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Photography — Intra-oral dental radiographic film — Specification

Photographie — Film pour la radiographie dentaire intrabuccale — Spécifications

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FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO Member Bodies). The work of developing International Standards is carried out through ISO Technical Committees. Every Member Body interested in a subject for which a Technical Committee has been set up has the right to be represented on that Committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the Technical Committees are circulated to the Member Bodies for approval before their acceptance as International Standards by the ISO Council.

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It has been approved by the Member Bodies of the following countries :

Australia	Italy	Spain
Belgium	Japan	Switzerland
Canada	Mexico	Turkey
France	Philippines	United Kingdom
Germany	Romania	U.S.A.
Ireland	South Africa, Rep. of	U.S.S.R.

No Member Body expressed disapproval of the document.

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Photography — Intra-oral dental radiographic film — Specification

1 SCOPE AND FIELD OF APPLICATION

This International Standard establishes a system for the classification of intra-oral dental radiographic film by ISO speed groups and sizes; specifies physical and sensitometric characteristics of the film and film packets made therefrom; lays down the sampling, inspection and testing procedures used in checking compliance, and the packaging and labelling requirements to be met in order to safeguard delivery and identification at the point of use. Supplementary information and instructions relating to storage, processing and use of the product and which the manufacturer is to provide in or on each package of film packets, are included.

This International Standard is applicable to intra-oral dental radiographic film coated on one or both sides with emulsion, for manual or automatic processing, but excluding films for "in-packet" processing and colour films.

2 REFERENCES

ISO 5, *Photography — Determination of diffuse transmission density.*¹⁾

ISO 543, *Cinematography — Motion-picture safety film — Definition, testing and marking.*

3 CLASSIFICATION

Intra-oral dental radiographic film shall be classified by the following ISO speed groups and sizes.

3.1 ISO speed groups

The ISO speed groups of intra-oral dental radiographic film shall be as given in table 1.

TABLE 1 — ISO speed groups

ISO speed group	ISO speed range* (in reciprocal röntgens)
C	6,0 to 12,0
D	12,0 to 24,0
E	24,0 to 48,0
F	48,0 to 96,0

* The upper limit of each ISO speed range shall be excluded from that range.

NOTE — Use of ISO speed group C films has been prohibited by a regulatory agency in at least one ISO Member Body's country, as a means of minimizing exposure of patients to radiation. Similar prohibitions may be applied elsewhere. Eventual deletion of group C films from this International Standard may be anticipated.

3.2 Film sizes

The film sizes of intra-oral dental radiographic film shall be as given in table 2.

TABLE 2 — Film sizes

Size number of dental films*	Dimensions of film**	Approximate radius at corners
	mm (tol. \pm 0,5)	mm (tol. \pm 2,0)
0	22,0 \times 35,0	6
1	24,0 \times 40,0	6
2	31,0 \times 41,0	6
3	27,0 \times 54,0	6
4	57,0 \times 76,0	8
5	40,0 \times 50,0	8

* Either a prefix or suffix "W" is used to indicate that the film has a bite-wing tab.

** Shorter dimension is given first.

1) This referenced International Standard defines and specifies techniques for the measurement of diffuse transmission densities (optical rather than mass densities) of processed black-and-white photographic films and plates. For simplicity in presentation, the abbreviated term "density" is substituted for "diffuse transmission density" throughout this International Standard.

The lengths of the diagonals of the quadrilateral based on the film shall be not greater than the diagonal length of a maximum true rectangle or less than a minimum true rectangle based on the dimensions and tolerances given in table 2.

3.3 Film packet size and thickness

The maximum length or width of the packets shall be not more than 3,5 mm greater than the maximum length or width of the film as specified in 3.2. The corners of the packet shall be rounded off smoothly to a radius appropriate to the corner radii given in table 2. The thickness of the packets, excluding the corners, shall be not more than 1,5 mm.

4 REQUIREMENTS

4.1 General

The film shall consist of a transparent base, uniformly coated with an X-ray sensitive emulsion on one or both sides, and shall be adequate for dental radiographic purposes.

4.2 Base

The base shall be of the safety type as defined in ISO 543.

The base shall be reasonably free from manufacturing defects. The thickness of the base shall be not more than 0,23 mm. Near the edge of the film there shall be an embossed dot, the raised portion of which shall indicate the tube side of the packet. For single-coated films the emulsion-coated side shall be towards the tube side of the packet.

4.3 Emulsion

After exposing to X-rays sufficiently to produce a density of $1,0 \pm 0,3$ on processing, the emulsion shall be seen to be of uniform response and evenly coated when viewed normally on a uniformly illuminated X-ray film viewer. The inherent fog of the emulsion shall be determined as specified in 5.3.1, comparing the density of a processed unexposed film with that of an unexposed and undeveloped film from the same package which has been fixed, washed and dried only and shall not exceed the limits specified in 4.4. The ISO speed and average gradient of the film (the slope of the characteristic curve at the points specified in the annex) shall be determined by the appropriate methods given in the annex. The ISO speed group shall be as indicated in 3.1 and the average gradient shall be not less than 1,5.

4.4 Density, base and fog

The density of the base, after fixing as described in 5.3.1.2, shall not exceed 0,20; that of the film after processing according to 5.3.1.1, shall not exceed 0,15 above base. The density of that portion of the film exposed to the safelight according to 5.3.1.3 shall be not more than 0,05

greater than the density of the unexposed portion. The values of density referred to herein shall be determined in accordance with ISO 5. All the density readings on any particular specimen shall be made on the same instrument.

4.5 Fog density, ISO speed and average gradient after keeping for 3 months

The fog density of the film, when tested as described in 4.4 and after storage for 3 months in the unopened regular commercial package in air of $70 \pm 5\%$ relative humidity at $32 \pm 2^\circ\text{C}$ and at a maximum background radiation of $10 \mu\text{R/h}$, shall be not more than 0,20 above base. The ISO speed (as defined in A.5) and average gradient (as defined in A.6) of the film after storage in the foregoing environment shall not differ by more than 20 % from the original ISO speed and average gradient.

4.6 Film packet

Dental radiographic film shall be made up in packets, adequately flexible for the intended use. Each packet shall contain a sheet of lead foil not less than 0,050 mm thick, or other equally flexible material with equivalent X-ray attenuation characteristics as measured at 90 kV peak. The foil or other material shall be located on the side of the film away from the tube. The film shall be placed between sheets of black paper or other lightproof flexible sheets. The covering of the packet shall be readily visible in the safelight illumination in the darkroom. It shall be slip resistant on the side facing the radiation source. The covering of each size of "W" (see 3.2) film shall have a tab on the side facing the radiation source so that the patient may hold the film in the proper position. Each packet shall be provided with means for easy unwrapping of the film.

The covering of the packet shall give the following information: the manufacturer's trade name; the ISO film speed designation; the number of films in the packet; the location of the embossed dot.

5 SAMPLING, INSPECTION AND TESTING PROCEDURES

5.1 Sampling

The method of procurement and the amount of film needed for testing shall be the subject of agreement between the parties concerned.

5.2 Inspection

Visual inspection shall be used in determining compliance with the requirements outlined in 4.1 and clause 6.

5.3 Tests

5.3.1 Fog and safelight conditions

The inherent fog of the emulsion and the response of the emulsion to light encountered in standard processing

rooms equipped with appropriate safelight filters shall be determined as follows :

5.3.1.1 PROCESSING UNEXPOSED FILM

One unexposed film shall be processed in total darkness under the applicable conditions as given in the annex.

5.3.1.2 FIXING UNEXPOSED AND UNDEVELOPED FILM

One unexposed and undeveloped test film shall be immersed in water for 1 min and then immersed in fixer until completely cleared and shall then remain in fixer for an additional 5 min. It shall be subsequently washed and dried.

5.3.1.3 EXPOSURE OF FILMS TO SAFELIGHT

The safelight screen and the wattage used shall be in accordance with the film manufacturer's recommendations. The unexposed test film, with one-half covered with opaque material, shall be positioned parallel to and 1225 ± 10 mm directly in front of the filter. The filter shall be 90 ± 5 mm in front of the safelight. The test film shall be exposed to the light from the safelight for $5 \text{ min} \pm 5 \text{ s}$. Processing shall be in accordance with details given in the annex. If a different filter-film distance is used, it shall be not less than 750 ± 10 mm subject to the exposure time being amended in accordance with the inverse square law.

5.3.2 ISO speed and average gradient

The ISO speed and average gradient of the film shall be determined as described in the annex. The film supplied under this specification shall be considered as falling within a specified ISO speed group indicated in 3.1 when the average speed of three films falls within the spread indicated for the ISO speed group. However, the maximum deviation of any one batch of film from this average shall be not greater than $\pm 10\%$ of the average of the three films. If more than one batch of film is used, the tolerance shall be $\pm 20\%$. The ISO speed shall be expressed as the nearest whole number.

5.3.3 Safety tests

Tests to determine compliance with the requirements of 4.2 shall be conducted as described in clause 5 of ISO 543.

6 PREPARATION FOR DELIVERY

6.1 Packaging

The film packets shall be packaged in standard commercial containers of the size and kind commonly used, providing such containers protect the contents against damage in shipment.

6.2 Marking

6.2.1 Manufacturer's identification

The manufacturer's name and the trade brand name of the

film shall be printed legibly on each package of film packets.

6.2.2 Batch number

Each package of film packets shall be marked with a serial number or a combination of letters and numbers that shall refer to the manufacturer's records for the particular batch of film.

6.2.3 Expiration date

An expiration date valid when the package of packets is subjected to a background radiation of not more than $10 \mu\text{R/h}$ shall be indicated on each package of film packets. Other expiration dates valid for higher background radiation levels may be added.

6.2.4 Safety type

Each package of all film of all sizes shall be marked to indicate that it is "safety" type.

6.2.5 ISO speed group and size

The ISO speed group determined as described in 5.3.2, at the time of manufacture, and the size number, shall be shown on all packages of film packets. Also the effective speed using the manufacturer's recommended process may be indicated in addition to the ISO speed group.

6.2.6 Number of films in each packet

The number of films in each packet shall be printed legibly on each package of film packets.

6.2.7 Quantity

The number of film packets in each package shall be printed legibly on each package.

6.2.8 Films coated on one side

If the film is coated with emulsion on one side only, it shall be so stated on the package.

6.3 Instructions to be supplied by the manufacturer

The manufacturer shall make available adequate instructions for proper storage and processing and shall indicate recommended basic exposures for the film placed in various positions in the mouth; these recommendations shall be based upon the following conditions : 65 kV peak, 10 mA; source-film distance of 200 mm; the total filtration (inherent plus added filtration) equivalent to approximately 1,5 mm of aluminium.

In addition, the manufacturer shall provide in the instructions conversion factors by graphs, tables or nomographs by which the user can estimate the exposure with commonly used dental X-ray equipment other than that operating at 10 mA, 65 kV peak and 200 mm source-film distance.

These instructions shall be printed legibly on each package of the film packets or shall be enclosed in each package of packets.

ANNEX¹⁾

DENTAL RADIOGRAPHIC FILMS EXPOSED DIRECTLY TO X-RAYS – SENSITOMETRY

A.1 SCOPE AND FIELD OF APPLICATION

This annex specifies methods for determining the ISO speed and contrast characteristics of dental radiographic film exposed directly to X-rays. They may be coated on one or both sides for manual or automatic processing, but films for "in-packet processing" and colour films are excluded.

A.2 REFERENCES

ISO 5, *Photography – Determination of diffuse transmission density.*²⁾

ISO/R 209, *Composition of wrought products of aluminium and aluminium alloys – Chemical composition (percent).*

ISO 418, *Photographic grade sodium sulphite, anhydrous – Specification.*

ISO 420, *Photographic grade potassium bromide – Specification.*

ISO 422, *Photographic grade p-methylaminophenol sulphate – Specification.*

ISO 423, *Photographic grade hydroquinone – Specification.*

ISO 3298, *Photographic grade glacial acetic acid – Specification.*

ISO 3300, *Photographic grade sodium thiosulphate, anhydrous – Specification.*

ISO 3620, *Photographic grade aluminium potassium sulphate – Specification.*

ISO 3627, *Photographic grade sodium metabisulphite, anhydrous – Specification.*

ISO 3628, *Photographic grade boric acid – Specification.*

ISO 3942, *Photographic grade sodium carbonate, monohydrate – Specification.*³⁾

ISO 3943, *Photographic grade sodium acetate, anhydrous – Specification.*³⁾

A.3 ISO SPEED

A.3.1 Definition

For films exposed directly to X-rays, without the use of fluorescent screens, ISO speed is defined as the reciprocal of the exposure in röntgens required to produce a density of 1,0 above the base and fog density under standard conditions of exposure and processing. The ISO speed is therefore expressed in reciprocal röntgens.

A.3.2 Factors influencing ISO speed

The following factors influence the ISO speed of a particular sample of film exposed directly to X-rays, and shall be specified :

- a) quality of X-radiation;
- b) processing conditions;
- c) temperature and moisture content of film during exposure and between exposure and processing;
- d) delay between exposure and processing.

A.4 TESTING CONDITIONS

The following conditions shall apply in the sensitometry of dental films exposed directly to X-rays without the use of screens.

A.4.1 Radiation quality⁴⁾

A.4.1.1 Dental films

With a total filtration (inherent filtration of X-ray tube plus added aluminium filter) [any grade (ISO symbol) in table 1 of ISO/R 209 may be used; the ISO symbols are Al 99.0; Al 99.5; Al 99.7 and Al 99.8] equivalent to 2,5 mm of aluminium, and a target-to-ion-chamber distance of not less than 1 m, the voltage shall be adjusted until the half-value layer in aluminium is 2,0 mm. That is, the exposure rate of

1) This annex is included as a temporary measure pending approval of an International Standard (ISO 5799) of similar title, currently under development, at which time this annex will be deleted and reference made to the new International Standard.

2) This referenced International Standard defines and specifies techniques for the measurement of diffuse transmission densities (optical rather than mass densities) of processed black-and-white photographic films and plates. For simplicity in presentation, the abbreviated term "density" is substituted for "diffuse transmission density" throughout this annex.

3) At present at the stage of draft.

4) Heavier filtration of the radiation is likely to be specified in the superseding International Standard mentioned in note 1).

the X-ray beam with a total filtration equivalent to 4,5 mm of aluminium shall be one-half its value with a total filtration equivalent to 2,5 mm of aluminium. The lightest supports possible, of low-atomic-number material, shall be used for supporting the ion chamber.

Exposure shall be made using the voltage thus determined and with a total filtration equivalent to 2,5 mm of aluminium. The radiation field shall not vary more than $\pm 5\%$ over the useful area.

Films shall be exposed in their individual packets or in a wrapping or covering of equivalent absorption.

A.4.1.2 Secondary radiation

In A.4.1.1 the X-ray beam shall be restricted with a diaphragm to as small a size as will include the ionization chamber and the film under test. The film holder shall be at least 1 m from any scattering structure irradiated by the beam after it leaves the exit port of the tube housing. The lightest supports possible, of low-atomic-number material, shall be used for supporting the film and ionization chamber. Whatever diaphragm size, target-to-film distance and film supports are used, it shall be determined that extraneous scattering is negligible.

The presence of excessive scattered radiation may be tested for by plotting the inverse square root of the intensity as a function of distance from the source. Absence of scattered radiation is indicated when the resulting plot is a straight-line passing through the origin. The scattered radiation is excessive if the point corresponding to the observed intensity at the distance to be used for film exposures is more than 3 % below the best straight line from the origin among the plotted points.

A.4.2 Temperature and moisture content of film during exposure

The temperature of the film during exposure shall be $20 \pm 5^\circ\text{C}$. The moisture content of the film shall be such that the film will be in equilibrium with a relative humidity of $50 \pm 20\%$.

A.4.3 Delay before processing

In order to minimize any effects due to latent-image instability, the films shall be processed not less than 2 h and not more than 10 h after exposure. Between exposure and processing, temperature and moisture content of the films shall be as specified in A.4.2.

A.4.4 Developer

The developer shall have the composition given in table 3. Photographic grade chemicals meeting the requirements of the appropriate International Standards listed in A.2 shall be used throughout.

A.4.5 Developer temperature

The developer temperature shall be $20,0 \pm 0,2^\circ\text{C}$.

A.4.6 Development time

Development time shall be $5 \text{ min} \pm 5 \text{ s}$.

TABLE 3 – Developer composition

Chemical	International Standard	Amount
Distilled water		500 ml
<i>p</i> -Methylaminophenol sulphate	ISO 422	2,2 g
Sodium sulphite, anhydrous	ISO 418	72,0 g
Hydroquinone	ISO 423	8,8 g
Sodium carbonate monohydrate	ISO 3942	56,0 g
Potassium bromide	ISO 420	4,0 g
Distilled water to make		1,0 l

Dissolve the chemicals in the order given. Each chemical shall be completely dissolved before the next one is added. Use without dilution.

The developing solution shall be freshly made and shall be not less than 1 day and not more than 7 days old when used. If stored, it shall be kept in completely filled airtight bottles.

A.4.7 Agitation

During development, agitation shall be provided equivalent to that produced by an up and down 2 cm stroke every 10 s.

A.4.8 Stop bath

Immediately following development, the film shall be immersed for 30 s, with some agitation, in a stop bath consisting of 3 % acetic acid at a temperature of $20 \pm 5^\circ\text{C}$.

The acetic acid, glacial, used in preparing the stop bath shall conform to the requirements as laid down in ISO 3298.

A.4.9 Fixation

After the stop bath, films shall be fixed in a fixing bath having the composition given in table 4. Photographic grade chemicals meeting the requirements of the appropriate International Standards listed in A.2 shall be used throughout. All films shall be immersed in the fixer until completely cleared and then shall be allowed to remain in the fixer for an additional 5 min. The temperature of the fixing bath shall be $20 \pm 5^\circ\text{C}$. Films shall be agitated vigorously during the first 30 s of immersion in the fixing bath, followed by moderate agitation during the remaining period in the bath.