

## **The Swedish Radiation Protection Institute 's General Advice on Performance Specifications for Purchasing Equipment for X-ray Diagnostics;**

September 11, 1995

These general advice are intended to be used as a basis for what requirements are reasonable from a radiation protection point of view and what hence should be part of the contract in connection with the purchase of equipment for x-ray diagnostics. The advice may even be useful for the work of radiation protection committees with new equipment and with quality assurance according to the regulations of the Swedish Radiation Protection Institute (SSI FS 1994:4) on radiation protection organisation and radiation protection committees etc. for medical application of ionising radiation.

### **Limitations**

These advice do not cover

- standard deals and agreements defining general conditions for the purchase of legal or economical nature,
- circumstances affected the Law on public purchasing (7) and consequences of the EC-directive about purchase (8) can be found in ref. (9),
- conditions affecting the safety of the worker, electrical safety or the environment which have no connection with radiation protection or image quality,
- technical preconditions for the installation like requirements on the power supply, space and room, air conditioning, patient throughput ergonomics and practical handling,
- performance not primarily influencing radiation protection and image quality like the speed and the memory capacity of computers, and the heat capacity and pause intervals of x-ray tubes.

### **General advice**

The following advice are based on international standards, internationally general accepted test methods and experiences from a large number of performance checks of modern x-ray equipment.

Specification of requirements should specify minimum requirements and not performance intervals.

As to avoid misunderstanding, the specification of requirements should be distinct and should not mix unconditional performance requirements with more general wishes.

The auxiliary verb "should" is used throughout the advice. In a negotiation about purchase of equipment the requirements naturally can be made mandatory for the supplier.

## **General**

### *Education and training*

The specifications of requirements should include

- Information on which categories of personnel are to be trained.
- The option for training that can be suggested by the supplier for the respective category. The number of days, how costs are shared etc. and
- come to an agreement in advance on when the planned training can be performed.

### *Instructions for use and technical documentation*

Instructions for use shall be supplied together with the equipment being available from the first day the equipment is used. The instructions for use should

- describe the various operation modes of the equipment,
- describe only the version that is delivered,
- describe error codes that are intended to initiate counter measures during use.

The technical documentation should

- meet the requirements on documentation in the standards from the International Electrotechnical Commission (IEC), 601-series,
- be available completely in either English or Swedish,
- contain information about software, e. g. for reprogramming or trouble shooting to an extent that should be defined in the offer,
- eventually contain a complete list of error codes,
- comprise written protocols from manufacturing and installation tests.

The material should be put together in marked files and contain perspicuous registers listing those documents belonging to the current installation.

### *Inspection*

The specifications of requirements should be formulated in such a way that they can be checked in the final inspection (acceptance test).

## **Conventional x-ray equipment**

### *X-ray tubes and - housings*

The specifications of requirements should comprise

- filtration in the x-ray tube that is desired,
- request of information about the focal spot size according to IEC 336, i.e. e. measured for two directions with 50% of the maximum tube current. X-ray tubes are almost never used with such low effect, therefore there is a need for,
- the same values for clinically relevant loading conditions for the equipment under consideration or complementary "blooming values" according to IEC 336,
- request of information about the modulation transfer function (MTF curves) characterising the imaging properties of the focal spot for clinically relevant loading conditions.

### *Beam limiting devices, beam indication and alignment*

The IEC 601 system is containing general references of minimum requirements for CE marking, but the following completion should be included in the specifications of requirements:

- Automatic beam limiting devices shall allow a manual adjustment to a radiation field smaller than that automatically achieved.
- Automatic beam limiting devices shall be able to adjust the radiation field to the same size, independent of the focal spot film distance.
- The light indication of the radiation field should differ from the radiation field by not more than 1 % of the distance to the focal spot for the clinically relevant settings. The shift of the position caused by changing the focal spot shall be recorded.
- The beam limitation should be circular for circular image receptors and rectangular for rectangular image receptors. If there are strong reasons for deviating from this rule the following requirements should be stated:
  - The edges of a rectangular radiation field shall never exceed a circular image receptor more than that they are touching the receptors border.
  - For mobile C-arm x-ray equipment with fixed focal spot to image receptor distance and removable cassette holder a circular radiation field can be accepted for radiography with the rectangular cassette provided the diameter of the field is equal or less the diagonal of the rectangular film.
- It shall be possible to align the radiation field with the centre of the image receptor within 1 % relatively to the focal spot to film distance with the patient present (not applicable for bedside examinations). This alignment may be achieved by electronic or mechanic connections (e. g. fixed positions).

### *X-ray generators*

The following minimum requirements should be requested for a modern, high quality x-ray generator

- Tube voltage (kV): Max 5 % deviation from the indicated value.
- Tube current (mA): Max 10 % deviation from the indicated value.
- Exposure time (s): Max 10 % deviation from the indicated value. For extreme low mAs values deviations up to 20 % may be accepted.
- Current time product (mAs): Max 10 % deviation from the indicated value. For extreme low mAs values deviations up to 20 % may be accepted, see below.
- Reproducibility: The weighted standard deviation for the radiation output of ten exposures with the same settings should be less than 5 %. That applies also when automatic exposure control is used (for film cassettes, cine, DSA, etc.). When changing the AEC sensor (dominant) or the tube voltage, figures up to 10 % may be accepted.
- Density control: At least 5 steps should be available. The difference between adjacent steps should be adjusted to the steps in the mAs scale (app. 25 %). The reproducibility should be retained.
- It should be possible to adjust the parameters tube voltage, tube current and exposure time separately.
- The presumptive supplier should be able to present PC or oscilloscope images showing the tube voltage for both short and long exposures, e. g. with the scale 1 ms/division for short times and 20 ms/division for long times.

#### *Choice of exposure parameters*

- The linear scales of tube loading, tube current and exposure time should have steps according to the Renard series 10. When film with very high contrast is used, a scale with 20 steps per decade may be adequate.
- The scale for the tube voltage (kV) should have a corresponding subdivision of the steps.
- The tube voltage (kV), the tube current (mA) and the fluoroscopy time should be readable under ongoing examination, and these parameters should be shown on the control panel in the control room and either on the monitor or on the operator's control panel in the examination room.
- The x-ray generator should be equipped with a post exposure mAs-meter.

#### *Associated equipment (patient table etc.)*

- Examination stands for fluoroscopy should be equipped with fixed radiation protection shields.
- Devices for compression of the patient should be included in the specification of requirements if the equipment is to be used for examinations of the abdomen or other soft tissue.

#### *Anti-scatter grids*

The clinical application is determining the requirements for the grids. Grids with carbon fibre materials are generally to be preferred from a radiation protection point of view.

#### *Image intensifier- TV-systems*

For image intensifier/TV-systems (II-TV-systems) the following requirements should be claimed:

- A statement of the largest image field in the plane where the radiation exits the patient. This value must be related to the associated equipment in question
- The spatial resolution in line pairs per mm (lp/mm) at the entrance plane of the image intensifier both in the horizontal and the vertical direction.
- At least two dose rate levels should be present and the highest dose rates measured in front of the image intensifier with an entrance field of 22 to 25 cm should be  
0,15 - 0,3  $\mu\text{Gy/s}$  for "low" dose rate and  
0,3 - 0,7  $\mu\text{Gy/s}$  for "high" dose rate
- Image storage should be available for most application fields.
- An integrating counter that can not be reset should be installed.
- An area dose product meters should be installed to be used for examinations where high patient dose can be expected.
- A description of the selection and indication of functions permitting high tube currents.

### *X-ray film cassettes*

The specification of the requirements should contain

- The sensitivity that is requested, usual expressed as air kerma free in air in  $\mu\text{Gy}$  necessary for the achievement of a net film density of 1.0, at the beam quality intended to be used, or as "speed class" calculated as  $1000/x$  where  $x$  = air kerma in  $\mu\text{Gy}$  for net density 1.0 at the specified beam quality.
- Request on suggestion for suitable film and processing chemistry.
- Request on information about the material of the intensifying screens, the spectrum of the light emitted and the variation of the sensitivity with the radiation quality.
- Request on the MTF measured with the radiation quality that is intended for use.
- Demands about the absorption of the front cover of the cassette, usually expressed in mm Al equivalence.
- Request on information about the weight of the cassettes, complete with intensifying screens.

### **X-ray equipment for computed tomography**

#### *General*

The specifications of the requirements should contain general information on the equipment for computed tomography like

- principle of operation (3rd or 4th generation),
- continuous rotation possible (slip ring technique),
- spiral scan technique available,
- whether continuous or pulsed radiation is asked for,
- which choice of exposure parameters and slice thickness are requested,
- the availability of reconstruction software and of the software for image manipulation,
- request about filtration and beam limiting devices,
- request about the radiation geometry,
- request about detectors: type, principle and efficiency.

#### *X-ray generators and x-ray tubes*

The specification of the requirements should contain:

- Need for high voltage values available. For more simple equipment one setting might be enough, e.g. 130 kV. More advanced equipment should have 2 or 3 alternatives, e.g. 80 kV, 120 kV and 140 kV.
- Need for mAs values available, specified for the different focal spots. They should cover the range between 50 and 800 mAs in steps according to the Renard scale. The reproducibility should be within  $\pm 5\%$ , the absolute and relative accuracy corresponding to that of ordinary x-ray generators
- Needs for overview image (scanning projection image). Choices of selection, settings, accuracy of the indication of the slice (should be within  $\pm 0.5$  mm).
- Needs for the techniques used for the indication of the scan position (e. g. laser) and the accuracy (should be within  $\pm 1$  mm).

### *Radiation dose*

The specification of the requirements should contain:

- Request of dose profiles (free in air) and sensitivity profiles for all slice thickness. When both profiles are adjusted to the same maximum value on the ordinate, the area beneath the dose profile should not exceed the area beneath the sensitivity profile by more than 10 % (20 % for slices < 2 mm).
- Request for CTDI values<sup>1</sup> free in air in the centre of rotation for all slice thickness and tube voltages. Normalised to the same mAs value the CTDI values should be identical within  $\pm 5$  % for the same tube voltage for the various slice thickness and mAs values.
- Request for CTDI values for these settings in the centre and in the periphery (10 mm beneath the surface) of a head and of a trunk phantom.

### *Image quality*

The specification of the requirements should contain:

- Request for the spatial resolution at clinically relevant mAs values, measured in a head phantom with bone simulating ring. Should be at least 1 line pair per mm. If possible, the MTF should be given.
- Request for the spatial resolution at clinically relevant mAs values, measured in a trunk phantom (diameter > 300 mm). Should be at least 0.8 line pair per mm. If possible, the MTF should be given.
- Request for the homogeneity when imaging a homogenous head phantom with a bone simulating ring with approximately 400 mAs. The homogeneity should be better than  $\pm 2$  HU (Hounsfield units) within 80 % of the radius and better than  $\pm 5$  HU within 90 % of the radius.
- Request for the homogeneity of the image when imaging a homogenous trunk phantom with approximately 400 mAs. The homogeneity should be better than  $\pm 5$  HU within 90 % of the radius.
- Request for the long term stability given as the deviation of the CT values in the centre of a head phantom during a period of time of five hours following the first scan of the day. It should not exceed  $\pm 2$  HU.
- Request for the contrast resolution given as three times the standard deviation for the mean CT values in 20 ROI with a diameter of 6 mm, randomly chosen in a homogenous head phantom with bone simulating ring and in a trunk phantom with approximately 300 mm diameter, respectively. The exposure should be performed with approximately 400 mAs. The contrast resolution determined by this method should be below 4 HU in both cases
- Request for the linearity in the CT values in the interval  $\mu = 19 - 36 \text{ m}^{-1}$ . It should be better than 10 HU, for advanced equipment better than 5 HU. The CT value for water shall be  $0 \pm 2$  HU.

### **Digital image intensifier based radiography systems**

The digital II-based radiography systems can be divided into three groups:

1. Digital radiography systems (DR), so called digital cameras
2. Digital subtraction angiography systems (DSA)
3. Digital cine systems for heart examinations (DCI).

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<sup>1</sup> CTDI (Computed Tomography Dose Index) is equal to the line integral over the dose profile parallel to the axis of rotation, from  $-7d$  to  $+7d$ , divided by  $d$  ( $d$  = nominal slice thickness).

*Digital radiography systems (DR)*

The quality and the noise of the images are influenced by the dose being used for the imaging. It should be possible to adjust the dose to different needs. At least two dose levels should be available.

Low dose 0.5 - 1.0  $\mu\text{Gy}/\text{image}$ ,

High dose 1.0 - 1.5  $\mu\text{Gy}/\text{image}$ .

*Digital subtraction angiography (DSA)*

Several dose levels should be possible to select within a wide range in a simple manner. The following range should be available:

1.0 - 5  $\mu\text{Gy}/\text{image}$ .

It should be requested that the image frequency during the examination series can be changed in the same way as for the old film changer technique.

*Digital cine systems for heart examinations (DCI)*

Several dose levels should be available in the interval

0.08  $\mu\text{Gy}/\text{image}$  - 0.12  $\mu\text{Gy}/\text{image}$ .

The possibility for the selection of a higher value for the dose/image is an advantage because there might be a need to evaluate single images with or without subtraction.

**Cine cameras**

The dose per image in Cine systems should be within the interval

0.08  $\mu\text{Gy}/\text{image}$  - 0.12  $\mu\text{Gy}/\text{image}$ .

**Imaging plates and imaging drums**

The specification of the requirements should request a description of the possibilities for image manipulation and that the data sheets of the manufacturer and technical specifications are part of the offer - the latter for providing support for the comparison of different systems.

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