ACR-SIIM PRACTICE PARAMETER FOR IMAGING ARTIFICIAL INTELLIGENCE (AI)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

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[1] *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.*

I. INTRODUCTION AND SCOPE

The goal of this practice parameter is to define the infrastructure, personnel, processes, and governance needed to establish a comprehensive framework for the safe, effective, and transparent integration of artificial intelligence (AI) into imaging practice. This practice parameter addresses principles of AI governance, model and product selection, local acceptance testing, real-world performance monitoring, and includes special considerations for non- FDA-regulated AI models and patient privacy considerations under HIPAA. It applies to all practitioners and support personnel—including but not limited to physicians, technologists, medical physicists, informaticists, data scientists, and administrators—who deploy, interpret, interact with, support, or act upon AI-derived outputs in the course of caring for patients during diagnostic imaging, image-guided procedures, post-

processing, and reporting of imaging.

The scope of this practice parameter covers

- Required principles to help qualified end-users champion safe, effective, and appropriate use of AI in medical imaging.
- Practice-based management of AI designed to process images within the clinical workflow which meets the FDA definition of Software as a Medical Device (SaMD), including but not limited to computer-aided detection (CADe), worklist triage (CADt), computer-aided diagnosis (CADx), and AI designed to achieve quantification of lesions, organ sizes, and other imaging features.
- AI not currently subject to FDA SaMD regulation, including but not limited to generative AI-powered tools for both pixel-based and non-pixel-based use cases.

The scope does not cover

- 3D printing
- AI that operates exclusively on modalities, a.k.a. Software in a Medical Device (e.g., for MRI acceleration, CT image reconstruction
- AI designed exclusively for the management of business processes, e.g. revenue cycle management, patient scheduling, etc.

II. PRINCIPLES FOR IMAGING AI

A. Relevant Definitions

- AI algorithm: An AI algorithm is a set of computational processes allowing suitable computers to mimic human cognition to achieve a task without an explicit (deterministic) set of pre-programmed rule-based code. Algorithms infer relationships between input data and a desired output to which the algorithm is tuned during training. The algorithm may be exposed to different types and combinations of input data and known associated outputs through a process called “training” which turns an algorithm into a model specific to a task.
- AI model: An AI model is an AI algorithm that has been trained on data that provides examples of the task that the AI is intended to perform. In radiology, AI models can analyze images, text (such as radiology reports or notes from the medical record), information from the medical record, and combinations of the above. AI can also identify and describe findings on radiology images and organize those findings in a particular format for review by a physician.
- Inference: Inference is the process by which an AI model takes an input and generates an output.
- Instructions for use (IFU): The US Food and Drug Administration (FDA) requires that AI vendors include IFU that describe how an imaging AI model is to be used and how it performed during the performance testing leading up to FDA clearance. The document includes information and directions for using the model in practice.
- Qualified end-user: A qualified end-user of an imaging AI model is a licensed practitioner with the necessary qualifications and training to independently interpret medical images without the aid of the imaging AI model, and who possesses specific qualifications and training in the use of the imaging AI model, including the ability to assess the validity of its output.
- Governance group: An AI governance group is responsible for the administrative, clinical, and technical aspects of AI deployment and use. The group is essential regardless of whether the AI in question is a commercial product, or a solution developed internally for the organization or practice. A Radiologist should be a part of this group.
- Deployment: Deployment of an AI model introduces that model into the clinical workflow for use by the qualified end-users for patient care.
- Local acceptance testing: Local acceptance testing of an AI model is the process of evaluating the model to ensure that it meets the performance expectations of the practice. In some cases, this evaluation takes place in a “sandbox” environment that is not connected to the systems used to care for patients (i.e., prior

to deployment), while in other cases it might occur after deployment to a small number of qualified end-users but not to the entire practice.

- More definitions are available at the FDA Digital Health and Artificial Intelligence Glossary

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

Successful AI deployment is a multi-stakeholder effort and may include the following roles: physicians (most often the qualified end-users of the AI), medical physicists, imaging informatics (II) and information technology (IT) professionals, data scientists, technologists, vendors/developers, administrators, and legal/compliance/privacy officers. The roles and tasks associated with each stakeholder in the integration of AI into clinical practice are summarized in this section.

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

A. Physicians/Qualified End-Users

1. The physician/qualified end-user (as defined in section II) must demonstrate qualifications as delineated in the appropriate ACR practice parameter or technical standard for the particular diagnostic modality for which the AI is being used.
2. Physicians/qualified end-users of the AI model should have a clear understanding of how the AI model works, including the type of input it requires, the data it uses for inference, its regulatory clearance and intended use, the nature of its output, and how to interpret that output. They should also understand the model's capabilities and limitations, and how factors such as image acquisition parameters (e.g., image quality, protocol, machine manufacturer) and patient characteristics (e.g., age, gender, race, ethnicity) may influence performance and affect clinical-decision making, and how disease prevalence affects AI performance.
3. At least one physician/qualified end-user should be a member of a practice's AI governance group (discussed further in section IV).

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

B. Medical Physicists

1. Medical physicists are often responsible for quality management of the modalities that will produce images to be analyzed by AI models. Specifically, they may be involved in ensuring that AI inputs are acquired according to manufacturer/developer specifications. As such, they may need to be involved in the integration of AI into clinical practice.
2. The role of a qualified medical physicist is described in the ACR–AAPM–SIIM TECHNICAL STANDARD FOR ELECTRONIC PRACTICE OF MEDICAL IMAGING.
3. The American Association of Physicists in Medicine (AAPM) Task Group Report 273 details recommendations on best practices for AI and machine learning for computer-aided diagnosis in medical imaging.

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

C. Imaging Informatics (II) and Information Technology (IT) Professional

1. Imaging informatics (II) and information technology (IT) professionals play an important role in ensuring that the computer systems and software that enable care of patients in radiology work as expected. As such, they should participate in the planning and integration of AI into clinical practice.
2. For successful AI deployment within a practice, they may be responsible for configuring the necessary cloud/on-premise IT infrastructure for an AI model, including hardware and software specifications for AI servers to meet expected volumes, provide timely output, and integrate with other relevant clinical systems.

3. II and IT professionals must also ensure the system is secure, managed for privacy requirements, and monitored and supported when technical issues arise. They may also configure and maintain technical infrastructure needed for post-deployment monitoring, such as integration with registries such as Assess-AI, and for cybersecurity and privacy related to AI deployment
4. They may also be responsible for ensuring that images are correctly and securely transmitted to an AI model both during testing and in production, and that results are correctly and securely returned to the patient's record in PACS, the reporting system, or the EMR.
5. Specific roles and responsibilities are described in the ACR–AAPM–SIIM TECHNICAL STANDARD FOR ELECTRONIC PRACTICE OF MEDICAL IMAGING

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

D. Data Scientists

1. Data scientists can play a valuable role in supporting safe and effective AI integration. Leveraging their expertise in AI algorithms and model behavior, data scientists can complement the clinical perspective of the physician/qualified end-user's experience of an AI model, and can contribute across the lifecycle of an AI model, from local acceptance testing to post-deployment monitoring. Specific responsibilities may include:
    a. Assisting in the design of statistically robust local validation protocols, including determining exam volumes and types.
    b. Developing automated data pipelines and infrastructure to support ongoing monitoring of AI model performance, data orchestration and system integration, and user interaction with AI output.
    c. Synthesizing feedback into actionable insights to inform governance and quality assurance processes.
2. In addition, data scientists may also provide more advanced contributions, including but not limited to:
    a. Developing new models
    b. Fine-tuning existing models for use
    c. Supporting local deployment efforts, if appropriate resources and oversight are in place.

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

E. Radiology Technologists

1. Radiology technologists should:
    a. Be certified by the appropriate registry and/or possess unrestricted state licensure.
    b. Meet the qualification requirements of any existing ACR practice parameter or technical standard for acquisition of a particular examination
    c. Be trained to properly operate those portions of the image data management system with which the individual must routinely interact.
    d. When the technologist is part of the AI model workflow, the technologist should be trained on the
        - AI use case and imaging parameters of the expected AI inputs
        - AI input image quality evaluation and remediation
        - AI-related quality assurance

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

F. Manufacturers/Developers

1. AI manufacturers/developers should support practices by providing clear guidance in the intended use of their products. Manufacturers of FDA-regulated AI models are required to provide standard guidance (IFU) on the product. In addition, manufacturers should deliver comprehensive documentation including release notes and model versioning and proactively notify customers prior to deploying new model versions. To enhance transparency and support effective human-AI collaboration, manufacturers are encouraged to provide additional information such as:

a. Model explainability and inference transparency (e.g., which images or text were used for inference)
b. Status of AI model output (e.g., processing, inferenced, rejected)
c. Reason for data rejection (e.g., inadequate image quality, unsupported data format)
d. AI model confidence scores or output uncertainty, when allowable through regulation

2. Sharing best practices from other model users may also be valuable. These materials may be used at the discretion of the local personnel responsible for model deployment and oversight.

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

G. Administrators

1. Administrators may be involved with AI procurement, deployment, and oversight at different levels of the practice. Any designated administrative lead(s) may provide structure and leadership to the local AI program.

III. OPERATIONAL AND ADMINISTRATIVE PERSONNEL, QUALIFICATIONS, AND ROLES

H. Legal/Compliance/Privacy Professionals

1. Duties of the legal/compliance/privacy professional and may include:
    a. Advising the practice on applicable scope of FDA clearance of a given AI model and associated capabilities, limitations, and off-label uses.
    b. Advising the practice of the legal and regulatory considerations for an AI model, including FDA, HIPAA, NIH, and any other state or local regulations or internal policies.
    c. Advising the practice on the common law and ethics of a particular imaging AI model as well as AI in general.
    d. Ensuring that the deployment and local use of AI occurs within the boundaries of applicable institutional guidelines and local, state, and national legislation.
    e. Confirming that any contracts, IRB oversight processes/documentation and other legal documentation pertaining to the AI in use are appropriately configured and executed

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

A. Governance

1. Practices should establish an AI governance group responsible for oversight of selection, local acceptance testing, deployment, monitoring, and sunsetting of AI models as necessary.
2. This group should include at least one physician/qualified end-user. The remainder of the group should be interdisciplinary and consist of members reflect the operational and administrative roles in section III.
3. Members of the governance group are expected to be impartial with respect to the AI model being considered. As such, the composition of the group may be dynamic in an effort to mitigate potential conflicts of interest. For example, a manufacturer/developer of an AI model would not be expected to participate in governance discussions related to deployment of their model into the practice.
4. Requests for new AI models to be introduced into the clinical environment should be brought by a clinical champion to this group for review. The clinical champion should not be a member of the governance group.
5. The group should meet regularly and keep meeting notes.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

B. Documentation & Inventory

1. Practices should maintain an up-to-date local inventory of all deployed AI models.
2. Key documentation for deployed AI models should include:
    a. documented model version

b. deployment date
c. IFU
d. intended purpose
e. local acceptance testing results
f. relevant input or output routing rules (including DICOM, HL7, and FHIR) and inclusion and exclusion criteria (e.g., applicability to pediatric vs. adult imaging)
g. qualified end-user training logs
h. post-deployment monitoring data
i. contact information for clinical champion(s) and manufacturer/developer support.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

C. Security & Compliance

1. Practices are expected to adhere to their organization's security and compliance requirements for AI.
2. This includes how AI results will be incorporated into the medical record and how the practice's policy on data retention, transparency, and purging will apply to these results.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

D. Model Selection

1. Practices should have defined process and criteria for determining which AI models they will deploy.
2. This process should include relevant clinical, technical and business considerations.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

E. Local Acceptance Testing

1. Practices should have a process by which local domain experts evaluate initial model performance using local data.
2. Predefined metrics for acceptable AI performance should be agreed upon prior to the evaluation process. and tailored to relevant patient populations and exam subgroups.
3. These metrics should align with clinical expectations and inform both model deployment decisions and physician/qualified end-user training prior to deployment.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

F. Training & Instructions for Use

1. Documented training procedures are recommended for qualified end-users and should be appropriate to the complexity of the clinical use case.
2. IFU should be made available and easily accessible to qualified end-users concurrent to deployment of the AI.
3. Supplemental training is encouraged after the model has been in use for some time, so that new issues identified by users can be shared across the practice and reported back to the governance group for review and appropriate action.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

G. Monitoring

1. A monitoring mechanism for AI models should be established to track ongoing performance.
2. Practices should use performance reports to ensure that their models are performing as expected.

3. Practices may also monitor how physicians/qualified end users interact with the AI, such as whether they engage with its output and how frequently they override or modify results, to identify users who may benefit from additional training or support or models that are not performing to expectations.
4. Practices should periodically review, as part of existing peer-review/peer-learning programs, complications or adverse events potentially related to AI use to identify improvement opportunities.

IV. SPECIFICATIONS FOR IMAGING AI BEST PRACTICES

H. Non-FDA-Regulated Models

1. If practices are deploying non-FDA-regulated models, additional oversight and compliance with local governance is recommended.
2. This includes locally developed models as well as emerging technologies such as generative AI (e.g., large language models/LLMs, vision-language models/VLMs, foundation models, etc.).
3. Special considerations may need to be taken with this class of AI models including review by the organization's Institutional Review Board (IRB), additional resources for post-deployment monitoring, and/or extra review by the practice's legal/compliance/privacy professionals.

V. OTHER CONSIDERATIONS

Practices using AI clinically should consider how their AI models release outputs, e.g., directly into the patient's record (e.g., PACS or EMR), or only after review by a qualified end-user. They should also consider whether the physician/qualified end-user reports the AI output (which may be required by law in certain states) and any concordance/discordance with their interpretation, and whether the AI outputs are directly accessible by other members of the care team or by patients. The ACR Practice Parameter for Communication of Diagnostic Imaging Findings

It is recommended that AI technology only be used by physicians/qualified end-users who can accurately assess the veracity of the model output. Furthermore, physicians/qualified end-users should be familiar with the IFU, including the capabilities and limitations of the model and its intended use in clinical workflow. For instance, AI triage software which is not intended to be used as a diagnostic device should not be used as such unless the practice has made an informed decision to use it "off-label." Communication and permanent storage of AI outputs is not recommended without physician/qualified end-user incorporation of the output into the standard of care reporting workflow. The practice's oversight entities are responsible for ensuring that duly licensed and credentialed physicians/qualified end-users apply the technology appropriately and within their scope of practice. Both the practices and their physicians/qualified end-users ultimately bear responsibility and liability for the care rendered by the physicians/qualified end-users under their oversight.

Foundation models for imaging that generate a holistic output rather than single task classification are not currently regulated by the FDA for use in patient care, and, as of the writing of this practice parameter, are not marketed for such use in the United States. There are multiple considerations when using these models, including but not limited to: model performance drift and unpredictability, limited clinical validation, and unclear regulatory governance and medical malpractice liability.

Data privacy considerations apply to the use of AI as they do elsewhere in healthcare. The following should be considered:

- HIPAA compliance
    - AI tools should adhere to the HIPAA Privacy, Security, and Breach Notification Rules.
    - Data used for model fine-tuning, local acceptance testing, or retraining should be de-identified to HIPAA Safe Harbor standards whenever feasible. If PHI is retained within these data, a business associate agreement (BAA) that includes such use and disclosure of PHI should be executed between the organization and the model manufacturer/developer prior to model deployment.
    - The HIPAA Notice of Privacy Practices (NPP) should be reviewed and updated if any new AI use cases

are not covered under the existing notice. Even if not required, transparency with patients is encouraged.

- Data security
  - Data encryption should be enforced in transit and at rest.
  - AI access should be restricted to approved networks, devices/endpoints, and authenticated users.
  - Multifactor authentication should be utilized to access AI systems/platforms, when feasible.
- Audit & breach notification
  - Data accessed by AI tools should be logged and logs should be auditable.

Any unauthorized access or disclosure of PHI by AI tools should be reported to the practice's legal/compliance/privacy professional and, if required, to the Department of Health and Human Services or other required external parties.

The AI governance group should evaluate whether their use of AI might implicate one or more of the following laws and rules (see table 1 in . This is not an exhaustive list. Physicians/qualified end-users should consult a qualified health care lawyer in their relevant jurisdiction to obtain counsel on specific medicolegal matters.

1. HIPAA/HITECH
2. FDA Software as a Medical Device (SaMD)
3. European Union (EU) Medical Device Regulation (MDR)
4. EU AI Act
5. General Data Protection Regulation (GDPR) - Europe
6. U.S. Civil Rights Act (Title VII) and Americans with Disabilities Act (discrimination and bias)
7. Local and state laws

ACKNOWLEDGEMENTS

This practice parameter was developed according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Commission on Informatics and the Commission on Quality and Safety in collaboration with SIIM.

Writing Committee – members represent their societies in the initial and final revision of this practice parameter

Comments Reconciliation Committee

REFERENCES

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.