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**Evaluation and routine testing in
medical imaging departments —
Part 2-1 : Constancy tests —
Film processors**

ICS 11.040.50; 37.040.10

Reference number : JIS Z 4752-2-1 : 2005 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japanese Society of Radiological Technology (JSRT)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Evaluation and routine testing in medical imaging departments—Part 2-1 : Constancy tests— Film processors

Introduction This Japanese Industrial Standard has been prepared based on the first edition of IEC 61223-2-1 *Evaluation and routine testing in medical imaging departments —Part 2-1: Constancy tests —Film processors* published in 1993 with some modifications of the technical contents.

The portions underlined with dots are the matters modified from the original International Standard. A list of modifications with the explanations is given in annex 2 (informative). In this Standard, the descriptions where the mark (*) is applied on the upper left of the clause number or detail code indicate that these supplemental explanations are specified in annex D (Rationale).

1 Scope and object

1.1 Scope This part of JIS Z 4752 applies to those components of X-ray equipment which process radiographic film and other photographic materials in X-ray facilities in which any of the following radiographic or photographic materials are handled. However, it does not apply to the dry-type film processor:

- all types of screen film;
- non-screen film;
- photographic film for indirect radiography, as used for recording
 - output images of X-ray image intensifiers,
 - other transferred radiological images;
- photographic material for copying radiograms;
- photographic material for making permanent images as used in diagnostic equipment such as for general reconstructive tomography (CT scanning), digital imaging, ultrasound, magnetic resonance, nuclear medicine.

The method described in this Standard is intended primarily for automatic film processors, but may be adapted for testing equipment for manual processing.

This Standard is a part of a series of standards which will describe test methods for the constancy of properties of various subsystems of diagnostic X-ray equipment, as described in IEC 61223-1.

Remarks : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

IEC 61223-2-1 *Evaluation and routine testing in medical imaging departments-part 2-1:Constancy tests- Film processors* (MOD)

***1.2 Object** This Standard describes constancy parameters in **film processors**, and a method to check these parameters, in order to ensure that the conditions for producing consistent **radiograms** of adequate quality on radiographic and photographic materials are maintained.

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. If the indication of the year of coming into effect or the year of publication is given to these referred standards, only the edition of the indicated year constitutes the provision of this Standard but the revision and amendment made thereafter do not apply. The normative references without the indication of the year of coming into effect apply only to the most recent edition (including amendments).

JIS T 0601-1 *Medical electrical equipment —Part 1:General requirements for safety*

Remarks : **IEC 60601-1:1988** *Medical electrical equipment — Part 1: General requirements for safety*, Amendment 1 : 1993 and Amendment 2 : 1995 are equivalent to the said standard.

JIS Z 4005 *Medical radiology —Terminology*

Remarks : **IEC 60788:1984** *Medical radiology —Terminology* is equivalent to the said standard.

JIS Z 4752-1 *Evaluation and routine testing in medical imaging departments —Part 1: General aspect*

Remarks : **IEC 61223-1:1993** *Evaluation and routine testing in medical imaging departments —Part 1: General aspects* is identical with the said standard.

JIS Z 4752-2-3 *Evaluation and routine testing in medical imaging departments —Part 2-3: Constancy tests —Darkroom safelight conditions*

Remarks : **IEC 61223-2-3:1993** *Evaluation and routine testing in medical imaging departments —Part 2-3: Constancy tests —Darkroom safelight conditions* is identical with the said standard.

JIS Z 4905 *Photography — Medical radiographic cassettes/screens/films and hard-copy imaging films —Dimensions and specifications*

JIS Z 4918 *Film illuminators for medical X-ray films*

ISO 4090 : 1991 *Photography —Film dimensions —Medical radiography*

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

ISO 8402 : 1986 *Quality — Vocabulary*

3 Terminology

3.1 Use of terms For the boldfaced terms that appear in this Standard, the definitions in the following standards apply:

- JIS Z 4005
- JIS Z 4752-1
- JIS Z 4905
- JIS Z 4918
- 3.2 of this Standard

3.2 Definitions

3.2.1 film processor for use in medical diagnostic radiology, a combination of equipment and devices to process the latent radiological information, recorded on, or transferred to, radiographic or photographic material, into a permanent, visible image

3.2.2 film base plus fog density for constancy tests in X-ray equipment, the optical density in an area of the radiogram on the processed control film, that has not been exposed to light from a sensitometer

3.2.3 speed index for constancy tests in X-ray equipment, the specific value of optical density in an area of the radiogram produced by a constant exposure to a light source

NOTE : The value of **speed index** normally is established at an optical density in the range from 0.8 to 1.2 above that of **film base plus fog density**.

3.2.4 contrast index for constancy tests in X-ray equipment, difference between the **speed index** and the value of optical density produced by a constant exposure from a light source, greater than that used for producing the **speed index**

NOTES 1 This exposure is normally aimed at an optical density in the range from 1.8 to 2.2 above that of **film base plus fog density**.

- 2 **Speed index** and **contrast index** are used as constancy parameters and are intended to facilitate the routine checks described in this Standard. They must not be confused with the sensitometric definitions of sensitivity in terms of speed and average gradient.

4 General aspects of constancy tests

4.1 Principle of the test procedures In an initial series of constancy tests, the baseline values of the three constancy parameters of the **film processor** (**film base plus fog density**, **speed index** and **contrast index**) are determined. This is achieved by exposing control films under specific conditions prior to processing them in the **film processor** under test.

NOTE: Whilst it is possible to use pre-exposed films available from the manufacturers of photosensitive materials, this method is not recommended in preference to the use of freshly exposed control films because of the differences in the characteristic response of the pre-exposed films from those currently in use in the X-ray department.

The subsequent performance of the **film processor** is monitored routinely by processing further control films, and the measured values of the constancy parameters are compared with the **baseline values** in order to detect deviations from constancy.

In X-ray departments where more than one **film processor** is in use, the performance of several **film processors** can be approximately harmonized by adjusting their individual developer temperatures (see annex E).

4.2 Test equipment

4.2.1 Control films Control film of photographic or radiographic film are produced by exposure under a stepwedge to light emitted from a calibrated and stable light source.

The control films should be of the same type as the radiographic material(s) normally used in the X-ray department and should be stored under the same conditions.

As far as is practicable, control films used for successive constancy tests should be of the same type and batch/emulsion number, and should be taken from the same package. One package should not be in use for a period exceeding six months, nor beyond its expiry date.

Prior to changing the batch or type of radiographic material used for the control films, it is necessary to adjust the **baseline values** of the constancy parameters. This is achieved by simultaneously processing control films from both the current and replacement batches. The appropriate degree of adjustment is then determined from a comparison of the measured constancy parameters.

If more than one type of radiographic material is processed in the same **film processor**, it may be necessary to use several series of control films, one representative of each type of radiographic material, in order to allow for differences in characteristic response of the different types of material.

4.2.2 Sensitometer Control films should be exposed by means of a sensitometer equipped with a suitable stepwedge. The light output should be reproducible to within $\pm 2\%$. The sensitometer should provide at least two levels of exposure which result in optical densities on the processed control films:

- a) within the range 0.8 to 1.2 above film base plus fog density, and
- b) within the range 1.8 to 2.2 above film base plus fog density.

No part of the control film should be exposed to light from the sensitometer in order to permit measurement of the **film base plus fog density** on the processed control film.

A stepwedge containing a series of steps will enable differences in the sensitivity of different types of control film to be taken into account.

4.2.3 Densitometer Optical densities are measured with a densitometer which reads consistently within ± 0.02 .

4.2.4 Thermometer The temperatures of the processing solutions are measured by a metal stem or digital thermometer to within $\pm 0.1^\circ\text{C}$.

A mercury in glass thermometer should not be used.

4.3 Film processor : Cleaning, maintenance and log book Prior to any constancy test, it shall be ensured that

- the **film processor** is set up in accordance with the instructions given in the **accompanying documents** for the radiographic materials, the **film processor** and the chemicals;
- the optimum developer temperature is known either as determined, see annex E, or as given in the **accompanying documents** for the radiographic materials;
- the **film processor** is maintained in accordance with the instructions given in the **accompanying documents** for the radiographic materials, the **film processor** and the chemicals.

A maintenance log-book attached to each **film processor** is essential in order to record:

- when maintenance is carried out;
- when the processing solutions are changed,
- when new replenishment solution is added, and
- when any other changes relevant to the performance of the **film processor** were made.

4.4 Darkroom safelight conditions Where, during a constancy test according to this technical report, radiographic or photographic materials are openly handled prior to the test, it must be insured that the darkroom conditions as well as the film storage conditions are satisfactory, and, if necessary, that constancy tests according to JIS Z 4752-2-3 have been carried out.

5 Test procedure

5.1 Determination of constancy of film processor performance

5.1.1 Method

- a) It should be assured that:
 - the **film processor** has undergone routine maintenance; and
 - its performance is satisfactory (see annex E).
- b) The **film processor** is set at the selected optimum temperature for the development solution.
- c) The “start-up” procedure recommended in the **accompanying documents** is followed, and a period of 30 min allowed for the solution temperatures to stabilize.

- d) The solution and wash water temperatures are checked. If feasible, the replenishment rates, wash water flow rate, and dryer temperatures are measured. Temperatures and flow rates are adjusted if necessary and allowed to stabilize.
- e) Using the sensitometer, a series of two to six control films are exposed. It is sufficient to expose only one side of a double emulsion film.
- f) After at least 30 min but no longer than 4 h, the control films are processed. However, if it is determined that the control films are constantly processed in a given time period after exposure, the above may be disregarded. The control films are processed so that the leading edge is the least exposed end of the stepwedge pattern.

The sheets of control film are passed into the film processor always at the same side of the feeding slit.

- g) In the three areas of each control film the optical densities are measured (see 4.2.2).
- h) For each constancy parameter, the average value is determined of the optical densities measured in the six radiograms.

In an initial constancy test, these three average values are the baseline values for film base plus fog density, speed index and contrast index.

5.1.2 Data evaluation In a subsequent constancy test, the average values of the constancy parameters are determined and compared with the baseline values, determined as described in item h) of 5.1.1.

This comparison is facilitated by the use of a control chart for each film processor on which the constancy parameters are plotted as a function of time. An example is shown in figure 2, which also indicates the baseline values and the limits of acceptable performance.

The test results and conditions should be recorded in a uniform manner, examples of which are given in figure 2 and annex B.

5.1.3 Established criteria The performance of the film processor is of adequate constancy if variations in the constancy parameters are within the following limits:

- a) the film base plus fog density shall be within ± 0.05 of the baseline value;
- b) the speed index and contrast index shall be within ± 0.15 of the baseline value, and should be within ± 0.10 of this value.

5.1.4 Further action If any of the constancy parameters are outside the established criteria described in 5.1.3 the constancy test should be repeated.

If any of the constancy parameters still remain outside these limits, or if the results of the last three constancy tests indicate a tendency for any index to consistently decrease or increase in value, then appropriate action should be taken as described in clause 6.

5.1.5 Frequency of constancy test

- a) Once per day at the same time, if use of the film processor is intense;
- b) prior to use, if the film processor has not been used for at least 24h;
- c) each time the processing solutions are changed;
- d) after maintenance or repair of the film processor.

5.2 Consistency of control films When the current batch of control films is about to become exhausted, a replacement batch of control films should be introduced in accordance with the following procedure.

- a) At least three control films from the current batch, together with at least three control films from the replacement batch, are exposed as described in 5.1.1.
- b) The control films are processed and evaluated as described in 5.1.1.
- c) The average values of the constancy parameters for the two batches of control films are compared.

The differences in these average values should be used to establish the new baseline values for the constancy parameters.

- d) If the difference in any single constancy parameter is outside the limits described in 5.1.3, an investigation should be carried out into the reason for the change in film characteristics. This investigation is beyond the scope of this Standard.

6 Action to be taken The control charts according to 5.1.2, and records of test results according to annex B, will clearly show any trend in the values of the constancy parameters with time, and will indicate any tendency to exceed the established criteria described in 5.1.3.

Should such a trend occur, the following checks should be carried out in order to determine what corrective action should be taken to halt the deterioration in processing conditions:

- a) The temperature of the development solution is measured.
- b) The replenishment rates are measured.
- c) The radiographic materials currently being processed are checked for changes in batch numbers, types and sizes.
- d) The replenishment solutions are checked for correct preparation.
- e) The expiry dates of control film and the radiographic materials currently in use in the X-ray department are checked.
- f) The wash water flow rate is measured.