Dental X-ray and Mammography Safety

Definition: Radiation safety inspections of dental X-ray offices determine the type of imaging system, provide estimates of patient radiation dose, measure the quality of image processing and evaluate X-ray machine performance. An indicator of unnecessarily high radiation exposure is determined by comparing average estimated patient radiation exposure (entrance skin exposure) from dental intra-oral X-ray procedures to national averages. Mammography facility inspections provide estimates of radiation dose to the breast (glandular dose) and data on image quality score (the ability of the image to show fine detail). Indicators of mammography quality are mean glandular dose and the percent of mammography facilities issued violations for not meeting Food and Drug Administration radiation standards. Image quality score is used as an indicator of the ability of the mammography X-ray system to allow accurate diagnoses to be made.

Summary

The Washington State Department of Health inspects X-ray facilities and equipment to improve safety for patients, the general public and healthcare workers. The goal is to achieve the best diagnostic quality image with the least amount of radiation exposure. Dental intra-oral X-rays and mammography are two common healthcare procedures using X-rays.

Radiation exposure from dental intra-oral X-rays depends primarily on the type of imaging system used. Digital imaging systems result in less radiation exposure than older methods. In Washington, the use of digital systems increased steeply from about 1% in 1998 to about 63% in 2011. The use of D-speed film, which is the slowest speed with the highest radiation exposure, decreased markedly from 78% of Washington dental offices inspected in 1998 to only 26% of Washington dental offices inspected in 2011.

The number of mammography facilities with inspection violations in Washington decreased from 53% in 2002 to 20% in 2005, then increased to a peak of about 70% in 2008. This marked increase was primarily due to intensified Food and Drug Administration (FDA) education of our inspectors and hence more rigorous mammography inspections starting around 2005. As the facilities became more compliant with the federal inspection requirements, the citations came down. In 2011, the violations dropped to about 37%, which is closer to the national average of 30%.

During 1998–2006, the increase in image quality in Washington paralleled a rise in the mean radiation dose. During 2007–2011, the mean dose went down due to the increasing use of digital imaging systems. The average mammographic image quality score continued to rise during the same period.

Introduction

More than 6,150 X-ray facilities operate in Washington. Major fields using X-ray devices are: dentistry, industry, medicine, chiropractic medicine, veterinary medicine, podiatry, academic centers, scientific research organizations and law enforcement agencies. The Washington State Department of Health has inspection programs for most types of X-ray equipment.

X-ray examinations account for much of the public's exposure to ionizing radiation. Regulations and inspections of medical and dental X-ray devices minimize unnecessary radiation exposure and help assure that patients receive the best diagnostic quality images with the least amount of radiation exposure.

This chapter focuses on two common types of X-ray procedures with national comparison values or standards: dental intra-oral radiography and mammography.

Description of Indicators

This chapter discusses radiation dose and type of equipment to assess potential unnecessary radiation exposure from dental X-rays. For mammography, the chapter discusses radiation dose, image quality and national standards. Radiation safety inspectors estimate patient dose by measuring radiation at the point where it enters the patient (entrance skin exposure, ESE). (See Technical Notes for a discussion of radiation measurement units.)

The principles of dose optimization and ALARA (As Low as Reasonably Achievable) apply to both dental X-rays and mammography. The tradeoff between higher radiation dose for better X-ray image quality and lower radiation dose for greater patient safety is termed radiation dose optimization. The ALARA principle states that no level of radiation exposure to the human population is acceptable unless the benefit to the individual and society outweighs the risk of adverse health effects from radiation exposure. This means that the radiation exposure from X-rays must be reduced to the lowest level possible. Radiation dose optimization is synonymous with ALARA. The Department of Health inspectors encourage all healthcare workers to comply with ALARA principles. Radiation dose to patients, healthcare workers and the general public varies depending on the type of equipment; manufacturer, model, age of a given piece of equipment; and factors related to X-ray operator skill. For example:

- Newer digital imaging equipment allows higher quality clinical imaging with lower radiation dose than older analog (film) imaging.
- Newer imaging equipment makes use of automatic exposure control (AEC) technology that automatically adjusts radiation levels to patient size (pediatric to adult) to obtain uniform image quality with the minimal dose. Older equipment that does not have AEC technology requires the operator to manually optimize exposure based on the size of the patient, so optimization varies with operator skill.

State X-ray inspectors measure radiation output of all dental X-ray and mammography machines when assessing X-ray safety in Washington's healthcare facilities.

The department not only measures an individual machine's radiation output but also the percent of facilities that do not maintain acceptable operational safety standards. For example, mammography facilities can be shut down for certain types of violations such as low image quality. The department also reviews construction plans for new or remodeled medical facilities for adequate shielding of scattered radiation to ensure the safety of workers and the general public.

This chapter does not include information on health outcomes. Modern dental and mammography X-ray machines do not cause immediate health conditions due to excessive radiation exposures. An exposure must be nearly 200,000 times greater than a normal dental or mammographic X-ray to cause acute radiation injuries such as burning of the skin and other tissues. Long-term effects, such as increased risk of X-ray radiation-induced cancer, are difficult if not impossible to attribute to modern medical imaging X-ray procedures such as single intra-oral dental X-ray exposures and single mammographic X-ray doses.

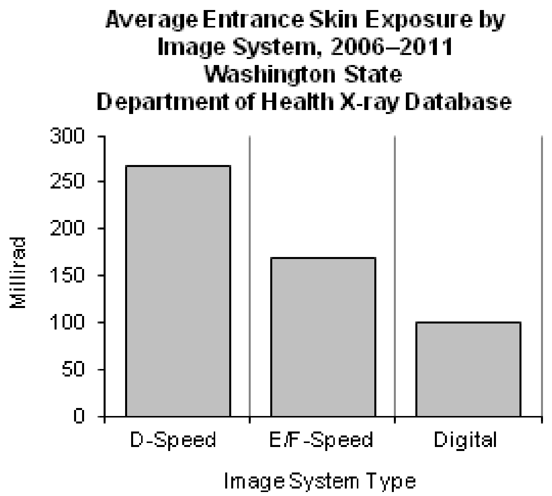
Dental X-ray Exposures

A dental facility provides care of the mouth, teeth, tongue, gums and jaw. More than 3,250 dental X-ray facilities are located in Washington, and the department inspects each one every four to five years to determine if it meets state radiation safety standards.

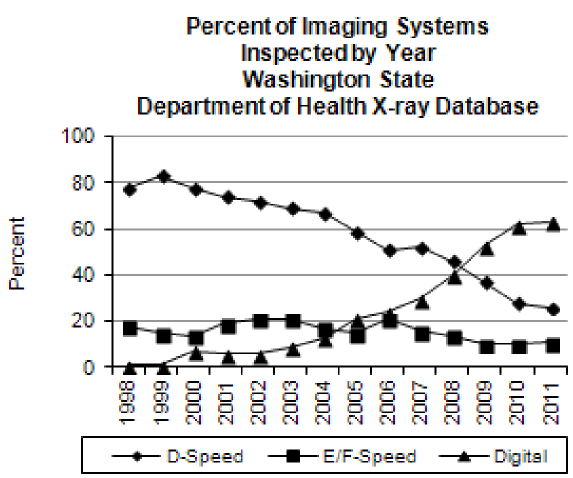
A dental radiation safety inspection determines the type of imaging system (D-speed film, E/F-speed film or digital), estimates patient exposure, measures the quality of the image processing and checks the X-ray machine settings and performance.

Time Trends

Dental image systems using D-speed film, which is the slowest speed film, require higher patient X-ray exposure than E/F-speed film or digital systems. Based on Washington State inspection data during 2006–2011, use of D-speed film resulted in an average entrance skin exposure (ESE) of 274 millirad, while E/F-speed film resulted in average ESE of 161 millirad. Use of a digital system resulted in an average ESE of 99 millirad, a 64% lower patient exposure than D-speed film. These doses have not changed since 1998.



As of 2012, the latest national comparison data for patient exposures from dental intra-oral X-ray procedures was from 1999. Comparing data for 2006–2011, Washington State's average ESE value for D-speed film was 274 millirad, which exceeded the 1999 national average ESE value of 195 millirad. The reason for this difference is not known. Washington's 2006–2011 average ESE value for E/F-speed film, 161 millirad, is close to the 1999 national average ESE value of 148 millirad. A national comparison value for digital X-ray imaging systems is not available.



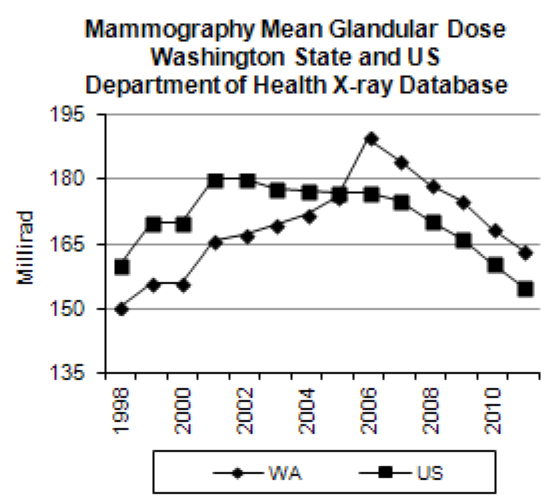
In Washington, the percent of facilities using D-speed film decreased from about 78% in 1998 to about 26% in 2011. In contrast, the use of digital systems rose from about 1% in 1999 to about 63% in 2011. The percent of facilities using E/F-speed film decreased from 18% to 11% during 1998–2011.

Mammography

Screening mammograms detect breast cancer at its earliest, most treatable stage. Consistent with the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention currently recommends routine screening mammography every two years for women ages 50–74. A healthcare provider might begin screening earlier or recommend more frequent screening based on individual circumstances. According to the 2011 Washington Behavioral Risk Factor Surveillance System, 76% (± 2%) of women ages 50–74 reported receiving a mammogram within the past two years, as did 63% (± 5%) of women ages 40–49.

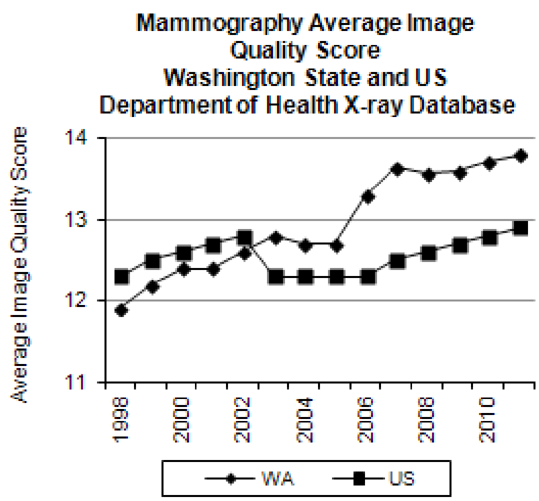
About 150 mammography facilities operate in Washington. Facilities are inspected annually to ensure that standards are met in terms of facility personnel experience and training; X-ray machine performance, including mean glandular dose (patient dose to the breast in units of millirad) and image quality or resolution score (ability to see fine detail); and quality control measures, such as weekly image quality tests. A lower mean glandular dose is not necessarily better, because image quality might suffer if the amount of radiation is not sufficient to ensure a diagnostic-quality image. The image quality score is derived from the number of objects visible in a breast model and indicates the quality of fine detail in the X-ray image.

Time Trends

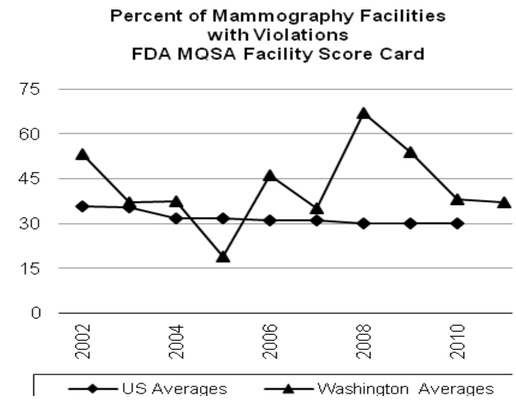


In Washington, the mean glandular dose rose from 150 millirad to 190 millirad during 1998–2006, but was still well below the maximum glandular dose allowed by the FDA (300 millirad). During 2007–2011, Washington's mean glandular dose declined as did the national mean dose. In 2011 the national mean glandular dose was about 154 millirad while Washington's mean glandular dose was 163 millirad. Washington's peak in 2006 is most likely attributable to the mammography clinics' inclination to retain old film machines in anticipation of buying new digital equipment. This peak occurred in 2002 nationally.

From 2006 to 2011, image quality scores, ranging from 0 to 16, steadily increased in Washington State and nationally. Scores did not show consistent patterns of increase or decrease from 1998 to 2005. Washington's average image quality scores increased from 13.3 in 2006 to 13.8 in 2011. The national average was 12.9 in 2011. The improvements since 2006 are primarily due to the change from film to digital imaging systems. FDA requirements for continuing education for practitioners and inspectors might also contribute to the improvements.



From 2002 to 2011, the percent of mammography facilities in Washington State with violations of the Mammography Quality Standards Act (MQSA) standards reached a low of about 19% in 2005 and increased to a peak of about 67% in 2008 before decreasing to about 37% in 2011. The department's X-ray Safety Program reports that the peak in 2008 was primarily due to an FDA education class taken by all Washington State mammography inspectors in 2007. Washington State mammography inspectors subsequently conducted more rigorous and thorough mammography facility inspections. Washington State mammography facilities subsequently achieved higher levels of compliance. The current violation rate reflects a combination of the change to digital imaging systems and the FDA requirements for continuing education for practitioners and inspectors. By 2011, the cited violation rate in Washington State was approaching the national violation citation rate of 30%.



2010 and 2020 Goals

There are no *Healthy People 2010* or *2020* objectives that pertain to X-ray procedures or inspections.

Intervention Strategies

Regulatory and educational strategies seek to produce the best diagnostic quality X-ray images for the least amount of radiation exposure. These strategies involve:

- Routinely inspecting X-ray facilities to assure compliance with relevant radiation safety standards, taking enforcement actions when required and fielding an adequate number of trained inspectors.
- Ensuring X-ray operator competence and certification, proper maintenance of equipment and safe operating procedures.
- Educational outreach to healthcare providers, workers and patients on ways to reduce unnecessary radiation exposure from X-rays and to improve facilities' quality assurance practices. In Washington State, the Department of Health oversees these educational outreach activities in cooperation with the FDA.
- Once inspectors are trained, the FDA requires them to complete continuing education classes annually to keep up with rapid technological advances, such as the move from analog to digital imaging. This facilitates inspectors communicating the latest advances in X-ray

technology to the healthcare community and helping healthcare workers to implement these technologies.

To accomplish these strategies for facilities other than mammography facilities, senior (lead) inspectors in the department train other department inspectors to assess the quality of X-ray imaging procedures. The department purchases new equipment as needed to enable using state-of-the-art X-ray diagnostic equipment to accomplish health industry best practice inspections. Senior inspectors also train other department X-ray inspectors to educate healthcare workers in methods to optimize X-ray image quality with the lowest possible exposure to patients and workers.

The Conference of Radiation Control Program Directors (CRCPD) provides guidance for inspecting most facilities that use X-rays. The department has adopted many CRCPD-suggested state regulations for X-ray techniques and incorporated them into Chapter 246-225 of the Washington Administrative Code (WAC). Having these standards incorporated into the WAC also assists with keeping patient and healthcare worker X-ray exposure for facilities other than mammography facilities as low as reasonably achievable.

The FDA sets mammography quality standards and regulates inspections of mammography facilities. For facilities in Washington, the FDA subcontracts with the Washington State Department of Health for these inspections. The FDA trains and certifies department staff to conduct inspections. Inspectors must maintain certification through a rigorous program of continuing education.

Inspectors issue citations to facilities that do not comply with standards. Facilities must correct those violations within 14 days or risk the loss of federal certification for mammography.

The Intersocietal Accreditation Commission offers voluntary accreditation to certain dental facilities, and the American College of Radiology (ACR) offers voluntary accreditation for hospitals and some clinics that use X-ray equipment including CT scan imaging centers. Most X-ray facilities in Washington State have not sought accreditation but the academic medical centers in the state have obtained accreditation.

See Related Chapters: Female Breast Cancer, Oral Health

Data Sources

Washington State X-ray facility database, 1997-2011

Conference of Radiation Control Program Directors (CRCPD). Nationwide Evaluation of X-ray Trends (NEXT) Tabulation and Graphical Summary of 1999 Radiography Survey, November 2003, CRCPD publication E-03-6

U.S. Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) Facility Score Card, http://www.fda.gov/cdrh/mammographpy/archives/scorecard-statistics-archive.html#0107

U.S. Centers for Disease Control and Prevention, Behavioral Risk Factor and Surveillance System survey, 2004

For More Information

Department of Health X-ray Hotline: (800) 299-9729

Department of Health X-ray website: http://www.doh.wa.gov/CommunityandEnvironment/Radiation/XRay.aspx

Technical Notes

X-Rays are electromagnetic waves emitted from the electron shells of the atom instead of the nucleus. They have no charge and are best shielded by thick layers of lead or steel. X-ray energy may cause an external or internal radiation hazard.[1]

The following paragraphs explain radiation measurement units and how they are used in this chapter.[2]

A **Roentgen i**s a unit of exposure to ionizing radiation. It is that amount of gamma or X-rays required to produce ions carrying one electrostatic unit of electrical charge in one cubic centimeter of dry air under standard conditions. It represents how much ionizing gamma or X-ray radiation enters from the air through the outer skin of a person's body. It is of limited value in assessing health effects of radiation since it is only defined for air.

Rad is a special unit of radiation absorbed dose. It is a measure of ionizing radiation energy absorbed per unit mass (100 ergs/gm) and used for both biologic and non-biologic materials. Dose to biological materials refers to the amount of radiation energy that is actually absorbed per gram of tissues. One rad = 1,000 millirads. The International System of Units (metric system) equivalent of the rad used in most countries other than the United States is the gray (Gy). One Gy = 100 rad and 100 millirad = 1mGy.

REM (Roentgen Man Equivalent) reflects the radiation dose received by the body, after accounting for the potential for biological harm from different types of radiation. To convert rad to rem, the number of rad is multiplied by a number called a quality factor (QF) that reflects the potential for biological damage caused by a given type of ionizing radiation. For beta, gamma and X-ray radiation, the quality factor for soft biological tissues is generally close to one. For some other types of ionizing radiation such as neutrons, protons, or alpha particles, the quality factor to convert rad to rem ranges between 10 and 20.[2] The metric system equivalent unit used for radiation absorbed dose in countries other than the United States is the sievert (Sv). One Sv = 100 rem.

This chapter uses millirad as the unit of measure for both exposure and dose. Technically, millirad is the unit for ionizing radiation absorbed dose, millirem is a unit of dose equivalent and milliRoentgen is the unit used for radiation exposure. In the case of diagnostic X-rays and beta radiation, all three units are essentially equivalent numerically for soft biological tissues. Bone is considered a hard biological material and is more efficient at absorbing X-rays than soft tissues such as muscle and glands. It is noteworthy that Roentgens are not defined for ionizing radiation exposure by radiation other than X-ray and gamma ray radiation in air. This limits the usefulness of Roentgens for describing radiation effects on biological systems.

Film speed used in dental intra-oral imaging systems: The X-ray film speed used for dental intra-oral examinations is D-speed (slowest), E-speed (faster) and F-speed (fastest). The faster the film used, the less exposure the patient experiences. This means a dentist using D-speed film uses more radiation exposure to obtain an X-ray image than if E- or F-speed film or digital imaging were used. It should be noted that E-speed film is no longer available and the difference in speed between E- and F-speeds is small compared to the difference between them and D-speed film. Consequently, data for E- and F-speed are combined in the text and accompanying charts.

The national comparative value for patient exposure from a dental intra-oral examination is found in the Nationwide Evaluation of X-ray Trends (NEXT) documents.[3] NEXT is a federal–state partnership between Food and Drug Administration and the Conference of Radiation Control Program Directors. The national dental intra-oral exam dose assessment was completed by CRCPD in 1999 and is used here for comparison purposes.

The commonly accepted phrase for the average radiation dose to the breast is mean glandular dose rather than average glandular dose. The term “average” rather than “mean” is used elsewhere in this document.

Mammography mean glandular dose: The peak in Washington’s mammography mean glandular dose in 2006 with a nearly 10% jump is mostly attributable to the timing and circumstances related to Washington’s transition from mostly film/screen mammography to full field mammography (FFDM) systems, which are digital. After the number of digital FFDM mammography systems outnumbered the film equipment, Washington’s mean glandular dose started to trend downward and has continued decreasing through 2011.

Acknowledgments

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Endnotes

[1] Washington State Department of Health, Office of Radiation Protection. *Radiation Glossary*. http://www.doh.wa.gov/ehp/rp/radgloss.htm; 2007. Accessed January 2008.

[2] Washington State Department of Health, Office of Environmental Health. *Hanford Health Information Network Glossary*. http://www.doh.wa.gov/hanford/glossary.html. Accessed January 2008.

[3] National Council on Radiation Protection and Measurements. *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States. NCRP Report No. 172.* Bethesda, MD: National Council on Radiation Protection and Measurements (NCRP); 2012.