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General guidelines about performance specifications for purchasing equipment for x-ray diagnostics, with comments

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General guidelines about performance specifications for purchasing equipment for x-ray diagnostics, with comments

Sammanfattning / Abstract:

These general guidelines 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. Technical performance requirements are addressed as well as items like documentation, instructions for use, and education and training. The guidelines are also useful for the design of quality assurance programmes.
In the comments in addition to these guidelines legal aspects are touched, including a list of relevant laws, regulations and directives. Standards - both national and international - wihtin the field are referred to with a short description of there content.

Nyckelord (valda av författaren) / **Key words** (chosen by the author):

Diagnostic x-ray equipment, performance requirements

CONTENT

Part I

Swedish Radiation Protection Institute - collection of regulations

General guidelines of the Swedish Radiation Protection Institute about performance specifications for purchasing equipment for x-ray diagnostics

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These general guidelines 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 guidelines 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) about radiation protection organisation and radiation protection committees etc. for medical application of ionising radiation.

Limitations

These guidelines 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 and consequences of the EU directive about purchase,
- 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.

Guidelines

The following guidelines 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 guidelines. 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 about 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 shall 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. 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 electronical or mechanical 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 μGy/s for "low" dose rate and

0,3 - 0,7 μGy/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 μGy 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 with x = air kerma in μGy 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),
- continuos rotation possible (slip ring technique),
- spiral scan technique available,
- whether continuos or pulsed radiation is asked for,
- which possibilities of choice of exposure parameters and slice thicknesses 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 effectivity.

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 ± 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 ± 0.5 mm).

- Needs for the techniques used for the indication of the scan position (e. g. laser) and the accuracy (should be within ±1 mm).

Radiation dose

The specification of the requirements should contain:

- Request of dose profiles (free in air) and sensitivity profiles for all slice thicknesses. 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 [1] free in air in the centre of rotation for all slice thicknesses and tube voltages. Normalised to the same mAs value the CTDI values should be identical within ± 5 % for the same tube voltage for the various slice thicknesses 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 ± 2 HU (Houndsfield units) within 80 % of the radius and better than ± 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 ± 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 ± 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 $\mu = 19 - 36$ m^{-1} . It should be better than 10 HU, for advanced equipment better than 5 HU. The CT value for water shall be 0 ± 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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[1] 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 available:

Low dose: 0.5 - 1.0 μGy/image

High dose: 1.0 - 1.5 μGy/image.

Digital subtraction angiography (DSA).

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

1 μGy/image to 5 μGy/image.

It should be requested that the image frequency during the examination series can be changed in the some 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 μGy/image - 0.12 μGy/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 μGy/image - 0.12 μGy/image.

Imaging plates and image drums

The specification of 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 later for providing support for the comparison of different systems.

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Part II

Comments on the general guidelines of the Swedish Radiation Protection Institute about performance specifications for purchasing equipment for x-ray diagnostics

These comments can be seen as a complement to the general guidelines and are providing a more detailed content e. g. background information for this guidance.

CONTENT

1. INTRODUCTION

1.1 Object

The object of this general guidelines is to provide the purchaser of diagnostic x-ray equipment with support for the specification of requirements and the contract for purchase. These guidelines may also provide support for acceptance testing and for status tests in a quality assurance programme.

General criteria for the assessment of parameter influencing radiation protection, image quality and general functional safety for diagnostic x-ray equipment are suggested, based on experiences from inspections, on standards and on other technical rules. Adequate measuring methods are proposed and recommended limiting values are presented when feasible. The material is presented in a general manner and must be checked critically before application in each single case.
These guidelines are also providing an inventory of the large numbers of regulations concerning x-ray equipment in the annex.

1.2 Limitations

These guidelines do not cover

- standard deals and agreements defining general conditions for the purchase of legal or economical nature(1-5).

- dental x-ray equipment and x-ray equipment that is outdated or by other reasons most unlikely will be subject of Swedish purchase contracts in the future.

- mammographic equipment which is already dealt with in general guidelines from the Board of Health and Welfare 1990:3 (6).

Information about the law on public purchasing (7) and other consequences of the EC directive about purchase (8) can be found in ref. (9).

Modern diagnostic x-ray equipment is complex and makes use of quite different technologies. The following parameters have been excluded:

- Technical preconditions for the installation (floor pressure, requirements on the power supply, air conditioning, etc.).
- Clinical-technical circumstances influencing mainly patient throughput, ergonomics and practical handling.
- Performance not primarily influencing radiation protection and image quality (the speed and the memory capacity of computers, the heat capacity and pause intervals of x-ray tubes etc.)
- Conditions affecting the safety of the worker, the environment, electrical safety etc. which is not influencing image quality or radiation protection. However, most of the legal rules are listed in annex 2.

- Magnetic resonance equipment is of current interest but are not dealt with here. However, conclusions in these guidelines may provide some guidance for the planning of purchase of magnetic resonance equipment as well.

2. TECHNICAL RULES FOR X-RAY EQUIPMENT

Safety requirements and technical performance for new x-ray equipment may be defined in three ways:

- By mandatory rules from Swedish authorities, see annex 2. Laws and other mandatory rules must be followed, even if not explicitly mentioned in the specification of requirements; but a reminder may facilitate the assessment of responsibilities.

- By specifying the requirements in the purchase contract. This confirms the agreement between purchaser and vendor and is conclusive according to the purchase law. Often reference is made to voluntary rules and regulations in order to simplify the text of the contract.

- According to the manufacturers technical specifications, if nothing else is mentioned. X-ray equipment is on a pronounced international market and the manufacturers often follow the rules in the USA and the EU where much equipment is sold. Data sheets that are part of the purchase contract are frequently containing reservations. That leaves the vendor with great freedom. Less serious vendors may take advantage of the situation and chose specifications giving a profitable deal.

2.1 General

Technical rules (clause 2 above) shall be common knowledge and shall be established if they are to be referred in the specification of requirements. The parameters shall be well defined and the measuring methods shall be described to such an extent that misinterpretation is avoided. It is less important that the performance requirements are in agreement with the wish of the purchaser. It is easy to include more rigorous requirements in the reference (e. g. "total filtration according to IEC 601-1-3 but with at least 4 mm Al").

2.2 EU - rules

The membership of Sweden in the EU implies that Sweden is obliged to adapt its legislation to the EU directives and other rules. Many EU directives are influencing the specification of requirements for x-ray equipment. The directive concerning purchase has been mentioned. The directives concerning responsibility and safety for products are further general examples where new Swedish law is introducing EU rules. It would go too far to treat them here.

The "law on medical devices" (10) and the Health and Welfare Board's regulation SOSFS 1994:20 (11) are implementing the EU "Directive concerning Medical Devices - MDD" (12) into the Swedish legislation. MDD is in accordance with the new scheme of the EU for giving rules, "the new approach". Products being merchandised with the CE sign shall be regarded as safe and are free to for sale in all EES member states. The condition for the CE

marking is that the product meets "basic requirements" being presented in an annex to the directive.

If the product complies with EN standards (more precisely so called "harmonised" standards listed in the EU Common Newspaper), the requirements are supposed to be fulfilled, but the manufacturer is obliged to take prescribed measures for verification. The measures are depending on the domain in which the equipment is used - a classification system exists. Generally x-ray equipment is belonging to class IIb implying requirements on complete quality assurance for the manufacturer or unchallengeable type testing of the equipment.

MDD's "basic requirements" are difficult to verify directly. Compliance with EN norms implies a large simplification for the manufacturer. EU's legislation is containing accordingly a powerful reference to standards.

MDD - and hence also SOSFS 1994:20 - came into force the 1 January 1995. Transitional regulations are permitting the application of the former rules until 14 June 1998. In Sweden very few mandatory rules for x-ray equipment existed before. The specification of requirements should therefore even now demand that the equipment is CE marked.

What is mentioned here is valid for safety requirements. EU approaches performance requirements with great caution. Here is still room for competition and freedom for specifications of the requirements.

2.3 Standards

(See annex 3 for a more comprehensive description and definitions of the abbreviations used).

A "standard" here applies to rules published on different levels within international standardisation. The same standard can usually be found at three levels, as Swedish SS-standard, European EN- or HD-standard and global ISO- or IEC standard.

The three versions are usually almost identical but the ISO and IEC standards are published first and are therefore most updated. Swedish standard is referred to in regulations issued by authorities (which bring EU directives into force) and are often mandatory in practice. Swedish standard is the last one in the process of standardisation and is occasionally out of date. A specification of requirements should refer to the SS standards unless standards on a different level are containing more actual information. Sometimes it might even be appropriate to refer to a draft standard.

In the text below only IEC terms are used. In the actual catalogue on Swedish standards the present status of EU harmonisation and transfer into Swedish standard can be seen.

The standards in the IEC 601 series "Medical electrical equipment - Requirements for safety" form the basis for medical technical device standards. The philosophy behind the structure of the IEC 601 series is explained in IEC 513 (13). The 601-standards concerning x-ray equipment are described in annex 3.

CE marking implies that the x-ray equipment shall comply with the requirements in the IEC 601-series and in harmonised standards, or with equivalent requirements - see clause 2.2. CE marking should even now be part of all specification of requirements. In

that way a complete reference to the standard system as a whole is achieved. The individual standards are containing cross references making the system as a whole applicable in one go. In a simple manner the level of a large amount of parameters is settled and an adequate level of safety is obtained with a generally accepted procedure. There is no need to mention the standards in the specification of requirements.

However, with regard to performance these requirements are insufficient in various aspects and should be strengthened in each single purchase contract - see clause 3. When applicable the technical content of a standard can be used but with higher performance requirements. (E. g. ...total filtration according to IEC 601-1-3 but with at least 4 mm Al).

The standard series IEC 1223 "Evaluation and routine testing" may also be of importance in connection with the specification of requirements. They can serve as support and co-ordination of quality assurance measures in x-ray departments. So far one general standard (IEC 1223-1) and six standards on constancy tests (IEC 1223-2-x) have been published. Additionally five have been accepted for publication. Three drafts on "acceptance tests" (IEC 1223-3-y) are available - see annex 3.

Some other standards are useful because they are defining a common "language" and accordingly are decreasing the risk of misunderstanding in the specification of requirements. Terms, measuring methods and technical parameters are defined, but tolerances and performance requirements are rarely stated. The IEC standard IEC 878 "Graphical symbols" should e.g. always be mentioned.

See annex 3 for more details.

2.4 Foreign regulations

Other collections of rules may be useful in the specification of requirements.
ICRP (International Commission on Radiological Protection) is presenting the basis for x-ray radiation protection in its publications (14-16). They are however mostly too difficult to interpret and formulated in a too general way as for being used directly for specification of requirements.

Some countries are offering such a large market for the equipment manufacturers that their national rules are gaining international bearing. The US so called "Performance standard" (17) is a good example. The requirements there are with certain exemptions in coincidence with the IEC-standards. American Association of Physicists in Medicine (AAPM) and Hospital Physicist's Association (HPA) are examples of organisations publishing documents on performance requirements, test methods and quality assurance for x-ray equipment (18, 19). They are far-reaching with requirements on image quality. The test methods are often well established and very useful, even in specification of requirements.

3. RECOMMENDED SPECIFICATIONS OF REQUIREMENTS

The following guide-lines are based on international standards, internationally general accepted test methods and experience from a large number of performance checks of modern

x-ray equipment. But every purchase is based on its special clinical prerequisites and the technical development is fast. Therefore the guide-lines have to be adopted critically.

specification of requirements should specify minimum requirements and not performance intervals. That will give the supplier the possibility of offering several alternatives comprising even new equipment with performance exceeding the conventional limits. For the same reason is it important to provide the supplier with adequate information about how the equipment is intended to be used.

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

That part of the specification of requirements that gives requirements on key performance should be presented as a reply paper in form of a table. The table should be completed by the supplier and attached to the submitted offer. The data sheets of the manufacturers do not always contain all desired information and the data given are often measured in different ways and hence equipment from different manufacturers is not comparable. The reply paper shall therefore define the testing methods preferred by the purchaser.

In the reply the performance asked for shall be reported clearly and in a comparable way. Thus the judgement of the offer is facilitated and can be done in a more just manner. The items that are differing from the desired performance should be presented in a special annex. Likewise should options be presented separately including performance and costs.

It is also essential to inform clearly about all eventually changes in the original specification of requirements. The final contract is often a compromise between the purchasers requirements and the manufacturers possibilities.. Specifications are frequently changed even after the purchase contract is signed. Such changes must be clearly documented.

3.1 Education and training

Training of the clinical staff, the medical engineers and the hospital physicists should be part of the contract for the purchase of x-ray equipment. In order to avoid misunderstanding the training should be an explicit part of the specification of requirements in the call for tenders.

The supplier has often systems for planning the application training and the service courses. In case these systems can be used the costs for the courses and hence the total cost will be lower. The specification of requirements should therefore define the following minimum requirements for training without entering into details, at least to begin with.

- The categories of personnel that shall 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. should be given.
- The time when the planned training can be conducted.

The training for application should be split up into two parts, the first when the equipment is brought into clinical use and the second some months later when the personnel got used to the

equipment and is prepared to be trained in more advanced applications. It is important that the radiologist is included in the planning of the training programme.

The software in modern computerised x-ray equipment is supplied with different secrecy levels which are assessable by means of codes. High level codes provide access to delicate parts of the programme in such a way that critical malfunctioning may be introduced. The supplier is often reluctant to reveal service software and codes, at least until the technical training is finished. This hesitance should be respected.

Future updating of the software free of charge is often part of the contract. But updating modern computerised equipment may lead to a severe change of the functioning. The staff may not be able at all to manage the operation of the equipment after a change in the control functions. The updating shall not be performed unless the customer's medical and technical staff has accepted the characteristics of the new software. Upgrading must also be combined with acceptance testing and adequate training.

3.2 Instructions for use

Both SSI, SoS, ASS and ESV are prescribing that all x-ray equipment is supplied with adequate manuals in Swedish. These are of such importance that they should be asked for as part of the offers to be evaluated - except maybe for recently developed equipment not delivered earlier in Sweden. In that case it is not appropriate to ask for a translation just for the offer, but an English manual of the same content and disposition like that to be translated should be presented for evaluation.

Updating of the software for the equipment must be combined with corresponding updating of the manuals. The requirement for translation into Swedish is valid even here.

The specification of requirements should contain the following:

- Adequate manuals shall be supplied together with the equipment being available from the first day the equipment is used.

- The various operation modes shall be described in a distinct and clear manner.

- Only the version that is delivered shall be described. The same manual is usually covering a large variety of types and options. The descriptions not applicable shall be excluded in an adequate way.

- Error codes that are intended to initiate counter measures during use shall be described in the manual. Reference shall be made to the technical documentation for the remaining error codes together with comments advising to "contact the service" (see even clause 3.3).

Spri recommendation 6.20 (22) gives requirements on the content of manuals and may be quoted or used as a reference.

3.3 Technical documentation

The technical documentation is frequently very comprehensive and specific for the type of equipment. It is beyond the scope of this paper to enter into details. However, the following should be mentioned in the specification of requirements:

- The requirements on documentation in the IEC 601-series shall be fulfilled.
- All material shall be available in either English or Swedish.
- Information in form of software (e. g. for trouble shooting and reprogramming) shall be made available to an extent that should be defined in the offer. Codes and emulation programmes should be handed over at least in connection with the training of the technical staff, if the purchaser so wishes, see note a) below.
- The material shall be put together in marked files and contain perspicuous registers listing those documents belonging to the current installation.
- Protocols from manufacturing and installation tests shall be included.
- Upgrading shall be documented.
- If the equipment is displaying error codes, a complete list shall be part of the documentation.

a) If the user has access to the service software he may be able to change the performance of the equipment in such a way that the safety system is overruled. Erroneous programming may lead to danger for personnel and patient and may also damage the x-ray equipment. With regard to responsibility reprogramming can be compared with changing components in the equipment. Ignorance and incorrect choice of components may lead to accidents and damage of the equipment.

The manufacturer is responsible for the equipment to be safe with the programming delivered but cannot be responsible for the purchaser's reprogramming. A purchaser who is accepting codes and service programmes is taking over part of the manufacturers responsibility. The knowledge may be invaluable with competent internal service but may be a burden when entrusting to service contract. Therefore the extent to which codes and service programmes are transferred should be dealt with in the specification of requirements and contract.

3.4 X-ray tubes and -housings

The general reference in the specification of requirements to the IEC 601 system covers the requirements concerning leakage radiation (21), maximum 1 mSv/h in a distance of 1 m from the focal spot. It covers also the requirement for beam limitation close to the focal spot for reducing the off-focal radiation.

The permanent total filtration should be mentioned in the specification of requirements. Reference to the IEC 601 system implies a minimum requirement corresponding to a filtration of 2,5 mm Al. In the Nordic countries the minimum requirement is 3 mm Al since long time

ago. Since modern equipment provide a more stable tube voltage and a slightly harder x-ray radiation, the international limiting value may be accepted if only low tube voltages are used clinically.
For more general application the specification of requirements should quote 3 mm Al filtration. For certain equipment (chest radiography, angiography etc.) access to considerably harder filtration should be required (3,0 mm Al plus 0,1 mm Cu or more) in order to achieve optimum image quality and radiation dose (22). If there is a need for variable filtration (23) the specification of requirements should also ask for information about interlock or similar systems that are preventing the use of the incorrect filter.

The influence of the x-ray tube on the image quality is frequently underestimated (24). The remaining parts of the imaging chain in modern x-ray equipment are of such high performance that the x-ray tube frequently is the limiting part.

Requirements on imaging characteristics are normally given merely as the geometrical focal spot size according to IEC 336 (25). This is a generous and uncomplete figure. The nominal focal spot sizes may be exceeded with up to 50 % . The statement of the focal spot size should be complemented with the following:

- The focal spot size according to IEC 336, i. 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.

- Modulation transfer function (MTF curves) characterising the imaging properties of the focal spot for clinically relevant loading conditions.

Regarding adequate performance like maximum loading, anode angle etc. for different clinical applications, see Spri råd 6.16 (Spri recommendations) "X-ray generators and x-ray tubes for diagnostics" (22).

3.5 Beam limiting devices, beam indication and alignment

Through the IEC 601 system the specification of requirements are containing reference to CE marking with basic minimum requirements (21) but the following completion and elucidation are recommended.

- Automatic beam limiting devices shall allow a manual adjustment to a radiation field smaller than that automatically achieved.

- Automatic beam limiting devices shall adjust the radiation field to be independent of the focal spot film distance.

- The light indication of the radiation field shall differ from the radiation field by not more than 1 % of the distance to the focal spot for the clinically relevant settings. The standard is allowing larger differences because it shall be possible to achieve compliance even with extreme conditions (21). That may be accepted for conditions that are rarely used. The

requirements are valid irrespective the choice of the focal spot. The shift of the position caused by changing the focal spot shall be recorded.

- The beam limitation shall 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 shall be stated:
    - The edges of a rectangular radiation field shall never exceed a circular image receptor more than that it touches 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 centre of 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 electronical or mechanical connections (e. g. fixed positions).

The remaining requirements concerning beam limitation (illumination of the light indicator, adjustment to zoomed mode in radioscopy etc.) are covered with the reference to IEC 601 (21).

3.6 X-ray generators

A general reference to the IEC 601 system is here not sufficient. In IEC 601-2-7 (26) safety requirements are given, but performance requirements for settings that are used clinically can often be tighter for modern x-ray generators (27, 28). The following minimum requirements for a modern, high quality x-ray generator should apply:

- 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, see below.

- 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 shall 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 shall be available. The difference between adjacent steps shall be adjusted to the steps in the mAs scale (app. 25 %). The reproducibility shall be retained.

- It should be possible to adjust the parameters tube voltage, tube current and exposure time separately.

- PC or oscilloscope images showing the tube voltage curves of the offered x-ray generator should be presented. The diagrams should show 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.

It is difficult to measure the time current product of small mAs values through a x-ray tube. IEC 601-2-7 is therefore stating that a reference time current product shall be measured for a large mAs value, where high accuracy can be obtained. The linearity of the mAs scale shall thereafter be measured as radiation output (kerma/mAs) with constant tube voltage.

Certain x-ray generators show a considerably large difference in the radiation output for small mAs values (22, 27). In earlier times this had no clinical importance, but as the imaging systems are getting more sensitive, lower and lower mAs values are used for imaging. The deviations of the tube voltage lead to incorrect image contrast and may cause increased radiation doses to the patients. The specification of requirements should hence comprise requirements for the presentation of diagrams with the linearity over the entire mAs scale.

3.7 Choice of exposure parameters

The settings of the exposure parameters shall follow steps that are adjusted to the eye's logarithmic sensitivity curve and its possibility to discriminate density differences (28, 29). The tube voltage is determining the image contrast - the scale must therefore cover an adequate range, usually from 50 to 150 kV. With the tube loading (mAs) that exposure giving the appropriate film density or image quality is chosen - the mAs scale should cover the range from 0,5 to some hundreds mAs.

Approximately a change of the exposure with at least 25 % is needed for the resulting change in film density to be felt as substantial (28, 29). Larger steps will give too rough settings and smaller steps will make the choice of the settings more difficult.

The IEC 601 system is hence recommending that the linear scales of tube loading, tube current and exposure time should have steps according to the Renard series 10 (30), i. e. a scale with 10 logarithmic steps per decade. (In exceptional cases, when film with very high contrast is used, a scale with 20 steps per decade may be adequate, but tighter steps should never be accepted).

The scale for the tube voltage (kV) shall have steps corresponding to the density differences for the other scales. Such a scale valid for intensifying screens of CaWO4 has been existing for many years (28, 29, 31). That scale has proved to work quite well also for other types of intensifying screens and should therefore be retained for the moment being.

The tube voltage (kV), the tube current (mA) and the fluoroscopy time shall be readable under ongoing examination. The specification of requirements shall require that these parameters are shown on the control panel in the control room and either on the monitor (without obscuring the x-ray image) or on the operator's control panel in the examination room.

The x-ray generator should be equipped with a post exposure mAs-meter to enable the operator to read the mAs value after the exposure. Controls and buttons not used in the current installation shall be covered at delivery.

3.8 Associated equipment (patient table etc.)

The image quality and radiation protection is strongly influenced by the material and the design of the table top, of the geometry for imaging (magnification factors etc.) and the design of the fixed radiation protection devices on associated equipment.

The material of the table top implies a well balanced compromise between mechanical stability and attenuation of the radiation beam. It shall be able to examine patients up to at least 135 kg without taking special measures, see (32), subclause 21.3. Offers shall contain information about the table's load capacity and attenuation properties. Table tops consisting of carbon fibre are available today from most manufacturers and should be present in the offers. IEC 601-1-3 (21) is giving limiting values expressed in mm Al equivalence at 100 kV.

Examination stands for fluoroscopy shall have fixed radiation protection shields except when fixed shields are a hindrance for the accessibility (certain angiography stands). General requirements for the design of these radiation protection shields cannot be given. The specification of requirements should instead ask for the design and the efficiency in the offer - e. g. by referring to IEC 601-1-3 (21) - so that these factors can be considered in the evaluation.

Examination tables for fluoroscopy shall be supplemented with other shields, when fixed radiation protection screens are not suitable. These may be fastened in the ceiling or standing on the floor. It is important that they are designed in such a way that they offer protection to the operator and other members of the staff without obstructing the performance of the examination more than necessary. It is always advantageous to shield the radiation near the source, in this case the part of the patient that is irradiated. The design of the radiation shields shall be given in the offer documents (33).

Devices for the compression of the patient shall be included in the specification of requirements if the equipment is to be used for examinations of the abdomen or other soft tissue.

3.9 Anti-scatter grids

The clinical application is determining the requirements for the grids. It would go too far to account for details concerning the performance (23). Generally it can be stated that grids shall be homogenous to such an extent that an x-ray image taken at 50 kV without any other object in the radiation beam is not showing visible inhomogenities (27).

Grids with ratio 10 or higher shall only be used for systems with means enabling the alignment of the x-ray tube to the grid in a reproducible manner (23, 27, 28).

Sometimes there are reasons for having removable grids for dose savings for certain examinations. This should be mentioned in the specification of requirements.

Grids with carbon fibre materials are to be preferred from a radiation protection point of view(23).

3.10 Image intensifier- TV-systems

Image intensifier - TV systems (II - TV) systems are used more and more both within and outside x-ray departments. They are frequently equipped with automatic settings of exposure data and beam limiting. It is important, both from the point of view of dose and of image quality, that these automatic systems are working well.

One characteristic dimension of image intensifiers is the entrance screen size defined in IEC 1262-1 (34). The nominal size refers to the diameter of the screen inside the tube and is always larger than the clinically useful diameter in the patient plane. The specification of requirements shall therefore contain requirements for stating the largest image field in the plane where the radiation exits the patient. This value must be related to the associated equipment in question (35). If more than one configuration exists with different maximum image field sizes the settings for which the measurements were performed shall be accounted for.

The spatial resolution is given in line pairs per mm (lp/mm) related to the entrance plane of the image intensifier. The resolution of the II-TV system must be specified both in the horizontal and the vertical direction. The specification of requirements shall require such information.

Modern II -TV systems consist of image intensifiers with large amplification (high G_x) and TV cameras with high sensitivity and are frequently equipped with digital noise reduction systems and image storage. That provides possibilities for reduced radiation doses during fluoroscopy.

In the 60-ties and 70-ties three dose rate levels were commonly found, 0,2, 0,35 and 0,6 μGy/s. Today there exist two levels at the most and frequently only one, despite the fact that IEC 601-2-7 is requiring at least two levels. In the specification of requirements at least two dose rate levels shall be required (27). The values for the dose levels shall be stated in the offer.

The patient dose is determined not only by the entrance dose rate to the II but also by the filtration and the tube voltage set by the system. The following dose rates, measured without grid in front of the image intensifier (27, 35), are providing acceptable image quality for modern II - TV systems with entrance field sizes between 22 and 25 cm.

Low dose rate	0,15 - 0,3 μGy/s
High dose rate	0,3 - 0,7 μGy/s

The radiation dose is increasing with decreasing image size and vice versa. Theoretically the dose is changed in inverse proportion to the entrance field size of the image intensifier, but the change in dose is frequently compensated electronically or by a diaphragm in the optical system. Because nearly always the grid is used the offer should state the dose rate with the grid in place in front of the grid, measured for all levels of automatic brightness control. The measuring method and the settings of the x-ray equipment (e. g. total filtration) for these measurements should also be stated.

Certain modern II - TV systems work with pulsed x-ray radiation or with special TV-cameras with low image recording frequency for reducing the radiation dose during fluoroscopy. Such systems enables the use of considerably lower dose rates for certain examinations. The specification of requirements should ask for details with regard to the availability and function of such systems.

For many examinations the use of image storage reduces the dose. Image storage should therefore be a requirement for many equipment.

According to SSI's conditions for licences the fluoroscopy times shall be recorded for equipment used outside the x-ray department. This is facilitated if an integrating counter is installed (that can not be reset) in addition to the timer.

The radiation doses from many angiographical and interventional procedures are occasionally very high (33). In the specification of requirements area dose product meters should be requested for equipment used for such examinations, displaying the integrated dose both at the control panel and in the examination room on the x-ray stand.

Many of today's equipment for fluoroscopy are supplied with special settings allowing extremely high tube currents, up to 20 - 30 mA. The selection of this function shall be indicated clearly, also in the examination room, in order to draw attention to the operator about the radiation burden. The specification of requirements shall also ask for a description of the selection and indication of such functions.

3.11 X-ray film cassettes

There is a large variety on the market of film cassettes with many different combinations of intensifying screen, film and processing. General requirements for the performance of cassette-film-screen combinations cannot be given, but it is important that the offer contains statements about the basic performance being significant in the process of selection (27, 29, 36-38). These are:

- Sensitivity with the beam quality intended to be used, usual expressed as air kerma free in air in μGy necessary for the achievement of a net film density of 1,0, or as "speed class" calculated as 1000/x with x = air kerma in μGy for net density 1,0.

- Suggestion for suitable film and processing chemistry.

- The material of the intensifying screens, the spectrum of the light emitted and the variation of the sensitivity with the radiation qualities (37 - 39).

- MTF measured with the radiation quality that is intended for use.

- The absorption of the front cover of the cassette, usually expressed in mm Al equivalence.

- The weight of the cassettes, complete with intensifying screens.

3.12 X-ray equipment for computed tomography

Computed tomography has been developing during the last decade from an exclusive examination method to a routine that is available in most of the hospitals. The development of the equipment has been proceeding in two different directions, on one hand towards simple, robust and fairly non-expensive CT scanners intended for large throughput of routine examinations, and on the other hand towards advanced and expensive equipment which compete with the latest technical achievements. The specification of requirements must be adapted to the respective type that is to be purchased.

CT scanners are complex equipment. Many characteristics and performance variables are acting together determining the image quality and the radiation conditions of the equipment. Apart from the general IEC 601-1 standard no general approved international standard for the safety and performance of CT scanners is yet existing. On the other hand there exist a number of more or less outdated regulations and standard drafts. SSI has issued a regulation in 1980 on performance, design and use of CT scanners (39), and a more up to date report on performance testing has been issued by the AAPM (18).

The performance requirements below are based partly on these documents.

Two different types of modern CT scanners are existing, the 3rd and the 4th generation. In the 3rd generation the detectors are linked firmly to the x-ray tube and are rotating together with the x-ray tube around the patient. In the 4th generation the detectors are attached in a circle at relatively large distance from the patient and the x-ray tube is rotating in an orbit with smaller radius inside the detectorring. There is a considerable difference between these two types, but none of them is considered to be superior to the other.

The performance of a CT scanner, i. e. the geometry and homogeneity of the slices, the radiation dose and the image quality, the scan time and the maximum load are depending on many factors which should be part of the specification of requirements - directly or indirectly. These parameters are listed below, together with recommendations on suitable limiting values/choices of variation.

3.12.1 General specifications

- Principle of operation (3rd or 4th generation)
- Continuos rotation possible (slip ring technique)
- Spiral scan technique available

3.12.2 X-ray generators and x-ray tubes

- How is the high voltage generated? (should be with high frequency technique).
- 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.

- 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. For advanced equipment mAs values up to 1200 mAs should be achievable, if spiral scan technique is available up to 6000 mAs is needed. The reproducibility should be within ± 5 %, the absolute and relative accuracy corresponding to that of ordinary x-ray generators.

- Continuos or pulsed radiation. In case of pulsed radiation the pulse length and pulse frequency shall be reported

- Which scan times can be chosen for the various selections of mAs and focal spot?

- The loading capacity, heat capacity and cooling characteristics of the x-ray tube. This performance is relevant for the examination capacity of the equipment, i. e. how many examinations may be carried out per hour without overloading the tube?

- For CT scanners with access to spiral techniques the longest scanning distance shall be given for a number of clinically relevant settings, with an indication on what is limiting the scanning distance (this could be the heat capacity of the x-ray tube, the memory capacity of the computer or something else). Eventually also the waiting time until the next scan shall be given.

- Overview image (scanning projection image). Choices of selection, settings, accuracy of the indication of the slice (should be within ± 0.5 mm).

3.12.3 Beam limiting and filtration

- The total filtration in the central beam

- Design of eventually "shaped filter".

- The design of the primary diaphragm, e. g. number of collimator leaves and the real slice thickness for the smallest nominal slice.

- The minimum slice thickness for the small focal spot size.

- Presence of secondary beam limiting devices.

- Technique used for the indication of the scan position (e. g. laser) and the accuracy (should be within ±1 mm).

3.12.4 Radiation beam geometry

- Distance between the centre of rotation and the focal spot of the x-ray tube

- Distance between the centre of rotation and the detectors.

- Choices for varying the gantry angle (should be at least ± 30 °)

- Angle of rotation per scan (360 °, over- or underscan).

- Reconstruction diameters available. Information about how the angle of the radiation beam is adjusted to the reconstruction diameter (the radiation beam should be limited in such a way that only the active detectors are irradiated).

- Slice thicknesses available. At least three different should be available, e. g. 2, 4, and 8 mm.

- Dose profiles (free in air) and sensitivity profiles for these slice thicknesses. 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).

3.12.5 Detectors

- Detection principle and detector material (gas, scintillator).

- The effectiveness of the detectors: absorption capacity (should be at least 60 %); the ratio between the active width of the detector segments (in the direction of rotation) and the width of the inactive part in between (should be at least 9:1); the ratio between active measuring time and dead time between measurements (for continuos radiation, should be at least 9:1).

3.12.6 Radiation dose

- In order to be able to perform objective comparisons between different offers, the radiation dose and the imaging parameters should be given for the same settings, e. g. " head" and "trunk"..

- CTDI values free in air in the centre of rotation for all slice thicknesses and tube voltages. Normalised to the same mAs value the CTDI values should be identical within ± 5 % for the same tube voltage for the various slice thicknesses and mAs values.

- 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.

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). Cylindrical PMMA phantoms with diameter 160 mm (head) and 320 mm (trunk) should be used.

3.12.7 Image quality

The supplier should provide the following parameter related to image quality.

- Spatial resolution for 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.

- Spatial resolution for 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.

- The homogeneity when imaging a homogenous head phantom with a bone simulating ring with approximately 400 mAs. Note that the bone simulating ring shall be in direct contact with the homogenous medium with now container in between of e. g. PMMA. The homogeneity should be better than ± 2 HU (Houndsfield units) within 80 % of the radius and better than ± 5 HU within 90 % of the radius.

- The homogeneity of the image when imaging a homogenous trunk phantom with approximately 400 mAs. The homogeneity should be better than ± 5 HU within 90 % of the radius.

- The noise (standard deviation in a circular ROI covering 80 % of the diameter in a circular water phantom) for various mAs values and slice thicknesses shall be reported. It is convenient to present these data as a diagram.

- 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 ± 2 HU.

- 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.

- The linearity in the CT values shall be better than 10 HU in the interval $\mu = 19 - 36\ m^{-1}$, for advanced equipment better than 5 HU. The CT value for water shall be 0 ± 2 HU.

3.12.8 Data collection, image reconstruction

The capacity and the possibilities of choice of the reconstruction software and of the software for image manipulation is of vital importance for the use and possibilities of a CT scanner. Most equipment provide different reconstruction programmes for special examinations. More advanced equipment with powerful computers provide the possibility of multiplanar reconstruction of slices in arbitrary directions and other advanced image treatment. It is important that these special functions are described in the offer clearly and exhaustively in

order to allow fair comparisons. However, there is still a lack of both standards and practice with regard to the manner of how to describe these functions.

3.13 Digital image intensifier based radiography systems

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

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

In order to make proper use of the image matrix the circular image of the image intensifier is cut by certain digital system's quadratic image matrix, so that only a part of the diameter can be used. The specification of requirements shall therefore specify which diameter of the object really can be seen in the images.

An important parameter for all digital systems is the spatial resolution. It is given in line pairs per mm in the entrance plane of the image intensifier. In the specification of requirements information shall be required about the resolution power, preferably both in the centre and in the periphery in both the horizontal and vertical direction.

For digital radiography systems generally the image quality can be improved if the radiation dose is increased, up to the level which leads to oversteering. Too high or too low dose will not lead to over- respectively underexposed images. What happens is that the signal to noise ratio (S/N) is increasing with increasing dose per image and higher S/N will give improved contrast resolution. Hence, there is a tendency to use unnecessary high radiation dose when taking images - this will never lead to "bad images". It is of importance that it is possible to vary the dose per image in such a way that the image quality can be adjusted to the clinical demands (27, 33).

The dose levels per image given below are appropriate for entrance fields sizes between 22 and 25 cm, without a grid. For smaller entrance fields the dose is increasing and decreasing for larger entrance fields. In theory the dose is varying in reverse proportion to the entrance area of the image intensifier, but the dose variation is often compensated for electronically or with a diaphragm in the optical system.

3.13.1 Digital radiography systems (DR), so called digital cameras

DR systems are used for replacing ordinary imaging on film or with fluorography cameras. The images are taken one by one or with low frequency, up to some images per second. Subtraction technique is not being used and image *treatment* is restricted to setting windows, edge enhancement or to equalise the intensity.

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

These should be:

Low dose: 0.5 - 1.0 μGy/image High dose: 1.0 - 1.5 μGy/image.

3.13.2 Digital subtraction angiography (DSA).

When using DSA systems images are taken after contrast injection into the vessel and two images are subtracted from each other in order to reduce the interference from the superposed organs. The result is mostly viewed with narrow settings of the windows giving high contrast in the images. By this procedure the noise is amplified and is often the limiting factor the quality of the images. Several dose levels must be selectable in a simple manner within a wide range, or else there is a high risk that always the high dose level is used. The following range should be available:

1 μGy/image to 5 μGy/image.

DSA systems are used for examinations of vessels in the abdomen and in the extremities. Contrast medium is directly injected into the vessel by means of a contrast injector and it is important that the distribution direct after the injection can be followed. For that purpose high image frequency is needed, up to app. 5 images/s during several seconds. Then the contrast medium is diluted more slowly, and a lower image frequency with only a few images/s is sufficient. The sequence is completed with a very low image sequence during rather long time.

In the specification of requirements for DSA systems a requirement shall be included as to allow a change of the image frequency during the examination series in the some way as for the old film changer technique.

The patient's skin dose can be very high during certain DSA examinations (33). A number of acute radiation damages, some of them quite serious, has been reported. In order to be able to continuously checking the patient dose DSA systems should be equipped with a measuring device for the area-dose product - see IEC 580.

3.13.3 Digital cine systems for heart examinations (DCI)

When imaging the movement of the heart high image frequency is needed, usually at least 25 images/s. Each imaging series is containing several hundreds of images. For evaluation they are mostly viewed as movable images with varying image frequency. Under these conditions the eye will not react on the noise in every single image, so the noise could be higher than in DSA systems. Therefore the dose per image may be considerably lower in DCI systems compared to DSA systems. Usually 0.08 μGy/image - 0.12 μGy/image is sufficient.

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. Higher dose/image is improving the image quality.

3.14 Cine cameras

When imaging the movement of the heart high image frequency is needed, usually between 25 images/s and 100 images/s. Each imaging series is containing several hundreds of images. For the evaluation they are viewed mostly as movable images with varying image frequency. Under these conditions the eye will not react on the noise in every single image, so a high noise level can be tolerated. Therefore the dose per image may be low in Cine systems, usually 0.08 μGy/image - 0.12 μGy/image is sufficient.

Note that generally it is not possible with cine systems - opposite of digital systems - to change the dose per image for different examinations because the film must be exposed to give the correct density.

Usually the film is exposed with so called overframing. The focal length of the lens is chosen in such a way, that the spherical output image of the image intensifier is cut at the top and at the bottom by the rectangular image window. The image area is reduced but the quality of the images is improved when using a projector for the evaluation. The offer should give information about the various focal lengths/degree of overframing that are selectable.

3.16 Imaging plates and image drums

Imaging plates are replacing ordinary x-ray film and intensifying screens when performing examinations at ordinary x-ray stands and at specially designed so called imaging plate stands, most frequently used for chest examinations. In 1993 a new imaging system was introduced for chest radiography with a large selenium drum as image receptor. Imaging plates and drums differ from screen film systems by the fact that images are not of an incorrect density when over- or underexposed - only the image quality (noise content) is changed. The risk of retakes due to incorrect exposure is decreased. Imaging plates are also allowing digital image manipulation.

Imaging plates exist, like x-ray cassettes, designed for different types of examination (skeleton, soft tissue, chest etc.). Exposures can be performed with mAs values within a large range, dependent on the clinical requirements. There is a risk that always a high dose per image is used. X-ray stands and x-ray generators used with imaging plates should be equipped with an automatic exposure control that easily can be adjusted for different values for the dose per image in order to enable the optimisation of imaging for different types of examinations and clinical requirements. The automatic exposure control shall however be restricted to values not exceeding the equivalent of film-screen system with the speed class 300 - 400.

New imaging plates are being developed continuously because the technique is new. New generations with improved noise characteristics (DQE/NEQ data) are produced. Information about generation and noise characteristics should be asked for in the specification of requirements.

Some systems are equipped with software based warnings or interlocks prohibiting over exposure and high doses. Items like this should be part of the specification of requirements.

Of great importance for the quality of the images is the image manipulation performed in the system's computer. Large differences exist between different systems. It is important that the image manipulation can be adjusted according to the user's wishes. The specification of requirements should therefore require a description of the possibilities for image manipulation.

The present fast development makes it difficult to provide advice about specification of requirements for imaging plate systems. No standards beyond the general IEC 601-1 are available and validation judgements that are valid for other image receptors are often not applicable. The specification of requirements should therefore require that the data sheets of the manufacturer and technical specifications are part of the offer.

3.16 Inspection

The purchase of x-ray equipment is a large and complex business that should be completed with a final inspection in which the installation's and the equipment's concordance with the purchase contract, the performance requirements, authorities' rules and safety rules are checked. See advises in BMU 93 (5).

The specification of requirements should be set up in such a way that they can be checked at the inspection. Technical requirements should be specified with measuring methods etc. to such an extent that problems with interpretation are avoided. This can be done by reference to standards or to other established measuring routines. Following the progress of new regulations and standards should be part of the hospitals' quality assurance programme, so that really applicable rules are referred to in the specification of requirements.

The inspection should also be planned for in time as to allow all parts to be prepared well. It might be suitable to choose the inspecting person already in the purchase contract.

The following items should be part of a final inspection.

- Check of the agreement between delivery and order.
- Check of the manuals and of how the staff is trained on the equipment in question.
- Check of the safety aspects(radiation protection, electricity, mechanics, environment).
- Check of the function and performance according to the specifications in the purchase contract.
- Check of the installation's quality and that the connections to the power supply (40) and to the water and sewer system agrees with valid regulation, see annex 2.

Annex 1

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Annex 2

MANDATORY RULES FOR X-RAY EQUIPMENT

Some important ordinances that are stating mandatory technical requirements on the design of x-ray equipment. Possible ordinances not mentioned in this annex but which are applicable to x-ray equipment are of course also mandatory.

The designation in the ordinances are indicating the authority being responsible.

Ordinance designation	**Title**
FS 1977:1160	Law on occupational environment
SFS 1982:762	Law on health care
SFS 1988:220	Radiation protection act
SFS 1993:584, revised 1994:860.	Law about medical technical devices
SFS 1993:1067	EMC-ordinance.
SFS 1993:1068	Ordinance on electrical material.
AFS 1981:9	Laser
AFS 1982:13	Personal protection equipment.
AFS 1983:11	Anaesthesia gases.
AFS 1985:12, revised 1992:14	Video display units
AFS 1986:21, revised 1993:10	Machines and certain other apparatus.
AFS 1987:2	Electromagnetic fields.
AFS 1987:13, revised 1992:12	Liquid nitrogen.
AFS 1989:18	Inspection of hoists.
AFS 1990:3	Lead.
AFS 1992:15	Safety colours and signs.
ELSÄK-FS 1993:14	Regulation about certain electrical material.
ELSÄK-FS 1993:15	Electromagnetic compatibility.
ELSÄK-FS 1993:16	Radio disturbance from electrical material.
ELSÄK-FS 1994:4	Ordinance on high-tension current. Is replaced 1996-05-01 by
ELSÄK-FS 1994:7	Ordinance on high-tension current. May be applied as from August 1994.
STEV FS 1990:4	Requirements on qualification for electrical installations.
SSI FS 1981:4	Ordinance on periodic checks of x-ray equipment
SSI FS 1989:1	Ordinance on dose limits for work with ionising radiation.
SSI FS 1991:1	Ordinance on radiation shielding of x-ray installations for medical diagnosis.
SSI FS 1992:2	Ordinance on disconnecting the fluoroscopy mode at certain x-ray equipment.
SOS FS 1978:26	About responsibility for medical technical equipment.
SOS FS 1977:50	About reporting of accidences and incidences.
SOS FS 1994:20	Ordinance and general guide-lines about medical technical devises

Abbreviations of the authorities' name

ASS	Board for occupational protection
ELSÄK	Authority for electrical safety.
KemI	Governmental chemicals inspection
SFS	Swedish catalogue of ordinances (of parliament and government).
SNV	Governmental environment protection board.
SOS	National board of health and welfare.
SSI	Swedish radiation protection institute.
STEV	National energy board, now national board for electrical safety.

Annex 3

STANDARDS FOR MEDICAL X-RAY EQUIPMENT

1. INTRODUCTION.

As mentioned in the report international standardisation is getting more and more important since Sweden has become a member of the European Union. With regard to technical details the EU directives, taken as political decisions, are referring to "harmonised standards", i. e. to CEN/CENELEC standards (EN-standards) published in the official journal of the EU. In formal terms Sweden has to apply the correspondent Swedish standards which are identical (SS-EN-standard). They are constituting one of three steps in the international standardisation.

1.1 Global standards

Manufacturers, authorities, testing organisations etc. are co-operating on a global level within ISO (International Standards Organisation), IEC (International Electrotechnical Commission) etc. for producing international acceptable standards for technical products. The work is performed within expert groups according to agreed directives. Drafts are submitted to the National Committees of the member states for comments. In the last submission the standard is finally settled by voting.

The results are published as ISO- or IEC-standards. The IEC domain is the most interesting because x-ray equipment is belonging there. Within radiology approximately 40 standards are published and many drafts exist in an advanced stage.

1.2 European standards

Evidently the global standardisation is based to a large extent on compromises. Within a smaller region it is likely to come farther in the details. Within Europe CEN and CENELEC are working with the further development and completion of ISO- and IEC-standards, respectively. CEN/CENELEC are joining fairly solidarily the global level of standardisation and at least within the x-ray domain hardly any changes in the ISO/IEC-standards are made. In addition there is a tight time schedule today with many ongoing projects. EN-standards are hence fairly identical to ISO/IEC-standards.

The "New Approach" of the EU has put more emphasis on this work because products that are complying with harmonised standards are presumed to comply with the general requirements in the EU directives.

1.3 National standards

All nations do have their own standardisation system which is transferring the international/regional standards to national standards according to the national legislation and practices. In Sweden, *Standardisering i Sverige* (Standardisation in Sweden, SIS) is the umbrella organisation with a number of professional bodies in the corresponding branch. Svenska Elektriska Kommissionen (Swedish Electrical Commission, SEK) and Hälso- och

Sjukvårdsstandardiseringen (Health- and Health care standardisation, HSS) are the most important professional bodies with regard to x-ray equipment.

Technical committees within HSS and SEK shall provide Sweden with standards that are considered necessary by the trade association. Global and European standards are accepted as national standards more or less automatically and general rules are preventing issuing separate national standards. In the commenting and referral procedure on the international level the technical committees have the opportunity of influencing the content of the Swedish standard. Already the level of CEN/CENELEC gives little room for national initiatives.

X-ray standards are drawn up in the IEC Technical Committee 62 - Electrical Equipment in Medical Practice" - and in its four subcommittees. The Swedish correspondence is SEK TK 62 "Electrical equipment for medical use" and TK 62BC "Equipment for x-ray, high-energetic radiation and nuclear medicine".

The process of harmonising an IEC standard to a SS-EN-standard is rather time consuming. Reference to the basic IEC standard implies usually that all SS-EN-requirements are covered but in addition a number of IEC standards that are not settled as Swedish standard yet. Therefore it may be appropriate to refer to IEC publications in the specifications of requirements.

IEC is using strictly defined terms. The advantage is that the standards become more consistent and distinct. The disadvantage is that they become heavy and difficult to read, if the key to the terminology is not available. The reader who wants to get engrossed in standard texts should acquire IEC 788, Terminology.

All standards can be ordered from SIS, tel. 08-613 53 50.

2 THE IEC 601-SYSTEM

Diagnostic x-ray equipment is regarded within the IEC as a "medical device" and therefore the standard series IEC 601 is applicable.

A reference to the IEC 601 system (SS-EN 60601) should always be part of the specifications of requirements. In principle a reference to the system as such is sufficient. The individual standards contain cross references so the entire system is applicable at the same time. In a simple manner the level of a large number of parameters is settled in a generally accepted way.

2.1 IEC 601-1 General Requirements for Safety

IEC 601-1, edition 2 (SS-EN 60601-1) is the introductory general standard with requirements on safety and to a certain extent on performance, common for all electromedical devices. It shall cover all areas of risk and is applicable as a whole, if there are no other standards giving more details. For a certain type of equipment many of the requirements are incomplete or not applicable. Completing is needed. But IEC 601-1 is establishing a broad spectrum of basic requirements and is defining a common structure for all standards in the 601-series.

A number of amendments are belonging to the standards

2.2 IEC 601-1-x Collateral Standards

"Collateral standards" are applying the same structure and numbering of the chapters as IEC 601-1 and are dealing with general amendments in 601-1 in order to cover special areas of problems. The requirements in IEC 601-1 are changed but not in any other standard in the system.

2.2.1 IEC 601-1-1 "Safety Requirements for Medical Electrical Systems"

Medical technical equipment is frequently used within connected systems in the clinical environment. X-ray equipment is a good example. The patient support, the x-ray tube assembly support, the generator and the imaging computer may be regarded as separate equipment in one system. Frequently contrast injection syringe, the anaesthesia equipment etc. is added. Even if all the components by themselves are safe enough, the interconnection may give rise to new risks, especially if devices not intended for medical application are part of the system, as e. g. computers. IEC 601-1-1 is dealing with these problems.

IEC 601-1-1 is part of the specifications of requirements if reference is made to the IEC 601-system, but it may be mentioned explicitly as to make this clearer.

2.2.2 IEC 601-1-2 "Electromagnetic Compatibility"

Electrical equipment is frequently influenced by electromagnetic radiation ("radiowaves") if these are of unfavourable frequency or high intensity. The sensitivity related to such disturbances are dealt with in IEC 601-1-2. On the other hand the equipment itself may be emitting such signals which may influence other equipment nearby. IEC 601-1-2 is giving certain limits for this as well.

X-ray equipment is containing sensitive electronics e. g. in the handling of the image and may be sensitive for disturbances. They are also containing powerful oscillators and high electrical power which may give large disturbances.

2.2.3 IEC 601-1-3 "Radiation Protection"

IEC 601-1-3 is containing general radiation protection requirements for diagnostic x-ray equipment, i. e. requirements on filtration, primary and overall beam limitation, leakage radiation, primary radiation shielding, attenuation in the patient support etc. The standard is valid in principle also for computed tomography and simulators for therapy, though many of the requirements are not applicable.

IEC 601-1-3 does not contain all requirements for radiation protection in the IEC 601-system. "Particular standards" may provide supplementing and amendments for different parts of the x-ray equipment or for special types of equipment.

Mainly, IEC 601-1-3 is based on the US Performance Standard (see ref. 17 in annex 1).

2.2.4 IEC 601-1-4 "Programmable systems" (only draft version is existing)

This standard contains requirements on the computer system of the x-ray equipment and provides guidelines about how to ensure that the computers is working as intended. Because it is still a draft it isn't included automatically yet when referring to the 601-system.

2.3 IEC 601-2-y "Particular requirements for safety"

These standards are containing supplements and amendments to the standards 601-1 and 601-1-x (x = 1 - 3) so that they become applicable for a certain type of equipment. Around 30 such standards are published and four of these are concerning x-ray diagnostics. Several more exist as far advanced drafts.

2.3.1 IEC 601-2-7 "Particular requirements for X-ray generators".

This standard is providing requirements (electrical safety, mechanical safety, radiation protection) for x-ray generators connected to the main system. It is valid for generators independent of the corresponding x-ray tubes. The standard was published in 1986, but is based on old material and is today quite out of date. Revision is in progress.

IEC 601-2-7 is part of the specifications of requirements when referring to the IEC 601-system and is known so well that it needs not to be addressed. On the other hand completion is needed - see section 3 in the report.

2.3.2 IEC 601-2-15 "Particular requirements for capacitor discharge generators".

This standard is based on IEC 601-2-7 and contains the same material though adjusted to capacitor equipment with the capacitor in the high voltage circuit. Therefore it is not applicable for a number of modern types of battery-driven mobiles. For those units the IEC 601-system do not comprise any automatically applicable standard. The specifications of requirements should mention that IEC 601-2-7 and IEC 601-2-15 shall be valid as far as they can be applied.

For certain equipment IEC 601-2-15 is part of the specifications of requirements when referring to the IEC 601-system - but how it is to be applied is obscure. The requirements are also insufficient and should be complemented.

2.3.3 IEC 601-2-28 "Particular requirements for x-ray tube assemblies and x-ray source assemblies.

This standard is providing mostly thermal, mechanical and electrical requirements for x-ray tubes and x-ray tube housings. It is also superseding IEC 637 "Marking and accompanying documents for x-ray tubes". IEC 601-2-28 is part of the specifications of requirements when referring to the IEC 601-system but is still new and not very well known. Therefore it should be mentioned explicitly.

2.3.4 IEC 601-2-32 "Particular requirements for associated equipment"

"Associated equipment" refers to stands, patient supports and other parts of the x-ray equipment that are not directly involved in the production and detection of x-rays. The standard contains mainly mechanical requirements for these components. IEC 601-2-32 is part of the specifications of requirements when referring to the IEC 601-system but is still new and not well known. Therefore it should be mentioned explicitly.

3 THE IEC 1223-SYSTEM "QUALITY ASSURANCE"

In this standard series IEC is dealing with quality control on x-ray equipment. A system with standardised "acceptance tests" is advocated when the equipment is brought into use followed by rather simple "constancy tests" that are checking periodically that the equipment remains in acceptable conditions. These "acceptance tests" may be important for future specifications of requirements but no such standard is published yet.

The main standard in the series, IEC 1223-1 "Evaluation and routine testing - General aspects" is important as an orientation about the system and as a basis for quality assurance. Six "constancy test standards", IEC 1223-2-x (x=1-6), are published and further five are approved for publication. A number of "acceptance tests" are also on the way and are expected for publication during 1996.

IEC 1223-2-1	Film processors
IEC 1223-2-2	Cassettes
IEC 1223-2-3	Dark rooms
IEC 1223-2-4	Hard copy cameras
IEC 1223-2-5	Image display units
IEC 1223-2-6	Computed tomography
IEC 1223-2-7	Dental x-ray equipment (to be published)
IEC 1223-2-8	Radiation shielding (to be published)
IEC 1223-2-9	Radioscopic equipment (to be published)
IEC 1223-2-10	Mammographic equipment (to be published)
IEC 1223-2-11	General radiographic equipment (to be published)

4 OTHER X-RAY STANDARDS

In addition to the systems mentioned a number of IEC standards exist describing measuring methods, special requirements for measuring equipment etc. They are often useful for elucidating a specifications of requirements and are defining how parameters are to be measured. The supplier is frequently referring to these standards in his technical specifications. A number of those are referred to in this report.

These standards are not automatically included in the specifications of requirements but must be referred to.

IEC 336 "Characteristics of focal spots in x-ray tubes".

This standard is defining methods for measuring the MTF and focal spot size and is used frequently. Edition 2 from 1993 should be referred to when measuring methods for the focal spot are to be defined. Be careful to avoid confusion with the old edition. The recommended methods allow for large tolerances and are defining the focal spot size at 50 % effect of the x-ray tube. The standard is also providing methods for the determination of the dependency of the focal spot on the loading.

IEC 406 "Radiographic cassettes".

Dimensions and other technical details for x-ray cassettes are specified. Edited in 1975. A new edition is in course of preparation.

IEC 520 "Entrance field sizes of electro-optical x-ray image intensifiers".

This standard was recently withdrawn. See IEC 1262-1

IEC 522 "Inherent filtration of an x-ray tube assembly".

Published in 1976. The standard is describing a method for measuring the inherent filtration by reference to a complicated laboratory set-up. The method concerns hardly others than x-ray tube manufacturers. It is scarcely applicable in the specifications of requirements. The total filtration is the interesting parameter and that is measured preferably in a different way (see IEC 601-1-3).

IEC 526 "High voltage plug and socket connections"

Published in 1978. This standard is scarcely interesting for others than manufacturers.

IEC 572 "Determination of the luminance distribution of image intensifiers".

This standard was recently withdrawn. See IEC 1262-3.

IEC 573 "Measurement of the conversion factor of image intensifiers".

This standard was recently withdrawn. See IEC 1262-2.

IEC 580 "Area exposure product meter".

This standard is defining the functioning and the dimensions of dosemeters for the quantity beam area times average dose (more precise kerma). Such measurements are mandatory in some countries. Modern x-ray equipment is of high capacity and increased radiation doses have been observed for certain examinations (angiographies etc.). In such cases area-product-

meters are recommended. The standard was published in 1977 and a revision is expected within some years.

IEC 613 "Electrical, thermal and loading characteristics of x-ray tubes".

Published in 1989. This standard is providing the technical basis for IEC 601-2-28 and is important as a basis in the specifications of requirements for x-ray tubes.

IEC 627 "Characteristics of anti-scatter grids"

Published in 1978.

IEC 658 "Intensifying screens - dimensions".

Published in 1979.

IEC 788 "Medical radiology - Terminology".

Published in 1984. Terminology is basic when reading standards. A study of definitions will solve most of interpretation disputes. This standard is absolutely necessary when intending really to understand the content of the x-ray standards. Revision is in progress.

IEC 806 "Determination of the maximum radiation field from an x-ray tube".

Published in 1986. Revision is in progress.

IEC 858 "Determination of the image distortion of image intensifiers"

This standard was recently withdrawn. See IEC 1262-4.

IEC 878 "Graphical symbols"

Published in 1988. A large number of additional symbols exist in far advanced drafts. They are already used as standard on delivered equipment . Equipment standards do frequently require "standardised symbols" and those are described in this standard and its amendments.

IEC 930 "Guidelines for staff concerned with the safe use of medical electrical equipment"

Published in 1988. The content is described quite well by the title.

IEC 1262-1 "Image intensifiers - Determination of the entrance field size"

Published in 1994. This standard is replacing IEC 520. Relevant parameters are defined. The field size is to measured within 1 cm from the front cover of the image intensifier. "Useful" is referring to a specified focal spot distance - normally 1 m, and "nominal" implies correction to parallel radiation field.

IEC 1262-2 "Image intensifiers - Determination of the conversion factor"

Published in 1994. This standard is replacing IEC 573. Relevant parameters are defined. When measuring the conversion factor the dose measurement shall be performed with the image intensifier removed in order to avoid influence of scattered radiation.

IEC 1262-3 "Image intensifiers - Determination of the luminance distribution"

Published in 1994. This standard is replacing IEC 572. Relevant parameters are defined. The values for the luminance shall be corrected if the radiation beam varies by more than 2%.

IEC 1262-4 "Image intensifiers - Determination of the image distortion"

Published in 1994. This standard is replacing IEC 858 and describes measuring methods for image distortion.

IEC 1262-5 "Image intensifiers - Determination of the detective quantum efficiency"

Published in 1994.

IEC 1262-6 "Image intensifiers - Determination of the contrast ratio and veiling glare index"

Published in 1994.

IEC 1262-7 "Image intensifiers - Determination of the modular transfer function

Published 1995. This standard contains measuring methods for the determination of the MTF.

IEC 1267 "Radiation conditions for use in the determination of characteristics."

Published in 1994. This standard is defining a large number of radiation beam qualities that are regarded to be suitable for various radiation measurements associated with x-ray equipment. They are currently referred to in other standards.

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