American College of Radiology

September 12, 2025

Attn: AI Standards Zero Draft/AI TEVV Project Staff
National Institute of Standards and Technology
Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

Re: Outline: Proposed Zero Draft for a Standard on AI Testing, Evaluation, Verification, and Validation; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists—appreciates the opportunity to comment on the National Institute of Standards and Technology (NIST) document released July 29, 2025, "*Outline: Proposed Zero Draft for a Standard on AI Testing, Evaluation, Verification, and Validation (TEVV)*." ACR understands the resulting draft will inform the U.S. Government's input to the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) JTC 1/SC 42, which is the subcommittee focused on AI standards development within ISO and IEC.

Background on ACR Data Science Institute

ACR established its Data Science Institute (DSI) in 2017 to advance safe, effective, and clinically useful radiology AI innovations. DSI collaborates with radiology professionals, industry, government, patients, and other stakeholders in developing programs and tools in support of the implementation of AI applications that will help improve patient care. Initiatives include:

- Defining clinically relevant use cases intended to guide the development of useful imaging AI (Define-AI).
- Establishing the first national recognition program for safe and effective implementation of AI in imaging practices (ARCH-AI), and making it broadly available in 2024.
- Creating opportunities for monitoring the effectiveness of AI models, including via the first large-scale quality registry for AI performance monitoring in real-world clinical practice (Assess-AI).

- Participating in the Healthcare AI Challenge, a multi-institution collaborative effort dedicated to the robust evaluation of clinical-grade AI solutions.
- Sharing information about radiology AI models with radiologists to help them choose what works for their practices and their patients (AI Central).
- Addressing the regulatory, legal, and ethical issues associated with radiology AI.

ACR Comments on "*Outline: Proposed Zero Draft for a Standard on AI TEVV*"

Clause 2: Normative References (Page 4)
ACR recognizes the future draft will be cross-sectoral and international in scope and will therefore reference exclusively ISO documents. There will be a need for additional consideration of Food and Drug Administration regulations and other existing healthcare requirements/standards in any downstream U.S. healthcare-specific implementations.

Clause 3: Terminology (Pages 4-5) and Clause 4: Key Terms and Concepts in TEVV for AI (Pages 5-12)
The document does not comprehensively address key AI TEVV terms and concepts (e.g., drift, continuous learning, model cards, data provenance). Additionally, it does not reconcile with ISO 22989 "*Information technology - Artificial intelligence - Artificial intelligence concepts and terminology*." ACR recommends the addition of a harmonized table.

Clause 5: Governance, Process, and Organizational Requirements (Page 13)
ACR recommends clarifying the concept of "ontological and epistemological questions" in the context of NIST's recommendation to consider such questions with respect to validity, reliability, and case sampling when settling on objectives, requirements, and evaluation activities and methods.

Other Considerations: Post-Deployment/Continuous TEVV
The document prioritizes pre-deployment AI TEVV and the discussion of continuous TEVV operations (i.e., post-deployment) is comparatively inadequate. For example, the document downplays the necessity of a process for ongoing monitoring, data drift detection, etc. ACR recommends adding content to address the need for, and content of, continuous TEVV.

Other Considerations: Differentiation of Validation and Evaluation Terms
ACR recommends the addition of examples to clearly illustrate the differences between the covered terms. For example, in healthcare AI contexts, regulators or others may use

the term “validation” when “evaluation” is the appropriate term in the NIST and ISO/IEC vernacular.

Other Considerations: AI Risk Management Framework and TEVV
ACR recommends mapping the future final document to the NIST “*AI Risk Management Framework*” where applicable.

Thank you for your consideration of these comments. ACR invites collaboration with NIST on AI TEVV. Please contact Michael Peters, Senior Director, Government Affairs, at mpeters@acr.org, with questions.

Sincerely,

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