HEALTH

HE301

RADIATION SAFETY ACT 1975

RADIATION SAFETY (GENERAL) AMENDMENT REGULATIONS 1993

Made by His Excellency the Governor in Executive Council.

Citation

1. These regulations may be cited as the *Radiation Safety (General) Amendment Regulations 1993*.

Principal regulations

2. In these regulations the *Radiation Safety (General) Regulations 1983** are referred to as the principal regulations.

[* *Published in the Gazette of 21 February 1983 at pp. 555-636. For amendments to 3 March 1993 see 1991 Index to Legislation of Western Australia, p. 460 and Gazettes of 24 January, 26 June and 7 August 1992.*]

Schedule IX amended

3. Schedule IX to the principal regulations is amended by deleting item 1 and substituting the following item —

" 1. In the case of irradiating apparatus which is operated or used for dental radiography, including panoramic (tomographic) and cephalometric radiography —

(a) the x-ray tube shall be enclosed in a housing in such a manner that the absorbed dose rate in air from leakage radiation measured at a distance of 1 metre from the focus of that x-ray tube does not exceed —

(i) for apparatus used with intra-oral x-ray film, 0.25 milligray in 1 hour; and

(ii) for other apparatus, 1 milligray in 1 hour,

at every rating specified by the manufacturer for that tube in that housing and, to determine compliance with this condition, measurements may be averaged over an area not larger than 10 000 square mms at a distance of 1 metre from that tube;

(b) cones, diaphragms or collimators which serve to limit the useful beam shall be so constructed that, in combination with the x-ray tube housing, they comply with the leakage radiation limits set out in paragraph (a);

(c) the minimum power capability of apparatus —

(i) used for —

(A) dental radiography with intra-oral x-ray film; or

(B) lateral oblique radiography of the mandible with extra-oral x-ray film,

or both, shall be 60 kV(peak) at 7 milliamps for 3 seconds;

(ii) used for dental radiography with intra-oral x-ray film but also used for cephalometric or trans-cranial tempero-mandibular joint radiography, shall be 70 kV(peak) at 10 milliamps for 3 seconds;

(d) the selected —

(i) tube potential difference in kV(peak), the x-ray tube current in milliamps (mA) and the exposure time in seconds or fractions of a second; or

(ii) kV(peak) and the product of the tube current and exposure time (mAs),

shall be indicated by analogue meters, digital displays or scales, or calibrated permanent markings, but apparatus which provides for object programmed control (exposure selection by diagrammatic representations of the part to be examined) shall indicate the exposure time in seconds on the control panel;

(e) when object programmed control exposure times can be modified by a further control which can be adjusted to account for variations in the speed of the film used —

(i) that control shall be provided with a tool for its adjustment;

(ii) that control shall be clearly labelled to indicate its purpose; and

(iii) there shall be clearly indicated on or adjacent to that control the setting to be used with "D" speed intra-oral x-ray film;

(f) all conductors to the primary winding of the high voltage transformer shall be effectively inoperable when the exposure switch is in the OFF position and the failure of any component of the timing circuit or an earth fault shall not lead to the production of x-rays;

(g) the useful x-ray beam shall incorporate filtration so that the half value layer of the useful x-ray beam for a given x-ray tube potential in kV(peak) is not less than the values given in the following table —

TABLE

Design Operating Range (kV(peak))	Measured Potential (kV(peak))	Half Value Layer (millimetres of aluminium)
60 to 70	60	1.5
	70	1.5

Design Operating Range (kV(peak))	Measured Potential (kV(peak))	Half Value Layer (millimetres of aluminium)
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(h) the exposure timer shall be electronic and the circuit of the apparatus shall be so designed that in the event of any component failure such failure is to a safe condition and does not lead to the x-ray tube becoming energized or continuing to be energized;

(i) it shall not be possible to initiate an exposure without the exposure timer set to a nominated exposure time greater than zero (or to a projection in the case of an object programmed control) and the exposure control switch shall be protected against accidental operation;

(j) the apparatus shall incorporate —

(i) a visual signal in the form of a yellow light which —

(A) is clearly visible;

(B) is marked as to its function; and

(C) illuminates when the x-ray tube is energized;

and

(ii) an audible signal (discernible from sounds produced by switching devices or contactors during the exposure) which sounds for the duration of the exposure or at its termination,

and both the visual and audible signals shall be —

(iii) located at the control panel; or

(iv) in the case of remotely controlled equipment, where those signals could not otherwise be seen or heard, at the position of the operator;

(k) the exposure control switch shall be so arranged that the operator can remain well outside the useful x-ray beam and at least 2 metres from the x-ray tube and the patient during the exposure, but if this distance cannot be achieved and if the Council so requires, a protective barrier shall be provided;

(l) where the exposure is initiated by an infra-red or wireless remote control handpiece, that handpiece shall —

(i) be encoded so that no other remote control handpiece can initiate exposures;

(ii) be permanently labelled with a warning identifying the purpose of the handpiece; and

(iii) have provision at the control panel for its storage;

(m) the exposure control switch, including that for infra-red or wireless remote control handpieces, shall be "dead man" so that continuous pressure is necessary to maintain the x-ray exposure and it shall not be possible to make repeat exposures without releasing that switch;

(n) it shall not be possible to initiate an exposure other than for a preset time interval, except in the case of apparatus equipped with an automatic exposure control device, in which case an overriding timer shall be provided to limit the total exposure time —

(i) in the case of apparatus used with intra-oral x-ray film for —

(A) lateral oblique examinations of the mandible; or

(B) cephalometric examinations,

to not more than 3 seconds; and

(ii) in the case of panoramic (tomographic) apparatus, to not more than 20 seconds;

(o) the accuracy of the timer shall ensure that —

(i) the measured exposure time is within plus or minus 10% for exposure times greater than or equal to 0.1 second and within plus or minus 20% for exposure times less than 0.1 second, with the exposure time in seconds determined —

(A) for single phase generators, by counting the total number of pulses in the radiation waveform and multiplying by a factor of 0.02 if half wave rectified or a factor of 0.01 if full wave rectified; and

(B) for other generators, from the time the radiation waveform first rises to 65-85% of the kV(peak) until the time at which it finally drops below this value of the final peak;

(ii) for any specified combination of selected exposure factors the coefficient of variation (as defined below) of radiation exposure does not exceed 0.05 and compliance with this requirement shall be based on 10 consecutive measurements taken within 60 minutes each with an exposure time of not less than 0.1 seconds.

Coefficient of variation (C) means the ratio of the standard deviation to the mean value of a series of measurements calculated as follows —

$$C = \frac{S}{\bar{X}} = \frac{1}{\bar{X}} \left[\frac{\sum_{i=1}^{n} (X_i - \bar{X})^2}{n - 1} \right]^{1/2}$$

Where —

X_i = ith measurement

$\bar{X}$ = mean value of measurements

S = estimated standard deviation

n = number of measurements;

(p) the current delivered to the x-ray tube shall be within plus or minus 15% of the indicated value;

(q) where the tube current can be varied, then for any single value of the x-ray tube voltage in kV(peak) within the range specified for the apparatus, the average ratios of the dose in air (in milligray) to the product of the tube current and exposure time (as mAs) obtained at any 2 tube current settings at the same focal spot size, shall not differ by more than 0.2 times their mean calculated as follows —

$$| \bar{K}_1 - \bar{K}_2 | \leq 0.2 \times \frac{\bar{K}_1 + \bar{K}_2}{2}$$

Where —

$\bar{K}_1$ and $\bar{K}_2$ = the average of 10 consecutive measurements of the ratios of the measured values of the dose in air to the mAs;

(r) the kilovoltage applied to the x-ray tube shall be within plus or minus 5% or plus or minus 5 kV(peak), whichever is the lesser, of the nominal or pre-set value averaged over the first 100 milliseconds of the exposure;

(s) except for equipment used for panoramic (tomographic) radiography, the x-ray tube head shall remain stationary when placed in position for radiography;

(t) where a light beam collimator is provided to define the shape and size of the useful x-ray beam —

(i) the illuminance of the light beam shall not be less than 100 lux at a distance of 1 metre from the focal spot of the x-ray tube or at the plane of the x-ray film, whichever is the lesser;

(ii) the contrast (as defined below) at the edge of the illuminated field at the distance referred to in subparagraph (i) shall not be less than 3.

"**contrast**" means the ratio of the illumination measured 3 mms from the edge of the field towards the centre of the field to the illumination measured 3 mms from the edge of the field away from the centre of the field, using a measuring aperture not greater than 1 mm;

(iii) the collimator shall be designed so that the irradiated area does not exceed the illuminated area under any conditions and the edges of the irradiated and illuminated areas are coincident to within 10 mm at 100 cms;

(iv) the collimator shall be attached to the x-ray tube housing so that it cannot be detached without the use of tools;

(u) for apparatus intended for use with intra-oral x-ray film and which may also be used for lateral oblique examinations of the mandible, the cone, diaphgram or collimator referred to in paragraph (b) —

(i) shall limit the diameter of the useful beam at the end of that cone, diaphragm or collimator to a diameter not exceeding 60 mm or, if the x-ray beam is not circular, to a maximum diagonal dimension of 60 mm; and

(ii) shall be open ended and shall be so constructed that the minimum distance from the outer end to the x-ray tube focus is not less than 200 mm and the internal diameter is greater than the diameter of the useful beam at the outer end;

(v) for apparatus used for panoramic (tomographic) radiography, the cone, diaphragm or collimator referred to in paragraph (b) —

(i) shall provide a useful x-ray beam with dimensions not greater than the dimensions of the slot in the secondary collimator immediately adjacent to the x-ray film and that cone or diaphragm shall also restrict the vertical dimension of the useful beam so that it cannot exceed the height of the x-ray film (or its smallest dimension); and

(ii) in conjunction with the x-ray tube housing shall limit the distance between the x-ray tube focus and the patient's skin to not less than 150 mm;

(w) for apparatus used for cephalometric radiography —

(i) the cone, diaphragm or collimator referred to in paragraph (b) shall restrict the useful beam to the size of the x-ray film and shall not exceed —

(A) 180 x 240 mm or 180 mm in diameter for an x-ray film with dimensions of 180 mm x 240 mm; and

(B) 240 x 300 mm or 240 mm in diameter for an x-ray film with dimensions of 240 x 300 mm;

and

(ii) the x-ray tube and x-ray film shall be so arranged that the x-ray tube focus to film distance is not less than 1.5 metres and the minimum x-ray tube focus to the patient entrance surface is not less than 300 mms;

(x) where the apparatus is designed —

(i) exclusively for one of the purposes referred to in paragraph (u) or (v), the cone, diaphragm or collimator shall be attached to the x-ray tube housing so that it cannot be detached without the use of tools;

(ii) for more than one such purpose, the cone, diaphragm or collimator selected shall be interlocked so that the use of the apparatus is restricted only to the purpose appropriate to that cone, diaphragm or collimator;

(y) the x-ray tube assembly shall be marked with —

(i) the name of the supplier or manufacturer;

(ii) the type number of the x-ray tube or the x-ray tube assembly;

(iii) the nominal value of the inherent filtration of the x-ray tube assembly and, where appropriate, the value of any permanently added filtration including that provided by cones, diaphragms or collimators;

(iv) the position and nominal size of the focal spot or spots;

(v) the values of the x-ray tube potential in kV(peak) and the tube current where those values are fixed;

(z) intra-oral x-ray tubes shall not be used;

and

(za) fluoroscopy shall not be used. ".

Schedule XI amended

4. Schedule XI to the principal regulations is amended in item 1 by deleting paragraphs (f) and (g) and substituting the following paragraphs —

" (f) facilities shall be provided to enable the x-ray film taken by that irradiating apparatus to be processed in the manner specified by the manufacturer of that film and —

(i) for other than dry to dry automatic film processors, those facilities shall include —

(A) a non-mercury thermometer with the scale marked at least every 1°C or a digital thermometer accurate to plus or minus 0.2°C;

(B) a timer to measure the elapsed developing time which can be set to within plus or minus 15 seconds of the required time prior to development;

(C) a time-temperature graph for the developer in use which indicates the appropriate developing time according to the temperature of the developer;

(ii) for self-contained processing systems that do not necessarily require a darkroom, those facilities —

(A) shall have inherent design and construction features which exclude all extraneous light; and any viewing window into a self-contained system shall provide illumination appropriate to the x-ray film in use and shall not visibly increase the density of the x-ray film if exposed to that light for a period equal to twice the normal handling time; and

(B) where self-contained processing systems are not specifically designed to process x-ray films other than intra-oral x-ray films, shall not be used for processing other than intra-oral x-ray films;

(iii) for the processing of panoramic, cephalometric, or lateral oblique radiographs of the mandible, the person in whose name premises are registered shall comply with the requirements of the publication entitled "Code of Practice for the Use of Panoramic (Tomographic) X-Ray Equipment" issued by the Council in December 1984;

(iv) where a darkroom is required, those facilities shall include a room that is —

(A) light tight; and

(B) illuminated by a safe light appropriate to the x-ray film being developed and that light shall be installed in a location where the illumination will not visibly increase the density of the x-ray film if exposed to that light for a period equal to twice the normal handling time;

and

(g) where the person in whose name premises are registered intends using a developer and film processing techniques other than those specified by the manufacturer for the x-ray film or films in use, that person shall provide data in a form acceptable to the Council which proves that the use of that developer and those techniques do not have the effect of lowering the speed of the x-ray film when compared with the developer and techniques specified by the manufacturer. ".

By His Excellency's Command,

D. G. BLIGHT, Clerk of the Council.