IHE Radiology Global Regulatory Monitoring Report

Volume 1 | Issue 7 | August 30, 2026

PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

Report date	August 29, 2026
Monitoring period	June 30, 2026 - August 30, 2026
Discovery window used	May 31, 2026 - August 30, 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 across North America (United States and Canada), the European Union, Japan, and Australia for the monitoring period of June 30, 2026 through August 30, 2026, with discovery extended to May 31, 2026. Execution followed the fixed protocol v14 search terms, required chronological listing-page reviews where available, official-source verification, the active-item and closed-comment rules, relevance scoring, and a direct item-by-item comparison with Volume 1, Issue 6 before report construction. All included policy items were verified against official government sources, and Appendix A records the discovery evidence for the required source pass.

The strongest current signals are concentrated in standards implementation, imaging AI governance, and direct imaging operations. In the United States, the CY 2027 CMS proposed rules remain open, USCDI v7 retains an active feedback window around its new Diagnostic Imaging Reference, updated FHIR API implementation guides approach their October effective date, and 2026 SVAP versions become available for voluntary certification on the report date. Canada's recognized-standards consultation remains open; Europe continues active medical-image AI pilot and screening-centre calls while clarifying the AI Act enforcement timeline; Japan is simultaneously advancing image-recognition SaMD review points, medical-radiation deliberations, and hospital information-system modernization; and Australia has established a national AU Core/AUCDI baseline while TGA consults on wider disclosure of post-market medical-device information.

Strategically, this cycle reinforces a shift from general digital-health policy toward testable implementation expectations: resolvable references to imaging, explicit FHIR version baselines, lifecycle

governance for imaging AI, national cloud and interoperability architectures, and accountable post-market oversight. IHE Radiology has near-term opportunities to connect FHIR-based clinical references and payer workflows to DICOM/DICOMweb and cross-enterprise imaging patterns, to make AI provenance and versioning testable across workflow boundaries, and to support national teleradiology and radiation-dose programs with interoperable implementation guidance. The most time-sensitive action windows are August 31, September 10, September 14, September 25, September 28, October 1, October 2, and December 31, 2026.

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
*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 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
*2026 SVAP Versions Become Available for Voluntary Health IT Certification	Office of the National Coordinator for Health Information Technology (ONC), HHS	Health IT certification standards implementation	June 30, 2026	Not applicable; available beginning August 29, 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 Updates AI Act Enforcement Framework and High-Risk AI Timeline	European Commission, AI Office / DG CONNECT	AI Act implementation and enforcement guidance	August 24, 2026 update	Not applicable; enforcement powers began 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 Advances Medical Radiation Management Deliberations Affecting Nuclear Medicine Operations	Japan Ministry of Health, Labour and Welfare (MHLW)	Regulatory advisory committee deliberation	July 8, 2026; Medical Division review July 24, 2026	Not applicable	5

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
Japan Launches FY2026 Council for Renewal of Hospital Information Systems	Japan Digital Agency and Ministry of Health, Labour and Welfare (MHLW)	National health IT modernization initiative	August 21, 2026	Not applicable	4
Australia Establishes AU Core and AUCDI as a National Interoperability Baseline for My Health Record	Australian Digital Health Agency	National interoperability standards implementation	August 7, 2026	Staged transition; timelines published in Connected Care Update August 2026	4
TGA Consults on Expanded Public Sharing of Medical Device Safety, Quality, and Performance Information	Therapeutic Goods Administration (TGA), Australian Government	Public consultation / medical-device regulatory transparency proposal	August 13, 2026	October 2, 2026	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
*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

Official Source Link: Official ONC Standards Bulletin 2026-2

Comment Deadline: September 28, 2026 for USCDI v8 feedback

Summary: ONC published USCDI Version 7 with Diagnostic Imaging Reference as a data element representing a link or other computable reference that enables access to an imaging study, series, or individual image. ONC states that consistent exchange of imaging references can improve access to prior studies and reduce duplicative imaging, while noting that actual access to images hosted externally still depends on interoperability arrangements. The next USCDI cycle is open for feedback through September 28, 2026. The item remains active because the current feedback window provides an opportunity to refine the data needed for reliable image access.

Impact Assessment:

- **Imaging Operations:** Direct. EHR and radiology workflows may need to create, preserve, display, and resolve references that lead clinicians to the correct diagnostic study or image.
- **AI Governance:** Material. Reliable image references can strengthen traceability between source images, AI-derived findings, software versions, and downstream clinical decisions.
- **Interoperability:** Direct. The policy establishes a national data expectation for computable imaging references while leaving endpoint discovery, authorization, patient matching, and image retrieval to implementation 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

Comment Deadline: Not applicable; effective October 1, 2026

Summary: ONC and CMS finalized updated FHIR implementation-guide versions for electronic prior authorization, payer-provider clinical data exchange, consumer payer data, formularies, and provider directories through the FY 2027 IPPS final rule. The adopted versions include updated Da Vinci CRD, DTR, PAS, and CDex implementation guides along with updated CARIN and PDex specifications. Where earlier versions had been adopted, the new versions replace them when the FY 2027 IPPS final rule becomes effective October 1, 2026. The pending effective date keeps this item active during the current monitoring cycle.

Impact Assessment:

- **Imaging Operations:** Material. Radiology ordering and supporting documentation often traverse prior-authorization workflows that will need to align with the finalized versions.
- **AI Governance:** Indirect but relevant. Standardized administrative and clinical context can improve auditability of AI-assisted ordering and utilization-management workflows.

- **Interoperability:** Direct. The final rule establishes specific FHIR implementation-guide versions and a concrete federal transition date.

Relevance Score: 4

*2026 SVAP Versions Become Available for Voluntary Health IT Certification

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

Policy Type: Health IT certification standards implementation

Publication Date: June 30, 2026

Official Source Link: Official ONC SVAP page

Comment Deadline: Not applicable; available beginning August 29, 2026

Summary: ONC's 2026 Standards Version Advancement Process versions become available for voluntary use in the ONC Health IT Certification Program on August 29, 2026. The approved set includes USCDI Version 6, newer C-CDA and FHIR-related specifications, electronic prior-authorization standards, and other updated standards used by certified health IT. ONC indicates that updated test tools and procedures for criteria using the approved standards will be made available by December 2026. This item was identified as an upcoming action in the prior report and now reaches its implementation date.

Impact Assessment:

- **Imaging Operations:** Material. Certified EHR and health IT products may begin adopting newer versions that affect the clinical context surrounding imaging orders, reports, and transitions of care.
- **AI Governance:** Indirect. More current standardized clinical data can improve the consistency of inputs and provenance used by AI-enabled workflows.
- **Interoperability:** Direct. SVAP provides a voluntary pathway for certified products to move to newer standards without waiting for a new regulatory baseline.

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 Health Canada consultation | Draft recognized-standards list

Comment Deadline: September 25, 2026

Summary: Health Canada is consulting on additions, updates, and removals to the List of recognized standards for medical devices through September 25, 2026. The draft contains a dedicated radiology section and includes imaging-relevant standards, including standards addressing MRI safety and compatibility issues. Health Canada also states that, after this consultation, it intends to accept continuous year-round feedback for incorporation into annual reviews of the recognized-standards list. The open consultation makes this a directly actionable medical-device policy item for imaging stakeholders.

Impact Assessment:

- **Imaging Operations:** Direct, particularly for MRI safety, device procurement, and evidence used to evaluate equipment and items entering the MR environment.
- **AI Governance:** Material. The broader recognized-standards framework also affects software lifecycle, quality, risk, and evidence expectations for regulated medical-device software.
- **Interoperability:** Indirect. Recognized standards can influence compatibility documentation, vendor evidence, software controls, and procurement requirements 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's Digital Europe Programme call for AI-based medical image screening remains open until October 1, 2026. The call provides EUR 9 million for two deployment-oriented projects using cloud-based AI in medical image screening, with a focus on cancer and cardiovascular disease. The Commission identifies objectives including improved diagnostic workflow efficiency, prioritization of critical cases, reduced pressure on radiology services, and more equitable access to screening. The active application window keeps this implementation initiative in the current monitoring cycle.

Impact Assessment:

- **Imaging Operations:** Direct. Participating sites will need scalable acquisition, routing, AI analysis, clinical review, escalation, reporting, and longitudinal evaluation workflows.
- **AI Governance:** Direct. Real-world pilots create a setting for validation, performance monitoring, safety, equity, and post-deployment governance.
- **Interoperability:** Direct-to-material. Multi-site and cloud deployment depend on consistent image access, metadata, results, provenance, identity, authorization, 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's second call for medical centres to join the European network of AI-powered advanced screening centres remains open through September 10, 2026. The network focuses

initially on cancer and cardiovascular disease and is intended to support real-world clinical validation, local performance assessment, workflow integration, and continuous evaluation of AI solutions. Participating centres may engage in clinical studies of innovative tools and connect with related European Health Data Space and imaging-AI infrastructures. The open call remains an active implementation opportunity for imaging organizations.

Impact Assessment:

- **Imaging Operations:** Direct. Participating centres require capacity to deploy and evaluate AI in routine imaging pathways across local populations, equipment, and workflows.
- **AI Governance:** Direct. The network explicitly emphasizes safe and trustworthy deployment, regulatory and ethical requirements, validation, data quality, and continuous performance evaluation.
- **Interoperability:** Direct. Cross-centre studies and evidence generation depend on interoperable imaging, report, metadata, outcome, identity, and access-control infrastructure.

Relevance Score: 4

European Commission Updates AI Act Enforcement Framework and High-Risk AI Timeline

Agency: European Commission, AI Office / DG CONNECT

Policy Type: AI Act implementation and enforcement guidance

Publication Date: August 24, 2026 update

Official Source Link: Official European Commission AI Act enforcement framework

Comment Deadline: Not applicable; enforcement powers began August 2, 2026

Summary: The European Commission updated its AI Act enforcement framework on August 24, 2026 after enforcement powers for the AI Office and national competent authorities began applying on August 2. The Commission identifies the provisions currently enforceable and the responsible enforcement authorities. It also states that rules for high-risk AI systems in Annex III apply from December 2, 2027, while rules for high-risk AI systems embedded in regulated products apply from August 2, 2028. For imaging organizations and vendors, the latter date is particularly relevant to AI incorporated into regulated medical-device products.

Impact Assessment:

- **Imaging Operations:** Material but not immediate for most diagnostic devices. Imaging organizations should align procurement and lifecycle planning with the staged applicability of AI Act obligations.
- **AI Governance:** Direct. The framework clarifies enforcement authority, investigative and sanctioning powers, and the timetable for high-risk AI obligations.
- **Interoperability:** Indirect. Governance, traceability, documentation, and evidence obligations may require consistent exchange of model identity, version, intended use, and output provenance 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 continues to solicit comments through December 31, 2026 on draft review points for several Software as a Medical Device categories. Two drafts are directly image-related: software used to support recognition of intraoperative images and software used for diagnosis using endoscopic images. The consultation is a formal opportunity to influence how PMDA evaluates evidence, intended use, and review issues for image-recognition software. The continuing open comment period keeps the item active.

Impact Assessment:

- **Imaging Operations:** Direct for image-recognition workflows in procedural and diagnostic care, particularly where clinician interpretation and software outputs are closely coupled.
- **AI Governance:** Direct. Draft review points can shape validation, limitations, human interaction, evidence, and oversight expectations for imaging SaMD.
- **Interoperability:** Material. Safe deployment depends on well-defined source-image inputs, outputs, patient/procedure association, workflow insertion points, and software-version provenance.

Relevance Score: 5

MHLW Advances Medical Radiation Management Deliberations Affecting Nuclear Medicine Operations

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

Policy Type: Regulatory advisory committee deliberation

Publication Date: July 8, 2026; Medical Division review July 24, 2026

Official Source Link: Official MHLW Medical Radiation Proper Management Committee page

Comment Deadline: Not applicable

Summary: MHLW's Medical Radiation Proper Management Committee met on July 8, 2026 to consider several operational issues involving medical radiation. The published agenda includes rationalized operation of drainage facilities, reporting of planned quantities for diagnostic radioactive isotopes, and handling of used radioactive isotopes and generator agents. The Social Security Council Medical Division subsequently took up medical-radiation deliberations on July 24. These are formal government deliberations rather than a completed final rule, but they are directly relevant to nuclear-medicine operations and radiation management.

Impact Assessment:

- **Imaging Operations:** Direct. Any resulting changes could affect nuclear-medicine facility operations, isotope accounting, drainage practices, and handling of generator-related radioactive materials.
- **AI Governance:** Limited direct effect.

- **Interoperability:** Material for compliance documentation. Standardized capture of radiopharmaceutical, procedure, inventory, and radiation-related data can support consistent reporting and auditability.

Relevance Score: 5

Japan Launches FY2026 Council for Renewal of Hospital Information Systems

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

Policy Type: National health IT modernization initiative

Publication Date: August 21, 2026

Official Source Link: Official Japan Digital Agency announcement

Comment Deadline: Not applicable

Summary: Japan's Digital Agency announced on August 21 that the FY2026 council for renewal of hospital information systems had begun its work, with a kickoff held August 4. The initiative is examining migration from current on-premises environments to modern cloud-based systems that integrate electronic medical records, billing systems, and departmental systems. For smaller hospitals, the government plans to begin certification review of private-vendor systems conforming to previously developed standard specifications, while work begins on requirements for large hospitals. This creates a new national implementation signal for connected departmental systems, including radiology information infrastructure.

Impact Assessment:

- **Imaging Operations:** Material. PACS, RIS, reporting, and modality-connected departmental systems may need to fit within broader cloud and hospital-system modernization architectures.
- **AI Governance:** Material. Cloud migration and certification can create stronger expectations for supplier governance, security, lifecycle controls, and integration of AI services.
- **Interoperability:** Direct. The initiative is explicitly concerned with modernizing and integrating hospital and departmental information systems and establishing standard specifications.

Relevance Score: 4

6. Australia Regulatory Scan

Australia Establishes AU Core and AUCDI as a National Interoperability Baseline for My Health Record

Agency: Australian Digital Health Agency

Policy Type: National interoperability standards implementation

Publication Date: August 7, 2026

Official Source Link: Official Australian Digital Health Agency announcement | Official My Health Record interoperability requirements page

Comment Deadline: Staged transition; timelines published in Connected Care Update August 2026

Summary: The Australian Digital Health Agency announced a national interoperability baseline for connections to My Health Record using AU Core and the Australian Core Data for Interoperability (AUCDI). The Agency states that AU Core and AUCDI will serve as the baseline for FHIR connections to My Health Record. It also plans to retire outdated Healthcare Identifiers and My Health Record conformance profiles and to use staged transition arrangements away from older versions of the

Healthcare Information Provider Service. The Agency's updated interoperability requirements continue to list diagnostic imaging report conformance profiles within the My Health Record standards environment.

Impact Assessment:

- **Imaging Operations:** Material. Radiology systems contributing reports or interacting with My Health Record must track the transition from legacy profiles to the new national FHIR baseline.
- **AI Governance:** Material. More consistent clinical-data exchange and stronger governance of interfaces can improve traceability and safer use of AI-generated or AI-assisted information.
- **Interoperability:** Direct. AU Core and AUCDI are being established as national FHIR baselines, with explicit retirement of legacy conformance arrangements and staged transition requirements.

Relevance Score: 4

TGA Consults on Expanded Public Sharing of Medical Device Safety, Quality, and Performance Information

Agency: Therapeutic Goods Administration (TGA), Australian Government

Policy Type: Public consultation / medical-device regulatory transparency proposal

Publication Date: August 13, 2026

Official Source Link: Official TGA consultation

Comment Deadline: October 2, 2026

Summary: TGA opened consultation on a proposal to improve public sharing of information about the safety, quality, and performance of medical devices. The proposal focuses on information arising from post-market reviews or investigations, including whether TGA should disclose that a device is under review and what information should be made public. TGA states that feedback will inform advice to the Australian Government on potential changes to the medical-device regulatory framework. The consultation remains open until October 2, 2026.

Impact Assessment:

- **Imaging Operations:** Material for procurement and post-market surveillance. Imaging organizations may gain more timely regulatory information about devices used in clinical operations.
- **AI Governance:** Direct-to-material for regulated AI-enabled medical devices. Greater transparency could strengthen local inventory, incident review, vendor oversight, and lifecycle risk management.
- **Interoperability:** Indirect. More precise device identity, intended use, and post-market status can improve provenance and configuration management across integrated imaging environments.

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.

Operationalize the USCDI Diagnostic Imaging Reference

Define a practical, testable pattern for a FHIR-based imaging reference to identify the correct study, series, or image and the endpoint and authorization method needed to retrieve it. The implementation guidance should clearly distinguish the presence of a computable reference from actual image availability and show how DICOMweb, XDS-I.b, MHD, patient identity, and cross-enterprise access controls fit.

Connect radiology workflows to the finalized FHIR prior-authorization baseline

Use the finalized CRD, DTR, PAS, and CDex versions to document how radiology orders, protocol changes, supporting documentation, authorization status, and results move between imaging workflow and payer APIs. The goal is to reduce custom interfaces while preserving imaging-specific workflow semantics.

Use the 2026 SVAP transition as a conformance-testing signal

Track voluntary adoption of newer USCDI, C-CDA, and FHIR versions by certified products and identify where imaging workflows encounter mixed-version environments. Connectathon test plans could explicitly exercise version transitions that affect image references, reports, and prior-authorization context.

Support European imaging-AI pilots with reproducible deployment patterns

The active screening call and screening-centre network create a direct setting for profiles and test plans covering image acquisition, work distribution, AI invocation, result representation, human confirmation, provenance, and post-deployment monitoring across institutions.

Make AI lifecycle provenance portable across regulatory regimes

FDA PCCP policy carried forward in the prior issue, the EU AI Act enforcement timeline, PMDA's image-recognition review points, and TGA's post-market transparency consultation all reinforce the need to associate AI results with product identity, software version, intended use, source images, and human review. IHE Radiology can define interoperable provenance patterns without prescribing regulatory compliance.

Map Japan's hospital-system modernization to imaging departmental systems

Japan's cloud-oriented hospital information-system initiative explicitly includes departmental systems. IHE Radiology can show how PACS, RIS, modalities, reporting systems, and enterprise viewers fit a standards-based hospital architecture while maintaining DICOM semantics and secure cross-system identity.

Align Australia's new FHIR baseline with diagnostic imaging report and image access

AU Core and AUCDI now provide a national FHIR baseline for My Health Record connections. IHE Radiology can help describe how diagnostic imaging reports carry durable identifiers and references that connect FHIR-based national exchange to diagnostic-quality images and DICOM/DICOMweb services.

Support global teleradiology and radiation programs with implementation building blocks

WHA79.9 and WHA79.13 remain active multi-year policy commitments. IHE Radiology can map existing profiles to secure teleradiology, image/report exchange, audit, identity, and radiation-dose data pathways while keeping policy-defined thresholds and clinical governance separate from transport standards.

8. Regulatory Early Warning Dashboard

Open Comment and Action Calendar

Date	Jurisdiction / Agency	Action	IHE Radiology Relevance
August 29, 2026	United States / ONC	2026 SVAP standards become available for voluntary certification.	Track voluntary adoption of USCDI v6, newer C-CDA/FHIR specifications, and electronic prior-authorization standards in imaging-adjacent health IT.
August 31, 2026	United States / CMS	Comments due on CY 2027 OPPS/ASC proposed rule.	Review imaging-without-contrast site-neutral proposal and other radiology payment/quality provisions.
September 10, 2026	European Union / European Commission	Second call closes for AI-powered advanced screening centres.	Potential clinical validation and implementation-network opportunity for imaging organizations.
September 14, 2026	United States / CMS	Comments due on CY 2027 Medicare Physician Fee Schedule proposed rule.	Final near-term opportunity for input on radiology-adjacent payment, quality, AI, and interoperability proposals.
September 25, 2026	Canada / Health Canada	Comments due on revised recognized standards for medical devices.	MRI safety and broader medical-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 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 implementations.
October 2, 2026	Australia / TGA	Medical-device information-sharing consultation closes.	Opportunity to address what post-market safety, quality, and performance information should be made public.
December 31, 2026	Japan / PMDA	Comments due on draft SaMD review points including image-recognition categories.	Opportunity to address validation, inputs, outputs, workflow, human oversight, and software provenance.

Early Warning Signals

Signal	Current Status	IHE Radiology Significance	What to Monitor

Signal	Current Status	IHE Radiology Significance	What to Monitor
USCDI imaging-reference implementation	Final data element published; USCDI v8 feedback remains open.	Could turn a computable image reference into a national expectation without guaranteeing cross-organizational image retrieval.	FHIR mapping, endpoint discovery, authorization, patient matching, DICOMweb/XDS-I.b alignment, and certification pathways.
CMS duplicate-imaging and result-sharing policy	Current PFS policy window remains open.	Could evolve into payment-linked expectations for access to prior reports and images.	Definitions of duplicate testing, clinical exceptions, and responsibility when prior images are unavailable.
EU high-risk medical AI implementation	AI Act enforcement has begun for currently applicable provisions; high-risk regulated-product rules are staged for 2028.	Imaging AI vendors and deployers will need to coordinate medical-device regulation, AI Act duties, and local clinical governance.	Final guidance, standards, quality-management expectations, evidence requirements, and implementation milestones for regulated-product AI.
Japan medical-radiation regulation	MHLW committees are actively considering isotope and radiation-management operations.	Could produce operational changes for nuclear medicine and radiation-management compliance.	Final decisions on drainage operations, planned-use reporting, and handling of used generator agents and isotopes.
Japan hospital information-system modernization	FY2026 council launched; cloud migration and certification work is active.	Departmental imaging systems may become subject to more explicit national architectural and standard-specification expectations.	Large-hospital requirements, vendor certification criteria, cloud/security architecture, and interfaces to departmental systems.
Australia national FHIR baseline	AU Core and AUCDI designated as the baseline for FHIR connections to My Health Record; legacy profiles will be retired in stages.	Creates a national standards transition with direct implications for imaging-report exchange and image-reference design.	Transition dates, imaging-report conformance updates, FHIR implementation guides, image access, and HIPS retirement.
TGA post-market transparency	Consultation is open through October 2.	May expand information available to providers when medical devices, including imaging and AI devices, are under review or investigation.	Government response, legislative change, scope of disclosed information, and linkage to ARTG/device identifiers.
WHO teleradiology and radiation implementation	WHA79.9 and WHA79.13 remain active with future WHO reports.	Could shape national procurement, interoperability, dose monitoring, and quality programs.	WHO normative guidance, technical tools, implementation work plans, and reporting frameworks.

9. Emerging Policy Signals (Pre-Regulatory)

Diagnostic Imaging Reference may become a bridge between EHR policy and image infrastructure.

ONC's final USCDI v7 data element and the still-open v8 feedback window create a policy path for more specific expectations about how clinical systems identify and reach external imaging resources. The unresolved question remains whether future certification, exchange-network, or payment policy will require only a reference or a reliably resolvable image-access workflow.

The 2026 SVAP cycle may accelerate mixed-version interoperability environments.

Voluntary certification to newer standards begins on the report date, while mandatory regulatory baselines and payer/provider API dates continue on separate schedules. Imaging interfaces may therefore need to tolerate multiple USCDI, C-CDA, and FHIR implementation-guide versions during transition.

European imaging AI policy is separating present enforcement from later high-risk product obligations.

The Commission's August enforcement update clarifies that some AI Act powers and duties already apply while high-risk rules for regulated products are staged to August 2028. This creates a multi-year preparation interval for medical-device AI in which governance, technical documentation, provenance, and post-market processes can mature before the high-risk product rules apply.

Japan is moving hospital information-system modernization and medical-radiation governance in parallel.

The Digital Agency's cloud and standard-specification initiative and MHLW's current radiation-management deliberations show simultaneous attention to digital infrastructure and imaging-specific operational regulation. Radiology may increasingly need to demonstrate both standardized connectivity and auditable radiation/radiopharmaceutical operations within national modernization programs.

Australia is converging My Health Record policy on a FHIR baseline while retaining an imaging report-to-image boundary.

AU Core and AUCDI now form the national FHIR baseline for My Health Record connections, but the established Share by Default model centers on diagnostic imaging reports rather than diagnostic-quality image transfer. Future policy may place greater weight on reliable image references or retrieval pathways, but no such expansion was identified as a formal proposal in this cycle.

Post-market transparency is becoming part of AI and medical-device governance.

TGA's consultation asks how much information should be released about devices under post-market review or investigation. For imaging AI, broader public regulatory information could increase expectations for local inventory accuracy, version tracking, vendor notification, and linkage of clinical use to regulated product identity.

10. International Policy Developments IHE Radiology Should Monitor

Two qualifying developments outside the primary monitored regions remain active through official World Health Organization 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 WHA79.9 on strengthening equitable access to diagnostic imaging through teleradiology. The resolution calls on Member States to integrate teleradiology into national health and digital-health strategies and to strengthen policy, regulatory, procurement, workforce, infrastructure, data-governance, and privacy capabilities. It also recognizes the growing role of AI while emphasizing validation, transparency, ethics, patient safety, and clinical oversight. WHO is requested to develop normative guidance, standards, and technical tools and to report on implementation progress in 2030.

Impact Assessment:

- **Imaging Operations:** Direct and global. Teleradiology is framed as a national health-system capability requiring quality, workforce, infrastructure, and sustainable operating models.
- **AI Governance:** Direct. The resolution calls for safe, ethical, transparent, validated, and clinically supervised AI and decision support in teleradiology.
- **Interoperability:** Direct and central. WHO is asked to support 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 WHA79.13 on radiation and health, covering ionizing and non-ionizing radiation and explicitly including medical exposure. The resolution urges Member States to strengthen legislation, institutional capacity, workforce training, equipment regulation, quality assurance, and systems for monitoring patient, worker, and public exposure. It also addresses medical imaging, radiotherapy, radiopharmaceuticals, and emerging technologies. WHO is asked to continue developing standards and technical tools and to report progress to the World Health Assembly in 2028.

Impact Assessment:

- **Imaging Operations:** Direct. The resolution supports stronger equipment regulation, quality assurance, workforce competency, radiopharmaceutical safety, and monitoring of medical exposures.
- **AI Governance:** Material. The resolution recognizes emerging technologies and supports continued assessment of 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. A complete source pass was performed before determining which candidates qualified. Search-enabled sources used the fixed protocol term set below; chronological listing pages were 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	Federal Register search and recent HHS/CMS/FDA regulatory listing review	May 31, 2026 - August 29, 2026	Full fixed term set; HHS/CMS/FDA recent regulatory actions	CMS proposed rules verified; no additional standalone Federal Register item meeting score/current-cycle rules retained.
CMS policy announcements	CMS newsroom, annual payment-rule pages, regulation notices	May 31, 2026 - August 29, 2026	Full fixed term set; CY 2027 OPPS/ASC, PFS, and FY 2027 IPPS pages	Retained active CY 2027 proposed rules and FY 2027 IPPS interoperability standards implementation.
ONC / ASTP publications	Official HealthIT.gov standards, bulletin, certification, SVAP, and policy-page review	May 31, 2026 - August 29, 2026	Full fixed term set; USCDI, SVAP, FHIR, certification, prior authorization	Retained USCDI v7 Diagnostic Imaging Reference, FY 2027 IPPS FHIR standards, and 2026 SVAP implementation.
FDA policy announcements	Official FDA/CDRH policy, guidance, AI/ML/SaMD and radiology-device review	May 31, 2026 - August 29, 2026	Full fixed term set; radiology; medical imaging; AI/ML; SaMD; PCCP	Discovery completed — no candidate items found for this source in the monitoring window.

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 31, 2026 - August 29, 2026	Full fixed term set; medical devices; diagnostic imaging; health information; AI	Discovery completed — no candidate items found for this source in the monitoring window.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Health Canada policy announcements	Medical-device announcements, consultations, guidance, standards, and What's New listing	May 31, 2026 - August 29, 2026	Full fixed term set; MRI; medical devices; AI/ML; recognized standards	Retained open recognized-standards consultation; other medical-device notices evaluated but did not qualify at score 3 or higher for imaging.
Government of Canada health interoperability publications	Canada.ca digital-health, health-data, and interoperability page review	May 31, 2026 - August 29, 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 digital-health, EHDS, medical-device, HTA, and implementation page review	May 31, 2026 - August 29, 2026	Full fixed term set; EHDS; imaging; AI in health; medical devices	Health and HTA implementation activity reviewed; no additional standalone imaging item retained from this source.
EUR-Lex regulatory publications	Recent EU regulatory publication/listing and targeted legal search	May 31, 2026 - August 29, 2026	Full fixed term set; AI Act; medical devices; EHDS; imaging	AI Act implementation context reviewed; qualifying current action verified through the Commission's official enforcement page.
EU Digital Strategy portal	Chronological policy, funding, implementation, and consultation-page review	May 31, 2026 - August 29, 2026	Full fixed term set; Apply AI; image screening; screening centres; AI Act	Retained image-screening call, screening-centre network, and August AI Act enforcement update.
European Medicines Agency (EMA) publications	Official AI, medical-device, news, workshop, guidance, and consultation-page review	May 31, 2026 - August 29, 2026	Full fixed term set; medical imaging; AI; SaMD; device software	AI and medical-device workshop materials reviewed; no standalone imaging regulatory item meeting current-cycle criteria retained.

Japan

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Ministry of Health, Labour and Welfare (MHLW)	Official committee, Medical DX, radiation-management, and new-information listings	May 31, 2026 - August 29, 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; 医療放射線	Retained current medical-radiation management deliberations; broader Medical DX activity evaluated.
Pharmaceuticals and Medical Devices Agency (PMDA)	Official SaMD, review-points, device-review, and consultation pages	May 31, 2026 - August 29, 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 open image-recognition SaMD review-points consultation.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Digital Agency	Official health, policy, standards, and announcement listings	May 31, 2026 - August 29, 2026	Full fixed term set plus Japanese digital-government and health-data terms	Retained August 21 hospital information-system renewal council announcement.
Ministry of Internal Affairs and Communications (MIC / Soumu)	Official policy, AI, telecommunications, and listing-page review	May 31, 2026 - August 29, 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 diagnostic-imaging, My Health Record, Medicare, policy, consultation, and resource-page review	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Share by Default and Medicare imaging activity reviewed; no new standalone Department item retained beyond cross-agency interoperability developments.
Federal Register of Legislation	Recent health legislative instruments and My Health Record / Health Insurance listing review	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Current My Health Record and Health Insurance instruments reviewed; no additional standalone item meeting current-cycle and relevance rules retained.
Therapeutic Goods Administration (TGA)	Consultation listings, medical-device, software/AI, ARTG, guidance, and news pages	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Retained August 13 medical-device information-sharing consultation.
Australian Digital Health Agency	Official interoperability, My Health Record, publications, and implementation pages	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Retained August national AU Core/AUCDI interoperability baseline and supporting My Health Record standards update.
MBS Online	Diagnostic imaging news, factsheets, schedule, and item-update pages	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Prior July imaging payment changes reviewed; no new standalone qualifying development identified after implementation.
Medical Services Advisory Committee (MSAC)	Application, meeting, publication, and consultation-page review	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets; PET/CT; nuclear medicine	Discovery completed — no candidate items found for this source in the monitoring window.
Australian Commission on Safety and Quality in Health Care	Official publications, digital-health safety, clinical governance, and AI page review	May 31, 2026 - August 29, 2026	Full fixed and Australia-specific term sets	Discovery completed — no candidate items found for this source in the monitoring window.

Official Source	Discovery Method	Date Range Applied	Exact Search Terms / Pages Reviewed	Outcome
Office of the Australian Information Commissioner	My Health Record, privacy, AI, and digital-health guidance page review	May 31, 2026 - August 29, 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 31, 2026 - August 29, 2026	Diagnostic imaging; teleradiology; radiation; medical imaging; AI; interoperability	Retained WHA79.9 on teleradiology and WHA79.13 on radiation and health as active carry-forward items.
International Medical Device Regulators Forum (IMDRF)	Consultation, final-document, AI/SaMD and medical-device page review	May 31, 2026 - August 29, 2026	AI lifecycle; SaMD; medical device software; imaging	Discovery completed — no candidate items found for this source in the monitoring window.
UK MHRA	Official software/AI medical-device, consultation, guidance, and announcement review	May 31, 2026 - August 29, 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, standards, and consultation-page review	May 31, 2026 - August 29, 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 6 (July 31, 2026)	Direct title, agency, initiative, publication/action-window, and material-policy comparison against every retained candidate before report construction.	Repeated or continuing policies/actions that independently qualified in the current cycle were prefixed with an asterisk as the first character of the Title. Completed or inactive prior items were not carried forward solely because they appeared previously.