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Quality Control of X-ray Equipment Used in Intervention Studies

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Abstract: Angiography equipment is one of the most used in interventionist medical techniques. However, in the image formation process, it uses X-rays, which are dangerous, since these cause harmful effects to the individuals involved. For this reason, and according to one of the pillars of radiological protection "as low as reasonably achievable" known as optimization, quality controls in these devices are essential to reduce the radiation dose while still obtaining a good image quality. This paper describes the most relevant quality control tests for fluoroscopy equipment, shows what is the role of each test, what type of instrument is used to perform it and what are the limits adopted by international regulatory bodies, and compiles the necessary information to determine whether or not an angiography equipment meets the minimum quality standards to operate.

Key words: radiation protection; optimisation; radiation dose; quality control

1. Introduction

Interventional medical techniques based on real-time X-ray imaging are becoming increasingly common in different specialties, thanks to their great usefulness and ease compared to conventional surgery; however, X-rays cause harmful health effects, both for the patient (skin burns, alopecia, erythema, among others) and for the medical staff (opacity in crystalline lens and cancer in different parts of the body) [1, 2]. Radiation protection plays a fundamental role, since by means of its rules: justification, optimization and dose control, it ensures to reduce the probability of occurrence of the aforementioned harmful effects through different methods. One of the most relevant are the quality control studies of the X-ray equipment, which have been established by entities such as the IAEA (International Atomic Energy Agency) and the ICRP (International Commission on Radiological Protection) and whose main objective is that the images delivered by the equipment have sufficient quality so that the physician or professional in charge of their interpretation can give an accurate judgment with the lowest possible dose in order to proceed appropriately in the intervention.

Currently in Colombia all institutions that have X-ray emitting equipment, such as angiographs, must perform quality control studies to comply with the standard that requires it and thus obtain their service license [3], since this certifies to the regulatory entity the state of the equipment's operation. Due to the fact that any X-ray equipment is a system composed of multiple components to form a set of images, quality control is responsible for evaluating each component through a series of tests and making a final decision, which may be helpful in proving its normal operation, but there must be one or

more component adjustment indications, or indications that the equipment can no longer provide service. In the case of fluoroscopy equipment used in interventional procedures, the need for monitoring is even more critical, since due to their long exposure times and the way in which the procedures are performed, they are the devices that irradiate the most, hence the need to have sufficient knowledge about the quality control tests dedicated to these devices and which are described in this work.

2. Quality Control Tests and Discussion

A fluoroscope is made up of several fundamental elements that form a chain: the generator, which is responsible for supplying power to the equipment; the tube, which produces the X-rays; the image receiver, which records the image with the rays that have passed through the patient -this can be an image intensifier or a flat panel; and the television system with one or more monitors, which allows the image of the organ or tissue to be displayed in real time. Due to the importance of these elements, quality control is based on a set of measurements made on them, starting with the quality of the monitor and ending with the generator and the tube, measuring the physical and geometrical parameters of the X-ray beam emitted by the equipment.

According to the type of medical need, fluoroscopes have variants in their design and characteristics; for example, equipment used in interventional procedures are known as angiographs (from the Greek prefix "angio", which means duct or vessel) and are of a very fine size compared to equipment used for other organs. This type of equipment must have a higher resolution capacity than a fluoroscope dedicated to another type of specialty. Among angiographic-type equipment, there are also differences, commonly in the size of the image receptor. In general, an image intensifier of a vascular radiology equipment has diameters between 28 to 40 cm, but when an angiograph is used in interventional cardiology or neurology, the diameters of this component are approximately 23 cm [4]; thus, the quality control tests are the same for any fluoroscopic equipment, but with different tolerance limits depending on its design orientation.

2.1 Image and monitor quality

Since the final product of the equipment is a series of images displayed by the monitor, these must comply with certain characteristics, for which it is necessary to define some parameters in order to obtain an image quality assessment with the least degree of subjectivity. The first parameter is spatial resolution, which indicates the finest detail that can be resolved in the image. Contrast is defined as the relative difference between the grayscale values of two regions. This parameter is one of the main problems in fluoroscopy equipment since the anatomical structures being analyzed usually have very similar attenuation coefficients; therefore, according to the need, agents such as iodine or barium are administered to the patient to obtain images with higher contrast levels. The image must also have uniformity; this requires that the difference between the values in the gray scale be very small for the regions in the organs and tissues that make up the image of an anatomically homogeneous structure. Noise must be taken into account, as well as the previous properties, since it can also alter the information contained in an image; it is defined as the random modification of the values of different pixels of the image. One of the main sources of noise is the quantum detection of the detector to the photon field of X-radiation; usually fluoroscopes with flat panel present more noise than those equipped with image intensifier at low dose rates [3]. Finally, the image must not have any type of artifact, i.e., any detail that appears in the image but is not present in the real anatomical structure; typically they appear in digital detectors, flat panel type, as stains, due to damage in some region of the same or malfunction of any individual detector. In equipment with image intensifier, geometric distortions are observed, such as the so-called S-type, barrel or cushion distortion.

Since the lack of any of the image characteristics mentioned in the previous paragraph can be attributed to any part of the fluroscopic image chain, in the first instance the final part of the system, the monitor, should be examined; for this

purpose, there are two types of testing tools, physical and digital, but if only the status of the monitor needs to be known, it is recommended to implement digital testing, such as the TG18 CQ of the American Association of Medical Physics (AAPM) (fig. 1) which opens DICOM format images from any type of memory in the device monitor and performs relevant measurements in the displayed test to determine that the screen status specified in the protocol is sufficient. Similarly, a physics simulator such as TOR18 FG can also be used, whose radiographic projection is shown in Figure 2. This is a test for overall evaluation of the image, as the projection depends on the X-ray beam emitted by the tube and the state of the image intensifier. If not, it depends on the flat panel. In addition to the display screen, this test has a distribution of objects in its body that allows evaluating the characteristics of the image as specified by the manufacturer in its manual [6]; however, if any nonconformity is found in the image, more exhaustive tests must be performed to determine where in the image chain is the origin of the problem.

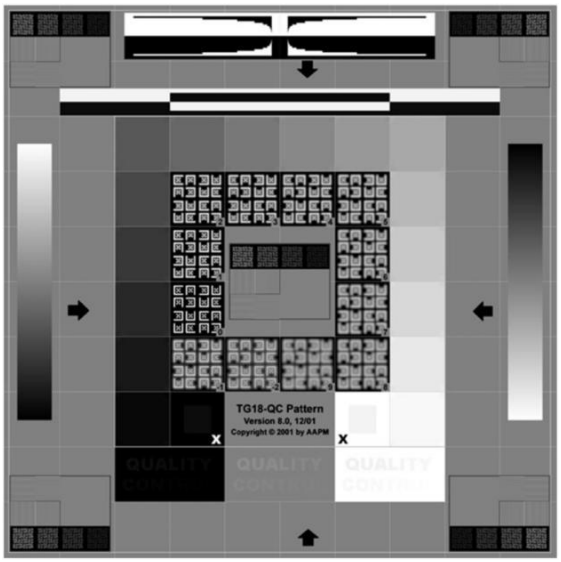

Figure 1. AAPM TG 18 CQ digital test [5].

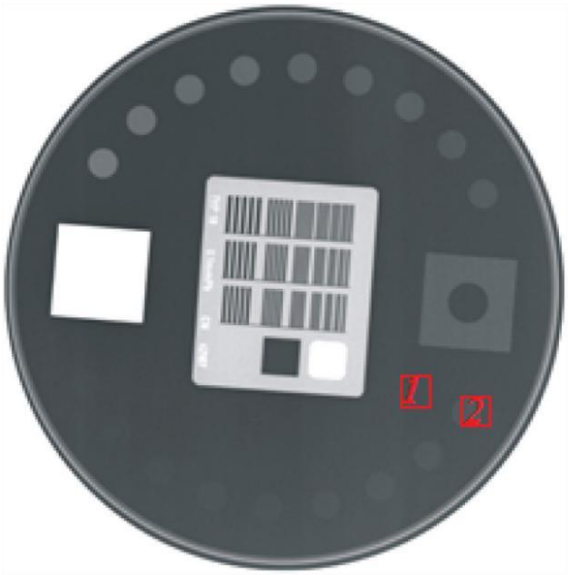

Figure 2. TOR18 FG X-ray [6].

The minimum tolerated limits for spatial resolution are shown in Table 1, which depend on the type of detector and field of view used, and their unit of measurement is lines per millimeter (pl/mm).

Table 1. Tolerance limits for spatial resolution [7]

Detector	Field size (cm)	Minimum value in resolution (Pl/mm)
X-ray image intensifier	36	1
	30	1.12
	23	1.2
	Under 15	1.6
Flat panel	In no case shall it decrease by more than 20% with respect to the initial value given by the manufacturer.	

To evaluate the contrast, it must be verified if the structures of the test tool dedicated to this are visible in the image; in the case of TOR 18FG, they are the disks located in the lower part of figure 2, which present attenuation values very close to the medium that contains them. The number of disks observed should not differ by more than two with respect to the number determined in the initial tests for the start-up of the equipment [7, 8].

Uniformity in the image is evaluated by measuring the gray scale value in lateral regions and comparing it with the value in the central region. These values should not vary by more than 12% [7]. To perform this test, a test with homogeneity conditions in the aforementioned regions should be used, such as the TG18 CQ (Fig. 1), which has five rectangles distributed in the center and corners, with the necessary characteristics to perform this test.

To quantify the noise, the signal-to-noise ratio (SNR) is used, calculated from an image of a physical test such as the TOR18 FG in DICOM format and projected in cine mode, measuring the mean pixel value (MV) with their respective standard deviations (SD) in regions 1 and 2 shown in Figure 2, where region 1 corresponds to the background of the test and region 2 is inside the circle number 1 of low contrast; these values are used to calculate the SNR by means of equation 1 [10]. The SNR value should not have a deviation from the reference value given by the manufacturer greater than 50%.

$$\mathrm{SNR} = \frac{\mathrm{VM1}-\mathrm{VM2}}{\sqrt{\frac{\mathrm{DS1}^2+\mathrm{DS2}^2}{2}}} \quad (1)$$

To find a value for the degree of geometric distortion of an image intensifier, it is sufficient to make a projection onto a grating with a constant pattern. This value is calculated according to equation 2, where each variable is measured from the resulting image on the screen and should not exceed a value of 10% [7].

$$\left(\frac{Mean\ diagonal\ of\ the\ largest\ square\ inscribed\ in\ the\ image}{Number\ of\ squares \times middle\ diagonal\ of\ the\ central\ box}-1\right)\times 100\% \quad (2)$$

To examine artifacts in flat panel equipment, it is sufficient to project the image of a physical test, such as the TOR18 FG, or a uniform plate of any material and evaluate if its image presents anomalies, although as mentioned above they can also be generated by reasons unrelated to the flat panel.

Image quality tests are recommended to be performed when the equipment is commissioned, after changes and on an annual basis [7]; however, the equipment should be monitored daily before starting its day of use, observing a test image, such as TOR18 FG, to identify abnormalities and, if any, to take corrective measures.

2.2 Dose

In view of the fact that quality control aims to optimize patient dose, it is necessary to establish quantifiable and measurable parameters, such as dose indicators. One of the most commonly used is the surface dose at skin entry (DSP) and although there are no limits for these, there are reference levels for X-ray imaging. In the case of fluoroscopy equipment dedicated to interventional procedures, the following dose indicators are used:

- Dose-area product (DAP): measured in the equipment by an ionization chamber generally at the exit of the tube with a determined area.
- Dose at the interventional reference point: this point is located 15 cm from the isocenter of the arc towards the focal point of the tube; it is the indicator most closely related to the dose in the skin for fluoroscopy-guided procedures; however, it is very difficult to measure.
- Number of projections performed in high dose rate mode or cine mode.
- Total time: it is composed of the sum of fluoroscopy time and cine time [3].

In contrast to conventional X-ray imaging, fluoroscopy-guided procedures do not have an exact time to finalize the diagnosis or therapy, and therefore do not refer to a surface dose at skin entry but to a dose rate. To evaluate this quantity requires a simulator with an attenuation equivalent to a patient, usually a block of PMMA (acrylic from the polymerization of methyl methacrylate) with a thickness of 20 cm and an ionization chamber or solid state detector calibrated in the dose variable, which is located between simulator and tube in position 2 as shown in Figure 3. The incoming dose rate limits to the patient's skin are classified according to the fluoroscopy mode and the thickness of the simulator (Table 2).

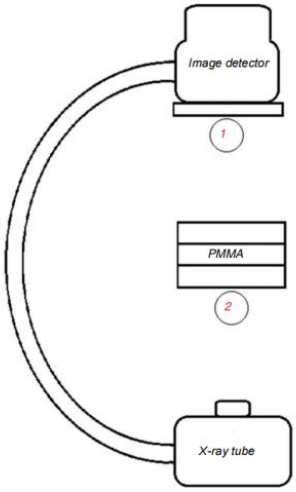

Figure 3. Schematic of relative positions of the simulator and ionization chamber for dose rate and automatic exposure control tests.

Table 2. Maximum tolerance limits for skin entry surface dose rate [7]

Fluoroscopy mode	PMMA thickness (cm)	Maximum dose rate (mGy/min)
Normal	20	50
	Over 20	100
High (cine)	20	100
	Over 20	200

In addition to not exceeding the limits set out in Table 2, the dose rate should be consistent over time; variations should not exceed 20% with respect to the initial ones [7].

To form each video image, the fluoroscopy equipment invests an amount of dose, known as "dose per patient image" and its measurement is also part of the quality control. As in the previous test, a simulator with patient-equivalent attenuation and an ionization chamber or solid-state detector calibrated in the dose variable and located in the same way are required [9]. According to Downling, this value ranges between 0.03 and 0.12 mGy/image in equipment dedicated to interventional cardiology; in addition, it must be consistent over time with respect to the manufacturer's specifications, with variations that do not exceed 20% [7].

To finish the dose evaluation in the quality control of fluoroscopy equipment, it is necessary to verify the dose measurement system of the equipment, either the dose-area product, the dose value in the interventional reference point or both. The objective of this test is to evaluate the difference between the values displayed by the equipment and the real value measured by the ionization chamber or detector previously calibrated. The values found should not exceed a deviation of 20% with respect to the value provided by the fluoroscopy equipment.

It is recommended to perform the dose tests mentioned above when the equipment starts its useful life, on an annual basis or in case the equipment is subjected to any type of change.

2.3 Pulsed fluoroscopy

It significantly reduces the radiation dose used to perform a scan. This system interrupts the X-ray beam during time lapses with a determined frequency, making the exposure time much less than the scanning time; despite the interruption of the beams, the video system of the equipment is synchronized with the pulses so that the image on the screen is refreshed before the beginning of each pulse, avoiding flickering in the video.

Additionally, in quality control, the duration and frequency of the pulses must be evaluated. To perform these tests, a radiological multimeter with high temporal resolution is required; since each manufacturer has its own parameters, the values found must be within the ranges specified by the manufacturer. In the case of equipment dedicated to cardiology, the pulses have a duration of between 3 and 8 ms, with frequencies of 7.5 to 30 or even 60 frames/s.

This test is extremely important at the beginning of the equipment's useful life and when it is subjected to any type of change; however, it is recommended to include it among the quality controls required by the national standard for equipment licensing [3, 7].

2.4 Automatic exposure control system

It is in charge of avoiding brightness fluctuations on the screen, since its function is to maintain a constant dose rate in the image intensifier or flat panel regardless of the patient's thickness or the anatomical region being studied at the time. In order to carry out this function, the equipment controls parameters such as kilovoltage and milliamperage, and in some equipment additionally the pulse width and filtration; that is to say, it takes care of maintaining the adequate parameters for a good visualization of the video images and also adapts the dose rate to optimize the process of image formation.

To evaluate the automatic exposure control system, it is important to perform 3 tests in no specific order, using a patient simulator with variable thickness; in general, PMMA plates with thicknesses between 10 and 20 cm and a dose-calibrated ionization chamber or solid state detector are used, which it is recommended to place in position 1 according to Figure 3 for the automatic exposure control tests mentioned above.

One of the tests is the verification of the dose rate at the entry plane in the imaging system, for which the 20 cm PMMA patient simulator is placed as if it were a patient under normal conditions and the dose rate is measured on the imaging system (intensifier or panel) using the radiation detector. The values found should not differ from the initial value or those provided by the manufacturer by more than 20%. This process is repeated three more times to find the repeatability coefficient and complete the second part of the assessment of the automatic exposure control system. A maximum value of 10% is allowed for this coefficient, which ensures that the dose rate in the imaging system does not have considerable spontaneous fluctuations that would alter the brightness of the image during a study.

Finally, the compensation of the automatic exposure control for different thicknesses is determined. In this test it is verified that the system is responding to changes in thickness, in order to verify that the image does not have fluctuations in brightness due to changes in the analysis of anatomically more or less voluminous regions of the body. For this purpose, a PMMA plate with a variable thickness of 10 to 20 cm is used between the tube and the imaging system, as well as a fixed position ionization chamber or detector located as close as possible to the amplifier or panel to measure the dose rate received by the amplifier or panel when the thickness of the simulator changes, such as PMMA of 10, 13, 15, 18, and 20 cm; the variation between these dose rates should not exceed 20%.

Due to the importance of this system, the tests mentioned above to verify its correct operation should be performed annually and immediately after its installation or if it is subjected to any type of modification [7].

2.5 Filtration

One of the main problems of X-ray tubes is their emission of photons with wide energy ranges, since the energetically weaker rays do not contribute to image formation but do contribute to patient dose. Therefore, it is necessary to eliminate them from the image formation process; due to this, filtration is of great importance since it is in charge of eliminating these photons from the primary beam and thus achieving a considerable decrease in the patient dose. Filtration in fluoroscopy equipment is a combination of high purity copper and aluminum foils of given thicknesses and whose unit of measurement is the equivalence of any filter to millimeters of aluminum (mm Al). A foil is attached to the tube outlet,

which is known as inherent filtration; in addition, the collimator is also equipped with some and is known as added filtration, which in modern fluoroscopy equipment changes automatically according to the requirements of the automatic exposure control for image formation.

The purpose of the test is to verify that the total filtration values (inherent plus added) are not below the minimum limits given in Table 3 according to the peak kilovoltage.

Table 3. Minimum values for total filtration in fluoroscopy equipment [8]

kV peak	Filtration (mm Al)
70	2.3
80	2.6
90	3.0
100	3.2
110	3.5
120	3.9
130	4.1

There are several ways to make the measurements; the most convenient is to use a radiological multimeter that has the ability to measure filtration, such as the PTW NOMEX, and that is also calibrated in this variable; however, another useful method, although more complex, is to collect a series of dose data using an ionization chamber and a set of high purity Al filters to then perform the calculations of the filtration that the equipment has [8].

To ensure that the filtration remains in good condition throughout the life of the equipment, it is recommended that this test be performed every year and whenever the equipment undergoes changes and at the beginning of its life of use.

2.6 Non-invasive testing for the generator

The generator is a fundamental part of the image formation in any X-ray equipment, since it is responsible for powering the tube. Therefore, it is necessary to ensure that it remains in the optimal state, in other words, the power of the tube can be maintained without causing its operating parameters (kV and mA) to fluctuate or decrease significantly over time, as these parameters have a high relationship with the final image; for this purpose, it is necessary to conduct kilovoltage and performance tests, and verify through measurement whether they are within the optimal range of testing.

3. Kilovoltage

In X-ray production, the kilovoltage (kV) is a highly relevant parameter since the energy range (X-ray spectrum) of the photons in the beam depends on this quantity and, consequently, the penetrability of the beam.

To monitor the kV, it is necessary to verify, through its measurement, that it is the same as the one configured in the console (manually or automatically) and also that it does not change considerably after each pulse, performing accuracy and repeatability tests respectively. To carry out these tests, it is necessary to have a kilovoltmeter, or a radiological multimeter, calibrated in this variable, with which four measurements will be made for each of 4 different kilovoltages, covering as much as possible the working range, for example 60, 80, 100 and 120 kV and evaluating the accuracy; the measurements obtained for each of the different values should not differ by more than 10% with respect to the value on the console. Similarly, repeatability is calculated with the variations between the measured values for the same kV and should not exceed 10%.

3.1 Performance

The current (mA) is another important parameter, since it determines the number of photons in the X-ray beam emitted by the tube and therefore has a direct bearing on the quantum noise in the image. However, this parameter is not easy to measure, so it is customary to use the yield as an indicator of the tube current setting and is defined as the value of absorbed dose in air without backscattering per unit charge over time (μGy/mAs) at 80 kV, expressed at 1 m distance from the tube focus [7].

To find the yield, an ionization chamber or solid state detector calibrated in dose is required, which must be placed under the beam without any type of simulator, in order to measure the absorbed dose in air without backscattering, at 1 m from the focus of the tube; if the measurement is made at a different point, it is expressed at this distance by mathematical calculations. Subsequently, the measured value is divided by the product between the current (mA) and the shot duration time (s) given by the equipment, if this was performed in continuous time mode; on the contrary, if the test is performed in pulsed fluoroscopy mode, the dose per pulse will be measured and the pulse time will be used to make the appropriate calculations and avoid erroneous performance data.

In fluoroscopy equipment, it should be checked that the performance value is constant over time with respect to the reference value given by the manufacturer, with a tolerance for variation of up to 25% or, as a guideline, use the values given in Table 4; in addition, it should be investigated both in fluoroscopy mode and in high dose rate mode or cine mode.

Table 4. Suggested ranges of values for performance at 1 m from the focal point and 80 kV according to total leakage [7]

Filtration total (mm Al)	Yield (μGy/mAs)
2.5	Over 25
Between 2.5 and 5.0	Between 30 and 65
Greater than 5.0	Manufacturer's specifications

If the yield differs by more than 25% from the reference, possible causes, such as leakage, tube deterioration, waveform, should be investigated. For this parameter, it is also necessary to evaluate the repeatability of the same, measuring four times the yield and checking that they do not differ from each other by more than 10%.

Indirect tests to the generator, such as kV and performance, are of great importance, hence these should be performed periodically every year, at the beginning of the useful life of the equipment and when it is subjected to any modification or maintenance.

4. Geometric Parameters

Since fluoroscopy-guided procedures are generally limited to a specific region of the body, it would be unnecessary to irradiate organs that are not the object of study, for which reason it must be verified that the geometric parameters of the radiation beam have the necessary characteristics so that this does not happen.

First of all, the X-ray beam must be perpendicular to the image detector (intensifier or panel) with a maximum tolerance of 1.5°. To perform this test, a cylindrical simulator is used, which is placed over the detector to project an image, and according to the specifications of its use the perpendicularity will be calculated.

Subsequently, it must be verified that the size of the field at the input of the image detector is indeed the one selected in the console. For this purpose, a metal grid of known spacing or a ruler with lead patterns is used, which must be placed over the detector to measure the diameter or diagonal of the radiation field and calculate the relationships described in equations 3 and 4 for circular or rectangular fields, respectively.

$$\frac{Measured\ diameter\ (displayed)}{Nominal\ diameter\ (selected\ on\ console)} \quad (3)$$

$$\frac{Average\ diagonal\ (displayed)}{Nominal\ diagonal\ (selected\ in\ console)} \quad (4)$$

Whatever the case, the ratios described by equations 2 and 3 should not have values less than 0.85 [7].

Finally, the coincidence of the radiation field with the visualized area of the detector must be measured. To perform this test, a loaded chassis is required, which is placed over the detector to be irradiated with the fluoroscope collimator at its maximum aperture and then by means of the veiling measure the area of the same and find the value of the indicator given by equation 5.

$$\frac{Radiation\ field\ area}{Displayed\ area\ on\ th\ e\ input\ surface\ of\ th\ e\ image\ detector} \quad (5)$$

The value found in the above ratio should not exceed 1.15, and indicates that the area of the radiation field should be close to the useful area of the detector.

These tests should be performed after changes in the fluoroscopy equipment, at the beginning and every year, since they guarantee a good degree of optimization in the dose to the patient.

5. Conclusion

Due to the fact that fluoroscopy-guided interventional medical techniques are one of the processes that generates the highest doses for both patients and professional staff, it is extremely important to optimize this practice. For this purpose, quality controls are the first option, thanks to the exhaustive investigation of the condition of the equipment, which makes it possible to find or anticipate the negative characteristics of the equipment. Although the main objective of the quality control tests is to optimize the dose to the patient, it is worth mentioning that the dose received by the occupational personnel will also have a proportional reduction. For a good medical practice with fluoroscopy equipment, the most advisable is to perform the evaluations with a periodicity appropriate to each type of test.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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