IHE Radiology Global Regulatory Monitoring Report

Volume 1 | Issue 6 | July 31, 2026

PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

Report date	July 31, 2026
Monitoring period	June 1, 2026 - July 31, 2026
Discovery window used	May 2, 2026 - July 31, 2026
Source policy	All included items were verified against official government sources and include working official links.

Prepared for strategic monitoring of diagnostic imaging, interoperability, clinical AI governance, and digital health infrastructure.

1. Executive Summary

This report covers official government policy activity reviewed across North America (United States and Canada), the European Union, Japan, and Australia for the monitoring period of June 1, 2026 through July 31, 2026, with discovery extended to May 2, 2026 and supplemented by review of active carry-forward items from the prior regular report. Discovery used the fixed protocol v14 search terms and required official listing-page reviews, followed by official-source verification, active-item screening, relevance scoring, and direct comparison with both Volume 1, Issue 5 and the intervening July 15 Special Edition before report construction. At the user's direction, the two CY 2027 CMS proposed rules are acknowledged and retained in the open-comment calendar, but their detailed provisions are not repeated here because the Special Edition already provides the focused analysis.

The strongest new developments are unusually specific to diagnostic imaging and imaging informatics. FDA established a class II pathway with special controls for radiological machine-learning quantitative imaging software using predetermined change control plans; ONC added a Diagnostic Imaging Reference to USCDI v7 and finalized updated FHIR API implementation-guide versions through the FY 2027 IPPS final rule; Health Canada opened consultation on recognized medical-device standards that include a substantial MRI-safety package; PMDA opened consultation on review points for image-recognition SaMD; Australia implemented Share by Default diagnostic imaging report requirements and MBS imaging payment changes; and the World Health Assembly adopted separate resolutions on teleradiology and radiation and health. European activity continues to emphasize real-world validation

and scaled deployment of AI-based image screening, while Japan's Version 7.0 medical information-system security guidance reinforces cyber-resilience as a prerequisite for connected imaging services.

Strategically, the current cycle shows policy moving beyond general encouragement of digital health toward more concrete requirements for resolvable links to images, governed algorithm changes, secure cross-organizational workflows, validated AI deployment, and national accountability for image access and radiation safety. These developments create a particularly strong opportunity for IHE Radiology to define how FHIR references connect to DICOM and DICOMweb resources, how AI workflow and results remain traceable across software versions, and how teleradiology and radiation-dose programs can be implemented with testable profiles rather than local interfaces. The most time-sensitive windows are the August 31 and September 14 CMS deadlines, the September 10 European screening-centre call, the September 25 Health Canada consultation, the September 28 USCDI v8 feedback deadline, the October 1 European image-screening call, and the December 31 PMDA consultation.

Asterisk Definition: Items marked with an asterisk (*) indicate that the policy, rule, or regulatory action was also identified in the immediately preceding Volume/Issue of the Monitoring Report. These items remain active, evolving, or unresolved and are carried forward for continued visibility.

2. Policy Signal Dashboard

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
*CY 2027 CMS OPPS/ASC and Medicare Physician Fee Schedule Proposed Rules - See Special Edition	Centers for Medicare & Medicaid Services (CMS), HHS	Federal Register - Proposed Rules	July 7 and July 16, 2026	August 31, 2026 (OPPS/ASC); September 14, 2026 (PFS)	5
FDA Classifies Radiological ML-Based Quantitative Imaging Software With a Predetermined Change Control Plan	Food and Drug Administration (FDA), HHS	Federal Register - Final amendment; final order	June 17, 2026	Not applicable; effective June 17, 2026	5
USCDI v7 Adds a Diagnostic Imaging Reference	Office of the National Coordinator for Health Information Technology (ONC), HHS	Final interoperability standard / ONC Standards Bulletin	July 23, 2026	September 28, 2026 for USCDI v8 data-element feedback	4
*ONC Finalizes Updated FHIR API Standards in the FY 2027 IPPS Final Rule	Office of the National Coordinator for Health Information Technology (ONC) and CMS, HHS	Final rule standards adoption / official ONC fact sheet	July 31, 2026	Not applicable; effective October 1, 2026	4
Health Canada Consults on Revised Recognized Standards for Medical Devices	Health Canada, Medical Devices Directorate	Public consultation / draft recognized-standards list	July 27, 2026	September 25, 2026	5

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
*Apply AI: Piloting AI-Based Image Screening in Medical Centres	European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)	Digital Europe Programme call for proposals / implementation initiative	April 21, 2026; implementation materials updated June 4, 2026	October 1, 2026 at 17:00 CET	4
*European Commission Expands the Network of AI-Powered Advanced Screening Centres	European Commission, DG CONNECT	Call for expression of interest / AI-health implementation network	July 6, 2026 update	September 10, 2026	4
European Commission Publishes AI Act Transparency Guidelines Ahead of August 2026 Application	European Commission, AI Office	Final implementation guidelines under the EU AI Act	July 20, 2026	Not applicable; Article 50 obligations apply August 2, 2026	3
PMDA Opens Comment Period on Review Points for Image-Recognition SaMD	Pharmaceuticals and Medical Devices Agency (PMDA)	Public consultation / draft review points for Software as a Medical Device	July 1, 2026	December 31, 2026	5
MHLW Publishes Medical Information System Security Management Guidelines Version 7.0	Japan Ministry of Health, Labour and Welfare (MHLW)	Final national healthcare information-security guidance	June 2026	Not applicable	3
*Share by Default Requirements for Diagnostic Imaging Reports Commence	Australian Government Department of Health, Disability and Ageing / Australian Digital Health Agency	Statutory implementation / My Health Record policy	July 1, 2026	Not applicable; requirements commenced July 1, 2026	5
Australia Implements July 2026 MBS Diagnostic Imaging Changes	Australian Government Department of Health, Disability and Ageing / Medicare Benefits Schedule (MBS)	Medicare payment regulation implementation	June 1, 2026; effective July 1, 2026	Not applicable; effective July 1, 2026	5
*TGA Updates Public List of AI-Enabled Medical Devices in the ARTG	Therapeutic Goods Administration (TGA)	Official regulatory transparency listing / AI-enabled medical-device oversight signal	July 27, 2026	Not applicable	3
WHO Member States Adopt Resolution WHA79.9 on Equitable Access to Diagnostic Imaging Through Teleradiology	World Health Assembly / World Health Organization (WHO)	International health policy resolution	May 23, 2026	Implementation ongoing; WHO progress report requested for 2030	5

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
WHO Member States Adopt Resolution WHA79.13 on Radiation and Health	World Health Assembly / World Health Organization (WHO)	International health policy resolution	May 23, 2026	Implementation ongoing; WHO progress report requested for 2028	5

3. North America Regulatory Scan

United States

*CY 2027 CMS OPPS/ASC and Medicare Physician Fee Schedule Proposed Rules - See Special Edition

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Rules

Publication Date: July 7 and July 16, 2026

Official Source Link: Official OPPS/ASC proposed rule | Official PFS proposed-rule page

Comment Deadline: August 31, 2026 (OPPS/ASC); September 14, 2026 (PFS)

Summary: The two annual CMS proposed rules remain open for comment and continue to present major radiology payment, quality-measure, interoperability, and clinical-AI policy issues. Because the July 15, 2026 Special Edition of this report examined both rules in detail, this regular issue does not repeat that analysis. Readers should consult the Special Edition for the provision-by-provision review and IHE Radiology opportunity assessment.

Impact Assessment:

- **Imaging Operations:** Direct and potentially substantial, but the operational details are intentionally not restated here; the Special Edition covers imaging payment, quality reporting, duplicate-imaging, and radiopharmaceutical proposals.
- **AI Governance:** Direct policy signals include Medicare payment treatment of algorithmic services and proposed MIPS activities related to responsible AI use and diagnostic performance.
- **Interoperability:** Direct and central, particularly through the duplicate-imaging and result-sharing RFI and the proposed transition toward FHIR-based digital quality measures.

Relevance Score: 5

FDA Classifies Radiological ML-Based Quantitative Imaging Software With a Predetermined Change Control Plan

Agency: Food and Drug Administration (FDA), HHS

Policy Type: Federal Register - Final amendment; final order

Publication Date: June 17, 2026

Official Source Link: Official Federal Register document

Comment Deadline: Not applicable; effective June 17, 2026

Summary: FDA classified radiological machine learning-based quantitative imaging software with a predetermined change control plan as a class II device subject to special controls under 21 CFR 892.2055. The device type is software-only, uses machine learning on radiological images, and can support functions such as view selection, segmentation, and landmarking. The special controls address

training and test data, subgroup performance, software verification and validation, planned modifications, risk management, compatible imaging hardware and protocols, labeling, and version history.

Impact Assessment:

- **Imaging Operations:** Direct. Imaging organizations may encounter more products whose cleared design includes planned post-market algorithm modifications, increasing the importance of inventory, version awareness, local validation, and change-control procedures.
- **AI Governance:** Direct. The classification translates predetermined change control plans into device-specific requirements for planned modifications, validation, risk mitigation, performance evidence, labeling, and user notification.
- **Interoperability:** Material. FDA requires identification of compatible imaging hardware and protocols and detailed descriptions of device inputs and outputs, which should be reflected in integration testing and procurement documentation.

Relevance Score: 5

USCDI v7 Adds a Diagnostic Imaging Reference

Agency: Office of the National Coordinator for Health Information Technology (ONC), HHS

Policy Type: Final interoperability standard / ONC Standards Bulletin

Publication Date: July 23, 2026

Official Source Link: Official ONC Standards Bulletin

Comment Deadline: September 28, 2026 for USCDI v8 data-element feedback

Summary: ONC published USCDI Version 7 and added Diagnostic Imaging Reference as a new data element. ONC defines it as a link or other computable reference that enables access to an imaging study, series, or individual image and states that exchange of these references can support access to prior imaging and reduce duplicative examinations. ONC also cautions that the data element does not itself ensure image exchange from an external PACS and that interoperability agreements with image-hosting organizations remain necessary.

Impact Assessment:

- **Imaging Operations:** Direct. EHR and radiology workflows may need to create, preserve, display, and resolve references that lead clinicians from the longitudinal record to the correct diagnostic images.
- **AI Governance:** Indirect but important. Reliable image references can improve traceability between AI results, source studies, prior examinations, and downstream clinical decisions.
- **Interoperability:** Direct. The new element creates a national policy-level expectation for computable image references, while leaving implementation details such as endpoint discovery, authorization, patient matching, and image retrieval to standards and agreements.

Relevance Score: 4

*ONC Finalizes Updated FHIR API Standards in the FY 2027 IPPS Final Rule

Agency: Office of the National Coordinator for Health Information Technology (ONC) and CMS, HHS

Policy Type: Final rule standards adoption / official ONC fact sheet

Publication Date: July 31, 2026

Official Source Link: Official ONC fact sheet | Federal Register public-inspection document

Comment Deadline: Not applicable; effective October 1, 2026

Summary: ONC and CMS finalized updated implementation-guide versions supporting FHIR APIs for electronic prior authorization, payer-provider clinical data exchange, consumer payer data, formularies, and provider directories. The adopted standards include updated Da Vinci Coverage Requirements Discovery, Documentation Templates and Rules, Prior Authorization Support, Clinical Data Exchange, CARIN Blue Button, PDex Drug Formulary, and Plan Net implementation guides. The updated versions replace previously adopted versions when the FY 2027 IPPS final rule becomes effective on October 1, 2026.

Impact Assessment:

- **Imaging Operations:** Material. Radiology orders and supporting documentation often pass through the same prior-authorization ecosystem, so vendors and providers should track the finalized versions used by payers, certified health IT, and workflow intermediaries.
- **AI Governance:** Indirect. More standardized payer-provider exchange can support auditability and consistent availability of administrative and clinical context used by AI-enabled ordering and utilization workflows.
- **Interoperability:** Direct. This final action moves several FHIR implementation guides from proposed policy into adopted federal standards and establishes a concrete version transition date.

Relevance Score: 4

Canada

Health Canada Consults on Revised Recognized Standards for Medical Devices

Agency: Health Canada, Medical Devices Directorate

Policy Type: Public consultation / draft recognized-standards list

Publication Date: July 27, 2026

Official Source Link: Official consultation page | Draft recognized-standards list

Comment Deadline: September 25, 2026

Summary: Health Canada opened consultation on proposed additions, updates, and removals to its recognized standards for medical devices. Imaging-relevant additions include ASTM standards addressing magnetically induced displacement force, MR image artifacts, radiofrequency-induced heating, magnetically induced torque, and MR safety marking. Health Canada also announced that, after this consultation, it plans to accept continuous year-round feedback for incorporation into annual reviews of the recognized-standards list.

Impact Assessment:

- **Imaging Operations:** Direct for MRI safety and device procurement. The proposed additions reinforce recognized methods for evaluating implants and other items used in the MR environment.
- **AI Governance:** Indirect. The broader recognized-standards framework also includes software lifecycle and quality-management standards relevant to regulated medical device software.
- **Interoperability:** Indirect. Recognized standards do not prescribe exchange transactions, but they can influence device compatibility documentation, software controls, and vendor evidence used in integration decisions.

Relevance Score: 5

4. European Union Regulatory Scan

*Apply AI: Piloting AI-Based Image Screening in Medical Centres

Agency: European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)

Policy Type: Digital Europe Programme call for proposals / implementation initiative

Publication Date: April 21, 2026; implementation materials updated June 4, 2026

Official Source Link: Official European Commission call information

Comment Deadline: October 1, 2026 at 17:00 CET

Summary: The European Commission continues the DIGITAL-2026-AI-PILOTING-10-SCREENING call for deployment-oriented pilots of AI-based medical image screening. The call provides EUR 9 million, anticipates two projects, uses a 50 percent funding rate, and indicates a 36-month action duration. Although this is a funding instrument rather than a regulation, it is an active policy implementation mechanism directed specifically at medical image screening in cancer and cardiovascular disease.

Impact Assessment:

- **Imaging Operations:** Direct. Selected sites will need scalable workflows for acquisition, routing, AI analysis, clinical review, reporting, escalation, and longitudinal evaluation.
- **AI Governance:** Direct. The pilot context is likely to emphasize clinical validation, performance monitoring, safety, equitable deployment, and evidence generation under real-world conditions.
- **Interoperability:** Material. Multi-site and cloud-based screening depends on consistent image access, metadata, result representation, provenance, identity management, and integration with clinical systems.

Relevance Score: 4

*European Commission Expands the Network of AI-Powered Advanced Screening Centres

Agency: European Commission, DG CONNECT

Policy Type: Call for expression of interest / AI-health implementation network

Publication Date: July 6, 2026 update

Official Source Link: Official European Commission network page

Comment Deadline: September 10, 2026

Summary: The Commission opened a second call for medical centres to join the European network of AI-powered advanced screening centres. The network initially focuses on cancer and cardiovascular imaging and is intended to support real-world validation, local performance assessment, clinical integration, continuous performance evaluation, and evidence for adoption at scale. Members may participate in studies of pre-market AI tools and receive access to outputs from related European Health Data Space and imaging-AI initiatives.

Impact Assessment:

- **Imaging Operations:** Direct. Participating centres will need operational capacity to evaluate AI in routine screening pathways and compare performance across populations, equipment, and local workflows.

- **AI Governance:** Direct. The network explicitly emphasizes clinical validation, ethical and regulatory requirements, data quality, and continuous performance evaluation.
- **Interoperability:** Direct-to-moderate. Cross-centre evidence generation and data reuse will depend on interoperable image, report, metadata, and outcome-data pipelines.

Relevance Score: 4

European Commission Publishes AI Act Transparency Guidelines Ahead of August 2026 Application

Agency: European Commission, AI Office

Policy Type: Final implementation guidelines under the EU AI Act

Publication Date: July 20, 2026

Official Source Link: Official European Commission guidelines

Comment Deadline: Not applicable; Article 50 obligations apply August 2, 2026

Summary: The Commission published final guidance on transparency obligations for providers and deployers of certain AI systems under Article 50 of the AI Act. The obligations primarily concern interactive AI, AI-generated or manipulated content, deepfakes, emotion recognition, and biometric categorization and begin applying on August 2, 2026. The guidance is not a medical-device-specific rule, but it contributes to the wider governance environment in which healthcare organizations deploy AI-enabled communication, patient-facing, and administrative tools.

Impact Assessment:

- **Imaging Operations:** Limited direct effect on core diagnostic imaging devices, but radiology organizations may use patient-facing assistants, generative reporting support, communications tools, or other systems that require transparency review.
- **AI Governance:** Direct as an enterprise governance signal. Organizations should classify AI use cases by applicable obligation rather than assume that all clinical AI is governed identically.
- **Interoperability:** Indirect. Transparency notices and provenance may need to travel with generated content and AI-assisted communications across connected systems.

Relevance Score: 3

5. Japan Regulatory Scan

PMDA Opens Comment Period on Review Points for Image-Recognition SaMD

Agency: Pharmaceuticals and Medical Devices Agency (PMDA)

Policy Type: Public consultation / draft review points for Software as a Medical Device

Publication Date: July 1, 2026

Official Source Link: Official PMDA consultation page

Comment Deadline: December 31, 2026

Summary: PMDA published draft review points and opened public comment for several categories of Software as a Medical Device. Two drafts are directly imaging-related: software used to support recognition of intraoperative images and software used for diagnosis using endoscopic images. The consultation provides a formal opportunity to influence how PMDA evaluates evidence and review issues for image-recognition software.

Impact Assessment:

- **Imaging Operations:** Direct for organizations and vendors using image-recognition software in procedural and diagnostic workflows, especially where human interpretation and software output are closely coupled.
- **AI Governance:** Direct. Draft review points can shape expectations for validation, intended use, user interaction, limitations, and oversight of imaging SaMD.
- **Interoperability:** Material. Safe review and deployment require clear definitions of source-image inputs, output formats, workflow insertion points, patient and procedure association, and software-version provenance.

Relevance Score: 5

MHLW Publishes Medical Information System Security Management Guidelines Version 7.0

Agency: Japan Ministry of Health, Labour and Welfare (MHLW)

Policy Type: Final national healthcare information-security guidance

Publication Date: June 2026

Official Source Link: Official MHLW guideline page

Comment Deadline: Not applicable

Summary: MHLW revised its Medical Information System Security Management Guidelines to Version 7.0 and published executive-management, planning, system-operation, and outsourced-maintenance volumes. The release is accompanied by updated cybersecurity checklists and implementation materials for medical institutions, pharmacies, and service providers. Although the page does not single out radiology, the guidance applies to medical information systems and therefore is relevant to connected PACS, RIS, VNA, reporting, cloud, and image-exchange environments.

Impact Assessment:

- **Imaging Operations:** Material. Imaging departments depend on high-availability, interconnected systems and outsourced services that must be incorporated into security governance, business continuity, and incident-response planning.
- **AI Governance:** Indirect but important. Imaging AI platforms are part of the medical information system environment and should be included in access control, supplier management, monitoring, and recovery planning.
- **Interoperability:** Direct as a security condition for exchange. Secure interfaces, service-provider responsibilities, continuity arrangements, and cyber-resilience are prerequisites for dependable image and report exchange.

Relevance Score: 3

6. Australia Regulatory Scan

*Share by Default Requirements for Diagnostic Imaging Reports Commence

Agency: Australian Government Department of Health, Disability and Ageing / Australian Digital Health Agency

Policy Type: Statutory implementation / My Health Record policy

Publication Date: July 1, 2026

Official Source Link: Official implementation guidance

Comment Deadline: Not applicable; requirements commenced July 1, 2026

Summary: From July 1, most pathology and diagnostic imaging reports authored by or on behalf of a pathologist or radiologist must be uploaded to My Health Record by default unless an exception applies or an extension has been granted. Reports generally must be uploaded within 24 hours after they are provided to the requesting provider, another treating provider, or the patient. The requirement applies to written reports and does not require diagnostic images to be uploaded.

Impact Assessment:

- **Imaging Operations:** Direct. Radiology organizations need reliable identification of in-scope services, timely report completion, exception handling, upload monitoring, and remediation of failed submissions.
- **AI Governance:** Indirect. AI-assisted reporting and communication workflows must preserve the authorized final report, timing, provenance, and clinician accountability used for My Health Record submission.
- **Interoperability:** Direct. The policy mandates national report sharing but leaves a clinically important gap between report availability and access to the related diagnostic-quality images.

Relevance Score: 5

Australia Implements July 2026 MBS Diagnostic Imaging Changes

Agency: Australian Government Department of Health, Disability and Ageing / Medicare Benefits Schedule (MBS)

Policy Type: Medicare payment regulation implementation

Publication Date: June 1, 2026; effective July 1, 2026

Official Source Link: Official MBS diagnostic imaging update

Comment Deadline: Not applicable; effective July 1, 2026

Summary: Australia implemented MBS changes affecting breast imaging, nuclear medicine imaging, and echocardiography from July 1, 2026. The changes include removing selected co-claiming restrictions involving breast ultrasound and MRI, removing the multiple-services rule when breast imaging items apply together, and increasing schedule fees for nuclear medicine examinations using gallium-67 or thallium-201. The update is a direct payment-policy change for diagnostic imaging services.

Impact Assessment:

- **Imaging Operations:** Direct. Providers should update billing rules, scheduling and protocol guidance, staff education, and revenue-cycle validation for the affected services.
- **AI Governance:** Limited direct effect, although payment and utilization changes may affect adoption priorities for decision support, workflow automation, and quantitative tools.
- **Interoperability:** Indirect. Accurate service identification and exchange of order, procedure, radiopharmaceutical, and report data support correct billing and auditability.

Relevance Score: 5

*TGA Updates Public List of AI-Enabled Medical Devices in the ARTG

Agency: Therapeutic Goods Administration (TGA)

Policy Type: Official regulatory transparency listing / AI-enabled medical-device oversight signal

Publication Date: July 27, 2026

Official Source Link: Official TGA AI-enabled device list

Comment Deadline: Not applicable

Summary: TGA updated its public table of AI-enabled medical devices included in the Australian Register of Therapeutic Goods. The table includes imaging analysis, triage, planning, and radiation-related software, but TGA cautions that it is not a complete list because inclusion depends on AI or machine-learning terms in the product name or intended purpose or on sponsor reporting after March 2025. The update remains useful as a regulatory transparency and procurement reference rather than as a comprehensive census of medical AI.

Impact Assessment:

- **Imaging Operations:** Material for vendor due diligence. Imaging organizations can use ARTG status, intended purpose, classification, and sponsor information as part of procurement and inventory review.
- **AI Governance:** Direct as an oversight signal. The update reinforces the need to verify the regulated intended purpose and not rely solely on marketing descriptions of AI functionality.
- **Interoperability:** Indirect. Listed products still require local assessment of inputs, outputs, workflow integration, versioning, and data-transfer responsibilities.

Relevance Score: 3

7. IHE Opportunity Scan

The opportunities below are IHE Radiology interpretations of the verified policy developments. They do not indicate that any government agency or international body has endorsed, required, or referenced a specific IHE profile.

Turn the USCDI Diagnostic Imaging Reference into an implementable image-access pattern

Define a practical pattern linking a FHIR ImagingStudy, DiagnosticReport, document, or other reference to the correct study, series, or image and to the endpoint and authorization method needed to retrieve it. The guidance should distinguish a resolvable reference from actual image availability and show where DICOMweb, XDS-I.b, MHD, patient identity, and cross-enterprise access controls fit.

Add radiology-specific detail to FHIR prior-authorization workflows

Use the finalized CRD, DTR, PAS, and CDex versions as a stable policy backdrop for describing radiology order initiation, protocol changes, supporting documentation, authorization status, and result linkage. The goal should be to reduce custom interfaces without implying that payer APIs replace imaging workflow standards.

Provide a testable governance pattern for algorithm changes under a PCCP

FDA's radiological ML classification creates a concrete need to associate AI results with the algorithm product, version, planned modification, source images, compatible protocols, and human review. AI Workflow for Imaging, AI Results, AI Results Assessment, and audit/provenance mechanisms can be presented as implementation building blocks for local change control and post-deployment monitoring.

Support European AI screening pilots with Connectathon-tested deployment patterns

The screening call and centre network can benefit from profiles and test plans covering image acquisition, work distribution, cloud access, structured results, clinical confirmation, longitudinal outcomes, and multi-site performance monitoring. IHE Radiology can offer an integration framework without prescribing a particular algorithm or procurement model.

Close Australia's report-to-image gap

Share by Default creates national report availability but explicitly excludes image upload. IHE Radiology can describe how a shared report should carry sufficient identifiers and references to locate the related study and how failure, unavailability, or incomplete transfer should be communicated.

Connect Canadian MRI standards to procurement and lifecycle documentation

Purchaser guidance can ask vendors and facilities how recognized MR safety tests, labeling, compatibility information, software changes, and integration responsibilities are documented and maintained. This would complement, not replace, Health Canada's regulatory standards framework.

Position IHE profiles as implementation building blocks for WHO teleradiology guidance

WHA79.9 calls for standards, interoperability, security, privacy, reporting, national-system integration, and AI oversight. IHE Radiology can prepare a concise global implementation map showing how existing profiles support image acquisition, cross-enterprise discovery and retrieval, report exchange, identity management, audit, and secure transport in resource-variable settings.

Link radiation-dose interoperability to the WHA radiation agenda

WHA79.13 calls for monitoring medical exposure, equipment regulation, quality assurance, radiopharmaceutical safety, and harmonized standards. REM and related dose-data pathways can be positioned as technical foundations for national exposure monitoring and quality programs, while clearly separating data transport from policy-defined thresholds and clinical review.

8. Regulatory Early Warning Dashboard

Open Comment and Action Calendar

Date	Jurisdiction / Agency	Action	IHE Radiology Relevance
August 2, 2026	European Union / AI Office	EU AI Act Article 50 transparency obligations begin to apply.	Review patient-facing, interactive, generative, and communication AI uses for applicable notice and labeling obligations.
August 29, 2026	United States / ONC	2026 Standards Version Advancement Process standards become available for voluntary certification use.	Monitor which certified-health-IT developers adopt newer data and API versions that affect imaging-adjacent exchange.
August 31, 2026	United States / CMS	Comments due on CY 2027 OPPS/ASC proposed rule.	See the July 15 Special Edition for the radiology-specific provisions and response opportunities.
September 10, 2026	European Union / European Commission	Second call closes for AI-powered advanced screening centres.	Potential participation and evidence-generation opportunity for cancer and cardiovascular imaging sites.

Date	Jurisdiction / Agency	Action	IHE Radiology Relevance
September 14, 2026	United States / CMS	Comments due on CY 2027 Medicare Physician Fee Schedule proposed rule.	See the July 15 Special Edition, including the duplicate-imaging and FHIR dQM RFIs.
September 25, 2026	Canada / Health Canada	Comments due on revised recognized standards for medical devices.	MRI-safety standards and broader device/software standards may warrant imaging stakeholder input.
September 28, 2026	United States / ONC	USCDI v8 data-element feedback period closes.	Opportunity to refine Diagnostic Imaging Reference and propose related data needed for reliable image access.
October 1, 2026	European Union / European Commission	Apply AI image-screening pilot proposals due at 17:00 CET.	Implementation opportunity for scalable, validated AI screening workflows.
October 1, 2026	United States / CMS and ONC	Updated FHIR implementation-guide versions become effective through the FY 2027 IPPS final rule.	Version transition affects prior authorization and payer-provider API implementation.
December 31, 2026	Japan / PMDA	Comments due on draft SaMD review points, including image-recognition categories.	Opportunity for imaging and standards stakeholders to address inputs, outputs, workflow, validation, and provenance.

Early Warning Signals

Signal	Current Status	IHE Radiology Significance	What to Monitor
USCDI Diagnostic Imaging Reference implementation	Final data element published; certification and implementation pathways remain unsettled.	Could create a national expectation that clinical systems carry computable links to images without guaranteeing that those links resolve across organizations.	FHIR mappings, endpoint discovery, authorization, patient matching, DICOMweb/XDS-I.b alignment, and conformance testing.
CMS duplicate-imaging and result-sharing policy	RFI remains open; detailed analysis is in the July 15 Special Edition.	Could evolve into payment-linked expectations for prior-image and result availability.	Definitions of duplicate testing, clinical exceptions, responsibility when priors are unavailable, and whether images as well as reports are included.
EU high-risk medical AI implementation	The Commission is developing and finalizing AI Act implementation guidance while product-related high-risk requirements follow a separate timetable.	Imaging AI vendors and deployers will need to reconcile medical-device regulation, AI Act duties, and clinical governance.	Final high-risk classification guidance, medical-device coordination, standards, quality-management expectations, and implementation dates.
Canadian MRI and device standards	Health Canada consultation is open and continuous feedback will follow.	Recognized MR safety standards can influence evidence, labeling, procurement, and local safety programs.	Final additions and removals, edition recognition, and how software/device standards are updated annually.
Australia report-only Share by Default model	Written reports are now mandatory for in-scope services; images are expressly excluded.	National report availability may expose the clinical limitations of a result-sharing model that lacks diagnostic image access.	Whether future policy adds image references, retrieval pathways, conformance requirements, or additional record types.

Signal	Current Status	IHE Radiology Significance	What to Monitor
PMDA image-recognition SaMD review points	Draft review points are open for comment through year-end.	May become an important reference for evidence and review expectations for image-based diagnostic software in Japan.	Final review points, validation requirements, user interaction, software updates, and treatment of AI/ML changes.
WHO teleradiology implementation guidance	WHA79.9 requests WHO normative guidance, standards, technical tools, and a 2030 progress report.	Could shape national teleradiology policy and procurement in resource-variable settings.	WHO work plans, technical guidance, interoperability specifications, data-protection models, and capacity mapping.
WHO radiation and health implementation	WHA79.13 requests global mapping, updated standards/tools, and a 2028 report.	Could strengthen national expectations for dose monitoring, QA, radiopharmaceutical safety, and exposure surveillance.	WHO/IAEA/UNSCEAR coordination, global surveys, exposure-data standards, and emerging-technology guidance.

9. Emerging Policy Signals (Pre-Regulatory)

USCDI may become the policy bridge between the EHR and external imaging infrastructure.

Diagnostic Imaging Reference is notable because ONC explicitly recognizes both its value and its limitation: a reference can support access to prior imaging, but external PACS exchange still depends on agreements and infrastructure. Future certification, network, or payment policy could convert this data element into a practical expectation for discoverable image access.

Federal prior-authorization standards are stabilizing around specific FHIR implementation-guide versions.

The FY 2027 IPPS final rule gives payers, providers, and health IT developers a clearer version baseline. Radiology will need to determine where imaging-specific order, protocol, documentation, and result workflows complement these administrative APIs.

Medical AI governance is shifting from a one-time clearance model toward managed change.

FDA's PCCP-based radiological classification, PMDA's image-recognition SaMD review points, and TGA's transparency list all reinforce lifecycle governance, intended-purpose verification, evidence, and software-version awareness.

European policy is using real-world clinical networks as an adoption and evidence mechanism.

The screening-centre network and funded pilot call emphasize local performance assessment, continuous evaluation, data quality, and scale across health systems. This may influence future expectations for post-deployment evidence and interoperability in imaging AI.

Report sharing without image access is becoming an explicit policy boundary.

Australia's Share by Default requirements and the U.S. CMS duplicate-imaging discussion both separate report portability from access to the diagnostic study. This distinction creates pressure for standards that reliably link the report to retrievable images.

WHO has elevated teleradiology and radiation safety to global Member State commitments.

The two WHA resolutions create a multi-year policy agenda for interoperability, data protection, AI oversight, workforce, dose monitoring, quality assurance, and technical guidance. Their practical

influence will depend on the implementation tools and reporting frameworks developed before 2028 and 2030.

Australia may expand the set of health information shared by default.

Official implementation guidance states that additional information types may be considered after further consultation. Image references, key images, or complete diagnostic studies are plausible future topics, but no such expansion has been proposed in the current cycle.

10. International Policy Developments IHE Radiology Should Monitor

Two qualifying developments outside the primary monitored regions were identified through official World Health Organization sources. Both are formal World Health Assembly resolutions with multi-year implementation and reporting expectations.

WHO Member States Adopt Resolution WHA79.9 on Equitable Access to Diagnostic Imaging Through Teleradiology

Agency: World Health Assembly / World Health Organization (WHO)
Policy Type: International health policy resolution
Publication Date: May 23, 2026
Official Source Link: Official WHO resolution PDF
Comment Deadline: Implementation ongoing; WHO progress report requested for 2030
Summary: The World Health Assembly adopted a resolution urging Member States to integrate teleradiology into national health, digital health, and diagnostic strategies. It calls for national policies, standards, regulatory frameworks, secure infrastructure, data governance, privacy protections, workforce development, integration with national health information systems, and equitable access for rural and underserved populations. The resolution also calls for validated, transparent, human-supervised AI and asks WHO to develop normative guidance, standards, and technical tools including interoperability and data protection.

Impact Assessment:

- **Imaging Operations:** Direct and global. The resolution elevates teleradiology from an operational service model to a national health-system capability requiring workforce, infrastructure, quality, and sustainable financing.
- **AI Governance:** Direct. It expressly calls for safe, trustworthy, robust, ethical, transparent, validated, and clinically supervised AI and decision-support tools in teleradiology workflows.
- **Interoperability:** Direct and central. WHO is asked to develop guidance and tools for secure image acquisition, transmission, storage, reporting, integration with national systems, interoperability, and data protection.

Relevance Score: 5

WHO Member States Adopt Resolution WHA79.13 on Radiation and Health

Agency: World Health Assembly / World Health Organization (WHO)
Policy Type: International health policy resolution
Publication Date: May 23, 2026
Official Source Link: Official WHO resolution PDF

Comment Deadline: Implementation ongoing; WHO progress report requested for 2028

Summary: The World Health Assembly adopted a resolution on radiation protection, preparedness, and response that expressly includes medical imaging, radiotherapy, and radiopharmaceuticals. Member States are urged to strengthen legislation, institutional capacity, workforce training, equipment regulation, quality assurance, and systems for monitoring patient, worker, and public exposure. WHO is asked to continue developing and updating standards and technical tools, map relevant actors and gaps, and report progress to the 2028 World Health Assembly.

Impact Assessment:

- **Imaging Operations:** Direct. The resolution supports stronger equipment regulation, quality assurance, workforce competency, safe radiopharmaceutical use, and monitoring of medical exposures.
- **AI Governance:** Material. The resolution recognizes emerging technologies that combine radiation with AI and reinforces the need to evaluate safety and health outcomes as technology evolves.
- **Interoperability:** Material. Exposure monitoring, quality assurance, global surveys, and harmonized standards depend on consistent capture and exchange of radiation-dose and procedure data.

Relevance Score: 5

11. Appendix A - Regulatory Sources Monitored

Discovery evidence log for required monitored sources. The complete source pass was performed before determining that no additional qualifying items existed. All search-enabled sources used the fixed protocol term set below; chronological listing pages were also reviewed where available.

Fixed Discovery Search Terms

General imaging terms: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose.

Interoperability and health IT: interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support.

Artificial intelligence and digital health: artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD.

Healthcare policy relevant to imaging operations: physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.

Australia-specific terms: Australia; My Health Record; Share by Default; diagnostic imaging reports; pathology and diagnostic imaging; Medicare Benefits Schedule; MBS; TGA; ARTG; medical device software; AI-enabled medical devices; Australian Digital Health Agency; ADHA; AU Core; AUCDI; Sparked; FHIR Gateway; Healthcare Identifiers; National Healthcare Interoperability Plan.

United States

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Federal Register	Site search plus HHS/FDA/CMS chronological listing review	May 2, 2026 - July 31, 2026	Full fixed term set; radiology-device and HHS rule listings	Retained FDA radiological ML classification and CMS OPPS/ASC proposed rule; FY 2027 IPPS final rule verified through public inspection.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
CMS policy announcements	Official CMS payment-rule, newsroom, and regulation-notice pages	May 2, 2026 - July 31, 2026	Full fixed term set; CY 2027 OPPS/ASC, PFS, and IPPS pages	Retained active CMS proposed rules by cross-reference to Special Edition and verified FY 2027 IPPS final action.
ONC / ASTP publications	Official HealthIT.gov standards, bulletin, certification, and policy-page review	May 2, 2026 - July 31, 2026	Full fixed term set; USCDI, standards bulletins, rules, and certification updates	Retained USCDI v7 Diagnostic Imaging Reference and final FHIR API standards adoption.
FDA policy announcements	Official FDA/CDRH pages and Federal Register radiology-device listing review	May 2, 2026 - July 31, 2026	Full fixed term set; radiology devices, AI/ML, SaMD, PCCP	Retained final class II radiological ML quantitative imaging software classification.

Canada

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Canada Gazette	Chronological Part I/II listing and site search	May 2, 2026 - July 31, 2026	Full fixed term set; medical devices, diagnostic imaging, health information	Candidate medical-device actions evaluated; no additional item scored 3 or higher beyond Health Canada's recognized-standards consultation.
Health Canada policy announcements	Medical-device announcements, consultations, guidance, and standards pages	May 2, 2026 - July 31, 2026	Full fixed term set; medical devices; AI/ML; MRI; recognized standards	Retained consultation on revised recognized standards, including MRI safety standards.
Government of Canada health interoperability publications	Canada.ca digital-health, health-data, and interoperability page review	May 2, 2026 - July 31, 2026	Full fixed term set; interoperability, FHIR, health information exchange, diagnostic imaging	Discovery completed — no candidate items found for this source in the monitoring window.

European Union

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
European Commission Health Directorate	Official public-health, medical-device, digital-health, and implementation pages	May 2, 2026 - July 31, 2026	Full fixed term set; imaging, AI in health, EHDS, medical devices	General health and AI activity reviewed; retained imaging-specific items through DG CONNECT sources.
EUR-Lex regulatory publications	Recent Official Journal and EUR-Lex search/listing review	May 2, 2026 - July 31, 2026	Full fixed term set; AI Act, medical devices, EHDS, imaging	Candidate AI Act implementation actions evaluated; qualifying transparency item verified through the Commission's official implementation page.
EU Digital Strategy portal	Chronological policy, funding, consultation, and event-page review	May 2, 2026 - July 31, 2026	Full fixed term set; Apply AI, image screening, advanced screening centres, AI Act	Retained image-screening call, screening-centre network, and final Article 50 transparency guidance.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
European Medicines Agency publications	Official news, consultations, medical-device and AI page review	May 2, 2026 - July 31, 2026	Full fixed term set; medical imaging, AI, SaMD, device software	Discovery completed — no candidate items found for this source in the monitoring window.

Japan

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Ministry of Health, Labour and Welfare (MHLW)	Official new-information, medical DX, cybersecurity, and guideline listings	May 2, 2026 - July 31, 2026	Full fixed term set plus Japanese equivalents: 医療, AI, 医療機器, 画像情報, 医療 DX, 情報連携	Retained Medical Information System Security Management Guidelines Version 7.0.
Pharmaceuticals and Medical Devices Agency (PMDA)	Official announcement, SaMD, device-review, and consultation pages	May 2, 2026 - July 31, 2026	Full fixed term set plus Japanese equivalents: プログラム医療機器, 画像認識, 画像診断, AI	Retained consultation on SaMD review points for intraoperative and endoscopic image-recognition software.
Digital Agency (Japan)	Official policy, standard, and digital-health page review	May 2, 2026 - July 31, 2026	Full fixed term set plus Japanese digital-government and health-data terms	Discovery completed — no candidate items found for this source in the monitoring window.
Ministry of Internal Affairs and Communications (MIC / Soumu)	Official policy and listing-page review	May 2, 2026 - July 31, 2026	Full fixed term set plus Japanese telecommunications, AI, and health-data terms	Discovery completed — no candidate items found for this source in the monitoring window.

Australia

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Department of Health, Disability and Ageing	Official policy, My Health Record, MBS, consultation, and announcement pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Retained Share by Default implementation and MBS diagnostic imaging changes.
Federal Register of Legislation	Recent instruments and relevant Health Insurance / My Health Records compilation review	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Legislative context for Share by Default and diagnostic imaging payment changes verified; no additional standalone item retained.
Therapeutic Goods Administration (TGA)	Consultation listings, AI/software pages, ARTG transparency listings, and guidance pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Retained July 27 update to the AI-enabled medical devices list; other device actions evaluated.
Australian Digital Health Agency	Official publications, implementer guidance, My Health Record, and interoperability pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Retained July 1 Share by Default implementation guidance and report-only scope.
MBS Online	Diagnostic imaging news, factsheets, and schedule update pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Retained July 1 diagnostic imaging payment changes.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Medical Services Advisory Committee (MSAC)	Application, meeting, publication, and consultation pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Candidate PET/CT dopaminergic imaging application monitored; no decision available by report date, so not retained as a policy item.
Australian Commission on Safety and Quality in Health Care	Official publications and AI / digital-health safety pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Discovery completed — no candidate items found for this source in the monitoring window.
Office of the Australian Information Commissioner	My Health Record, privacy, and digital-health guidance pages	May 2, 2026 - July 31, 2026	Full fixed and Australia-specific term sets	Discovery completed — no candidate items found for this source in the monitoring window.

Supplemental International Sources

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
World Health Organization / World Health Assembly	WHA79 resolution list, official resolution PDFs, and WHO policy/news review	May 2, 2026 - July 31, 2026	Diagnostic imaging; teleradiology; radiation; medical imaging; AI; interoperability	Retained WHA79.9 on teleradiology and WHA79.13 on radiation and health.
International Medical Device Regulators Forum (IMDRF)	Consultation, final-document, and AI/SaMD page review	May 2, 2026 - July 31, 2026	AI lifecycle; SaMD; medical device software; imaging	AI lifecycle consultation was reviewed but excluded as a standalone item because the comment period closed July 10 and no new final action was published in the monitoring cycle.
UK MHRA	Official software/AI medical-device, consultation, and announcement review	May 2, 2026 - July 31, 2026	Radiology; medical imaging; AI; SaMD; software medical device	Discovery completed — no candidate items found for this source in the monitoring window.
New Zealand Medsafe / Ministry of Health	Official medical-device, digital-health, and consultation page review	May 2, 2026 - July 31, 2026	Radiology; medical imaging; AI; interoperability; medical device software	Discovery completed — no candidate items found for this source in the monitoring window.

Prior Report Comparison Evidence

Comparison Artifact	Method	Result
Volume 1, Issue 5 (May 30, 2026)	Direct title, agency, initiative, action-window, and material-policy comparison against all retained candidates.	Repeated or continuing initiatives marked with an asterisk when they otherwise qualified; closed or superseded items were not carried forward solely because they appeared previously.
Volume 1, Special Edition (July 15, 2026)	Direct comparison against the two CY 2027 CMS proposed rules and the nine retained policy topics analyzed in that edition.	The two rules are marked with an asterisk, summarized only at a high level, and cross-referenced to the Special Edition in accordance with the user-directed exception.