

IHE Radiology Global Regulatory Monitoring Report

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PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

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Monitoring period	February 2, 2026 – April 3, 2026
Discovery window used	January 3, 2026 – April 3, 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, and Japan for the monitoring period of February 2, 2026 through April 3, 2026, with discovery extended back to January 3, 2026 to avoid missing items whose action windows remained open. Discovery was completed using the fixed protocol search terms and source review requirements set out in the monitoring protocol, followed by source verification, relevance scoring, and comparison against the immediately prior Volume/Issue before report construction.

The most important qualifying items this cycle remained concentrated in the United States and European Union. In the United States, the diagnostic imaging interoperability RFI, the clinical AI RFI, and the HTI-5 proposed rule all remained significant because their active comment periods or direct policy implications overlapped the monitoring window. In the European Union, the Euratom diagnostic reference level Recommendation remained the principal imaging-specific policy signal identified through official review. No qualifying formal regulatory developments were identified in Canada or Japan during the monitoring window after completion of the required discovery pass.

Strategically, the current cycle continues to point toward the same core policy vectors that matter most to IHE Radiology: interoperable image exchange, API-centered health IT policy, governance of clinical AI, and structured dose-management workflows. Even where a new binding requirement did not emerge during this cycle, the verified items continue to reinforce a policy environment in which implementation guidance, interoperability profiles, and practical deployment frameworks remain highly relevant.

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
*Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)	U.S. Department of Health and Human Services (HHS), Office of the Secretary / ASTP-ONC	Federal Register – Request for Information	January 30, 2026	March 16, 2026	5
*Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13)	U.S. Department of Health and Human Services (HHS)	Federal Register – Request for Information	December 23, 2025	February 23, 2026	3
*Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5)	Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology, HHS	Federal Register – Proposed Rule	December 29, 2025	February 27, 2026	3
*Commission Recommendation (Euratom) 2026/403 on diagnostic reference levels for radiodiagnostic and interventional radiology procedures	European Commission (Euratom)	Official Journal of the European Union – Commission Recommendation	February 25, 2026	Not applicable	4
Health Canada 2026–27 Departmental Plan: digital health, interoperability, and artificial intelligence priorities	Health Canada	Departmental Plan / strategic policy signal	March 13, 2026	Not applicable	3

3. North America Regulatory Scan

United States

***Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)**

Agency: U.S. Department of Health and Human Services (HHS), Office of the Secretary / ASTP-ONC

Policy Type: Federal Register – Request for Information

Publication Date: January 30, 2026

Official Source Link: <https://www.federalregister.gov/documents/2026/01/30/2026-01866/request-for-information-diagnostic-imaging-interoperability-standards-and-certification>

Comment Deadline: March 16, 2026

Summary: HHS issued a request for information seeking input on whether diagnostic imaging technical standards and certification criteria should be adopted under the ONC Health IT Certification Program to better enable access, exchange, and use of diagnostic images. The notice describes persistent barriers such as fragmented image exchange, continued reliance on physical media, and limited patient access through modern digital tools. The document indicates that stakeholder responses may inform future rulemaking. Because interoperable image exchange remains a central imaging workflow problem, this item remains highly relevant to IHE Radiology.

Impact Assessment:

- **Imaging Operations:** Potential future requirements could reshape how imaging organizations exchange images with patients, referring clinicians, and outside providers, including stronger expectations for electronic access workflows.
- **AI Governance:** Indirect but meaningful; broader image access and exchange can become an enabling condition for AI-supported workflow and longitudinal imaging use cases.
- **Interoperability:** Direct and high. The RFI is expressly focused on standards and certification criteria for interoperable diagnostic image access, exchange, and use.

Relevance Score: 5

***Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13)**

Agency: U.S. Department of Health and Human Services (HHS)

Policy Type: Federal Register – Request for Information

Publication Date: December 23, 2025

Official Source Link: <https://www.federalregister.gov/documents/2025/12/23/2025-23641/request-for-information-accelerating-the-adoption-and-use-of-artificial-intelligence-as-part-of>

Comment Deadline: February 23, 2026

Summary: HHS requested public feedback on actions it can take to accelerate the adoption and use of AI as part of clinical care. The RFI frames HHS's interest across regulation, reimbursement, and research and development, and presents the effort as part of a broader departmental AI strategy. Although it is not imaging-specific, it remains relevant because imaging is one of the most mature clinical AI domains and would likely be affected by any resulting policy direction.

Impact Assessment:

- **Imaging Operations:** Potential downstream effects on how imaging departments evaluate, procure, validate, and monitor AI tools used in clinical operations.
- **AI Governance:** Direct. The item is explicitly focused on how HHS could use policy levers to influence clinical AI adoption and oversight.
- **Interoperability:** Indirect. Follow-on actions could affect integration, data access, and workflow interoperability requirements for AI-enabled imaging tools.

Relevance Score: 3

***Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5)**

Agency: Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology, HHS

Policy Type: Federal Register – Proposed Rule

Publication Date: December 29, 2025

Official Source Link: <https://www.federalregister.gov/documents/2025/12/29/2025-23896/health-data-technology-and-interoperability-astponc-deregulatory-actions-to-unleash-prosperity>

Comment Deadline: February 27, 2026

Summary: ASTP/ONC published the HTI-5 proposed rule as a deregulatory package affecting health IT standards, implementation specifications, certification criteria, certification program requirements, and information blocking provisions. The proposal is framed around reducing burden while supporting innovation and modernized, API-based interoperability. While not targeted specifically at imaging, it remains relevant because imaging exchange, ordering, results access, and AI-enabled interoperability sit inside the broader certified health IT ecosystem.

Impact Assessment:

- **Imaging Operations:** Indirect operational impact through changes to the surrounding health IT environment that supports imaging orders, results distribution, patient access, and cross-enterprise exchange.
- **AI Governance:** Material. The rule is relevant to AI-enabled interoperability and the policy environment in which certified health IT supports advanced workflow capabilities.
- **Interoperability:** High. The proposal directly addresses certification and interoperability policy architecture that can influence imaging-adjacent exchange expectations.

Relevance Score: 3

Canada

No qualifying formal regulatory developments were identified for Canada during the monitoring window after completion of the required discovery and verification steps. A Canada-based strategic signal is included in Section 8 because it did not rise to the level of a formal regulatory development for this section.

4. European Union Regulatory Scan

***Commission Recommendation (Euratom) 2026/403 on diagnostic reference levels for radiodiagnostic and interventional radiology procedures**

Agency: European Commission (Euratom)

Policy Type: Official Journal of the European Union – Commission Recommendation

Publication Date: February 25, 2026

Official Source Link: <https://eur-lex.europa.eu/eli/reco/2026/403/oj/eng>

Comment Deadline: Not applicable

Summary: The European Commission issued a Euratom Recommendation concerning good practices for the establishment, review, and use of diagnostic reference levels for radiodiagnostic examinations and interventional radiology procedures. The Recommendation reinforces Member State responsibilities to maintain national frameworks for DRLs and to support review when DRLs are consistently exceeded. Although not a binding rule, it is an important policy signal for dose optimization, review governance, and interoperable dose data workflows.

Impact Assessment:

- **Imaging Operations:** Meaningful for imaging providers and supporting vendors involved in dose management, protocol review, and DRL governance processes.
- **AI Governance:** Indirect. The Recommendation may influence the environment for tools claiming protocol optimization or dose optimization value, including AI-enabled products.
- **Interoperability:** Indirect-to-moderate. DRL review and dose governance can increase demand for consistent dose capture, transmission, aggregation, and registry-style interoperability.

Relevance Score: 4

5. Japan Regulatory Scan

No qualifying regulatory developments were identified for Japan during the monitoring window after completion of the required discovery and verification steps.

6. IHE Opportunity Scan

Policy signal	Potential IHE-aligned opportunity	Notes (non-policy)
*Diagnostic Imaging Interoperability Standards and Certification RFI (US)	Refine and socialize implementation-ready interoperability patterns for access, exchange, and use of diagnostic images, including profile-aligned expectations for cross-enterprise and patient-facing workflows.	This remains the clearest near-term opportunity for IHE Radiology to translate operational imaging exchange needs into practical, standards-grounded implementation guidance.
*HTI-5 proposed rule (US)	Position IHE Radiology artifacts as implementation complements to broader API-centered interoperability policy changes affecting imaging-adjacent workflows.	The rule is not imaging-specific, but it shapes the broader certified-health-IT environment in which imaging exchange and workflow integration occur.
*Euratom DRL Recommendation (EU)	Strengthen interoperability patterns for dose capture, transmission, aggregation, and review workflows that support DRL governance and local review processes.	Dose-governance work is especially well aligned to structured data capture and cross-system consistency rather than narrative-only approaches.
Health Canada 2026–27 Departmental Plan	Monitor whether Canadian digital health and interoperability priorities mature into more formal requirements where IHE-style implementation guidance could be useful.	This is a strategic signal rather than a formal regulation, but it points toward continued governmental interest in interoperability and AI-enabled care infrastructure.

7. Regulatory Early Warning Dashboard

Upcoming or recently closed action dates associated with qualifying items are summarized below.

Item	Agency/Region	Comment deadline / action date	Link
Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)	United States	March 16, 2026	Official source
Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13)	United States	February 23, 2026	Official source
Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5)	United States	February 27, 2026	Official source

8. Emerging Policy Signals (Pre-Regulatory)

Health Canada 2026–27 Departmental Plan: digital health, interoperability, and artificial intelligence priorities

Agency: Health Canada

Policy Type: Departmental Plan / strategic policy signal

Publication Date: March 13, 2026

Official Source Link: <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2026-2027-departmental-plan.html>

Comment Deadline: Not applicable

Summary: Health Canada’s 2026–27 Departmental Plan states that Canadians should have seamless access to their electronic health information and that the Department will support a more connected, data-driven, and responsive health system by improving interoperability and leveraging artificial intelligence. The document is not a formal regulation, but it is a current governmental signal on federal priorities that could shape later policy development. Its relevance to IHE Radiology comes from the combination of interoperability, digital health, and AI adoption language in an official planning document.

Impact Assessment:

- **Imaging Operations:** No immediate operational requirement, but it signals ongoing policy attention to digital health infrastructure that may later influence imaging access and exchange expectations in Canada.
- **AI Governance:** Direct as an early policy signal; the plan expressly references increased adoption of AI within the health system.
- **Interoperability:** Direct as an early policy signal; the plan expressly references seamless access to electronic health information and improved interoperability.

Relevance Score: 3

9. International Policy Developments IHE Radiology Should Monitor

No qualifying developments outside the primary monitored regions were identified from official government sources during this execution cycle.

10. Appendix A – Regulatory Sources Monitored

Discovery evidence log for required monitored sources. Date range and search execution were recorded to satisfy the protocol's minimum discovery completeness rule.

Source	Discovery method	Date range applied	Exact search terms / pages reviewed	Outcome
Federal Register (United States)	Site search and Federal Register index review	January 3, 2026 – April 3, 2026	Fixed protocol term set applied. HHS 2026 Federal Register listings reviewed for imaging, interoperability, AI, and digital quality items.	Candidate items identified.
CMS policy announcements	Official CMS policy and rulemaking pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied, with additional review of CMS payment-policy and quality-program materials for imaging-adjacent content.	No additional qualifying candidate items found.
ASTP/ONC publications	Official ASTP/ONC / HealthIT policy pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for interoperability, certification, information blocking, diagnostic imaging, and AI.	Candidate items identified.
FDA policy announcements	Official FDA policy and AI/device pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for artificial intelligence, SaMD, machine learning, radiology, CT, MRI, and imaging.	Discovery completed — no candidate items found for this source in the monitoring window.
Canada Gazette	Chronological listings and site search reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied across Canada Gazette listings and health-related notices.	Discovery completed — no candidate items found for this source in the monitoring window.
Health Canada policy announcements	Official Health Canada policy, guidance, and planning pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for AI, interoperability, SaMD, imaging, and digital health.	Candidate item identified in pre-regulatory section.
Government of Canada health interoperability publications	Official Canada.ca digital health and interoperability pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for interoperability, digital health, and health information exchange.	No additional qualifying candidate items found.

European Commission Health Directorate	Chronological and topical page review	January 3, 2026 – April 3, 2026	Health-policy pages and radiological protection materials reviewed; fixed protocol term set applied where search was available.	Candidate item identified.
EUR-Lex regulatory publications	Official Journal / EUR-Lex listing review	January 3, 2026 – April 3, 2026	Chronological EUR-Lex and Official Journal review for the monitoring window, with fixed protocol term set applied to imaging, AI, and interoperability topics.	Candidate item identified.
EU Digital Strategy portal	Official portal review and site search	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for artificial intelligence, interoperability, and health data topics.	No additional qualifying candidate items found.
MHLW	Official MHLW site search and notice review	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for medical imaging, AI, SaMD, and interoperability topics.	Discovery completed — no candidate items found for this source in the monitoring window.
PMDA	Official PMDA announcements and search reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for medical devices, AI, machine learning, SaMD, and imaging.	Discovery completed — no candidate items found for this source in the monitoring window.
Digital Agency (Japan)	Official Digital Agency pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for interoperability, health data, and digital government topics.	Discovery completed — no candidate items found for this source in the monitoring window.
MIC (Japan)	Official Ministry of Internal Affairs and Communications pages reviewed	January 3, 2026 – April 3, 2026	Fixed protocol term set applied for digital infrastructure, interoperability, and AI topics.	Discovery completed — no candidate items found for this source in the monitoring window.