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Environmentally sustainable and climate neutral health and care systems

NetZeroAICT

Digital Contrast for Computerised Tomography

-Towards Climate Neutral and Sustainable Health Systems-

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Duration: 48 months

= Deliverable D1.3 =

Ethical compliance, governance architecture defined

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Work Package: 1

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Responsible Task Leader: Steven Van Wortswinkel, GZA/ZAS

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SE	Sensitive — limited under the conditions of the Grant Agreement	



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V1.1	31/05/2024	<ul style="list-style-type: none"> - First draft of ethical management procedure <p>Feedback WP 1</p> <ul style="list-style-type: none"> - Change to EMG composition: implemented a tiered approach - Minor adjustments to code of conduct
V1.2	05/09/2024	<ul style="list-style-type: none"> - Developed structure and workflow for ethical management procedure <p>Feedback by PSC:</p> <ul style="list-style-type: none"> - Added time commitment estimations to EMG composition proposal - No adjustments to code of conduct
V2	03/10/2024	<p>Based on lack of EMG recruitment:</p> <ul style="list-style-type: none"> - Developed adjusted EMG composition - Developed adjusted procedural workflow for ethical management
V3	17/11/2024	<ul style="list-style-type: none"> - Restructuring of Code of Conduct - Addition of participatory research to code of conduct - Final EMG composition - Final ethical management procedures <ul style="list-style-type: none"> o Removed voting from SOP E2 & E3
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Lay summary of NetZeroAICT's Ethics Guidelines in this document

About NetZeroAICT

NetZeroAICT is a project focused on making healthcare systems more environmentally friendly by using advanced technology like artificial intelligence (AI). To ensure they do this responsibly and ethically, they've created clear guidelines and a team to oversee ethical practices.

Purpose of the Ethics Document

The ethics document explains how NetZeroAICT is planning to handle ethical considerations throughout the project. It includes:

1. **Simple Rules Everyone Follows (Code of Conduct):** a first draft of basic guidelines for behavior and collaboration.
2. **An Ethics Team (Ethics Management Group):** A group dedicated to overseeing ethical aspects of the project.
3. **Clear Procedures (Ethical Management Procedures):** Step-by-step processes to identify and manage any ethical issues.

1. Simple Rules for Everyone (Code of Conduct)

What is it?

The project Ethics lead has drafted a set of basic rules for everyone involved in the project to follow to ensure respectful and fair collaboration.

Main Points:

- **Respect and Teamwork:** Treat everyone kindly and work together cooperatively.
- **Honesty and Openness:** Be truthful and transparent in all actions and communications.
- **Fairness:** Ensure everyone is treated equally and consider different viewpoints.
- **Responsibility:** Be mindful of how your actions affect others and the environment, and take responsibility for them.
- **Continuous Improvement:** Regularly review and update the rules to keep them effective and relevant.

2. The Ethics Team (Ethics Management Group)

What is it?

A dedicated team that ensures the project stays on track ethically.

Structure:

- **Core Group:** A small team handling day-to-day ethical matters.
- **Deliberation Group:** A larger team that addresses more complex or significant ethical issues.

What They Do:

- **Monitor Ethical Practices:** Make sure everyone follows the Code of Conduct.
- **Provide Guidance:** Help team members with any ethical questions or concerns.
- **Resolve Issues:** Address any ethical problems or conflicts that arise.
- **Include Diverse Perspectives:** Bring in different viewpoints to make well-rounded decisions.

3. Clear Steps to Handle Ethics (Ethical Management Procedures)

What are they?

Simple, clear processes to help identify and manage any ethical risks during the project.

Key Components:

- **Regular Ethical Check-Ups:**
 - Continuously look out for any potential ethical issues.
 - Adjust plans if new concerns come up.
- **Trustworthiness Reviews:**
 - Carefully examine important parts of the project to ensure they meet ethical standards.
 - Provide feedback to improve practices where needed.
- **Standard Operating Procedures (SOPs):**
 - **How the Ethics Team Works:** Guidelines on the team's operations and decision-making.
 - **How Reviews Are Done:** Steps for conducting ethical reviews.
 - **Handling Ethical Risks:** Procedures for assessing and reducing any ethical risks.

Why This Matters

- **Developing Responsible AI:** Ensures that the AI tools created are safe, fair, and beneficial to people and the environment.
- **Building Trust:** Being open and ethical builds trust among team members, partners, and the public.
- **Better Collaboration:** Clear guidelines help everyone work together smoothly and respectfully.
- **Making a Positive Impact:** By focusing on ethics, the project aims to address important challenges like climate change and improving healthcare.

In Simple Terms

NetZeroAICT wants to make sure they're doing the right thing as they develop new AI tools for healthcare. They've set up:

- **Basic rules** that everyone agrees to follow to ensure respectful collaboration.
- **An ethics team** to oversee ethical practices and help with any concerns.
- **Clear procedures** to identify and manage any ethical issues that might come up.

This approach helps ensure that their work is not only innovative but also responsible, aiming to benefit both people and the planet.

Conclusion

By establishing these ethical guidelines and procedures, NetZeroAICT is committed to creating AI technology in a way that's good for everyone involved. They're setting a positive example for how to responsibly develop new technologies that can help solve big challenges in healthcare and the environment.

Executive Summary

This deliverable describes the second result of task T1.2 “building the ethical compliance and governance architecture”. It contains the NetZeroAICT code of conduct, the composition of the ethical management group, its meeting rules and procedures as well as the overarching NetZeroAICT ethical management procedures in the Annex.

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Acronyms and abbreviations

EMG	Ethics Management Group
EMT	Ethical Management Tool (see also: D1.2)
GA	NetZeroAICT General Assembly
PSC	NetZeroAICT Project Steering committee
PAG	NetZeroAICT Public Advisory Group
FRIA	Fundamental Right Impact Assessment

1. Introduction

Deliverable D1.3 describes the NetZeroAICT Ethical governance structure. To this end, it contains the consortium code of conduct, the composition and procedures of the NetZeroAICT Ethical Management Group and the NetZeroAICT Ethical review and risk management Procedures. Together with the NetZeroAICT Ethical Management Tool (deliverable D1.2) it construes the ethics-by-design approach to responsible and trustworthy AI development, as described in the grant agreement. Deliverable D1.4 describes the process of internal alignment and validation of the ethics by design management. Deliverable D8.7 reports the application of the ethical management during the first year of the project.

2. Results and discussion

Code of Conduct

The code of conduct serves as an explicit exercise in researching and experimenting behavioural, scientific and corporate guidelines that capture and reinforce the consortium values and ambitions. It can be interpreted as a *code of conduct for collaboration*¹ between transdisciplinary individuals and organizations. As described in D1.2, the relational and political dimensions of a research endeavour on the intersection of industry, academia and the medical profession, are commonly missing or underrepresented in ethical risk management frameworks. The current code of conduct is developed as a first attempt to capture the essence of the naturally occurring value discourse within the consortium. It can be seen as a result induced from the first year of project discourse through *participant observation*² by the ethicist.

Ethics Management Group (EMG)

The EMG has a dual composition, with different responsibilities for the two sets of members. We distinguish between the EMG Core Group and the EMG Deliberation Group for ease of reference. Through the process described in Deliverable D1.4 both structure and memberships were conceptually validated during the November 2024 PSC and nominatively through this deliverable's review process.

¹ Scholz, Roland W., en Ortwin Renn. 'Codes of Conduct for Collaboration as Social Rule Systems for Transdisciplinary Processes'. *Systemic Practice and Action Research* 37, nr. 1 (1 februari 2024): 81-101. <https://doi.org/10.1007/s11213-023-09641-3>.

² Kivle, Benedicte Maria Tveten, en Gry Espedal. 'Identifying Values Through Discourse Analysis'. In *Researching Values: Methodological Approaches for Understanding Values Work in Organisations and Leadership*, onder redactie van Gry Espedal, Beate Jelstad Løvaas, Stephen Sirris, en Arild Wæraas, 171-87. Cham: Springer International Publishing, 2022. https://doi.org/10.1007/978-3-030-90769-3_10.

Member	Affiliation	EMG Core Group	EMG Deliberation Group
Steven Van Wortswinkel (chair)	ZAS	Yes	Yes
John Kellas (co-chair)	UoO	Yes	Yes
Ernest (secretary)	CMRAD	Yes	Yes
Sage Banner	Unity Insights	No	Yes
Mariana Pacheco Blanco	Amires	No	Yes
Richard LW	Unity Insights	No	Yes
Matt Brown	UoL	No	Yes
Sean Walsh	AI Sentia	No	Yes
Anders Nordel	CMRAD	No	Yes
Regent Lee	UoO	No	Yes
PAG member	/	No	Yes
PAG member	/	No	Yes
PAG member	/	No	Yes
		3 Members	13 Members

Ethics

Management Procedures

The Ethical Management Procedures have been developed to ensure a structured, transparent, and proactive approach to managing ethical risks throughout the lifecycle of the project. They outline the specific responsibilities, operating methods, timing, and the tools necessary to achieve the two primary objectives of the ethical management, as described in the Grant Agreement:

- *To continuously monitor and revise the ethical risk-assessment framework. This involves identifying and defining ethical risks associated with each project milestone and the governance of the consortium, enabling dynamic responses to evolving ethical concerns.*
- *To conduct comprehensive ethical reviews, termed trustworthiness reviews, of all project milestones and the consortium's governance. These reviews ensure that every stage of the project aligns with established ethical standards and principles.*

The foundation for these procedures, along with their rationale and validation processes, is described in deliverable D1.4, that serves as a reference point, providing the context and justification for implementing this ethical management structure to safeguard project integrity and trustworthiness. The results included in the Annex to this deliverable, represent the current ethical management system that will continuously be monitored and evaluated throughout the project. Changes to these procedures require validation by the

EMG Deliberation Group in addition to the standard validation of consortium procedures by PSC and/or GA. If validated updates to these procedures occur, the revised procedures will be annexed to deliverables D.8.8, D8.9 or D8.10.

3. Conclusions

Deliverable D1.3 complements deliverable D1.2 to form an all-encompassing ethical management architecture as described in the grant agreement.

4. Degree of progress

Deliverable D1.3 completely fulfils the task activities as described in the “Description of the action” part of the Grant Agreement. Deliverables D1.2, D1.3 and D1.4 complete the construction and validation of the initial NetZeroAICT ethical management architecture defined as Task T1.2. This deliverable has been 100% completed.

5. Dissemination level

Public

6. References

AccountAbility AA1000 Series of Standards

ALLEA - All European Academies. *The European Code of Conduct for Research Integrity*. DE: ALLEA - All European Academies, 2023. <https://doi.org/10.26356/ECoC>.

Centre for Social Justice and Community Action & National Coordinating Centre for Public Engagement (2022) Community-based participatory research: A guide to ethical principles and practice (2nd edition), CSJCA & NCCPE, Durham and Bristol.

Hiroshima Process International Guiding Principles for Organizations Developing Advanced AI System.

Kivle, Benedicte Maria Tveter, en Gry Espedal. ‘Identifying Values Through Discourse Analysis’. In *Researching Values: Methodological Approaches for Understanding Values Work in Organisations and Leadership*, onder redactie van Gry Espedal, Beate Jelstad Løvaas, Stephen Sirris, en Arild Wæraas, 171-87. Cham: Springer International Publishing, 2022. https://doi.org/10.1007/978-3-030-90769-3_10.

Scholz, Roland W., en Ortwin Renn. ‘Codes of Conduct for Collaboration as Social Rule Systems for Transdisciplinary Processes’. *Systemic Practice and Action Research* 37, nr. 1 (1 februari 2024): 81-101. <https://doi.org/10.1007/s11213-023-09641-3>.

TRUST. ‘The TRUST Code -A Global Code of Conduct for Equitable Research Partnerships’. TRUST, 2018. <https://doi.org/10.48508/GCC/2018.05>.

7. Annex

Code of Conduct

NetZeroAICT and the AICT Consortium form an ecosystem committed to the development of sustainable and trustworthy Artificial Intelligence applications for healthcare. The code of conduct considers stakeholders to be the members of the ecosystem that adhere to this code of conduct (consortium partners and subcontractors of NetZeroAICT, engaged stakeholders and external advisers). Stakeholders are committed to thorough education and implementation of this code of conduct. The ecosystem commits the necessary recourse to develop, maintain and proliferate educational materials concerning this code of conduct.

1. Code of Partnership

1.1 Consortium partners commit to meaningful and inclusive engagement within the NetZeroAICT and AICT Consortium ecosystem by adhering to the AccountAbility AA1000 Series of Standards.

- Consortium partners identify and prioritize relevant stakeholder groups, including but not limited to affected communities, workers, customers, NGOs, and government authorities.
- Consortium partners engage in two-way, interactive processes of communication with prioritized groups.
- Consortium partners ensure engagement is timely, accessible, and appropriate for each stakeholder group.
- Consortium partners provide clear, understandable information to all engaged parties.
- Consortium partners actively seek and consider stakeholder perspectives in decision-making processes.
- Consortium partners establish and maintain accessible grievance mechanisms for both internal and external stakeholders
- Consortium partners commit to addressing stakeholder concerns and grievances promptly and fairly
- Consortium partners ensure protection against retaliation for those who raise concerns or file complaints
- Consortium partners regularly review and improve engagement processes based on feedback and lessons learned
- Consortium partners integrate stakeholder engagement into project planning, implementation, and evaluation phases
- Consortium partners respect local cultures, traditions, and the rights of communities affected by consortium activities.
- Consortium partners commit to transparency in sharing information about project impacts and mitigation measures.

1.2 Stakeholders commit to continuously evaluating and iterating the code of conduct.

1.3 Stakeholders engage the ecosystem with respect, humility, curiosity and transparency.

- Stakeholders interact with sensitivity to diverse perspectives.
- Stakeholders welcome every opinion that is formulated in good faith to propagate the goals of NetZeroAICT and the AICT consortium.

- Stakeholders are at all times modest, respectful and open to learning from others.
- Stakeholders listen actively without assuming superiority or dominance based on position or expertise.
- Stakeholders are open for feedback and commit to continuous learning and growth.
- Stakeholders are honest about their mistakes and commit to learning from them.
- Stakeholders are open minded and adapt their perspectives based on new evidence or insights.

1.4 Stakeholders commit to resolving conflicts constructively and professionally within the NetZeroAICT and AICT Consortium ecosystem.

- Stakeholders address conflicts promptly and directly with the involved parties.
- Stakeholders approach conflicts with a solution-oriented mindset, focusing on mutual understanding and compromise.
- When direct resolution is not possible, stakeholders agree to use a designated mediator or follow the established escalation process.
- Stakeholders maintain confidentiality during conflict resolution processes.
- Stakeholders refrain from public criticism or disparagement of other consortium members during conflicts.
- All parties involved in a conflict commit to implementing agreed-upon resolutions in good faith.

1.5 Stakeholders adhere to transparent and inclusive decision-making processes within the NetZeroAICT and AICT Consortium ecosystem.

- Critical project decisions are made through a consensus-based approach whenever possible.
- When consensus cannot be reached, stakeholders agree to follow the voting procedures outlined in the Consortium agreement.
- Stakeholders ensure all relevant parties are consulted and their perspectives considered before making significant decisions.
- Decision-making processes prioritize the overall goals of the NetZeroAICT Grant and AICT Consortium over individual stakeholder interests.
- Stakeholders commit to documenting the rationale behind major decisions for future reference and transparency.
- All stakeholders agree to support and implement decisions once they are finalized, even if they initially disagreed.
- Stakeholders regularly review and evaluate the effectiveness of decision-making processes, adjusting as necessary to improve efficiency and inclusivity.

1.6 Stakeholders adhere to protocols and procedures approved by the AICT Consortium general assembly. Stakeholders are honest and transparent about breaches of protocol and collaborate to analyse and remedy any and all consequences.

- Stakeholders adhere to the formal review procedure of all external communication concerning the NetZeroAICT Grant and the AICT Consortium.
- Stakeholders adhere to the Chatham House Rules for all formal and informal NetZeroAICT and Consortium meetings.
 - o Anyone is free to express their own views and opinions during discussions,

- Anyone is free to use information from meetings within the NetZeroAICT and/or AICT Consortium ecosystem.
- No one reveals who stated a particular comment, contribution or opinion, nor reveals their affiliations.
- Stakeholders agree to non-disclosure outside the ecosystem of NetZeroAICT for information specifically identified as confidential within the consortium, in the same way as provided by the Consortium Agreement or the Grant agreement.
- Stakeholders apply discretion to sharing information that is not deemed confidential outside the ecosystem.
- When in doubt, stakeholders should consult the consortium before publishing or disclosing any information that could be considered sensitive or proprietary.

2. Code of Research

Stakeholders conducting scientific research within the NetZeroAICT and AICT Consortium ecosystem adhere to [the European code of conduct for Research Integrity](#) and [The TRUST Code](#).

2.1 The TRUST Code

The Trust Code considers the values of fairness, respect, care and honesty to oppose double standards in research and foster long-term and equitable research relationships between partners, especially where research engages both lower-income and higher-income settings.

Fairness

Article 1 through 7 refer to the proper engagement, compensation and inclusion of local researchers and local research subjects. Additionally, fairness commits us to informing local communities, considering the relevance of the research for the local community and sharing the scientific and eventually medical benefits in a culturally accessible, trustworthy and appropriate way.

Respect

Article 8 through 11 refer to the alignment with relevant cultural sensitivities, the local acceptability of the research as evaluated by local ethics or IRB reviews and the community and individual assent for the research.

Care

Articles 12 through 19 refer to the adaptation of communication, consent processes, feedback processes, complaints or whistleblowing procedures to local requirements. Research has to be conducted minimizing the risks of discrimination or stigmatization of local research subjects and with respect to the continuity and availability of local resources. Research needs to be undertaken in line with the highest standards of protection for humans, animals, the environment and the rights and freedoms of research subjects. Where necessary risks to the health, safety and security or the rights of researchers and research subjects are identified and mitigated.

Honesty

Articles 20 through 23 require all rules, roles, responsibilities and plans for the research to be comprehensible and feasible for all local researchers and research subjects. Measures need to be put in place to cross language, literacy and educational barriers to the necessary information. Corruption or bribery are not accepted and the most stringent privacy regulations and procedures are in place.

2.2 The European code of conduct for research integrity

The European code of conduct for research integrity bases good research practices on these fundamental principles for research integrity:

- *Reliability in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources.*
- *Honesty in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way.*
- *Respect for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment.*
- *Accountability for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts.*

2.3 Participatory research

In addition, stakeholders adhere to the ethical guidelines outlined in “Community-Based Participatory Research: A Guide to Ethical Principles and Practice”, and continuously reflect on power dynamics and ethical considerations throughout the research process. The stakeholder communities of concern are those involved with and affected by the AICT project and include internal contributors like project team members, public and external advisory boards, and external stakeholders including patients, healthcare professionals, industry representatives, legal and ethical experts, as well as policymakers and regulators, ensuring a comprehensive, multidisciplinary perspective.

- Stakeholders commit to meaningful and active involvement of community members and end-users throughout the research process.
- Stakeholders ensure research questions and objectives are co-created with community partners and reflect their priorities and needs.
- Stakeholders recognize and value diverse forms of knowledge, including experiential and traditional knowledge.
- Stakeholders establish clear communication channels and decision-making processes that promote equity among all research partners.
- Stakeholders ensure transparency in all stages of the research process, from planning to dissemination of results.
- Stakeholders commit to building capacity within communities through skills transfer and shared learning experiences.
- Stakeholders prioritize research outcomes that directly benefit the communities involved.
- Stakeholders ensure that data ownership, control, access, and possession rights are clearly defined and agreed upon by all parties.
- Stakeholders commit to flexible timelines that accommodate community needs and participatory processes.
- Stakeholders establish mechanisms for ongoing feedback and adjustment of research processes based on community input.

- Stakeholders ensure that research findings are disseminated in accessible and culturally appropriate formats to all participants and stakeholders.
- Stakeholders commit to long-term relationships with community partners that extend beyond individual research projects.

3. Code of Development

Stakeholders developing AI research applications or AI healthcare applications using or engaging with resources from the NetZeroAICT and/or AICT Consortium ecosystem adhere to the [Hiroshima Process International Code of Conduct for Organizations Developing Advanced AI Systems](#).

8. Take appropriate measures throughout the development of advanced AI systems, including prior to and throughout their deployment and placement on the market, to identify, evaluate, and mitigate risks across the AI lifecycle.
9. Identify and mitigate vulnerabilities, and, where appropriate, incidents and patterns of misuse, after deployment including placement on the market.
10. Publicly report advanced AI systems' capabilities, limitations and domains of appropriate and inappropriate use, to support ensuring sufficient transparency, thereby contributing to increased accountability.
11. Work towards responsible information sharing and reporting of incidents among organizations developing advanced AI systems including with industry, governments, civil society, and academia.
12. Develop, implement and disclose AI governance and risk management policies, grounded in a risk-based approach – including privacy policies, and mitigation measures.
13. Invest in and implement robust security controls, including physical security, cybersecurity and insider threat safeguards across the AI lifecycle.
14. Develop and deploy reliable content authentication and provenance mechanisms, where technically feasible, such as watermarking or other techniques to enable users to identify AI-generated content.
15. Prioritize research to mitigate societal, safety and security risks and prioritize investment in effective mitigation measures.
16. Prioritize the development of advanced AI systems to address the world's greatest challenges, notably but not limited to the climate crisis, global health and education.
17. Advance the development of and, where appropriate, adoption of international technical standards.
18. Implement appropriate data input measures and protections for personal data and intellectual property.

References

ALLEA - All European Academies. *The European Code of Conduct for Research Integrity*. DE: ALLEA - All European Academies, 2023. <https://doi.org/10.26356/ECoC>.

TRUST. 'The TRUST Code -A Global Code of Conduct for Equitable Research Partnerships'. TRUST, 2018. <https://doi.org/10.48508/GCC/2018.05>.

Centre for Social Justice and Community Action & National Coordinating Centre for Public Engagement (2022) Community-based participatory research: A guide to ethical principles and practice (2nd edition), CSJCA & NCCPE, Durham and Bristol.

[Hiroshima Process International Guiding Principles for Organizations Developing Advanced AI System.](#)

[AccountAbility AA1000 Series of Standards](#)

SOP E1: Ethics Management Group

i. Goals

Establishing a procedurally bound *protected discourse arena* for ethical deliberation that ensures the following general goals:

- A space for ethical consideration, reflection and discourse on key project tasks, milestones and deliverables;
 - o Which fosters an ethical culture and the practice of value discourse across all stakeholder groups;
- Providing a mechanism to address ethical risks, issues or conflicts in support of the decision making process.
 - o Which strengthens transparency and accountability in the decision-making processes;

ii. Application

- This procedure applies to all EMG members, including those members that are not formally part of the NetZeroAICT consortium and all ad hoc invitees.
- This procedure applies to all EMG meetings, including all scheduled and ad hoc EMG Core Group or EMG Deliberation Group meetings.

iii. Acronyms and abbreviations

GA	General Assembly
PSC	Project Steering Committee
EMG	Ethics Management Group
PAG	Public Advisory Group
EAB	External Advisory Board

iv. Operating procedure

- o **EMG Core Group**

Chairperson	<p>NetZeroAICT (or AICT Consortium) Ethicist</p> <p>The Chairperson is responsible for all planning aspects of the meeting, including determining time, date, location, providing meeting links and/or calendar invites. These tasks can be delegated to other EMG Core Group Members.</p>
Secretary	Determined at the start of every meeting
Meeting structure	The EMG Core Group adheres to a fixed meeting schedule, convening every other week. A meeting time of 1 hour is reserved, but can be flexibly altered based on the agenda requirements at the start of the meeting. Any EMG Core Group member can call for additional ad hoc EMG Core Group meetings, whenever deemed appropriate by all EMG Core Group members.

Meeting composition	<p>The EMG Core Group meetings have a fixed composition, based on the membership validated by the PSC. The EMG Core Group can unanimously decide to invite additional internal stakeholders (project partners, PAG members). The inclusion of additional participants needs to be based on their expertise in the topic matter at hand. They can only be included for the discussion of the topic their expertise is relevant for. The minutes record all attendance (but not the specific contributions) of additional participants.</p> <p>The EMG Core Group has no quorum requirements.</p>
Agenda:	<ul style="list-style-type: none"> - All stakeholders can raise a topic with an EMG Core Group member or ask an EMG Core Group <i>statement of advice</i>. The Core Group Member schedules the topic, disclosing only the relevant and necessary source information. Topics can be scheduled by adding them to the living document described in <i>meeting minutes</i>. - All members of the EMG Core Group can add topics to the agenda for deliberation. Topics can be scheduled by adding them to the living document described in <i>meeting minutes</i>. - The ethicist manages the fixed agenda items, consisting of: <ul style="list-style-type: none"> o Trustworthiness Reviews (see SOP Trustworthiness Review) o Ethical Risk Assessment (see SOP Ethical Risk Assessment)
Meeting Rules	<p>The EMG Core Group follows the Chatham House Rules for meeting minutes and for sharing information within the NetZeroAICT consortium. For external project stakeholders, like PAG members or EAB members, all <i>decisions</i> and <i>statements of advice</i> are accessible.</p> <p>The EMG Core Group adheres to the NetZeroAICT Code of Conduct.</p> <p><i>Decisions or statements of advice</i> from the EMG Core Group are only valid if all three members are actively consulted and have been able to contribute to the discussion.</p>
Meeting Results	<p>The EMG Core Group discussions can lead to either <i>decisions or statements of advice</i>.</p> <ul style="list-style-type: none"> - The EMG Core Group can <i>decide</i>: <ul style="list-style-type: none"> o To schedule a topic for ethical deliberation and formulation of a <i>statement of advice</i> on the agenda of the EMG Deliberation Group; o To call for an additional ad hoc EMG Deliberation Group meeting for ethical deliberation and formulation of a <i>statement of advice</i>; o To schedule a topic for ethical deliberation and decision-making on the agenda of the PSC or GA (this entails the availability of a formal <i>statement of advice</i> on the matter, either by the EMG Core Group or the EMG Deliberation Group);

	<ul style="list-style-type: none"> ○ To consider an ethical issue sufficiently mitigated and resolved, to be further monitored through the Ethical Risk Assessment. (See SOP Ethical Risk Assessment) - The EMG Core Group can formulate a <i>statement of advice</i>: <ul style="list-style-type: none"> ○ On a Trustworthiness Review that does not require the expertise, nor the scope of the EMG Deliberation Group; ○ On a Trustworthiness Review that for practical or moral reasons overrides the possibility of convening an EMG Deliberation Group; ○ On all detected, persisting ethical risks as identified by the Ethical Risk Assessment.
Meeting Minutes	<p>The meeting minutes contain records of:</p> <ul style="list-style-type: none"> - The discussed agenda items; - For each item, a general description of the discussion; - For each item, the relevant <i>statement of advice</i> or <i>decision</i> <p>The meeting minutes are recorded in a living document stored on the CMRAD cloud drive, accessible and adjustable by all EMG Core Group members. The document is subject to automated version-control and retention, as well as tracked changes.</p>

- **EMG Deliberation Group**

Chairperson	<p>NetZeroAICT or AICT consortium Ethicist</p> <p>The Chairperson is responsible for all planning aspects of the meeting, including determining time, date, location, providing meeting links and/or calendar invites. These tasks can be delegated to other EMG Deliberation Group Members.</p>
Secretary	EMG Core Group member appointed at the start of every meeting
Meeting structure	The EMG Deliberation Group adheres to a 6 month meeting schedule. A meeting time of 2 hours is reserved and maintained. Any EMG Deliberation Group member can invite the EMG Core Group to schedule additional ad hoc EMG Deliberation Group meetings. The EMG Core Group decides and provides a written statement from the EMG Core Group minutes explaining its decision to the EMG Deliberation Group member.
Meeting composition	<p>The EMG Deliberation Group meetings have a fixed composition, based on the membership validated by the PSC. The EMG Core Group can unanimously decide to invite additional internal stakeholders (project partners, PAG members). The inclusion of additional participants needs to be based on their expertise in the topic matter at hand. They can only be included for the discussion of the topic their expertise is relevant for. The minutes record all attendance (but not the specific contributions) of additional participants.</p> <p>The EMG Deliberation Group has no quorum requirements.</p>

Agenda:	<ul style="list-style-type: none"> - All stakeholders can raise a topic with an EMG Deliberation Group member or ask an EMG Deliberation Group <i>advice</i>. The Deliberation Group Member or chairperson schedules the topic, disclosing only the relevant and necessary source information. Topics can be scheduled by adding them to the living document described in <i>meeting minutes</i>. - All members of the EMG Deliberation Group can add topics to the agenda for deliberation. Topics can be scheduled by adding them to the living document described in <i>meeting minutes</i>. - The ethicist manages the fixed agenda items, consisting of: <ul style="list-style-type: none"> o Trustworthiness Reviews (see SOP Trustworthiness Review) o Ethical Risk Assessment (see SOP Ethical Risk Assessment)
Meeting Rules	<p>The EMG Deliberation Group follows the Chatham House Rules for meeting minutes and for sharing information within the NetZeroAICT consortium. For external project stakeholders, like PAG members or EAB members, all <i>decisions</i> and <i>statements of advice</i> are accessible.</p> <p>The EMG Deliberation Group adheres to the NetZeroAICT Code of Conduct.</p>
Meeting Results	<p>The EMG Deliberation Group discussions can lead to either <i>decisions</i> or <i>statements of advice</i>.</p> <ul style="list-style-type: none"> - The EMG Deliberation Group can <i>decide</i>: <ul style="list-style-type: none"> o To schedule a topic for ethical deliberation and decision-making on the agenda of the PSC or GA (this entails the availability of a formal <i>statement of advice</i> on the matter, either by the EMG Core Group or the EMG Deliberation Group); o To consider an ethical issue sufficiently mitigated and resolved, to be further monitored through the Ethical Risk Assessment. (See SOP Ethical Risk Assessment) o In conjunction with PSC or GA, the EMG Deliberation Group can make changes to the standard operating procedures governing the ethical management. (NetZeroAICT SOP E1, E2 and E3) - The EMG Core Group can formulate a <i>statement of advice</i>: <ul style="list-style-type: none"> o On a Trustworthiness Review that requires the expertise of the EMG Deliberation Group; o On a Trustworthiness Review; o On all detected, persisting ethical risks as identified by the Ethical Risk Assessment.
Meeting Minutes	<p>The meeting minutes contain records of:</p> <ul style="list-style-type: none"> - The discussed agenda items; - For each item, a general description of the discussion;

	<ul style="list-style-type: none">- For each item, the relevant <i>statement of advice or decision</i> <p>The meeting minutes are recorded in a living document stored on the NetZeroAICT cloud drive, accessible and adjustable by all EMG Deliberation Group members. The document is subject to automated version-control and retention, as well as tracked changes.</p>
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v. **Related documents**

- SOP Trustworthiness Review
- SOP Ethical Risk Assessment

vi. **Evaluation**

This procedure is evaluated and validated as part of the D1.3 NetZeroAICT Deliverable validation process.

The procedure will be evaluated by the EMG Core Group in NetZeroAICT M21, M33 and M45.

The procedure will be evaluated by the EMG Core Group in NetZeroAICT M22, M34 and M46.

The procedure will be evaluated by the PSC in NetZeroAICT M23, M35 and M47.

Based on these evaluations, the procedure is amended and incorporated as an annex to the respective deliverables D8.8, D8.9 and D8.10.

SOP E2: Trustworthiness Review

i. Goals

Establishing a procedurally bound and standardised approach to the NetZeroAICT Consortium ethical review process.

- To ensure systematic ethical review of key project components and incidents;
- To embed the Ethics Tool (D1.2) into the review process;
- To provide timely and constructive feedback on ethical aspects of project milestones and deliverables;
- To address ethical concerns arising from complaints, data breaches, and other incidents.

ii. Application

This procedure applies to a specific subset of topics raised during the EMG Core Group, or the EMG Deliberation Group meetings.

- It applies to explicit ethical reviews of NetZeroAICT project deliverables;
- It applies to ethical reviews of both internal or external, formal complaints, questions, suggestions,... the NetZeroAICT consortium receives (further referred to as "formal feedback");
- It applies to ethical reviews of all forms of incidents that have an effect on existing, or pose additional ethical risks.

The procedure determines the responsibilities of the Ethicist, the EMG Chairperson, the EMG Secretary and other EMG members and participants. It standardises both the workflow and the output of the review process.

iii. Acronyms

GA	General Assembly
PSC	Project Steering Committee
EMG	Ethics Management Group
PAG	Public Advisory Group
EAB	External Advisory Board

iv. Operating procedure

○ Trustworthiness Review of a NetZeroAICT milestone or deliverable

A Trustworthiness Review of a project milestone or deliverable can be triggered by:

- The Work Package Leader inviting the EMG to the review;
- The EMG Core Group, based on the impact of the deliverable on the Ethical Risk Assessment. The ethicist communicates the reasoning behind the EMG decision to the Work Package Leader in advance of the review process.

A Trustworthiness Review of a project milestone or deliverable is executed by the EMG Core Group unless all EMG Core Group members conclude that additional expertise is necessary to adequately review the

deliverable. In that case, the EMG Core Group can refer the review to the EMG Deliberation Group or invite ad hoc participants to the EMG Core Group as described in SOP E1: Ethics Management Group.

The workflow spans at least 7 working days and can require more time.

- The ethicist compiles a short presentation outlining the values, criteria and indicators in the Ethics Management Tool (see D1.2) that are affected by the deliverable (further “value-criteria-indicator chains”). The ethicist distributes the presentation to all reviewers (EMG members and participants).
- The EMG Chairperson adds the review to the relevant meeting agenda, or organises an ad hoc EMG meeting as agreed upon;
- The Work Package Leader shares the most up-to-date version of the deliverable to the EMG chairperson.
- The EMG chairperson uploads the deliverable to the NetZeroAICT Google Drive Cloud environment hosted by CMRAD, and notifies the reviewers of its availability.
- Reviewers get at least 7 working days:
 - o to comment on the deliverable, adding remarks, questions, suggestions to the document;
 - o to expand or challenge the list of “Value-Criteria-Indicators Chains” that they deem affected by the deliverable.
- During the meeting the Chairperson opens the discussion by:
 - o Inviting all members to declare personal conflicts of interest,
 - o Inviting all members to voice concerns about possible conflicts of interest that were not spontaneously reported or are not apparent due to the composition of the EMG executing the review.

⇒ The Secretary summarises all self-reported conflicts of interest and all concerns in the Trustworthiness Review Report. The Secretary omits who voices a particular concern, only the content of the concern is incorporated into the report.
- The Chairperson summarises the “Values–Criteria–Indicator chains” that are affected by the deliverable. Reviewers can challenge and discuss this summary until a consensus is reached. If no consensus is reached or proves to be unattainable, all “Values–Criteria–Indicator Chains” are included in the review.

⇒ The Secretary summarises the “Values–Criteria–Indicators chains” that are affected by the deliverable in the Trustworthiness Review Report. If no consensus is reached, the Secretary includes all “Value–Criteria–Indicators Chains” that are discussed.
- The Chairperson goes over every comment made in the deliverable, inviting discussion to either:
 - o Resolve the comment;
 - o Find consensus on how to phrase the comment;
 - o Explain the comment as a personal opinion of one or more reviewers, not an opinion shared by all reviewers. (SR (single reviewer), MR(multiple reviewers) or AR(all reviewers) opinion)

⇒ The Secretary removes the existing comment and rephrases or repeats the comment explaining it as a SR (single reviewer), a MR (multiple reviewers) or AR(all reviewers) opinion. This way the identity of the author of the comment is omitted in the final review report.
- The Chairperson invites all members to evaluate the review process.

⇒ The Secretary incorporates the evaluation in the minutes of the meeting, not in the Trustworthiness Review Report.

- After the meeting, the Ethicist:
 - Duplicates the deliverable to reset the automated version control,
 - Adds the Trustworthiness Review Report as a front page to the deliverable and distributes the document to the EMG Core Group for approval. Once approved the Chairperson delivers the Trustworthiness Review Report to the responsible Task Leader.
 - **Trustworthiness Review of formal feedback**

A Trustworthiness Review of “formal feedback” is automatically triggered upon reception.

A Trustworthiness Review of “formal feedback” is executed by the EMG Core Group unless all EMG Core Group members conclude that additional expertise is necessary to adequately review the deliverable. In that case, the EMG Core Group can refer the review to the EMG Deliberation Group or invite ad hoc participants to the EMG Core Group as described in SOP E1: Ethics Management Group.

The timespan of the workflow is variable, to be determined by the EMG Core Group, based on the urgency and risks involved.

- The ethicist compiles a short presentation outlining the values, criteria and indicators in the Ethics Management Tool (see D1.2) that are affected by the “formal feedback” (further “Value-Criteria-Indicators Chains”). The ethicist distributes the presentation to all reviewers (EMG members and participants).
- The EMG Chairperson adds the review to the relevant meeting agenda, or organises an ad hoc EMG meeting as agreed upon;
- During the meeting the Chairperson opens the discussion by:
 - Inviting all members to declare personal conflicts of interest,
 - Inviting all members to voice concerns about possible conflicts of interest that were not spontaneously reported or are not apparent due to the composition of the EMG executing the review.

⇒ The Secretary summarises all self-reported conflicts of interest and all concerns in the Trustworthiness Review Report. The Secretary omits who voices a particular concern, only the content of the concern is incorporated into the report.
- The Chairperson summarises “Value-Criteria-Indicators Chains” that are affected by the “formal feedback”. Reviewers can challenge and discuss this summary until a consensus is reached. If no consensus is reached or proves to be unattainable, the Chairperson calls for a vote.

⇒ The Secretary summarises the “Value–Criteria–Indicators chains” that are affected by the “formal feedback” in the Trustworthiness Review Report. If no consensus is reached, the Secretary includes all “Value–Criteria–Indicators Chains” that are discussed and their representative weight in the vote.
- The Chairperson invites reflection on all possible courses of action that can mitigate and/or remedy the feedback, by addressing the impact on the identified “Value–Criteria–Indicators chains” as well as remedy any negative impact on the individual reporting the “formal feedback”.

⇒ The Secretary catalogues the conceived courses of action in the Trustworthiness Report.
- The Chairperson invites reflection on the impact and the ethical weighing of the possible courses of action. The EMG searches for one or more courses of action that mitigate and/or minimise the residual ethical risks associated with the “formal feedback” and the impact on the reporting

individual. The EMG constructs a statement of advice containing a practical course of action and a possible response to the “formal feedback”.

⇒ The secretary catalogues the advised course of action and response in the Trustworthiness Report.

- The Chairperson invites all members to evaluate the review process.

⇒ The Secretary incorporates the evaluation in the minutes of the meeting, not in the Trustworthiness Review Report.

- After the meeting, the Ethicist:

- Finalises the Trustworthiness Review and distributes the document to the EMG Core Group for approval. Once approved the Chairperson delivers the report to the PSC or GA chairperson as a motivated ethical *statement of advice* concerning a “formal feedback”.

- **Trustworthiness Review of an incident**

The necessity of a Trustworthiness Review of an incident is discussed during the first EMG Core Group meeting following the occurrence. All members of the EMG Core Group add any and all incidents that are sufficiently known by or reported to them to the agenda. The EMG Core Group decides whether or not the incident poses sufficient ethical threats or risk to necessitate a Trustworthiness review. If such Review is required, the duration of the workflow is adapted to the urgency of the matter. This can influence the decision whether or not the EMG Core Group, or the EMG Deliberation Group manages the review.

The remaining workflow for Trustworthiness Reviews of incidents is identical to the reviews of “formal feedback”.

- **Reporting of Trustworthiness Reviews**

The Ethicist is responsible for summarising all Trustworthiness reviews into the Trustworthiness review report Deliverables D8.6, D8.7, D8.9 and D8.10. The validation of this summary follows the regular approval of NetZeroAICT Deliverables.

v. **Related documents**

SOP E1: Ethics Management Group

SOP E3 : Ethical Risk Assessment

vi. **Evaluation**

This procedure is evaluated and validated as part of the D1.3 NetZeroAICT Deliverable validation process.

The procedure will be evaluated by the EMG Core Group in NetZeroAICT M21, M33 and M45.

The procedure will be evaluated by the EMG Deliberation Group in NetZeroAICT M22, M34 and M46.

The procedure will be evaluated by the PSC in NetZeroAICT M23, M35 and M47.

Based on these evaluations, the procedure is amended and incorporated as an annex to the respective deliverables D8.8, D8.9 and D8.10.

SOP E3: Ethical Risk Assessment

i. Goals

Establishing a procedurally bound systematic and continuous development, maintenance and application of the Ethics Management Tool described in D1.2.

- To ensure continuous ethical risk assessment and management during the NetZeroAICT project's lifespan;
- To test, optimise and internally validate a risk assessment approach that can support the ethical management of the AICT Consortium in perpetuity.

ii. Application

This procedure applies to the ethicist responsible for developing, maintaining and applying the Ethics Management Tool (EMT) described in D1.2.

It also applies to all EMG members and participants, describing the methodology used to determine, based on the EMT, the weight of the established ethical risks, the weight of corresponding mitigation measures and the weight of any persisting ethical risks. Furthermore, it standardises both the workflow and the output of an Ethical Risk *statement of advice* formulated to the NetZeroAICT PSC or GA.

The procedure applies to all NetZeroAICT partners concerning the necessary and timely involvement of the EMG Core Group and the NetZeroAICT Ethicist to ensure that project information flows through to the Ethical Risk Assessment as frictionless as possible.

iii. Acronyms

GA	General Assembly
PSC	Project Steering Committee
EMG	Ethics Management Group
PAG	Public Advisory Group
EAB	External Advisory Board
EMT	Ethics Management Tool

iv. Operating procedure

o Ethical risk assessment: VCIO Analysis

- The Ethicist develops the EMT as described in the Grant agreement, based on research described in D1.2 and D1.4. At any time the latest valid iteration of the EMT is the version incorporated as an annex to the most recent Ethics Trustworthiness Report Deliverable under WP8 (D8.7, D8.8, D8.9 or D8.10).
 - o Based on literature review and utilising the VCIO methodology, the ethicist defines the values, criteria and indicators for ethical development and testing of the AI algorithms developed according to the NetZeroAICT Grant Agreement.
 - o Based on literature review and utilising the VCIO methodology, the ethicist defines the values, criteria and indicators relevant to all other lifecycle phases of the AI algorithms developed according to the NetZeroAICT Grant Agreement. The ethicist clearly

differentiates between those criteria and indicators that are relevant to the lifecycle phases incorporated in the NetZeroAICT Grant Application and those that are not.

- Following Trustworthiness Reviews or Risk Assessment processes, the ethicist adapts the values, criteria and indicators in the EMT based on the results of the reviews or assessments.
- The ethicist monitors all project plans, decisions and results by participating in PSC or GA meetings, Work Package or Task meetings or interpreting project deliverables.
 - The ethicist condenses all project plans, decisions and results into relevant observables fulfilling (in part or in full) relevant ethical indicators.
 - The ethicist periodically schedules a EMG Core Group review of the interpretation of project plans, decisions and results as relevant observables.
- **Ethical risk assessment: VCIO interpretation**
- Based on the VCIO analysis³, the ethicist quantifies the fulfilment of all identified Value-Criteria-Indicators chains applicable and relevant to the project phase at hand.
 - The ethicist ensures that each indicator contributing to a criteria and each criteria contributing to an overall value is treated equally. No single part is given more importance than the others.
 - The ethicist arguments why observables fulfil or fail to fulfil relevant indicators;
 - The ethicist arguments why indicators fulfil or fail to fulfil relevant Criteria;
 - The ethicist arguments why Criteria fulfil or fail to fulfil relevant Values.
- Through the VCIO analysis and interpretation, the ethicist construes a continuous risk assessment profile of the project, as much as possible in real time throughout the project workflow. The profile can at any time identify where observables relevant to the project phase at hand are lacking.
 - **Ethical risk assessment: VCIO reporting**
- The ethicist maintains a record of the EMT (reporting the ongoing VCIO analysis and interpretation) on the NetZeroAICT Consortium Google Drive (hosted by CMRAD) in a comprehensive spreadsheet where it is consultable by all project Partners in real-time.
- The ethicist maintains records of all changes to the EMT in relation to the latest published and validated version in a deliverable under Work Package 8.
- The ethicist maintains records of all VCIO interpretations in relation to the latest published and validated version in a deliverable under Work Package 8.
- In NetZeroAICT M21, M33 and M45, the ethicist invites the EMG Core Group to review and validate the adjustments to the EMT in relation to the latest published and validated version.

³A Value-Criteria-Indicator-Observation (VCIO) chain in ethical analysis is a systematic framework to evaluate ethical standards: Value: The core ethical principle or moral ideal (e.g., human rights)

Criteria: Specific standards that define how the value is applied (e.g., "respect for individual autonomy")

Indicator: Measurable signs that show the criteria are being met (e.g., "percentage of informed consent obtained")

Observation: Actual data or evidence collected to assess the indicator (e.g., documented consent forms, survey results)

This method helps translate abstract ethical principles into concrete, measurable assessments.

- In NetZeroAICT M22, M34 and M46, the ethicist invites the EMG Deliberation Group to review and validate the adjustments to the EMT in relation to the latest published and validated version.
- The formal validation of the EMT iterations is conducted through the respective WP 8 deliverable validation processes.

- o **Ethical risk management: Ethical Risk Advice**

Based on the Ethical Risk Assessment Profile:

- any EMG Core Group member can initiate an ethical risk advice process for a specific, unmitigated ethical risk.
- Any EMG Deliberation Group Member, Project Partner or PAG Member can request an ethical risk advice process for a specific, insufficiently mitigated ethical risk. The EMG Core Group decides whether or not to initiate the advice process and motivates its decision.

An Ethical Risk advice process is executed by the EMG Core Group unless all EMG Core Group members conclude that additional expertise is necessary. In that case, the EMG Core Group can refer the review to the EMG Deliberation Group or invite ad hoc participants to the EMG Core Group as described in SOP E1: Ethics Management Group.

The timespan of the workflow is variable, to be determined by the EMG Core Group, based on the urgency and risks involved.

- The ethicist compiles a short presentation outlining the “VCIO chain” in question. The ethicist distributes the presentation to all reviewers (EMG members and participants).
- The EMG Chairperson adds the review to the relevant meeting agenda, or organises an ad hoc EMG meeting as agreed upon;
- During the meeting the Chairperson opens the discussion by:
 - o Inviting all members to declare personal conflicts of interest,
 - o Inviting all members to voice concerns about possible conflicts of interest that were not spontaneously reported or are not apparent due to the composition of the EMG executing the review.

⇒ The Secretary summarises all self-reported conflicts of interest and all concerns in the Ethical Risk statement of advice. The Secretary omits who voices a particular concern, only the content of the concern is incorporated into the report.

- The Chairperson summarises the analysis and interpretation of the “VCIO chain”. Reviewers can challenge and discuss this analysis and interpretation until a consensus is reached on the nature, the severity and the urgency of the persisting ethical risk(s). If no consensus is reached or proves to be unattainable, the Chairperson calls for a vote.

⇒ The Secretary summarises the analysis and interpretation of the “VCIO chain”. If no consensus is reached, the Secretary includes all discussed “VCIO chain” alternatives and their impact on the nature, severity and urgency of the ethical risk(s).
- The Chairperson invites reflection on all possible courses of action that can mitigate and/or remedy the ethical risk(s).

⇒ The Secretary catalogues the conceived courses of action in the Ethical Risk statement of advice.
- The Chairperson invites reflection on the impact and the ethical weighing of the possible courses of action. The EMG searches for one or more courses of action that mitigate and/or minimise the

ethical risk(s) or their possible impact on project values, milestones or stakeholders. The EMG constructs a *statement of advice* containing a practical course of action.

- ⇒ The secretary catalogues the advised course of action in the Ethical Risk *statement of advice*.
- The Chairperson invites all members to evaluate the review process.
 - ⇒ The Secretary incorporates the evaluation in the minutes of the meeting, not in the Trustworthiness Review Report.
- After the meeting, the Ethicist:
 - Finalises the Ethical Risk *statement of advice* and distributes the document to the EMG Core Group for approval. Once approved, the Chairperson delivers the report to the PSC or GA chairperson as a motivated ethical advice concerning a perceived and documented ethical Risk.

v. Related documents

SOP E1: Ethics Management Group

SOP E2 : Trustworthiness Review

vi. Evaluation

This procedure is evaluated and validated as part of the D1.3 NetZeroAICT Deliverable validation process.

The procedure will be evaluated by the EMG Core Group in NetZeroAICT M21, M33 and M45.

The procedure will be evaluated by the EMG Deliberation Group in NetZeroAICT M22, M34 and M46.

The procedure will be evaluated by the PSC in NetZeroAICT M23, M35 and M47.

Based on these evaluations, the procedure is amended and incorporated as an annex to the respective deliverables D8.8, D8.9 and D8.10 in NetZeroAICT M24, M36 and M48.