INTERNATIONAL STANDARD

ISO 3665

Second edition
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Photography — Intra-oral dental radiographic film — Specification

Photographie — Film pour la radiographie dentaire intrabuccale — Spécifications

Reference number
ISO 3665:1996(E)

Introduction

The principal changes in this revision of ISO 3665 pertain to speed, safelight sensitivity and two added film sizes.

Speed is determined by measurements expressed in grays rather than coulombs per kilogram of air. This change in units was made to adopt the recommendation of the International Commission of Radiation Units and Measurements to use the gray as a measure of absorbed X and gamma radiation as opposed to coulombs per kilogram of air (a unit which simply measures ionization). The constant in the equation for determining speed and the limits for the speed groups have been correspondingly changed so that the classification of products by speed in this International Standard essentially remains unchanged.

Manufacturers are now required to specify a suitable safelight screen or filter to be used with the product. This enables an "ISO safelight condition" as described in ISO 8374 to be realised; i.e. a safelight condition that will provide no measurable or visible effect upon a sensitized emulsion.

The conditions of the storage test have been kept unchanged from the first edition of ISO 3665, and are in line with long established and proven testing conditions in the photographic industry. The storage test is primarily a test to determine the degree of sensitometric changes that might result from normal transient conditions which could be encountered during shipment and storage. Although the 70 % relative humidity conditions stated in this International Standard are beyond those suggested for storage by most manufacturers, experience has shown that such conditions, on a transient basis, would still allow for acceptable diagnostic radiographs. This test allows for the measurement of the sensitometric effects of such transient conditions.

A storage abuse test for abnormal conditions has been added as annex A.

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Photography — Intra-oral dental radiographic film — Specification

1 Scope

This International Standard establishes a system for the classification of intra-oral radiographic film by the speed of the film/process system and by the size of the film. It specifies the sensitometric characteristics of the film/process systems and the physical characteristics of the film and packets; it also describes packaging and labelling requirements.

This International Standard is applicable to intra-oral dental radiographic film for manual or automatic processing. It does not apply to films intended to be exposed with fluorescent intensifying screens, or films intended to be viewed primarily by reflected light.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1:1975, *Standard reference temperature for industrial length measurements.*

ISO 5-2:1991, *Photography — Density measurements — Part 2: Geometric conditions for transmission density.*

ISO 543:1990, *Photography — Photographic films — Specifications for safety film.*

ISO 554:1976, *Standard atmospheres for conditioning and/or testing — Specifications.*

ISO 5799:1991, *Photography — Direct-exposing medical and dental radiographic film/process systems — Determination of ISO speed and ISO average gradient.*

ISO 8374:1986, *Photography — Determination of ISO safelight conditions.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 packet: Receptacle containing one or more radiographic films intended primarily for intra-oral use.

3.2 package: Receptacle containing multiple packets.

3.3 gray (Gy[1]): That dose of X and/or gamma radiation absorbed by 1 kg of air which imparts 1 J of initial kinetic energy to those charged particles which it produces.

4 Classification

4.1 ISO speed groups

The ISO speed of the film/process system shall be designated in terms of speed groups as specified in ISO 5799 and given in table 1.

Table 1 — ISO speed groups

ISO speed group	ISO speed range[1] $(Gy \times 10^2)^{-1}$
C	7,0 to 13,9
D	14,0 to 27,9
E	28,0 to 55,9
F	56,0 to 111,9

4.2 ISO size numbers

The size of intra-oral radiographic film shall be designated in terms of ISO size numbers as given in table 2.

Table 2 — Film sizes

Dimensions in millimetres

ISO size number	Dimensions of film (tol. ± 0,5)	Approximate radius of corners (tol. ± 2,0)
0	22,0 × 35,0	6
1 A	24,0 × 30,0	6
1	24,0 × 40,0	6
2[1]	30,5 × 40,5	6
3	27,0 × 54,0	6
4	57,0 × 76,0	8
4 A	54,0 × 70,0	8
5	40,0 × 50,0	8

1) The former size of 31 mm × 41 mm is, in practice, cut to 30,5 mm × 40,5 mm.

5 Requirements

5.1 General

5.1.1 Each packet shall contain one or more sheets of radiographic film, a sheet of lead foil or other material with equivalent X-ray attenuation characteristics, together with components which limit film bending and provide a light-tight enclosure.

1) 1 Gy = 1 J/kg of air (equivalent to 114,5 R or to 0,029 5 C/kg).

5.1.2 The covering of the packets shall have high visibility under the recommended safelight illumination, shall be resistant to the ingress of moisture, and shall be able to be disinfected with a liquid disinfectant.

5.1.3 Edges of the packets shall be smoothly rounded and sufficiently blunt to avoid the sensation by the patient that the film packet is cutting into his/her mucosa.

5.1.4 Each packet shall be provided with a means for easily unwrapping the film.

5.1.5 The lead foil or other equivalent material shall be positioned on that side of the film intended to face away from the radiation source.

5.1.6 The film shall be of the safety type as defined in ISO 543 and shall be housed within the light-tight enclosure.

5.2 Identification of the irradiated side of the packet

Each packet shall have an indicator that tells which side should face the radiation source. An embossed dot, located near the edge of the film, is the preferred method of identification. Its raised portion indicates the side facing the radiation source. This is usually combined with a second means of identification on the side not facing the radiation source, such as a coloured tab with or without the words “opposite side toward tube”.

5.3 Identification of the radiation side of the processed film

The film shall have an indicator at or near one edge denoting the side intended to be towards the radiation source. A preferred means is an embossed dot with the raised portion indicating the irradiated side.

5.4 Uniformity

The film shall exhibit a uniform response to radiation.

5.5 Evaluation before elevated temperature storage test

The base plus fog density of films of speed groups C and D shall be less than 0,25.[2)]

The base plus fog density of films of speed groups E and F shall be less than 0,35.

The ISO speed shall be within the designated ISO speed group of the film.

The ISO average gradient shall be greater than 1,50.

5.6 Evaluation after elevated temperature storage test

The base plus fog density of films of speed groups C and D shall be less than 0,30.[2)]

The base plus fog density of films of speed groups E and F shall be less than 0,40.

The speed and average gradient shall not differ by more than 20 % from the ISO speed and ISO average gradient values, as determined before the elevated temperature storage test.

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2) A manufacturer's recommended monobath process may produce an increase in fog value of 0,05.

5.7 Safelight sensitivity

When testing a film by means of the procedures described in ISO 8374, no portion of the film exposed to a safelight shall have any visible or measurable difference in density when compared to that portion not exposed to the safelight.

5.8 Packet and lead foil dimensions

The thickness of unprocessed film shall not be greater than 0,25 mm.

The thickness of the lead foil shall not be less than 0,05 mm. If a lead-equivalent material is used, then the thickness of the material used shall provide attenuation at least equivalent to 0,05 mm of lead.

NOTE 1 It is recommended to collect lead foils during processing for environmentally safe recycling or disposal.

The maximum length or width of the packets shall not be more than 4,0 mm greater than the corresponding length or width of the film. This does not apply to any holding tab attached to the packet.

The maximum thickness of the packet shall be 2,0 mm. For interproximal film, the Bite wing[3] tab shall have a minimum length and width of 20 mm.

6 Sampling, inspection and testing

6.1 Sampling

At least six unopened packages of film packets shall be obtained for testing. It is recommended that each test be performed on samples from three separate packages, but a further three packages will also be required for testing to be performed on unopened packages subjected to an elevated temperature and humidity storage test.

Approximately 50 packets will be needed from each package for testing. Should a product be supplied with fewer packets per package, then a proportionately larger number of packages shall be obtained for testing.

The elevated temperature and humidity storage test shall be initiated not later than 6 months prior to the expiry date. All testing shall be completed prior to the expiry date. The films shall be stored in accordance with the manufacturer's recommendations, with the exception of those required for the elevated temperature and humidity storage test.

6.2 Inspection

Visual inspection shall be used to determine compliance with 5.1 and 5.2.

6.3 Testing

6.3.1 Base plus fog density, ISO speed and ISO average gradient

Three independent determinations of base plus fog density, ISO speed and ISO average gradient shall be made by the methods described in ISO 5799, using film from at least three separate packages.

For base plus fog density, each film shall comply with the requirements given in 5.5.

For ISO speed and ISO average gradient, take the average of the three determinations as the test result. Each determination, however, shall not differ from the average by more than ± 20 %.

ISO speed groups shall be determined in accordance with 4.1.

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3) Bite wing is a trademark of Eastman Kodak Company.

6.3.2 Elevated temperature storage

At least one unopened package of film packets shall be kept for 90 days at 32 °C ± 2 °C, at a relative humidity of (70 ± 5) % and at a maximum background radiation of $8,7 \times 10^{-2}$ μGy/h.

6.3.3 Size numbers

The length, width and corner radius of a film from three separate film packages shall be measured by means of a ruler with 0,5 mm calibrations, or by other means of at least equivalent accuracy.

ISO size numbers shall be determined from table 2.

Each film shall correspond to an ISO size number and its package shall be marked as indicated in 7.2.

6.3.4 Conditions for measurement of dimensions

The dimensions and tolerances specified in this International Standard apply at the time of manufacturing, measured under atmospheric conditions of 23 °C ± 2 °C and (50 ± 5) % relative humidity, as specified in ISO 554. All measuring instrument calibrations shall be referred to a temperature of 20 °C (as specified in ISO 1) and a relative humidity of 50 %.

6.3.5 Squareness and edge straightness

Squareness, edge straightness, shape and compliance with specified dimensions shall be checked at the same time by comparison of any given film with two perfect rectangles, independently located: one made to the minimum dimensional tolerance specified in this International Standard, and the other to the maximum tolerance. No point on the perimeter of the film shall fall within the smaller rectangle, nor shall any point fall outside the larger rectangle.

6.3.6 Uniformity

A film packet from three separate packages shall be exposed and processed in accordance with the methods of ISO 5799 to produce an ISO standard visual diffuse transmission density of 1,0 ± 0,3 above fog and base on the film measured in accordance with ISO 5-2.

The films shall be evaluated visually on a uniformly illuminated film viewer. Each film shall comply with the requirements given in 5.4.

6.3.7 Safelight sensitivity

Safelight sensitivity shall be determined by the methods described in ISO 8374.

A set of films from at least three separate packages shall be exposed in accordance with ISO 5799 by the same technique as used in 6.3.1 for determination of ISO speed and ISO average gradient.

After removal of the films from the packets in total darkness, approximately one-half of each film shall be covered by an optically opaque material and then exposed to the safelight set-up under test, using the type of safelight filter recommended by the manufacturer.

The films shall be processed in accordance with ISO 5799.

The ISO standard visual diffuse transmission density of the covered and uncovered portion of each film shall be measured in accordance with ISO 5-2. Alternatively, each film shall be inspected for a visible line of demarcation between the covered and uncovered portions.