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Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or redesigning relevant processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

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Radiation risks of diagnostic imaging

Correction: *The American College of Radiology (ACR) launched its National Radiology Data Registry (NRDR) in 2008. Its Dose Index Registry (DIR), which is part of the NRDR, launched in May 2011 (see fourth paragraph).*

Diagnostic radiation is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.^{1,2,3} Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.⁴ The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.^{1,5,6,7} X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.¹

Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.⁸ Diagnostic imaging can occur in hospitals, imaging centers, physician and dental offices, and any physician can order tests involving exposure to radiation at any frequency, with no knowledge of when the patient was last irradiated or how much radiation the patient received. From the 72 million CT (computerized tomography) scans performed in the U.S. during 2007, one study estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).⁹ Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.¹⁰ While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information.

While experts disagree on the extent of the risks of cancer from diagnostic imaging, there is agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation.⁷ Patients most prone to harm from diagnostic radiation are children and young adults;¹¹ pregnant women;¹² individuals with medical conditions sensitive to radiation, such as diabetes mellitus and hyperthyroidism;⁶ and individuals receiving multiple doses over time.² The diagnostic procedures most commonly associated with avoidable radiation doses are CT, nuclear medicine and fluoroscopy.¹³ This Alert focuses on diagnostic radiation and does not cover therapeutic radiation or fluoroscopy. While fluoroscopy is used diagnostically, there are special issues associated with its use that make it inappropriate to be included here.

As a result of the potential dangers associated with ionizing radiation, the Centers for Medicare & Medicaid Services (CMS) requires the accreditation of facilities providing advanced imaging services (CT, magnetic resonance imaging (MRI), positron emission tomography (PET), nuclear medicine) in non-hospital, freestanding settings, as of January 1, 2012. In addition, the state of California has mandated that facilities that furnish CT X-ray services become accredited by July 1, 2013. In addition, in May, the American College of Radiology (ACE) launched its



[National Radiology Data Registry](#) (NRDR), a warehouse of ACR registry databases that compares radiology facilities regionally and nationwide according to facility type. The fee-for-service registry includes a tool that can be used to target specific areas for improving practice.

Addressing contributing factors to eliminate avoidable radiation dosing

There are actions that organizations can take to eliminate avoidable radiation. First, staff should be aware of the contributing factors to, and activities that can help eliminate, avoidable radiation doses, which include:

- A comprehensive patient safety program, including education about dosing in imaging departments.
- Awareness of the potential dangers from diagnostic radiation among organizational leadership, hospital staff and patients.
- Adequate awareness among physicians and other clinicians about the levels of radiation typically used and related risks.^{1,6,14,15}
- Training on how to use complex new technology.⁴
- Guidance in the appropriate use of potentially dangerous procedures and equipment.¹⁶
- Adequately trained and competent staff.
- Knowledge regarding typical doses.
- Clear protocols that identify the maximum dose for each type of study.
- Consulting with a qualified medical physicist when designing or altering scan protocols.
- Communication among clinicians, medical physicists, technologists and staff.
- Safety, operational and functional checks of the equipment before initial use and periodically thereafter.

Actions suggested by The Joint Commission

Health care organizations can reduce risks due to avoidable diagnostic radiation by raising awareness¹⁷ among staff and patients of the increased risks associated with cumulative doses and by providing the right test and the right dose through effective processes, safe technology and a culture of safety.

Right test

1. In order to reduce the exposure of the patient to ionizing radiation, use other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level.¹⁷
2. Create and implement processes that enable radiologists to provide guidance to and dialogue with referring physicians regarding the appropriate use of diagnostic imaging

using the American College of Radiology's *Appropriateness Criteria*^{®17}

See relevant Joint Commission requirements: LD.04.04.07 (hospital and critical access hospital); LD.04.04.09 (ambulatory)

Right dose

3. Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for "as low as reasonably achievable" – making sure doses are as low as possible while achieving the purposes of the study.¹⁸
4. Adhere to the **Image Gently Alliance's Image Gently**[®] guidelines when providing imaging radiation (or fluoroscopy) to children^{11,19,20} and, for adults, adhere to the *Image Wisely*[®] guidelines (developed by the American College of Radiology and the Radiological Society of North America in collaboration with the American Association of Physicists in Medicine and the American Society of Radiologic Technologists).²²
5. Provide physicians and technologists with reference doses based on anatomy, purpose of the study, and patient size. Establish appropriate dose ranges for high-volume and high-dose diagnostic imaging studies.
6. Radiologists should assure that the proper dosing protocol is in place for the patient being treated.
7. Institute a process for the review of all dosing protocols either annually or every two years to ensure that protocols adhere to the latest evidence.
8. Investigate patterns outside the range of appropriate doses. Track radiation doses from exams repeated due to insufficient image quality or lack of availability of previous studies to identify the causes. Address and resolve these problems through education and other measures.⁴
9. Record the dosage or exposure as part of the study's summary report of findings.

See relevant Joint Commission requirements: LD.04.04.07 (hospital and critical access hospital); LD.04.04.09 (ambulatory)

Effective processes

10. Create and implement policies and procedures delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging. Provide for oversight of these policies and procedures and related activities, including control of the password, by a multidisciplinary group with expertise in radiation (such as a radiation

safety committee), including a medical physicist.⁴

11. Develop and implement policies and procedures that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients, including appropriate lead shielding for both patients and employees and radiation-protection training for all technologists.^{4,21}
12. Expand the radiation safety officer's role to explicitly include patient safety and involve the officer in the organization's patient safety committee.
13. Ensure all physicians and technologists who prescribe diagnostic radiation or use diagnostic radiation equipment receive dosing education and are trained on the specific model of equipment being used.^{4,17,21} Institute a process for annual education, review and competency testing.

See relevant Joint Commission requirements: HR.01.02.01, HR.01.02.05, HR.01.04.01, HR.01.05.03 (all programs), HR.02.02.01 (ambulatory), MS.03.01.01, MS.03.01.03, MS.06.01.03 (hospital)

Safe technology

14. Perform an organization-wide audit/survey of diagnostic imaging equipment that have the potential of emitting high amounts of cumulative radiation (related standard EC.02.04.01 EP 2). Implement a system for centralized quality and safety performance monitoring of this inventoried equipment under the supervision of a qualified medical physicist or your organization's multidisciplinary group with radiation expertise or both. (This equipment may no longer solely be within the province of the radiology department and may be located within a variety of hospital or clinical departments, including the cardiac catheterization suite and the OR. In the ambulatory setting, this equipment may be found in physician or dental offices.)
15. Have a qualified medical physicist test all diagnostic imaging equipment initially and at least annually or every two years thereafter to assure proper installation and calibration, and review scanning protocols and doses.⁴ Such tests should be conducted in accordance with applicable state and federal laws and regulations. Where no such regulations exist, tests should be conducted in accordance with the applicable standards as promulgated by the American Association of Physicists in Medicine.
16. Ensure that recommended quality control, testing (including daily functional tests) and

preventive maintenance activities are performed in accordance with manufacturer's guidelines. The health care organization, in consultation with the medical physicist, should identify in writing these activities, their frequencies, and who will perform them.

17. Invest in technologies that optimize or reduce dose.^{4,19,22,23}

See relevant Joint Commission requirements: EC.02.02.01, EC.02.04.01, EC.02.04.03, EC.04.01.01 - EC.04.01.05 (all programs); EC.02.04.01, EP 7 and EC.02.04.03 EP 15 (ambulatory)

Safety culture

18. Use the following Joint Commission standards to support the use of safe and effective diagnostic radiation: LD.03.01.01, LD.03.04.01, LD.03.05.01, LD.03.06.01 (all programs). The concepts in these standards promote a safety culture, which is necessary for the safe use of diagnostic radiation. A safety culture is expressed in the beliefs, attitudes and values of an organization's employees regarding the pursuit of safety. It is present in the organization's structures, practices, controls, and policies, which are used to achieve greater safety. For more information about safety culture, see [Sentinel Event Alert Issue 57: The essential role of leadership in developing a safety culture](#).
(Note: This alert replaced Sentinel Event Alert 43: Leadership committed to safety).

In addition, The Joint Commission:

19. Endorses the creation of a national registry to track radiation doses as the start of a process to identify optimal and reference doses.^{1,7,16}
20. Encourages manufacturers to incorporate dosage safeguards into equipment and to capture dose information in the patient's electronic medical record and national dose registry.¹³
21. Supports stricter regulations designed to eliminate avoidable imaging and monitor the appropriateness of self-referred imaging studies (referral of a patient to a facility in which the referring physician has a financial interest).¹⁶

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References

- ¹ Amis, Jr. ES, et al: American College of Radiology white paper on radiation dose in medicine. *Journal of the American College of Radiology*, 2007;4:272-284
- ² Holmberg O, et al: Current issues and actions in radiation protection of patients. *European Journal of Radiology*, 2010, doi:10.1016/j.ejrad.2010.06.033
- ³ Smith-Bindman R, et al: Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Archives of Internal Medicine*, 2009;169(22):2078-2086
- ⁴ ECRI Institute: CT radiation dose, *Health Devices*, April 2010;110-125
- ⁵ Koenig TR, et al: Radiation injury to the skin caused by fluoroscopic procedures: lessons on radiation management. Annual Meeting of the Radiological Society of America, 2000
- ⁶ Koenig TR, et al: [Skin injuries from fluoroscopically guided procedures](#). *American Journal of Roentgenology*, 2001;177:3-11 (accessed Nov. 15, 2010)
- ⁷ U.S. Food and Drug Administration, [White Paper: Initiative to reduce unnecessary radiation exposure for medical imaging](#), February 16, 2010, (accessed May 12, 2017)
- ⁸ National Council on Radiation Protection and Measurements: Ionizing radiation exposure of the population of the United States (2009). NCRP Report No. 160, Bethesda, Md., 142-146
- ⁹ Berrington de Gonzales A, et al: Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine*, 2009;169:2071-2077
- ¹⁰ Radiological Society of North America: Exposure to ionizing radiation and estimate of secondary cancers in the era of high speed CT scanning. Presentation to 96th Scientific Assembly and Annual Meeting, December 1, 2010
- ¹¹ Firestone, K: CT dose reduction in pediatric patients. *Radiology Management*, March/April 2011
- ¹² Diagnostic ionizing radiation and pregnancy. Is there a concern? *Pennsylvania Patient Safety Advisory*, March 2008;5(1):3-15
- ¹³ U.S. Food and Drug Administration: [FDA unveils initiative to reduce unnecessary radiation exposure from](#)

[medical imaging](#). FDA news release, February 9, 2010, (accessed May 12, 2017)

¹⁴ Kim C, et al: Radiation safety among cardiology fellows. *American Journal of Cardiology*, 2010;106:125-128

¹⁵ Richardson L: Radiation exposure and diagnostic imaging. *Journal of the American Academy of Nurse Practitioners*, April 2010;22(4):178-185

¹⁶ Baerlocker MO, et al: Radiation safety: have we let the public down? *Journal of the American College of Radiology*, August 2010;7(8):557-558

¹⁷ American College of Radiology: [2017 ACR Appropriateness Criteria](#) (accessed May 19, 2017)

¹⁸ United States Nuclear Regulatory Commission: [ALARA](#) (accessed January 20, 2011)

¹⁹ [The Image Gently Alliance: Image Gently®](#) (accessed May 12, 2017), and [Pause & Pulse: Image Gently in Fluoroscopy](#) (accessed May 12, 2017)

²⁰ Harolds J: Some recent steps taking by private organizations and the federal government to increase the safety of medical imaging. *Clinical Nuclear Medicine*, July 2010;35(7):510-511

²¹ Watson DS: Radiation safety. *Association of periOperative Registered Nurses Journal*, August 2010;92(2):233-235

²² American College of Radiology: [Image Wisely®](#) (accessed January 19, 2011)

²³ Medical Imaging and Technology Alliance: [Nation's CT manufacturers unveil new industry-wide medical radiation patient safety features](#), MITA news release, February 25, 2010, (accessed May 12, 2017)

Resources

[The Joint Commission Standards FAQs on radiation overdose](#) (accessed May 12, 2017)

Patient Safety Advisory Group

The Patient Safety Advisory Group informs The Joint Commission on patient safety issues and, with other sources, advises on topics and content for *Sentinel Event Alert*. Members: Patrick J. Brennan, MD; Todd Bridges, RPh; Michael Cohen, RPh, MS, ScD; Michael El-Shammaa; Frank Federico, BS, RPh; Marilyn Flack; Tejal Gandhi, MD, MPH, CPPS; Martin J. Hatlie, Esq; Robin R. Hemphill, MD, MPH; Paul Kelley, CBET; Heidi B. King, MS, FACHE, BCC, CMC, CPPS; Grena Porto, RN, MS, ARM, CPHRM; Matthew Scanlon, MD; Ronni P. Solomon, JD; Dana Swenson, PE, MBA