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Standard Practice for Digital Radiography of Cast Metallic Implants¹

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1. Scope*

1.1 This practice covers the procedure for digital radiographic testing of cast metallic surgical implants and related weldments.

1.2 Digital X-ray is an alternative method for radiography of cast metallic surgical implants and related weldments (see Practice F629).

1.3 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*³

- E94 Guide for Radiographic Examination
- E192 Reference Radiographs of Investment Steel Castings for Aerospace Applications
- E746 Practice for Determining Relative Image Quality Response of Industrial Radiographic Imaging Systems
- E1030 Test Method for Radiographic Examination of Metallic Castings
- E1316 Terminology for Nondestructive Examinations
- E1742 Practice for Radiographic Examination
- E2007 Guide for Computed Radiography
- E2033 Practice for Computed Radiology (Photostimulable Luminescence Method)

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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³ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

E2660 Digital Reference Images for Investment Steel Castings for Aerospace Applications

E2669 Digital Reference Images for Titanium Castings

F629 Practice for Radiography of Cast Metallic Surgical Implants

2.2 *ASNT Standard:*

ASNT-TC-1A Personnel Qualification and Certification in Nondestructive Testing⁴

3. Terminology

3.1 *Definitions*—For additional terminology, consult Terminology E1316.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *contrast, n*—difference in gray scale level between an area and its immediate surroundings as presented on the final digital radiographic image.

3.2.2 *digital image, n*—image composed of discrete pixels of digital brightness values.

3.2.3 *digital image contrast, n*—range of gray scale values in an image in which a high contrast indicates that the image contains largely black-and-white brightness values with a wide range of gray shades.

3.2.4 *electronic imaging, v*—means of converting the image stored on the imaging plate or detector into a standard video output format.

3.2.5 *electronic imaging system, n*—system that takes data from a storage imaging plate or detector and converts it into a standard analog or digital electronic signal.

3.2.6 *filters, n*—sheets of copper or other material placed in the radiation beam either at the X-ray tube or between the specimen and the detector to improve the quality by selectively removing low-energy radiation from the radiation beam and absorbing scattered radiation.

3.2.7 *gray scale, n*—numeric values representing display brightness.

3.2.8 *gray scale range, n*—range of numeric values representing the brightest and darkest portion of the image display.

3.2.9 *image display parameters, n*—all variables necessary to standardize the video image.

⁴ Available from the American Society for Nondestructive Testing, Inc., PO Box 28518, Columbus, OH 43228-0518, http://www.asnt.org.

*A Summary of Changes section appears at the end of this standard

3.2.9.1 *Discussion*—These include, but are not limited to, brightness, contrast, and linearity.

3.2.10 *image processing, v*—electronic enhancement of the raw image signal to improve fine-detail detectability in the test object and achieve required sensitivity.

3.2.10.1 *Discussion*—These include, but are not limited to, techniques such as noise reduction, contrast enhancement, and spatial filtering.

3.2.11 *image quality level, n*—ability of the inspection system to demonstrate a specific relative image quality indicator (RIQI) sensitivity.

3.2.12 *imaging plate, IP, n*—radiation sensitive detector that is capable of detecting and storing input signal information that can subsequently be converted into a corresponding optical signal.

3.2.13 *IP reader, n*—device capable of retrieving stored information from the imaging plate and converting this information into digital data for subsequent viewing on a video monitor.

3.2.14 *masking, n*—lead or other high-density material placed on or around a test object during exposure for the purpose of minimizing the effect of secondary or scattered radiation.

3.2.15 *material thickness, n*—shall be the nominal thickness or actual thickness if measured at the area being radiographed.

3.2.16 *National Institute of Standards and Technology, NIST, n*—federal technology agency that develops and promotes measurements, standards, and technology.

3.2.17 *nondestructive inspection (NDI) procedure, n*—written set of instructions that identify equipment standardization, parameters, and setup for conducting a non-destructive test or inspection.

3.2.17.1 *Discussion*—The procedure may be broken into the following two parts: a general procedure that has the basic instructions on performing an inspection and a technique sheet that has the detailed instructions for specific parts.

3.2.18 *penetrameter, n*—strip of material of the same or similar composition as that of the material being examined representing a percentage of section thickness and provided with a combination of steps, holes, or quality levels.

3.2.18.1 *Discussion*—When placed in the path of radiation, the resultant radiographic image demonstrates the quality of the radiographic technique. It is also known as an image quality indicator (IQI). It is not intended for use in judging the size or for establishing acceptance limits of discontinuities.

3.2.19 *penetrameter sensitivity, n*—indication of the ability of the radiographic process to show: (1) the difference in material thickness by exhibiting a difference of radiographic contrast and (2) detail definition by the resolution of holes of a specific size.

3.2.20 *pixel, n*—smallest unit of storage in a digital image that can be discretely controlled by the display system.

3.2.20.1 *Discussion*—A pixel is described by its horizontal and vertical location within a digital matrix.

3.2.21 *pixel intensity value, PV, n*—see Practice E746 for description and discussion.

3.2.22 *quality level 2, n*—quality level designation in which the 2T hole is visible in a 2 % penetrameter; previously known as 2–2T sensitivity.

3.2.23 *radiation source, n*—machine or radioisotope that emits penetrating radiation.

3.2.24 *radiographic image, n*—visible image produced by the penetration of radiation through the material being tested.

3.2.25 *radiographic inspection, n*—use of penetrating radiation source to detect discontinuities in material by presenting their images on a recording medium suitable for interpretation by qualified personnel.

3.2.26 *radiographic quality level, n*—ability of a radiographic procedure to demonstrate a certain penetrameter sensitivity.

3.2.27 *recording media, n*—recording media and storage format for mandatory radiographic image storage.

3.2.28 *recording medium, n*—detector that converts radiation into a visible image or a signal that can be transformed into a visible image at a later date.

3.2.28.1 *Discussion*—Also known as an *imaging plate*.

3.2.29 *relative image quality indicator, RIQI, n*—image quality measuring device that is capable of determining meaningful differences between two or more radiographic imaging systems or changes of individual components of radiographic imaging systems.

3.2.30 *sensitivity, n*—general or qualitative term referring to the size of the smallest detail that can be seen on the imaging display or recording medium or both or the ease with which details can be seen.

3.2.31 *technique, n*—category within a method, for example, digital radiographic testing or fluorescent penetrant inspection.

3.2.32 *technique card, n*—detailed, written instructions (may be in the form of a sheet, card, or other documentation) that supplement the instructions of a general procedure.

3.2.33 *test object, n*—material, component, or assembly that is the subject of the radiographic examination.

3.2.34 *X-ray control number, n*—inspection serial numbers or code letters used to provide traceability.

4. Significance and Use

4.1 The requirements expressed in this practice are intended to control the quality of the digital radiographic image of cast metallic surgical implants.

5. Radiographic Methods

5.1 The radiographic method shall be agreed upon between the purchaser and supplier but should be in accordance with Test Method E1030, Guides E94 and E2007, and Practice E2033.

5.2 *Frequency and Coverage*—The number of components inspected (frequency) and the coverage of each component shall be mutually agreed upon between the supplier and the