

APPENDIX I

Basic Radiological Equipment Specifications

Appendix I-A

*Specifications for the WHIS-RAD Radiographic Unit**

* Taken from: World Health Organization. *Report from the Consultation Meeting on the WHO Basic Radiological Systems held at the WHO Collaborating Centre for General and Continuing Radiological Education, University Hospital, Lund Sweden, 7-11 June 1993, including the Technical Specifications for the World Health Imaging System for Radiography, the WHIS-RAD* Geneva: WHO; 1994. (RAD/94.1)

Technical Specifications for the Radiation *Source* of the WHIS-RAD

HT *Generator* and X-ray Tube

1. High-tension *Generator*

1.1 *Mains connection*

A wall outlet or a separate 50/60 Hz AC generator, which can deliver 2.3 kW within 10%, is required. This corresponds to nominal values of 10 A at 230 V or 20 A at 115 V.

Note: Solutions without mains connection, using a battery with other type of charging, e.g. solar cells or a small AC *generator*, are also acceptable.

1.2 *Energy storage*

The power rating of the *x-ray generator* will be much higher than the instantaneous power (2.3 kW) available from the AC source described above. The high tension *generator* therefore must have an integrated energy storage unit. An individual *exposure* of a very dense object may in rare occasions require close to 30 kW_s (kilowatt-seconds) at 90 kV. *Generators* without energy storage, intended to operate directly from the mains, are not recommended. Peak power loads in the range of 12-30 kW for 0.1 s and 12-15 kW for 2 s may be expected.

Note: The energy storage unit shall be maintenance-free and carry a 5 year *pro rata temporis* warranty. It is preferable to use a battery for energy storage but other methods may also be acceptable, such as a large capacitor on the primary side of the high-tension transformer or a fly-wheel.

1.3 *High-tension transformer frequency*

Only high-tension *generators* using multipulse inverter technology are acceptable. Frequencies from a few kHz to 100 kHz are used with satisfactory results. The high-tension voltage ripple shall be no larger than 4%, measured at 100 kV (kVp) and 100 mA.

1.4 *Generator control panel*

Only the following switches or controls shall be available: ON/OFF, kV-selector, mAs-selector, anode rotation, and *exposure*. The *exposure* switch should be mounted on the control panel, so that the operator must stand behind a protective screen or wall during *exposures*. The selected values for kV and mAs shall be shown before and after the *exposure*. A light signal shall indicate if the *generator* is READY for the selected tube loading. The actual tube loading (*exposure*) shall be indicated with a sound and/or a light signal.

1.5 *Nominal x-ray tube voltage*

The nominal *x-ray* tube voltage (highest available kV) shall be at least 120 kV.

Note: The high-tension *generator* must have circuits which automatically protect the *x-ray* tube from overload (tension and temperature) and the high-tension circuit from damage by flash-over

1.6 Available *x-ray tube current*

The tube current shall be or exceed 100 mA.

1.7 Electric power rating

The nominal electric power rating (kW) shall be stated as the highest constant electric power in kilowatts, which the high-tension *generator* can deliver for a loading time of 0.1 s in the voltage range of 90-100 kV. The minimum acceptable power rating for a WHIS-RAD *generator* is 12 kW at 100 kV.

1.8 Electric energy rating

The nominal electric energy (total available energy for one single *exposure*), measured at 90 kV and a tube loading time not exceeding 2.5 s, shall be in the range of 23-30 kW (kilowatt-seconds). (See below and note under item 1.9 d.)

The measurement at 90 kV (instead of 100 kV, which is customary) depends on the fixed selection of kV-values used in the WHIS-RAD philosophy. Typical peak load situations, using current and *exposure* time values available in the Renard-10 series (see item 1.9 d), are: 90 kV + 160 mA + 2 s, resulting in 28.8 kW or 90 kV + 100 mA + 2.5 s, resulting in 22.5 kW.

Note: This type of electric energy rating (not yet applied by the International Electrotechnical Commission—IEC) is necessary if the *generator* uses power storage or falling tube current during the tube loading (*exposure*).

Exception: The electric energy rating specified above, presumes that the image recording medium (screen-film combination) used has a nominal speed of at least 200 in the 70-120 kV range, corresponding to an *exposure* requirement of 0.5 mR (air *kerma* of close to 5 μ Gy) at the input side of the film cassette. When a recording medium is used, which has a nominal speed of 500, requiring 0.2 mR/*exposure* (air *kerma* close to 2 μ Gy) at 90 kV (retaining acceptable image quality), the nominal electric energy, measured as above, may be as small as 12 kW.

For the time being this requires the use of green-emitting intensifying screens and green-sensitive x-ray film. The use of such film requires special attention to the darkroom lighting and the film development. Free access to green-sensitive (orthochromatic) x-ray film is also required, which may be a problem in some remote areas

1.9 Selection of loading factors

The selection of loading (*exposure*) factors is optimized in the WHIS-RAD Unit and limited to kV- and mAs-values. *Exposure* times and mA-values shall not be set separately, but only selected as current-time products (mAs-values). The shortest possible *exposure* time and the highest possible mA-value shall be automatically selected for each mAs-value used

Adequate information shall be available to the operator before, during and after the loading of the *x-ray tube* about which loading factors (kV and mAs) that are used.

- a) Values of *x-ray* tube voltage shall be measured as kVp but indicated as kilovolts (kV) because the voltage ripple is no more than 4%. The concept of kVp shall not be used in the manual or on the control panel.
For didactic reasons the choice of kV-values is limited to a small number of fixed steps, which do not limit the practical use of different radiation qualities in radiography.

Recommended values of x-ray tube tension
46 - 53 - (60) - 70 - 80 - 90 - (100) - 120 kV

Note: 60 kV and 100 kV are required for testing purposes, but not needed for clinical use. A larger number of kV-steps or continuously variable tube tension are not acceptable.

The selected kV-value must not fall more than 5% from the initial value during the *exposure* (corresponding to about 10% in air *kerma* loss).

- b) Values of *x-ray* tube current shall be selected automatically and not displayed. If the tube current is constant during the *exposure*, its minimum value shall be 100 mA. If the tube current is falling during the *exposure*, the initial value should be in the range of 200-320 mA.

Note. If *exposure* times and mA-values are selected from ranges of fixed values, these must be taken from the Renard-10 series, thus resulting in mAs-values according to item 1.9 d below.

- c) Values of loading time (*exposure* time) need not be displayed. Shortest reproducible *exposure* time (measured as the time during which the kV is 75% of the selected value) shall be 5 ms or shorter. *Exposure* times longer than 2.5 seconds are not permitted.
- d) Values for current-time product shall be indicated in milliampere-seconds (mAs) and shall be chosen as decimal multiples and submultiples from the rounded values of the Renard-10 series (R'10) shown below (ISO Standard 497/1973).

R'10 = the Renard-10 Series

1	1.25	1.6	2	2.5	3.2	4	5	6.3	8
1 0000	1 2589	1 5849	1 9953	2 5119	3 1623	3 9811	5 0119	6 3096	7 9433

The minimum range of fixed mAs-values to be used in the WHIS-RAD is:

							0.5	0.63	0.8
1	1.25	1.6	2	2.5	3.2	4	5	6.3	8
10	12.5	16	20	25	32	40	50	63	80
100	125	160	200	250	(320)				

Note: It is not required that the entire range of mAs-values is available at all tube tensions. Thus it is acceptable that only 20 kWs is reached at 80 kV (with 250 mAs) and that only 12 kWs is reached at 120 kV (with 100 mAs). The combination of 250 mAs and 90 kV (= 22.5 kWs) is usually enough as the peak output. The combination of 320 mAs and 90 kV (= 28.8 kWs) is needed extremely seldom in a population with an average weight of individuals around 80 kg and never in a population with an average weight of 70 kg

- e) Precalculated current-time products shall be shown by the control panel. The lowest mAs-value should be stated, which is within the specified ranges of compliance for linearity and constancy (see below).

Note: This information is very important. The energy loss in the high-tension circuit may be in the order of magnitude of 0.06 kWs at each *exposure*, which corresponds to 0.5 mAs at 120 kV (= the lowest possible combination of loading factors used in chest radiography).

1.10 *Reproducibility, linearity and constancy of radiation output*

Multipulse *x-ray generators* with energy storage inherently have much better reproducibility and linearity than required in the IEC Standard 601-2-7/1987 (Medical electrical equipment, part 2: Particular requirements for the safety of high voltage *generators* of diagnostic *x-ray generators*). This standard does not apply to battery-operated *generators*.

- a) Reproducibility of air *kerma*: The coefficient of variation of measured values of air *kerma* shall not be greater than 0.1 (10%) for any combination of loading factors within the available range.
- b) Linearity of air *kerma*: Within the available *x-ray* tube voltage range (46-120 kV) the quotient of the measured values of air *kerma* divided by the indicated precalculated value of current-time product ($\mu\text{Gy/mAs}$) shall not differ from the quotient of the measured value of air *kerma* and indicated current-time product at 10 mAs by more than 0.1 (10%) of that latter quotient. Comments: Measurements of air *kerma* shall be made with a minimum added filtration on the *x-ray* tube of 20 mm Al or equivalent.

Measurements of mAs inside the *x-ray* tube are not made and measurements in the grounded centerpoint of the high-tension transformer are of no value. The linearity requirement is only related to the magnitude of the steps in the precalculated mAs-scale, representing 26% increments of air *kerma*.

The linearity requirement is more strict than the corresponding IEC requirement for mains-connected *x-ray generators*. Practical experience at the WHO Collaborating Centre for General and Continuing Radiological Education in Lund, Sweden, has shown, however, that multipulse *x-ray generators* using energy storage can easily be modified to give a $\mu\text{Gy/mAs}$ quotient, which does not differ more than 2-5% from the reference value (at 10 mAs) over the entire mAs-range.

- c) Agreement between indicated and measured values of loading factors: At a given measurement date, using the same measuring instrument, the permissible average error of the indicated value of *x-ray* tube voltages shall

not be greater than 0.025 (2.5%), approximately corresponding to the requirements of air *kerma* given above.

Under the same conditions the permissible average error of current-time products shall not exceed the value 0.05 (5%) or 0.1 mAs, whichever is larger.

2. The X-ray Tube

Due to the long time usually required to change an *x-ray* tube at a remote location and the very high tube replacement costs, longevity of the *x-ray* tube is a very important characteristic. An *x-ray* tube for a WHIS-RAD unit benefits from design features which promote a long tube life such as a large anode diameter and rhenium/tungsten alloy in the anode surface.

2.1 Expected lifetime

An *x-ray* tube for a WHIS-RAD installation should have an expected lifetime of 10 years or more with the types and mixture of examinations to be found in an x-ray department at primary-care or first referral level (see below). This may correspond to a total of about 50,000 *exposures* in normal use.

Distribution of examinations to be expected in primary care or at first referral level.

- 35-40% chest
- 8-10% abdomen
- 38-42% extremities
- 10-15% spine and pelvis
- 3-4% head and neck

The anode of an *x-ray* tube develops small cracks in the target surface due to heat variations. These cracks lead to reduction in the output of the *x-ray* tube. When the output reduction reaches 20%, corresponding to one *exposure* step in the Renard-10 series, the demand on the *x-ray generator* power output has increased with 25%, which may prove critical for some examinations.

The average tube load at this type of work is around 3 kW/*exposure*, corresponding to 10% of the permitted maximum load. However, the actual tube load varies within a very wide range: from 0.25 kW for a normal PA chest to 30 kW for a lateral view of the lumbo-sacral junction of a heavy person.

2.2 Focal spot

A rotating anode must be used. The focal spot of the *x-ray* tube shall have a nominal size no larger than 1 mm, measured according to IEC 336.

Note: A new IEC standard for focal spot measurements is anticipated. In this the nominal figure for focal spot size is dimensionless and specified in terms of detail resolution in lines/mm at a specified geometric magnification. This practice, however, is not yet in general use by manufacturers, users or purchasing agents and its introduction is beyond the scope of this publication. For practical purposes the nominal values may still be interpreted as representing millimeters

2.3 Anode angle

The anode angle should be in the range of 12-15°. No special recommendations are given about anode diameter or rotation speed.

Note: An anode angle in the range of 12-15° is compatible with a nominal focal spot size of 0.8-1.0 (mm) and a tube rating of 23-30 kW (at 0.1 s).

An anode angle of 12° easily permits an *x-ray* field of 45 x 45 cm without visible heel effect at the expected working conditions.

Comments: The aging of the anode is very dependent on how it can withstand heat. Anodes made of pure tungsten may not live up to the requirements stated in this paragraph. Reliable figures for the drop in anode output with normal clinical use are not available. The output from a tungsten target containing 10% rhenium and 90% tungsten drops at a rate which is about 25% of the rate for a pure tungsten target. The overall lifetime of a 90/10% tungsten/rhenium target is about 4 times longer than that of a pure tungsten target.

2.4 Tube rating

The high-tension rating of the *x-ray* tube shall be 125 kV (from a low-ripple HT *generator*).

The nominal power rating shall be in the range of 23-30 kW at an *exposure* time of 0.1 s.

The long time power rating shall be in the range of 12-15 kW at an *exposure* time of 2 s, corresponding to a total energy load of 24-30 kWs.

2.5 Tube filtration

The total filtration (inherent + added) shall be within the range of 3-4 mm Al. The filtration shall be determined by *half-value layer* (HVL) measurements of the emerging radiation, which may be performed with a penetrameter.

2.6 X-ray beam collimator

It is recommended to use a standard, multilevel light-beam collimator. Special attention should be paid to the following features:

- The controls should have reliable format indicators (e.g. for 12, 18, 24, 35 and 43 cm) for a focus-film distance of 140 cm, so that the collimator can be used also in case of mains power failure or a light-bulb blow-out.
- It is advantageous if the collimator controls are no more than 110 cm away from the front wall of the cassette holder, enabling a person not taller than 155 cm to reach them, when the *x-ray* tube is in normal position for examination of a recumbent patient on a 70 cm high patient trolley.
- The collimator should be designed in such a way that the light bulb can be replaced with retained exact position without the use of special tools. The position of the centre of the light field shall not vary more than 14 mm (1% of the FFD) from the point, where the central *x-ray* beam reaches the cassette holder. The limits of the light field may not vary more than 1% of the FFD from the limits of the *x-ray* field.
- Spare collimator bulbs, sufficient for an estimated 10 year's consumption, should be provided.

Specification for the WHIS-RAD Examination Unit

1. *General Description of the Examination Unit*

The examination unit consists of a support for the *x-ray* tube and the cassette holder, usually called the stand, and a patient trolley, which can be used as a floating-top table.

The examination unit combines the functions of a chest unit, a vertical bucky, and a floating-top table with an *x-ray* tube stand. It must permit the use of horizontal, vertical and angulated *x-ray* beam on lying, sitting and standing patients, also in emergency situations.

2. *The Support for X-ray Tube and Cassette Holder*

It is necessary to use a design of the stand which will ensure that the *x-ray* tube can always be connected to the cassette holder in a rigid and stable way, providing precise and simple centering of the *x-ray* beam.

The focus-film distance (FFD) shall be fixed at 140 cm. The *x-ray* tube and the cassette holder shall be mounted in such a way that also a recumbent patient can be examined with a horizontal *x-ray* beam. The arm assembly shall be perfectly balanced (with a 24 x 30 cm cassette in place) in two basic positions: horizontal and vertical.

It must be possible to angulate the arm $\pm 30^\circ$ from both these positions, retaining the balance, and to use a horizontal central *x-ray* beam in the minimum range of 50-170 cm above the floor. No individual tube angulation is acceptable in a standard installation.

Comments: If a WHIS-RAD unit is extensively used in traumatology, e.g. in an emergency room, it should be possible to create a horizontal *x-ray* beam, which is not directed towards the cassette holder. It should also be possible to tilt the *x-ray* beam 90° downwards, when the tube arm is horizontal, for radiography of patients which cannot be moved from the bed or stretcher, on which they have arrived. This use implies taking away the radiation protection included in the cassette holder and should be applied only under the supervision of a qualified radiographer.

3. *Cassette Holder*

The cassette holder shall be fixed at right angles to the central *x-ray* beam and shall accept any standard cassette format in longitudinal and transversal position. Critical dimensions are given in Table 6.

Note: The largest format may be different in different parts of the world, depending on the size and constitution of the individuals to be radiographed. In many parts of the world the 35.6 x 35.6 cm format ("35 x 35") is satisfactory for PA chest, abdomen and pelvis due to the advantageous imaging geometry of the WHIS-RAD (the FFD is 140 cm and the skin-film distance is 2.5 cm in chest radiography). However, the 35 x 43 cm format is required in large parts of Africa and in most parts of Australia, Europe, and North America.

It must be possible to change cassettes with minimal difficulty also when the *x-ray* beam is used in the vertical direction, with the trolley in place above the cassette holder.

The cassette holder may be used as a small horizontal examination table without using the trolley. It must permit a load of at least 15 kg without unwanted downward movement or disalignment of the focused grid.

The centre of the *x-ray* beam and vertical film format dimensions for the four most used film formats shall be indicated on the front wall of the cassette holder. If the 35 x 43 cm format is anticipated to be used also in the transverse position, this must be indicated on the cassette holder.

The front wall of the cassette holder shall contain a fixed anti-scatter grid (see below).

The back wall of the cassette holder shall contain a protective screen with a density equivalent to 0.8 mm of lead and outer dimensions not smaller than 49 x 49 cm.

4. *Anti-Scatter Grid*

The anti-scatter grid must be focused at a distance of 135-140 cm. The grid ratio shall be 10:1 with a line density of 40-60 lines/cm. The grid shall be large enough to cover a vertical film format of 35 x 43 cm. If the 35 x 43 cm format will be used in transversal position, the grid must be 43 x 43 cm.

Note: Practical experience has shown that a grid with 40 lines/cm is satisfactory and practically invisible, when correctly focused and when the resulting film is viewed at a distance longer than 30 cm. Lead with interspacing aluminum is advantageous in the 90-120 kV-range and acceptable in the 70-80 kV-range.

Grids using carbon fiber as interspacing material usually come with at least 60 lines/cm. They are advantageous in the 53-70 kV range but not equally effective (resulting in lower contrast) in the 90-120 kV range.

5. *Examination Table*

The examination table shall be a trolley, which can be used as a floating-top table. The table top shall be rigid and be able to support a patient weighing 110 kg, sitting on the middle of the table, without appreciable distortion. The equivalent density of the table top should not be more than 1 mm Al.

The design of the trolley must permit the use of the cassette holder in horizontal position under the trolley in such a way that the distance between the table top and the film plane does not exceed 8 cm. In this position it must be possible to use the trolley as a floating-top table, so that the longitudinal midline of the trolley can be offset no less than ± 12 cm from the midline of the cassette holder.

The trolley shall have large wheels, with locks on at least two of them. A central lock for the wheels is preferred. The table surface should be flat. Dimensions are given on the following section 6: Summary of critical dimensions of the examination unit.

6. Summary of Critical Dimensions of the Examination Unit

<i>Focus-film distance</i> (fixed, not variable)	140 cm	
Distance between arm pivot and x-ray film	80-100 cm	
<i>Space available for trolley with patient:</i> a. minimum trolley clearance at a level 8 cm below the central horizontal <i>x-ray</i> beam. b. minimum possible lateral movement of the patient trolley with vertical <i>x-ray</i> beam: c. space under cassette holder arm for patient lying in lateral decubitus position:	trolley width + 5 cm (min 70 cm) ± 12 cm from central <i>x-ray</i> beam minimum 25 cm from arm to central <i>x-ray</i> beam	
<i>Tube/cassette-holder arm angulation</i> from vertical and horizontal position - Brake for arm rotation - Brake for height adjustment (additional option) - Distance from pivot to central <i>x-ray</i> beam	±30° mechanical mechanical (electro-magnetic brake) 0 (or very short)	
<i>Height above floor for horizontal beam:</i>	variable: min 50-170 cm	
<i>Optional tube angulation</i> of horizontal arm for use in traumatology by qualified operator:	30° down and 90° down	
<i>Cassette holder</i> - Cassette holder height (=length): - Distance between front wall and film: - Largest distance between front wall and floor at vertical <i>x-ray</i> beam: - Film cassette formats: small format intermediate format long format large format	maximum 50 cm	
	2-3 cm	
	90-100 cm	
	recommended	alternate
	18 x 24 cm	-
	24 x 30 cm	-
	18 x 43 cm	15/20 x 40 cm
	35 x 43 cm	35 x 35 cm
<i>Patient trolley:</i> table width table length table height table top density equivalence dimension of wheels	65-70 cm 200-210 cm 70 cm ± 1 cm 1 mm Al or less diameter 10-15 cm	
<i>Distance from table top to film with no angulation of the x-ray beam:</i>	maximum 8 cm	

Protective Devices

It is recommended that the control panel is installed behind a protective screen or wall, separating an area from the x-ray room, large enough for two people (e.g. operator and interpreter or parent). The lead equivalence of the wall should be no less than 0.5 mm Pb.

The screen or wall must have a lead glass window, adjusted to the average height of a standing radiographer, thus providing a good view of the patient being examined. The lead glass window may be as small as 30 x 30 cm in a thin screen but should be at least 40 x 50 cm in a brick wall.

The back wall of the cassette holder contains 0.8 mm lead (or equivalent), which usually will make regular solid 12 cm thick brick or concrete walls satisfactory as general radiation protection around the x-ray room, if the room is at least 18 square meters in size and no more than 2,000 examinations are made per year.

At least two full length (shoulder to knee, adjusted to the size of a normal person) radiation protection aprons and two pairs of radiation protection gloves with 0.25 mm Pb equivalence should be offered with the *x-ray* equipment.

Appendix I-B

*Specifications for a General-Purpose Ultrasound Scanner**

* Taken from: World Health Organization. *Future use of new imaging technologies in developing countries: report of a WHO scientific group*. Geneva: WHO; 1985 (Technical report series 723).

Specifications for a General-Purpose Ultrasound Scanner

- 1) *Transducer*
Standard unit: 3.5 MHz center frequency.
Optional unit: 5.0 MHz center frequency.
Fixed in-slice focusing on both units desirable but not essential.
Sector angle 40° (sector scanner) or better.
Array length: 5-8 cm (linear array scanner).
- 2) *Controls*
To be simple and clearly arranged
Gain control is required.
Time gain compensation to be by choice of preset and variable conditions.
- 3) *Frame rate*
5-10 Hz (sector scanner), 15-30 Hz (linear array scanner).
- 4) *Frame freeze and display*
512 x 512 x 4 bits (to provide 16 "gray" levels)
- 5) *Omnidirectional calipers*
One pair to be provided, with facility for quantitative read-out and recording.
- 6) *Patient identification*
Facilities to be provided for manually entering and recording data-patient identification, date, etc. —on the image screen.
- 7) *Permanent recording*
Provision must be made for the economical preparation of good-quality permanent image records.
- 8) *Construction*
The unit should be portable (not more than 8 kg), drip-proof, and dust-proof. Proper and continuous operation should be possible under the following conditions:
 Temperature: 0°C to +40°C
 Humidity: up to 95%
Prolonged storage should be possible under the following conditions:
 Temperature: -30°C to +50°C
 Humidity: up to 100%.
The unit should be rugged and capable of withstanding the vibration likely to occur during rough, cross-country transport. Special care should be taken to avoid failure of the transducer, its cable, and its connector under the above conditions. The mechanical design of the transducer should include:
a) Maximum protection against damage by dropping:

- b) Tolerance of the use of a variety of coupling media, particularly local vegetable oils.

9) *Electrical and mechanical safety*

The equipment should conform to the standards set out by the International Electrotechnical Commission for Medical Electrical Equipment. Where interventional use is intended, particular care must be taken to ensure that the relevant standards of equipment earthing (grounding) and leakage of current are met.

10) *Power supply*

The equipment must be capable of working from any of the following types of supply:

Direct current: standard batteries, preferably rechargeable

Alternating current:

- 50 and 60 Hz

- 100, 110, 117, 125 and 200, 220, 240 V

- line voltage variation $\pm 15\%$

Surge protection to be provided.

11) *Servicing and quality control*

Although modern equipment should be reliable and stable in performance, both failures and degradation should be anticipated; the following **quality control** procedures are highly recommended:

- a) At regular intervals (at least every 3 months and preferably every week) the resolution and sensitivity performance of the unit should be checked using a suitable **phantom**. Corrections should be made if there is any appreciable change in performance over a period of time.
- b) Arrangements should be made (with the manufacturer or otherwise) for a centralized repair and maintenance service to be provided, to cover a number of units in a country or region.
- c) Provision must be made for a supply of spare parts to be rapidly available. These parts must include spares for the transducer, the display monitors, and the principal electronic assemblies.

12) *Space*

Ultrasound examinations may be made at the bedside, but it is preferable to set aside a room that will provide both privacy (if necessary by curtains) and a suitable horizontal support for the patient. It is helpful if the room illumination can be reduced. A toilet should be provided close to this room. In busy departments the provision of several changing cubicles will increase the number of patient examinations that can be carried out. No added structural protection is required.

Appendix I-C

Design Requirements for Megavoltage

*X-Ray Machines for Cancer Treatment in Developing Countries**

* Taken from: Borrás C, Stovall J, eds. *Design Requirements for Megavoltage X-Ray Machines for Cancer Treatment in Developing Countries. Report of an Advisory Group Consultation. Washington, D.C., 6-10 December 1993.* Los Álamos: Los Alamos National Laboratory; 1995. (LA-UR-95-4528).

Executive Summary

An Advisory Group Consultation on the Design Requirements for Megavoltage *X-Ray* Machines for Cancer Treatment in Developing Countries was organized by PAHO in Washington, D.C., 6-10 December 1993, with the collaboration of WHO Headquarters, the IAEA, and UNIDO. It was attended by 40 participants including radiation oncologists, physicists, technologists, and representatives from radiotherapy equipment manufacturers. The goal of this Consultation was to propose design alternatives for megavoltage *x-ray* units that have the potential of lower manufacturing cost, simpler design, and less frequent and costly maintenance than current *electron accelerators*.

As the populations age, the availability of equipment, facilities, and staff for cancer treatment is emerging as a major problem in developing countries since they have only a very small percentage of the world's cancer therapy resources. According to estimates by WHO there are currently 9 million new cancer cases per year worldwide. This number is expected to increase to about 15 million new cases by the year 2015, with about two-thirds of these cases occurring in developing countries. It is likely that radiotherapy will, for years to come, remain one of the most important treatment modalities, for both cure and palliation.

The dimensions and radiation characteristics of high-energy *x-ray* machines required to meet the needs of developing countries were defined and found to be very similar to those of high-quality low-voltage machines presently used in the developed countries. The Consultation concurred that such a machine would be equally suited for use in both developing and developed countries.

Major performance characteristics agreed upon

Two-thirds of patients in developing countries are treated with simple parallel-opposed fields. It is desirable to avoid the more complex treatment planning required when using more than two fields. Therefore, the *photon* beam energy should be selected to limit hot spots and the consequent *risk* of fibrosis at the depth of maximum *dose* in thick patient sections when using parallel-opposed fields. The *dose* buildup should provide an adequate *dose* at 5 mm depth for superficial lymph node irradiation, while minimizing the skin *dose* to avoid telangiectasia. The beam quality should therefore be selected so that for a 25 cm thick patient the maximum *dose* in a 10 cm x 10 cm field will be less than 115% (preferably less than 110%) of the *dose* delivered to a central tumor in an equally weighted parallel-opposed beam configuration. In addition the superficial 90% isodose should occur at a depth of less than 5 mm. In practice this implies that the *photon* beam should provide deeper penetration than a ⁶⁰Co beam. In general a *photon* beam in the 5-6 MV range or a highly filtered 4 MV beam with low *electron* contamination is needed to meet these requirements. There was a strong feeling that if the machine is to be an *accelerator*, it must provide significantly greater beam penetration than ⁶⁰Co.

The proposed *x-ray* machine should have the following dimensions:

1. Low isocenter height. No higher than 130 cm, with 115 cm preferred. A small depression in the couch turntable is permissible but generally not desirable for safety reasons.
2. A 100 cm *source*-to-axis distance (SAD) is preferred; a SAD of 80 cm is acceptable if adequate field sizes and patient clearance in isocentric treatments are provided. An isocentric clearance of at least 35 cm from the front flange of the collimator head is required when accessories are attached.
3. The vertical travel of the couch should be at least 65 cm below isocenter. The couch rotation should be at least 90 degrees from the isocentric axis. The field size at isocenter should be at least 30 cm x 30 cm (at least 42 cm x 42 cm on the surface of a 25 cm thick patient with the couch fully lowered).

The following *accelerator* technologies were considered as Category A - meriting further exploration or Category B - probably usable to reach the goal

- A-1. Low-energy linac, in-line *accelerator* design.
- A-2. Low-energy linac, bent beam design.
- A-3. Integrated pulsed *klystron* and low-energy linac combined in same vacuum envelope.
- A-4. Low-energy microtron mounted in line with the radiation head.
- A-5. Low-energy *accelerator* built of replaceable, standardized modules for ease of maintenance.
- A-6. Miniaturization via shorter microwave wavelength (e.g., 3 cm instead of present 10 cm) with possible improvement of *magnetron* reliability.
- A-7. Replacing the high-voltage modulator with a pulsed *magnetron* magnet.
- B-1. Low-energy betatron mounted in the radiation head, with its magnet driven at about 10 kHz to achieve adequate *x-ray* intensity at 6 MV.
- B-2. Low-energy rhodotron, a continuous-wave (cw) *electron accelerator* using a half-wave coaxial cavity to accelerate the beam on multiple passes.
- B-3. cw microwave *accelerator* (no modulator, simple *magnetron*) with reflected beam to increase accelerating potential to 4 or 6 MV
- B-4. A 2 or 2.5 MV direct current (dc) *accelerator* with power supplies cascaded, transformer-coupled, nested, or of an electrostatic type (i.e., Laddertron or Pelletron). *X-ray* beam filtered to 3 MV penetration.
- B-5. ⁶⁰Co unit with a 100 cm SAD at 1.6-1.8 Gy/min (~3 MV equivalent penetration).

The following descriptions summarize some of these systems

1. *Electron Linear Accelerators (Linac)*. There are approximately 2,500 linacs operating in the U.S. and perhaps double that number worldwide. Linacs are the most widely used device for the production of *x-rays* in the range of 4-20 MV. However, their complexity results in frequent breakdowns that can cause unacceptably long delays in patient treatments. In the U.S. these machines cost between \$500,000 and \$1.2 million excluding installation. To be a serious contender for developing countries, linacs would have to be

simplified to reduce their cost, and their reliability would have to be markedly improved.

2. Cobalt-60 The ^{60}Co radioactive *source*, having a 5.3 year *half-life*, provides a level of reliability not yet achieved by electrically powered devices. However, mechanical problems do arise that can pose serious radiation *exposure risks* for both the patient and medical staff because the radiation *source* cannot be turned "off." Because of their relatively simple mechanical construction and few electrical components, the cost of ^{60}Co units is typically less than that of *electron accelerators*. The main problems with ^{60}Co units are their relatively low *dose* rates, which reduce patient throughput, a steadily decreasing *dose* rate over time, which dictates that the *source* be changed every 3-4 years, *dose* distributions in the patient that are inferior to those provided by high-energy *x-ray* machines, and disposal of spent *sources* which, in the past, has created public health problems in developing countries.
3. *Microtron*. There are about 40 commercially produced microtrons operating worldwide. Microtrons are inherently simpler than linacs and, with a comparable level of development, might achieve greater reliability. The production of 4-8 MV *x-rays* is easily achieved in a microtron 30-50 cm in diameter (depending on the injection method), which can be mounted at the treatment head of a rotating *gantry*.
4. *Direct-coupled-klystronlinac*. This device, under development at Los Alamos National Laboratory, is similar to the standard linac in the way it accelerates *electrons*. However, it differs in that the *klystron* that is directly coupled to the *accelerator* is used as a radiofrequency (rf) oscillator as well as an rf amplifier. Some of the most fault-prone components of the standard linac are eliminated, simplifying both the electronic and mechanical aspects of the *x-ray* system.
5. *Modular-rf-supply linac*. In this proposed linac design, the rf power supply (*magnetron*-or *klystron*-based) and the *accelerator* would be constructed as an integral unit, which would be replaced in its entirety should any component fail. To increase the lifetime of the *magnetrons*, their magnets would be pulsed by a dc supply, thereby eliminating thyratrons which have a high failure rate.
6. *High-frequency linac*. The operating frequency of a standard linac is 3 GHz. Frequencies higher than 10 GHz are being investigated. Such an increase in operating frequency would result in a more compact machine with a reduction in both weight and cost.
7. *High-frequency betatron*. The first betatrons were operating in the 1940s with *electron* beam energies of 20-50 MeV at frequencies of 60-180 Hz. A betatron operating at 10 kHz could produce 6 MV *x-ray* beams having clinically acceptable *dose* rates. The main advantage of the betatron is its high degree of reliability that derives from its simple, low-frequency electronic components.
8. *Rhodotron*. Designed in France for food sterilization, this nonlinear *electron accelerator* utilizes a cw, 300 MHz rf *source*. This lower frequency permits the use of reliable vacuum tubes, and its cw operation eliminates the need for

a high-voltage pulse modulator, hopefully improving its reliability compared with the standard linac.

9. *dc Accelerators*. In both clinical and research laboratories, these machines have proven to be highly reliable and, because of advances in technology, can now be mounted in a compact *gantry*. However, the 2-3 MeV maximum energy achievable was considered too low by most users. Heavy filtration would allow beam characteristics similar to a conventional 3 or 4 MeV *accelerator*. With heavy filtration low beam currents may continue to be a problem.

Additional aspects considered and recommendations made

Many interruptions in the use of modern medical *electron accelerators* are caused by failures of relatively simple electrical, hydraulic, or mechanical components. Difficulties in providing satisfactory maintenance are compounded by administrative problems and delays in addition to inadequate organization, infrastructure, and funding which often lie beyond the control of the individual radiotherapy facility. Some of the problems could be avoided at the equipment design stage by incorporating components of high reliability that are already available for industrial use, and by using a modular design with easily replaceable components. It would be of additional benefit if the modules were compatible in machines from different manufacturers.

Suggestions were made for training programs and for a suitable organization to provide maintenance and to stock spare parts. It was recognized that the term "Developing Countries" has been applied to an economically very heterogeneous group of nations. In many of these nations the economy is now expanding so rapidly that the term "Developing Countries" has been changed to "Emerging Markets" by investors. In these nations, the funding situation for radiation therapy can be expected to improve markedly. This situation will affect the types and numbers of *x-ray* equipment that will be put into service over the next 25 years, as well as the staffing for their operation and maintenance. It is hoped that this change will spread to all developing countries.

The current manufacturers of *electron* linear *accelerators* and microtrons should be encouraged to design and prototype a super-reliable *x-ray* system operating in the 4-6 MV range and meeting the established performance specifications. This encouragement should come from the *accelerator* designers who might cooperate with the manufacturers as well as representatives of the developing nations who can best make the case for their needs.