

SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted changes to the proposed regulations. In addition a report by the State of New Jersey Bureau of X-ray Compliance which can be viewed at <http://www.state.nj.us/dep/rpp/qa/index.htm>, is added to the rulemaking file. These changes in response to comments that were received during the 45-day public comment period, which ended on October 11, 2011 are discussed below.

Proposed subsection 30308.1(a) specifies the quality assurance requirements for each user who develops clinical radiographs with automatic film processors for other than mammographic, dental, or veterinary use. Based on public comments, it appears that these requirements could also be applied to each user who develops clinical radiographs for radiation therapy treatment planning purposes. However, the requirements specified in this subsection are based on standards that would assure the quality of clinical radiographs. Therefore, this proposed subsection is changed to clarify that the requirements apply only to users who develop clinical radiographs for diagnostic purposes.

Proposed subsection 30308.1(a)(6) requires certain records be maintained until the Department has completed its next routine inspection. Based on public comments and on a Department review of its inspection frequency of small businesses, this provision could result in some facilities being required to maintain these records for more than four years. The Department has determined through its inspection experience that maintaining these records for at least one year is sufficient for a user to identify recurring problems and for the Department to determine if a user needs technical assistance with their quality control program. Therefore this subsection is changed to require each user to assure that the specified records are maintained for a minimum of one year from the date the test was performed.

Proposed subsection 30311.1(a) specifies the quality assurance requirements for each user who performs radiographic examinations using intra-oral film systems for dental purposes. Based on public comments, it appears that some veterinary users believe that these requirements could also be applied to them. Therefore, this proposed subsection is changed to indicate that each user using intra-oral film for dental radiography of human beings shall meet the requirements specified in this subsection.

Proposed subsection 30311.1(a)(1) specifies that reference films are selected for daily comparisons of radiographs. Based upon a review by the Department, this requirement is changed to make clear that only one reference film is to be selected for daily comparisons of radiographs. This change, which is made for grammatical purposes, is needed for consistency with subsection 30311.1(a) which provides the requirements for "each user", and not for "users."

Subsection 30311.1(a)(4) specifies that records of the corrective actions are maintained until the Department has completed its next routine inspection. The reason for this record retention requirement is to enable the Department to determine if a user needs technical assistance in maintaining their radiographic quality control program and to aid the user in identifying recurring problems. Based on public comments and on a Department review of its inspection frequency of dental facilities, this provision could result in some dental facilities being required maintain these records for more than six years. Since these records only need to be maintained for one year to achieve the purposes for which this section is being proposed, this subsection is changed to require that each user shall assure that records of corrective actions are maintained for a minimum of one year from the date the corrective action was taken.

Subsection 30311.1(a)(5) specifies the acceptable ranges of entrance exposure values for “E” Speed Film. The California Dental Association pointed out in their public comments that “E” speed film has been largely phased out with “F” speed film becoming the most commonly used high speed film in dentistry. After reviewing of the notes to Table 1, Dental Intraoral (Bitewing) ESE (Entrance Skin Exposure) found on page 3 in the Conference of Radiation Control Program Directors, Inc. Publication E-03-2, Patient Exposure and Dose Guide – 2003, (Reference 3 on page 11 in the Initial Statement of Reasons), the Department agrees with the comment and has made a change to include “F” speed films in the acceptable ranges of entrance exposure values in order to ensure that dental users are using proper film processing techniques.

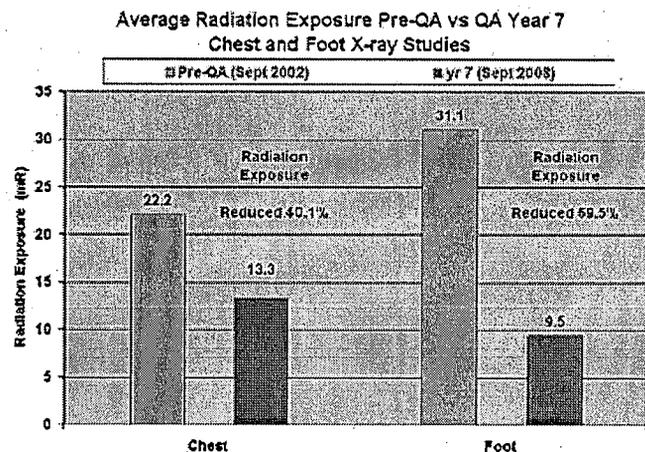
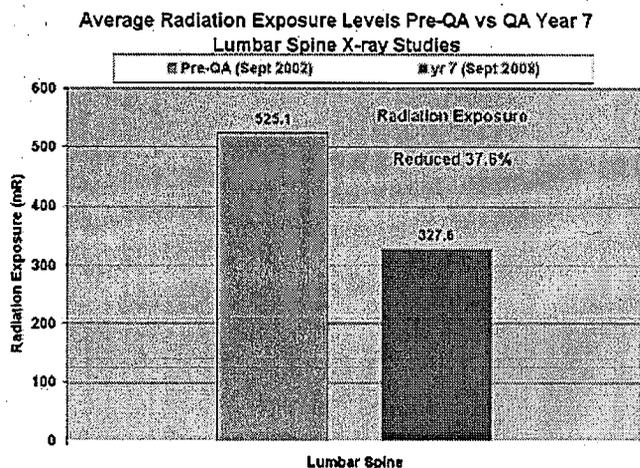
Quality Assurance Program For Medical Diagnostic X-Ray Machines

Introduction

Since 2001, New Jersey medical x-ray facilities have been continuously implementing a quality assurance (QA) program as required by New Jersey radiation protection regulations with the goal of reducing patient radiation exposure while increasing x-ray image quality.

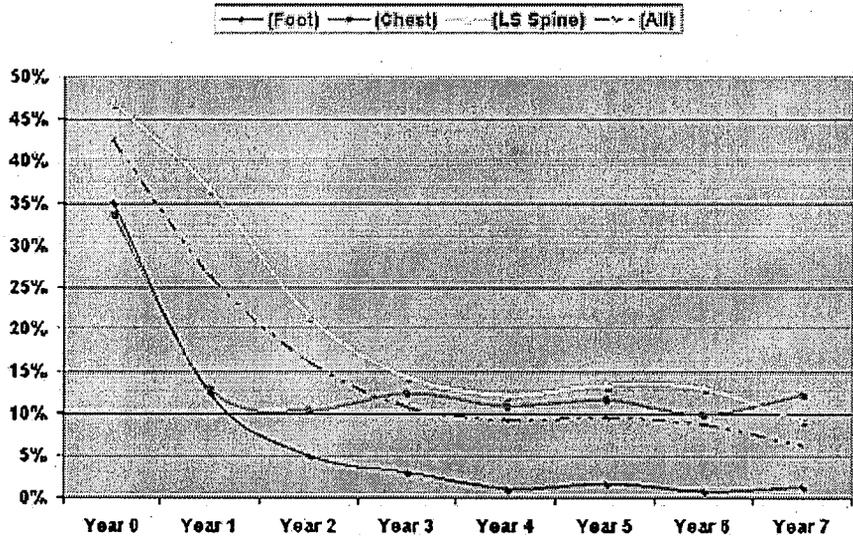
To measure the effectiveness of this program, the Bureau of X-Ray Compliance monitors Entrance Skin Exposure (ESE) and radiographic image quality (IQ) for three commonly performed radiographic exams: AP lumbar spine, PA chest and AP foot.

The Bureau is pleased to report that these efforts have resulted in reduced radiation exposure to patients while simultaneously improving radiographic image quality.



Patient radiation exposure measured as “Entrance-Skin-Exposure” (ESE) and reported as milliroentgens (mR).

Combined High & Extremely High Radiation Exposure By Discipline



Machines that measured high or extremely high radiation have steadily dropped from 42% prior to QA to just 6% in year-seven. Each discipline has demonstrated similar reductions in radiation exposure.

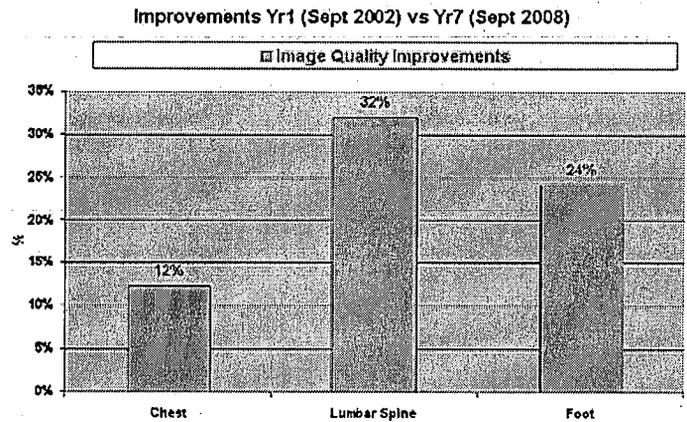
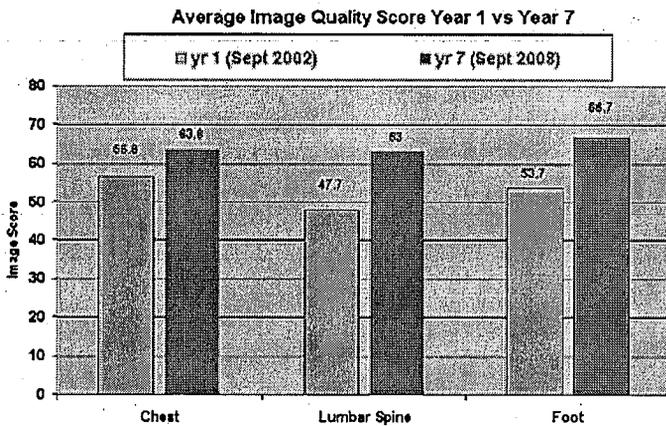
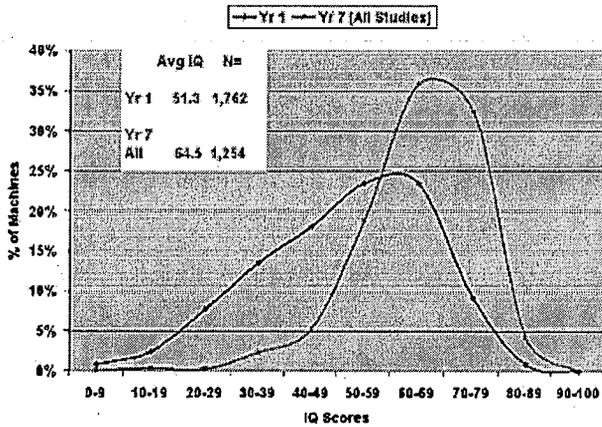


Image quality scores are measured and reported on a scale of zero to one hundred. Image quality scores are determined by the inspector's evaluation of a radiograph taken of an image quality phantom tool and processed using the facility's x-ray film/digital processor. The total image quality score is compiled by the inspector evaluating six areas of image quality including background density, high contrast resolution, low contrast resolution, density uniformity and noise/artifacts. Image quality scores of 0-29 are reported as poor; 30-49 as fair; 50-69 as good and 70 or greater as excellent image quality.

Distribution of IQ Scores Yr.1 vs Yr 7



Violation Rate by Discipline

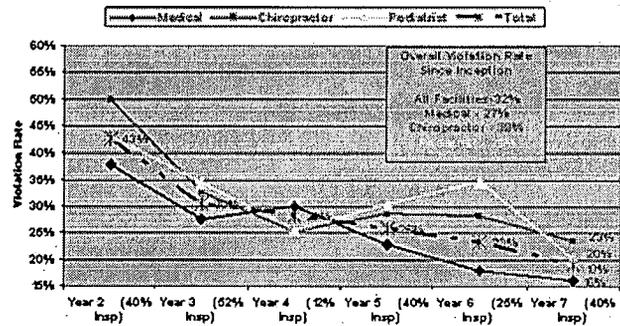


Image quality scores have dramatically improved from year-one to year-seven of the quality assurance program. In year-one, 43% of machines evaluated had image quality scores of 49 or lower. In year-seven, 9% of all machines evaluated had image quality scores or 49 or lower.

The above chart depicts the percentage of facilities in which violations of quality assurance regulations are discovered during inspections. In general, compliance with quality assurance regulations has improved.