National Regulations and Policies for the Promotion of Alternative Technologies

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Introduction

The purpose of this paper is to describe the complex set of organizational roles and government regulations that may affect the adoption of non-radioisotopic alternative technologies that serve the same function as radioactive source applications but that do not use radioactive material. Due to the diversity of technologies and applications, there are many different types of regulations that can influence adoption. By describing the international commitments, organizations, regulations observed from select nations, and other instruments commonly related to alternative technologies implementation, this paper provides a basis for preparing those interested in adoption of alternative technologies to understand potential drivers and inhibitors for projects early in the planning process. This paper references examples, where appropriate, to illustrate how countries have implemented specific regulations and policies.

International commitments and guidance

At present, there are no binding international instruments that mandate a transition from the use of radioactive sources to alternative technologies. However, adoption is being facilitated by several non-binding international commitments and guidance.

Non-binding international commitments: The Joint Statement on Strengthening the Security of High Activity Sealed Radioactive Sources, commonly referenced as International Atomic Energy Agency (IAEA) INFCIRC/910, issued in 2016, provides States with an opportunity to make an explicit commitment to alternative technologies through an international instrument. Prior to becoming an INFCIRC, this document was coordinated by France and issued as a gift basket contribution to the 2016 Nuclear Security Summit. Subscribers to INFCIRC/910 are called upon to support "the development of non-[high activity sealed source] technologies (whether isotopic or not) through research and development, and promot[e] them as far as technically and economically acceptable."[1] As of 2022, 32 States and INTERPOL have endorsed the Joint Statement.[2] Although INFCIRC/910 is not binding, its subscribers may have taken steps to facilitate alternative technology transitions by considering radiological source security externalities or by reducing legal barriers to alternative technology adoption in their regulatory arrangements, as called for in the document.

[1] IAEA, "Communication dated 30 December 2016 received from the Permanent Mission of France concerning a Joint Statement on Strengthening the Security of High Activity," INFCIRC/910, 20 January 2017, https://www.iaea.org/publications/documents/infcircs/communication-dated-30-december-2016-received-from-the-permanent-mission-of-france-concerning-a-joint-statement-on-strengthening-the-security-of-high-activity-sealed-radioactive-sources.

[2] Ibid.

The Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct), published by the IAEA in 2004, delineates a set of basic principles and recommendations, including provisions for legislation and regulations, regulatory bodies, import and export of radioactive sources, and the IAEA's role in fostering the safety and security of radioactive sources.[3] However, the Code of Conduct is not legally binding. Since the Code of Conduct was published, the IAEA has published two supplementary guidance documents: Guidance on the Import and Export of Radioactive Sources, first published in 2005 and updated in 2012,[4] and Guidance on the Management of Disused Radioactive Sources, published in 2018.[5] Pursuant to GC(47)/RES/7.B1, States are encouraged to make a political commitment to the Code of Conduct, and as of June 4, 2021, 140 States had done so.[6] States may also notify the IAEA that they intend to adopt the provisions in the Code of Conduct's subsidiary guidance documents.

The Code of Conduct covers activities that can facilitate alternative technology transitions, such as recommending the safe and secure storage of disused radioactive sources and calling for manufacturer States to allow for return of disused sources. However, it does not call upon States to minimize their use of radioactive sources or replace them with alternative technologies. Thus, States that have voiced a political commitment to the Code of Conduct have not necessarily made a commitment to alternative technologies. Should they decide to pursue alternative technology, some of the recommendations may help facilitate its adoption, such as having regulatory measures that govern the transport and disposition of disused sources.

Non-binding international guidance: Recommendations and guidance set out in the IAEA's Nuclear Security Series (NSS) publications encourage the employment of alternative technologies where feasible, although they do not explicitly call upon States to transition from radioactive sources. NSS 14, is a recommendation-level document (which sits at a higher level above NSS implementing guides and technical guides), addresses alternative technology in the following manner:

> "The State should consider ways of reducing the nuclear security risk associated with *radioactive material*, particularly *radioactive sources*, for example by encouraging the use of an alternative radionuclide, chemical form, or non-radioactive technology, or by encouraging device designs that are more tamper resistant."[7]

The IAEA's implementing guide on the Security of Radioactive Material in Use and Storage and of Associated Facilities (NSS 11-G, Rev. 1) expands on this language in NSS 14 quoted above. In discussing alternatives to radioactive material and sources, NSS 11-G provides examples that include using alternative forms of the same radionuclide (e.g., using ceramics instead of salts), using alternative

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[3] International Atomic Energy Agency (IAEA), *Code of Conduct on the Safety and Security of Radioactive Sources*, IAEA/CODEOC/2004 (Vienna, January 2004), http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf.

[4] IAEA, *Guidance on the Import and Export of Radioactive Sources*, IAEA/CODEOC/IMO-EXP/2012 (Vienna, 2012), http://www-pub.iaea.org/MTCD/Publications/PDF/8901_web.pdf.

[5] IAEA, *Guidance on the Management of Disused Radioactive Sources*, IAEA/CODEOC/MGT-DRS/2018 (Vienna, 2018), http://www-pub.iaea.org/MTCD/Publications/PDF/Guidance_on_the_Management_web.pdf.

[6] A current list of States that have made a political commitment to the Code of Conduct, as well as its subsidiary guidance, can be viewed at https://nucleus.iaea.org/sites/ns/code-of-conduct-radioactive-sources/Pages/default.aspx.

[7] International Atomic Energy Agency, *Nuclear Security Recommendations on Radioactive Material and Associated Facilities*, NSS 14 (Vienna, 2011), http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1487_web.pdf, para. 3.22.

radionuclides that present a lesser hazard, and adopting modified operational practices (such as only using radioactive sources at fixed, secure locations, instead of transporting them to work sites).[8] international drafting committee, Member States are not obliged to implement any of their content.

The IAEA's General Safety Requirements (GSR) series, also issued as non-binding guidance, touches on topics relevant to alternative technologies. Requirement 37 in GSR Part 3, covering radiation protection and safety of radioactive sources, states that "[r]elevant parties shall ensure that medical exposures are justified," further specifying, "[m]edical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure."[9] This language, however, does not explicitly endorse alternative technology (for medical devices) that generates radiation without using radioactive sources. On paper, the risk-benefit comparison is being made between procedures that involve a radiation dose, and those that do not. But this language does imply that in comparing two radiation procedures with equal benefit, the one that involves less dose to the patient, or a lesser security risk, is preferable. This interpretation may be relevant in cases (e.g., teletherapy) where the alternative technology option often results in lower patient doses, notwithstanding improved patient outcomes.

The IAEA is not the only source of international guidance relevant to alternative technologies. For example, the Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979), issued by the Food and Agriculture Organization of the United Nations (FAO), in collaboration with the World Health Organization (WHO), is a set of food safety standards that contains a section on food irradiation.[10] These standards are not legally binding, except within the European Union (EU), under EU law (discussed in the next section). In general, a State or a regional authority (e.g., the EU) may opt to make international guidance or recommendations binding through legislation.

Regional obligations and guidance

In addition to international commitments and guidance, countries (such as EU Member States) are subject to regional obligations and guidance, such as legally binding acts issued by EU legislative bodies. These acts include regulations, which have direct effect (i.e., their provisions, have automatic effect upon entry into force), and directives, which EU Member States must implement through national legislation.

European Council (EC) Directive 2013/59/Euratom of 5 December 2013 sets standards for radiation safety within the EU, and codifies a version of Requirement 37 in GSR Part 3 for radiation exposure via

[8] International Atomic Energy Agency, *Security of Radioactive Material in Use and Storage and of Associated Facilities*, NSS 11-G (Rev. 1) (Vienna, 2019), http://www-pub.iaea.org/MTCD/Publications/PDF/PUB1840_web.pdf, paras. 3.87-3.91.

[9] International Atomic Energy Agency, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, General Safety Requirements Part 3, STI/PUB/1578 (Vienna, 2014), https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards, paras. 3.155-3.161.

[10] Food and Agriculture Organization of the United Nations, "Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979)," *Codex Alimentarius* Revision 2003 (Editorial correction 2011), http://www.fao.org/input/download/standards/18/CXP_019e.pdf.

medical procedures (i.e. justification of medical exposure), as well as requiring states to implement the "justification principle" for public and occupational radiation exposure in general.[11] In this directive, the "efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation" are to be considered in evaluating a given procedure.[12] Unlike GSR Part 3, this language explicitly states that comparisons may be made to alternative procedures involving lower radiation exposure. Furthermore, EU Member States are compelled under the principle of "optimization" to limit public and occupational radiation exposure to levels "as low as reasonably achievable,"[13] which could favor the use of alternative technology devices. As such, Council Directive 2013/59/Euratom provides a mechanism by which EU Member States could derive a legal mandate for switching from radioactive sources to alternative technologies in medical applications. However, this directive does not specify a methodology for performing a risk/benefit analysis to justify use of a particular technique (which would have to be performed under the jurisdiction of Member States). As such, the directive cannot be interpreted to favor alternative technology in any specific application, or the use of any specific alternative technology device.

The European Commission has issued Radiation Protection Guide N° 162[14] to provide criteria for the acceptability of medical radiological equipment, against the justification and optimization principles given in a predecessor directive to Council Directive 2013/59/Euratom. Specifically, the guide sets "suspension levels" that describe a phenomenon (e.g., visible artefacts present) or measured quantity (e.g., dose at a set distance exceeding a threshold quantity) at which operation of a device should be suspended, pending examination of the equipment. However, this guide is not legally binding. Furthermore, the foreword to the document explicitly states, "the Commission **does not recommend** the direct adoption of the RP162 suspension levels in national regulations," noting that they would pose unnecessarily stringent restrictions on equipment operation, instead recommending "careful and thorough evaluation of national circumstances."[15]

The EU also has issued a set of regulations and directives that govern product specifications for certain items sold within its borders. These directives, taken together, form the EU's "new legislative framework" for facilitating its single market for goods, an element of which involves setting common safety standards for certain products, both to protect consumers, but also to facilitate trading of these products between its Member States.[16] Accreditation and market surveillance of products is governed by Regulation (EC) 765/2008 (which also governs use of the CE marking, discussed later in this paper),[17]

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[11] European Union, "Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom," Consolidated version as of January 17, 2014, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013L0059-20140117, art. 5(a)

[12] Ibid., art. 55, para. 1.

[13] Ibid., art. 5(b).

[14] European Union, "Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy," Radiation Protection N° 162, 2012, https://ec.europa.eu/energy/sites/ener/files/documents/162.pdf.

[15] Ibid, p. 3.

[16] European Union, "New legislative framework," accessed July 7, 2021, https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en.

[17] European Union, "Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and

Decision 768/2008,[18] and Regulation (EU) 2019/1020.[19] Specific standards for products are given in legal acts "aligned" with Decision 768/2008. Of relevance to alternative technology are Regulation (EU) 2017/745,[20] which covers standards for medical devices, and Directive 2014/32/EU,[21] which covers measurement devices (e.g., radiography equipment). Although none of these provisions directly prescribe requirements for replacing radioactive sources with alternative technologies, replacement devices that fall within the scope of these provisions must comply with them (and in the case of directives, with the relevant domestic law).

Finally, attention should be given to Directives 1999/2/EC[22] and 1999/3/EC,[23] which govern labeling of irradiated foods, approval of food irradiation facilities, recordkeeping of irradiated food products, importation of irradiated food, packaging, and harmonization of Member State laws to allow for "marketing and use of irradiated foodstuffs" within the EU. Under Directive 1999/3/EC, the only irradiated foodstuffs that can be sold and traded across the EU are "[d]ried aromatic herbs, spices and vegetable seasonings," which may be irradiated up to 10 kilogray. Furthermore, Directive 1999/2/EC makes the portion of the Codex Alimentarius on food irradiation legally binding within the EU.

National organizational roles and authorities

A government and a nuclear regulatory body can encourage the use of alternative technology through education, financial incentives and disincentives, and written justification requirements. This section will provide a concise summary of the incentives a government body could adopt to facilitate the adoption of alternative technologies.

repealing Regulation (EEC) No 339/93," OJ L 218, August 13, 2008, pp. 30–47, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765.

[18] European Union, "Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC," OJ L 218, August 13, 2008, pp. 82–128, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0768.

[19] European Union, "Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011," OJ L 169, June 25, 2019, pp. 1–44, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R1020.

[20] European Union, "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC," Consolidated text as of April 24, 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424.

[21] European Union, "Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of measuring instruments," Consolidated text as of January 27, 2015, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0032-20150127.

[22] European Union,"Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation," consolidated version as of 11 December 2008, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01999L0002-20081211.

[23] European Union, "Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation," 22 February 1999, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999L0003.

Educational: When a request is made for a new high-activity source, the government can provide educational material to inform the requestor of alternative technology that serves the same function as the radioactive source requested. The requester may not be aware of some of the new technologies or may be hesitant to try them. In this educational role, the requester would benefit from a list of end-users, provided voluntarily, that are using alternative technology, and their specific use-case scenarios. Additionally, the requester may require education on additional topics, such as the added security complications associated with some radioactive sources or the potential consequences of malicious acts involving radioactive sources. Requesters that do not work in a high-security environment regularly may not understand some of the complexities involved in this area.

Financial: The government can provide financial incentives for the use of alternative technology, or disincentives for using radioactive sources. Some examples of financial incentives include reduced licensing costs, national subsidies, or the reduced security costs associated with using alternative technology. Financial disincentives for using radioactive sources rather than alternative technology include the high costs associated with security requirements or requiring a large upfront deposit to ensure sufficient funding for source disposition.

Regulatory: A requestor can be asked to provide a written justification explaining why they must use a radioactive source instead of an alternative technology device. Without a compelling reason to use the radioactive source, the requestor could be required to use an alternative technology device. In cases where an alternative technology device will not be a sufficient replacement for a high-activity source, the regulatory body can issue the license for a short amount of time, requiring more frequent renewal applications. If technology advances in the field and an alternative option becomes available, the frequent renewal periods will force the end-user to reevaluate their use of the more dangerous high-activity source on a regular basis. The increase in paperwork may also discourage the use of radioactive sources. It is also likely that the licensing and approval process could be made significantly faster for alternative technologies compared to radioactive sources.

Key regulatory provisions encouraging or requiring use of alternative technologies

A broad analysis of laws and regulations identified diverse provisions that enable, encourage, or require the use of alternative technologies. These provisions can be grouped into the following categories: justification requirements, requirements to consider the use of alternative technologies, requirements prohibiting or imposing a phase-out of specific sources or technologies, requirements on the management of disused radioactive sources, and requirements for the security of radioactive sources.

Justification requirements: The principle of Justification is one of the IAEA's ten fundamental safety principles described in the IAEA Safety Fundamentals, No. SF-1. It states that "For facilities and activities to be considered justified, the benefits that they yield must outweigh the radiation risks to which they give rise to." In its most basic form, the justification principle is agnostic to the promotion of alternative technology, as, even a device utilizing a high-activity source could meet the standard set forth by this principle. However, in actual practice a country may decide to attach additional considerations or enhancements to justification requirements that make the provisions useful for the promotion of alternative technologies. For example, a provision utilizing the justification principle might also require

that, in the process of justifying the use of radiation, the operator must also weigh the benefits of alternative methods serving the same purpose but utilizing little or no radiation.

Requirements to consider the use of alternative technologies: Provisions of this type compel potential licensees to either use or consider the use of substitutes for certain technologies or processes using radiation. For example, The Radiation Protection Regulations in Norway provide that for non-medical use of radiation, an X-ray apparatus shall be used rather than radioactive sources when practically achievable. Besides the prescription of a specific technology, this set of regulations also encourages the use of alternative technologies by allowing the regulatory body to withdraw an authorization for the use of radioactive sources if the radiation can be significantly reduced or substituted.

Requirements prohibiting or imposing a phase-out of specific sources or technologies: Sometimes a specific technology or application may be expressly prohibited or targeted by a nation's regulator for phase-out. For example, following a 2006 national directive, France phased out cesium blood irradiators at its national transfusion centers, replacing them with x-ray irradiator alternatives. Some countries may approach this type of initiative through voluntary, non-legally-binding means such as with the Cesium Irradiator Replacement Project (CIRP) in the United States.

Requirements on the management of disused radioactive sources: This category of requirements imposes a financial cost on the machine user or on the source supplier for the costs of managing disused radioactive sources. Users may have to demonstrate that they have the financial means to provide for the cost of managing sources at the end of their useful life when applying for an authorization or alternatively may require a "return to supplier" agreement as part of the application. The additional

Requirements for the security of radioactive sources: Laws and regulations impose physical protection requirements for high-activity radioactive sources and include provisions that place the primary responsibility for security on operators. This means that the operator of a facility or end-user of a radioactive source is responsible for the costs associated with physical protection measures. When submitting a licensing application, operators must demonstrate that physical protection requirements will meet all requirements. Some regulations require the submission of a physical protection plan for this purpose. An example of this type of provision is the U.S. regulation 10 CFR Part 37, which establishes physical protection requirements for certain types of radioactive material.

Trade and professional associations

Within certain applications, trade and professional associations have also issued guidance that may be relevant to alternative technology. Some of these associations have an international reach (e.g., the International Organization for Standardization [ISO]), while others are domestic. Although these guidance documents are not legally binding, countries may opt to make them binding through national legislation. Additionally, procurement or construction contracts may require that a certain system or facility follow these standards, which would then become legally binding for a given project.

Trade associations: Trade associations are of particular relevance within the medical field. For example, the French Society of Oncological Radiotherapy has issued a guide on external radiotherapy procedures. Chapter 3 of the guide gives recommendations for infrastructure and equipment performance, as well

as staffing needs for radiotherapy facilities.[24] Although this guidance is not binding under French legislation, French hospitals or medical facilities may voluntarily choose to adopt its recommendations.

Professional associations: ISO and ASTM International (formerly the American Society for Testing and Materials) have issued numerous standards that mainly describe best practices for the operation of devices that use alternative technology, outside of medical patient treatments. These standards often focus on quality control, to ensure consistent device performance or outcomes.

Conclusion

The adoption of alternative technologies is one of the best ways to address the risks posed by high activity radioactive sources and their potential theft and use by terrorists or other bad actors. Unfortunately, a nation embarking on a project to promote and encourage the use of alternative technologies must navigate a complicated web of stakeholders and it is frequently unclear what roles the national government can and ought to play in accomplishing this mission. This paper is not a comprehensive listing of all considerations for a nation but hopefully a useful starting point.

[24] French Society of Oncological Radiotherapy, *Guide des Procedures de Radiotherapie Externe 2007* (2007), https://www.has-sante.fr/jcms/c_685062/fr/guide-de-radiotherapie-des-tumeurs.

Appendix A: International stakeholders and roles

Many governmental and non-governmental organizations throughout the world have expertise or interests relevant to the adoption of alternative technology. Table 1 lists possible international stakeholders and their potential nexus with alternative technology. While this list should not be viewed as exhaustive, it provides a range of organizations that can be leveraged for further investigation into roles and regulations.

Table 1 – Possible international stakeholders for alternative technology.

Organization	Potential Nexus with alternative technology
Federación Internacional de Organizaciones de Donantes de Sangre (FIODS)	Blood donation
Food and Agriculture Organization of the United Nations (FAO)	Food irradiation
International Committee for Non-Destructive Testing (ICNDT)	Non-destructive testing
International Federation of Red Cross and Red Crescent Societies (IFRC)	Blood donation
International Irradiation Association (iia)	Industrial irradiation
International Labour Organization (ILO)	Occupational safety and health
International Organisation for Medical Physics (IOMP)	Health physics
International Plasma Fractionation Association (IPFA)	Blood/plasma donation
International Radiation Protection Association (IRPA)	Radiation protection
International Society of Blood Transfusion (ISBT)	Blood donation
International Source Suppliers and Producers Association (ISSPA)	Radioactive sources
Nuclear Energy Agency of the OECD (NEA)	Radiation protection
Pan American Health Organization (PAHO)	Radiation protection, radiological safety
United Nations Environment Programme (UNEP)	Radiation effects and sources
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)	Radiation exposure assessment and reporting
World Customs Organization (WCO)	Illicit trafficking of radioactive sources
World Health Organization (WHO)	Radiation protection, public health issues related to ionizing radiation

Appendix B: Relevant trade and professional association standards

The ISO and ASTM International have issued numerous standards that focus on quality control, to ensure consistent device performance or outcomes. The following list includes relevant standards by alternative technology application, along with a description of their content.

Blood irradiation: ISO/ASTM 51939:2017

- "This practice outlines the irradiator installation qualification program and the dosimetric procedures to be followed during operational qualification and performance qualification of the irradiator. Procedures for the routine radiation processing of blood product (blood and blood components) are also given. If followed, these procedures will help ensure that blood product exposed to gamma radiation or X-radiation (bremsstrahlung) will receive absorbed doses with a specified range."

Sterilization of medical devices: ISO 11137-1:2006

- This standard provides international recommendations for sterilization of medical devices using radiation.

- ISO 11135:2014
  - This standard provides international recommendations for sterilization of medical devices using ethylene oxide.

Food irradiation: ISO 14470:2011

- This standard gives international recommendations for food irradiation using ^{60}Co or ^{137}Cs, electron beams or X-ray generators, including dose recommendations.

Sterile Insect Technique: ISO/ASTM 51940:2013

- This standard covers international recommendations for radiation dose to be applied when performing the sterile insect technique.

Industrial radiography: Multiple standards issued by technical committee ISO/TC 135/SC 5

- ISO/TC 135/SC 5 has issued multiple standards covering radiographic testing involving both X-ray, gamma ray, and neutron sources (because so many standards exist, the technical committee page is given in lieu of individual links)