product certification, and ISO 17067.

Annex 2 Tasks 7.2 and 7.4 stakeholder consultation table

Organisation	Method of consultation	Date	Topics
Marlou Biljsma & Thamar Ziljstra, NEN	Meetings (face to face and online), email.	Ongoing	Tasks 7.2 and 7.4 Research resources
Mirjam van der Gugten, NEN	Face to face meeting	(17/2/16)	Task 7.2 (views on conformity assessment and certification)
Signe Annette Bøgh & Katrine Bergh Skriver, Danish Standards	Meetings (face to face and online), email.	Ongoing	Tasks 7.2 and 7.4
Andrea Porcari, *AIRI*	Meetings (face to face and online), email.	Ongoing	Tasks 7.2 and 7.4
Alan Shipman (Group 5 Training Ltd)	Email	26/11/2015, 27/11/2015	Query re success factors of certifiable standards, impact.
Name anonymised upon request (UK)	Email	26/11/2015	Insights of certifiable standards challenges, success factors and impact
Fernando J. Utrilla Head of Research and Innovation AENOR, Standardization Department	Virtual meeting	7 Jan 2016	Views on conformity assessment in innovation management.
Gerardo Malvido, responsible for the Research and Innovation certifications in AENOR.	Email and virtual meetings.	11/01/2016 (emails); Interviewed via Skype 15.1.2016	Queries re factors, challenges, and success of innovation management certification.
CRISP project – VUB (Irene Kamara)	Email.	14 Sept 2016	Cross project information sharing on regulation of certification
Research ethics committees: Ethics Committee of the Medical University Graz, Austria; University Medical Center Ljubljana; Cambridge University REC; Riga Stradins University REC)	Interviews	June – August 2016	Views on conformity assessment and certification for ethics assessment.
National ethics committees (National Committee for Biosecurity, Biotechnologies, and Life Sciences; The Finnish national ethics committee ETENE; The Danish Council of Ethics; Nuffield Council on Bioethics)	Interviews	June – August 2016	Views on conformity assessment and certification for ethics assessment
SATORI consortium partners & Advisory Board	Workshop on certification; review of deliverable.	18 Feb 2016, Delft. 30 May- 1 June 2016, Copenhagen.	Views on conformity assessment and certification. Directions for Tasks. Feedback on final report.

Annex 3 Interview guide

INTERVIEW GUIDE ON CONFORMITY ASSESSMENT AND CERTIFICATION FOR ETHICS ASSESSMENT

The purpose of this interview is to gauge stakeholder views on conformity assessment for ethics assessment. It is part of the SATORI project (www.satoriproject.eu), a 45-month project, comprising 17 partners from 12 countries which aims to improve respect of ethics principles and laws in research and innovation. SATORI is funded by the European Union under Grant Agreement 612231. SATORI defines ethics assessment (ethical assessment, ethics review, ethical review) as any institutionalized kind of assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that makes use of primarily ethical principles or criteria. The objects of research or innovation that are assessed may be research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. Conformity assessment here refers to demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled. Its purpose is to help ensure that ethical policies, procedures, professionals deliver on their promises. **Certification is one of the methods of demonstrating conformity** (others are testing, inspection and declarations of conformity) and the intent here is to specifically gauge stakeholder views on this.
The interview is voluntary.

Type of organisation (delete what is not applicable): Research ethics committee (REC), Association of RECs, National ethics committee, national government organisation, international government organisation, university, research institute, Associations of Universities and Research Institutes, national research funding organisation, international research funding organisation, Science Academies and Associations of Science Academies, professional organisation, company, industry association, consumer organisation, civil society organisation, standards organisation, certification or accreditation organisation, individual, other (please state)

Part 1 Conformity assessment and ethics in general

1. Which of the following could most benefit from conformity assessment: (a) ethical products, technologies, systems, or services (b) ethics assessment procedures (c) ethics professionals (d) ethical organisations?
2. Do you think conformity assessment of ethics assessment procedures in research and innovation is necessary? Why?
3. What could be the challenges and difficulties involved in using conformity assessment for ethics assessment?

Part 2 Certification of ethics assessment procedures

4. Are you aware of ethics assessment procedures that are subject to certification? If yes, please provide some examples.
5. Do you support certification of ethics assessment procedures?
6. What could be the advantages of certifying ethics assessment procedures?
7. What could be the challenges or obstacles in certifying ethics assessment procedures?
8. What would need to be put in place to certify ethics assessment procedures? E.g. regulation? Other incentives?
9. What kinds of training and courses would be needed for certification of ethics assessment procedures? Who would be best placed to offer such training?
10. Who could be accredited to offer certification of ethics assessment procedures?

Part 3 Certification of ethics professionals

11. Is the certification of ethics professionals beneficial? If not, why?
12. Are you aware of any good examples of certification of ethics professionals?
13. What are the obstacles and problems in certifying ethics assessment professionals?
14. What are the gaps in the certification of ethics professionals? What needs to be done to make the certification of ethics professionals more effective?

Annex 4 Informed consent form

Stakeholders Acting Together On the ethical impact assessment of Research and Innovation (SATORI) http://satoriproject.eu/

Participant information sheet

By signing the attached form, I understand that I am consenting to participate in the European Union-funded (Grant agreement number 612231) SATORI research project conducted by the University of Twente, Trilateral Research Ltd. and other SATORI partners. I am aware that the purpose of this research is to understand the views and experiences of stakeholders on conformity assessment and certification for ethics assessment. This will involve will involve an interview lasting up to one hour where I will be invited to discuss my knowledge about this area. I understand that I am participating in this research voluntarily and that I am free to terminate the interview at any time. I am also aware that I am free to refuse to answer any questions that I feel are commercially or institutionally sensitive or relate to topics that I do not wish to discuss. I understand that I have the right to ask questions and receive understandable answers before making any decision.

I understand that I will only be asked to provide professional, not personal, information and that the record of my involvement in the research will be kept confidential. The interview data may be recorded via voice recorder. The interview data will used as input to a deliverable. I understand that I can request a copy of the interview summary. I understand that this research will be used to understand the views and experiences of stakeholders on conformity assessment and certification for ethics assessment. I understand that the interview may be stored and used for later research; however, it would only be used for publicly funded research.

I understand that this research conforms to European Commission guidelines and that it has been approved by the Ethics Committee in the Co-operation theme of the 7th Framework Programme. Finally, I have been given the contact details of the research team and I have been informed that I am free to contact Philip Brey (Project Coordinator) about any queries relating to my data or the project itself. Philip Brey's e-mail address is p.a.e.brey@utwente.nl and his telephone number is +31-53-4894426.

Consent form

Issue	Respondent's initial
I confirm that I have read the information sheet dated *[insert date]* explaining the above research project and I have had the opportunity to ask questions about the project. My participation is voluntary. I agree that the data collected from me can be used for a SATORI deliverable which will be made publicly available.	
I wish for my name to be anonymised for the purpose of this research. However, I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	
I wish for the name of the organisation to be anonymised for the purpose of this research.	
I agree that the data may be used for non-SATORI publicly funded research.	

Annex 5 SATORI certification workshop discussion: method and questions, Delft, 18 Feb 2016.

After preliminary input on "certification for ethics assessment" by Task 7.2 lead Rowena Rodrigues of Trilateral Research Ltd, a group discussion was held. Participants (total of 29) were divided into five groups of around seven participants (the allocations were made in advance of the workshop to ensure each group had a variety of participant (or stakeholder) types and the areas they represented, as much as was feasible given the profile of the attendees).

Group 1 participants included a representative of a research foundation (SATORI Advisory Board member), a policy maker, an academic (SATORI partner), an industry partner (SATORI partner), a public government science institution (SATORI partner). Group 2 participants included one internal academic (SATORI partner), one external academic, a cybersecurity centre, an industry association representative (SATORI partner). Group 3 participants included a consumer organisation (SATORI Advisory Board Member), a representative of a national research ethics committee, two academics (SATORI partner), a public government science institution (SATORI partner), and a standardisation body (SATORI partner). Group 4 participants included a representative of an EU RECs association (also a SATORI Advisory Board Member) a representative of a national research ethics committee, an academic (SATORI non-WP7 partner), a civil society organisation (SATORI partner), a non-profit policy advice foundation (SATORI partner) standardisation body (SATORI partner). Group 5 participants included a research SME (SATORI partner), a research ethics association representative, a science journalists' association (SATORI partner), an academic (SATORI partner), and a representative of a Europe-wide network for industrial research and development and an ICT company.

Each group had half an hour to deliberate two questions each followed by reporting to the entire workshop. The topics of deliberation (and questions) were:

Group 1: Is certification useful?

1. What aspects of ethics assessment in R&I, in your opinion, require or could benefit from certification?
2. Do you see a demand for, or added value in certification of ethics assessment? Why?

Group 2: The actors and measures

1. Which organisations do you see as playing a key role in certification of ethics assessment?
2. What needs to be put in place to promote certification of ethics assessment in the EU?

Group 3: Certifying ethics professionals

1. Would the certification of ethics assessment professionals be beneficial? If not, why?
2. What could be the obstacles and challenges in certifying ethics assessment professionals? How could this be addressed?

Group 4: Certification of ethics assessment procedures

1. What could be the challenges or obstacles in certifying ethics assessment procedures?
2. What would need to be put in place to certify ethics assessment procedures? E.g., regulation? Other incentives?

Group 5: Certification support measures

3. What kinds of training and courses would be needed for certification of ethics assessment procedures? Who would be best placed to offer such training?
4. Who could be accredited to offer certification of ethics assessment procedures?

Section 7.1 presents the results of the group discussion.

Annex 6 SATORI self-assessment/peer review template: Part 1 Ethics committees

The purpose of this open-ended assessment is to provide assessors with a tool to evaluate the strengths and weaknesses of an ethics committee based on the clauses of SATORI CWA Part 1[107]. The template is structured to take into account the diverse types of ethics committees. A thorough assessment is recommended. Please outline the response (summarised or detailed) and the potential for improvement (including specific implementation actions), and responsibility and timeline for implementation of improvement actions).

Name(s) of assessor(s): _____

Date of assessment: _____

Role and responsibilities of ethics committees

1. Does the organisation have an ethics committee that assesses, evaluates, reviews, appraises, or evaluates practices, products or uses of research and innovation?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

2. Has the ethics committee defined its objects of assessment?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

3. Does the ethics committee monitor and review the scope of its work (including mode of operation) by considering stakeholders' interests and opinions?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

4. Is the ethics committee independent in its decision-making i.e. independent of the researchers and institutions involved?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

5. Has the ethics committee been provided with adequate resources? (e.g. compensation in time, working space, secretarial support, other resources, and materials needed to carry out its tasks effectively)

[107] Part 1 of the SATORI CWA outlines recommendations for the composition, role, functioning and procedures of ethics assessors.

Response/evidence of effective working:

Potential for improvement:

Responsibility and timeline for improvement actions:

Competencies

6. Are the members of the committee *professionally* competent (e.g. administratively, ethically, technically) and have had training and/or experience?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

7. Are the members *independent* of the researchers and the institutions involved?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

8. Are the members *diverse* in gender, backgrounds, and expertise?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

9. Are the members' *representative* of the communities affected by its decisions?

   Response/evidence of effective working:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

10. Does the ethics committee have procedures to address issues relating to competence and evaluate the effectiveness of the actions taken? E.g., training, quality assurance processes.

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

11. Does the ethics committee chairperson possess good management competence (including interpersonal skills for managing group decisions and communication skills to convey the ethics committee's decisions)?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

Appointment of the ethics committee and its members

12. Are the processes by which the ethics committee members are appointed (and membership renewed) transparent and fair?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

13. If an ethics committee is embedded in a research performing organisation:
    a. Is its chairperson elected by its members?
    b. Has the organisation appointed qualified experts?
    c. Has it nominated external competent members (e.g., civil society representatives) in a transparent way?
    d. Has the chief executive of the organisation been excluded from membership of the ethics committee?
    e. Has a transition period been provided (where a newly elected member of the ethics committee will replace an outgoing member) to cater for knowledge transfer and training?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

14. Has the term of office of the ethics committee members including membership renewal been clearly prescribed? (This is important to maintain an appropriate balance between continuity of accumulated expertise and appointment of new members)

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

15. Do the members of the ethics committee receive adequate compensation (financial or equivalent non-financial) for their work?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

16. Have fair conditions for discharge of members been prescribed?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

Composition

17. Is the composition of the ethics committee best suited to identifying ethical concerns raised by R&I activity? The composition of an ethics committee should be optimised to encourage rigorous discussion and evaluation of ethical issues of research proposals.

Response/evidence of effective working:

Potential for improvement:

Responsibility and timeline for improvement actions:

18. Does the ethics committee (at least) include: scientific or technical expertise preferably both expertise related to the field being reviewed and outside; lay person(s), end users or their representative, an ethics expert, a legal expert?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

19. Is there a provision for including additional expertise if needed?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

Conflicts of interest

20. Does the research institution and/or its ethics committee have a conflict of interest policy to assess and manage conflicts of interest of members of the ethics committee?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

21. Does the conflict of interest policy contain:

	Yes/No
A clear definition of conflict of interest	
An acknowledgement of different types and dimensions of conflict of interest	
Provisions on conflicts of interest due to protocol involvement or personal and professional relationships	
Provisions on institutional conflicts of interests	
A specification of the general conditions for these kinds of conflict of interest to be considered problematic	
A specification about whom the policy applies to	
An adequate conflict of interest disclosure procedure	
A procedure on how to identify and address conflicts of interest especially whose value exceeds a minimum threshold	
An outline of possible consequences and penalties for non-compliance with the policy (e.g., exclusion or removal from the ethics committee)?	

    Potential for improvement:

    Responsibility and timeline for improvement actions:

22. Does the ethics committee have a procedure of appeal to allow the re-submission of an application for assessment to another ethics committee?

    Response/evidence of effective working:

Potential for improvement:

Responsibility and timeline for improvement actions:

Ethical issues and principles

23. Has the ethics committee determined and maintained a basic list of ethical issues and principles for consideration?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

24. In addition, is the ethics committee able to determine and maintain field specific ethical issues and principles relevant to the scope of ethics assessment?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

***Procedures for ethics* assessment**

25. Has the ethics committee determined, implemented, and maintained operating procedures that support its goals and expectations?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

26. Are the ethics assessment procedures clearly (and transparently) specified?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

27. Do the ethics assessment procedures protect stakeholders (e.g. individuals participating in research, parties that will be affected by the R&I activity) from undue risk and harm and violation of rights?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

28. Does the ethics assessment consider whether the research or innovation methods being assessed are appropriate for the purpose?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

29. Does the ethics assessment have the potential to increase the awareness of researchers of the ethical impact of research and innovation?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

30. In shaping its procedures, has the ethics committee considered available good practices, standard operating procedures, and voluntary harmonisation procedures at the national and international levels (including field specific ones?)

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

31. Has the ethics committee determined, implemented, and maintained any criteria and conditions for iterative ethics assessment (if applicable)?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

32. Is there adequate provision to keep applicants informed about the progress of the assessment?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

33. Are pre-assessment procedures clearly defined and communicated?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

34. Is there a clear assessment procedure and methodology for weighing the benefits of the research against risks and harms, to individuals, animals, society, and the environment?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

35. Does the ethics committee have confidentiality rules?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

36. Does the ethics committee have good mechanisms for recording and communicating its decisions?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

Quality assessment

37. (How) does the ethics committee evaluate the suitability, adequacy and effectiveness of its ethics assessment policies and procedures on a defined, regular basis using the PDCA (plan-do-check-act) guidance provided in the SATORI CWA?

    Response/evidence of effective working:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

OVERALL ASSESSMENT SUMMARY (including key actions to be taken to ensure compliance)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Annex 7 SATORI self-assessment/peer review template: Part 2 Ethical Impact Assessment (EIA) Framework

The purpose of this open-ended assessment is to provide assessors with a guidance tool to evaluate the strengths and weaknesses of their EIA based on Part 2 of the SATORI CWA[108]. Please outline the response (summarised or detailed) and the potential for improvement (including specific implementation actions), and responsibility and timeline for implementation of improvement actions).

Name(s) of assessor(s): _____

Date of assessment: _____

1. Is the EIA methodology comprehensive in line with the SATORI CWA? I.e. does it include the key stages i.e. threshold analysis, identification of ethical impacts, evaluation of ethical impacts, formulation and implementation of remedial actions, and the review and audit of outcomes.

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

2. Is there provision for an adequate threshold analysis to determine if an EIA is needed?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

3. Is responsibility for the threshold analysis appropriately designated? i.e. to the right person/team with adequate knowledge to make an informed decision.

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

4. Is the timing of the threshold analysis suitable (i.e. timely, early)?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

5. Does the ethical impact assessment plan include the following elements: (a) assessment of the scale of the EIA, (b) budget allocation, (c) team composition, (d) review criteria (e) conditions/grounds for review (f) consultation with stakeholders?

   Response/evidence of compliance:

   Potential for improvement:

[108] Part 2 of the CWA provides researchers with guidance to carry out ethical impact assessments.

Responsibility and timeline for improvement actions:

6. Is there a provision for the review and approval of the EIA plan?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

7. Are there provisions for communication of the review of the EIA plan?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

8. Does the EIA describe all the relevant research outcomes that can lead to ethical impacts?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

9. Has the EIA team clarified the ethical principles and values at stake, if applicable?

   Response/evidence of compliance:

   Potential for improvement:

   Responsibility and timeline for improvement actions:

10. Does the EIA map the ethical impacts that might occur in the context of the R&I project?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

11. Does the EIA identify the ethical values and principles and relevant stakeholder interests regarding these impacts?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

12. Are ethical impact (foresight) activities conducted at an early stage in the R&I project?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

13. Have appropriate ethical impact determination methods been selected based on the scale of the EIA, type of analysis, and type of ethical issues raised by the R & I project?

Response/evidence of compliance:

Potential for improvement:

Responsibility and timeline for improvement actions:

14. Is there provision for/has the EIA team documented the outcomes of the ethical impact foresight activities?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

15. Has the EIA team assessed the relative importance, the likelihood of occurrence and the possible value conflicts of identified ethical impacts?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

16. Have potential or actual value conflicts (and resolutions) been identified and if possible, resolved by appropriate means?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

17. Has the EIA team documented the outcomes of the impact evaluation activities as per the EIA plan?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

18. Has the EIA adequately addressed the formulation and execution process for remedial actions?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

19. Has the EIA team clearly specified to whom the remedial recommendations are directed and the responsibility for implementing the remedial actions?

    Response/evidence of compliance:

    Potential for improvement:

    Responsibility and timeline for improvement actions:

20. Does the EIA include a review and audit stage? This will ensure independent evaluation of the EIA process and, if necessary, independent intervention.

Response/evidence of compliance:

Potential for improvement:

Responsibility and timeline for improvement actions:

21. Is there a provision for a final review of the EIA? (i.e. after remedial actions have been taken, the review and audit stage has been completed)

Response/evidence of compliance:

Potential for improvement:

Responsibility and timeline for improvement actions:

OVERALL ASSESSMENT SUMMARY (including key actions to be taken to ensure compliance)

_____
_____
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_____

Annex 8 SATORI self-declaration of conformity form

Declaration of Conformity

Validity period:

In accordance with SATORI CEN Workshop Agreement Ethics assessment for research and innovation

Part 1 Ethics committees/Part 2 Ethical Impact Assessment* 2017

We (*Name of ethics committee/ethical impact assessor/organisation*) of *(Address*)

hereby declare that: (*Generic description of the ethics committee/ethical impact assessment object and evaluation*)

is in conformity with the applicable requirements of the following documents:

(Standard numbers) (Standard title) (Year of issue and amendment numbers if applicable)

I hereby declare that the committee/ethical impact assessment named above has been designed to comply with the relevant sections of the above referenced specifications.

The report on our self-assessment can be found on [webpage].

Signed by: .....

Name (full name of signatory):

Position:

Place:

On (date):

Document ref. No. xxxxxxxx

*cross –out if not relevant