



Standard Practice for Digital Radiography of Cast Metallic Implants¹

This standard is issued under the fixed designation F2895; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

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.

Current edition approved May 15, 2015. Published June 2015. Originally approved in 2010. Last previous edition approved in 2010 as F2895 – 10. DOI: 10.1520/F2895-15.

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

customer. If the amount of inspection is not specified, all castings requiring radiographic inspection shall receive 100 % radiographic coverage. The orientation of the radiation beam and the number of exposures for any casting shall be governed by the test object geometry, the probable size and location of the various types of discontinuities to be detected, and the requirements of the applicable specifications and drawings.

5.3 Image Quality Indicators (IQIs)—IQIs shall preferentially be from material of the same composition or radiographically similar material as the object to be radiographed, except that IQIs of less dense material may be used in lieu of high-density penetrameters (that is, stainless steel in place of nickel). Undersized IQIs may be used in lieu of proper thickness size.

5.4 IQIs and blocks shall be used and procured in accordance with Practice E1742. The supplier shall certify compliance with respect to alloys and dimensions.

5.4.1 In some cases components created from alloys that have a high degree of grain diffraction may in certain size ranges be difficult to image the 2T on cast IQI blocks. In that situation the radiographic system shall be validated using specimens that contain a known discontinuity.

5.5 Energies between 250 and 400 kV may be required to radiograph surgical implants with a 12.7 mm [$\frac{1}{2}$ in.] or greater material thickness.

5.6 Computed Radiography (CR)—Uses very similar equipment to conventional radiography except that in place of a film to create the image, an imaging plate (IP) made of photostimulable phosphor is used. The imaging plate housed in a special cassette and placed under the body part or object to be examined and the X-ray exposure is made. The imaging plate is then run through a special laser scanner, or CR reader, that reads and digitizes the image. The digital image can then be viewed and enhanced using software that has functions very similar to other conventional digital image-processing software, such as contrast, brightness, filtration and zoom.

5.7 Digital Radiography (DR) or (DX)—Referred to as filmless X-ray image capturing. In place of X-ray film, a digital image capture device is used to record the X-ray image and make it available as a digital file that can be presented for interpretation and saved as part of a permanent record. DR allows the user to immediately preview the image. A wider dynamic range makes it more forgiving for over- and under-exposure; as well as the ability to apply special image processing techniques that enhance overall display of the image.

5.8 When required a gage repeatability and reproducibility study may be required on personnel and equipment. The results of the study must show equivalence between the film image and the digital image.

6. Sensitivity Requirements

6.1 Unless otherwise specified, the required image quality level shall be 2, previously known as 2–2T sensitivity per Practice E1742. This shall be demonstrated by the ability of the radiographer to discern the 2T hole on the required penetrameters.

6.2 IQI Coverage and Area of Interest—IQIs shall be included in all radiographic images for product acceptance. Each IQI shall represent an area of interest in which radiographic pixel values are within 15 % of the pixel value measured through the body of the IQI.

6.3 Penetrameter material selection shall be based on Practice E1742.

7. Metallurgical Requirements

7.1 The product acceptance and rejection criteria shall be as agreed upon between the purchaser and supplier.

7.2 The mutually agreed upon acceptance or rejection limits shall use ASTM reference radiographs E192 or digital reference images E2660 or E2669.

8. Personnel Certification

8.1 The personnel performing radiography under this practice shall be certified in accordance with ASNT–TC–1A or a recognized national equivalent.

8.2 The personnel performing radiographic interpretation shall be certified Level II or Level III individuals, or equivalent, in accordance with ASNT–TC–1A or a recognized national equivalent.

9. Report and Storage

9.1 A certified report shall be maintained showing radiographic test results including any rejected pieces. The report content when required shall be agreed between purchaser and supplier.

9.2 The archived radiographic image may be reproduced, re-recorded, or transferred to another storage media provided the quality level of the reproduction is the same image quality as that used to disposition the casting initially.

9.3 Storage of digital images shall be in a format as agreed upon between the purchaser and supplier.

9.4 Reports and radiographs, or an equivalent digital image of a radiograph, shall be maintained by the purchaser, or as agreed upon between purchaser and supplier.

10. Keywords

10.1 cast metallic surgical devices; cast metallic surgical implants and weldments; computed radiography; digital image; digital radiography; digital x-ray; electronic imaging; implants; NDT; NDTE; nondestructive testing

APPENDIX**(Nonmandatory Information)****X1. RATIONALE**

X1.1 The acceptance criteria for the digital radiographic examination of cast metallic surgical implants and related weldments are based on reference radiographs presented in Reference Radiographs **E192**, or digital reference images **E2660** or **E2669**.

X1.2 Cobalt-, iron-, and titanium-based surgical implant castings may be digital radiographically examined according to the procedures referenced in this practice.

X1.3 Radiography of cobalt- or iron-based surgical implant castings may create radiographic images resulting from grain diffraction. Radiographic techniques shall be used to ensure differentiation between these images and actual discontinuities.

X1.4 Generally, cobalt- or iron-based surgical implant castings require radiation energies higher than normal, facilitating reduced exposure times.

X1.5 In some instances, filters, at the tube head, and relatively thick lead-intensifying screens may reduce grain diffraction while sustaining adequate radiographic sensitivity.

X1.6 Multiple radiographic exposures in which the implant is rotated between 5 and 180°, relative to the detector, may help reduce grain diffraction. Additionally, multiple radiographic exposures in which the detector is moved relative to the central ray of radiation also help to change the diffraction pattern.

X1.7 Radiography of titanium-based surgical implant castings may create a general mottled image. However, standard low-energy radiation should produce acceptable sensitivity.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2895 – 10) that may impact the use of this standard. (Approved May 15, 2015.)

- (1) Revised **3.2.4**, **3.2.5**, **3.2.10**, **3.2.23**, and **3.2.25** to clearly define digital terminology.
- (2) Added **5.4.1** to address grain diffraction concerns.
- (3) Added the phrase “or greater” to **5.5**.

- (4) Correctly referenced digital reference images in **7.2**.
- (5) Revised **X1.1**, **X1.3**, **X1.4**, and **X1.6** to correctly reference digital terminology.

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