HERCA

HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Statement

Justification and use of hand-held X-ray equipment

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Statement on the justification and use of hand-held X-ray equipment

A number of technologies now use hand-held, often battery powered, X-ray technologies and their increasing availability and ionising radiation outputs concern European Regulators. As the technology grows the variety of applications has increased and equipment costs have decreased significantly. This has led to wide ranges and quality of equipment being available from many different suppliers. The European Regulators are aware that employers sometimes receive insufficient information from the suppliers on the radiation hazard and are led to believe that the equipment is 'safe'. This leads to inappropriate use and insufficient training and information for equipment users. Such X-ray equipment is capable of producing high levels of radiation in the immediate vicinity and this statement has been produced to raise awareness of the risks in order to help ensure safe use.

Hand-held X-ray technologies typically include:

- X-ray fluorescence (XRF) analysers (e.g. alloy analysis, scrap metal identification, archaeology, precious metals industry and even the toy industry.)
- Industrial radiography X-ray equipment
- Security X-ray equipment

1. Radiation hazards

The equipment contains an X-ray tube (mains or battery-powered) which emits a radiation beam (the "main beam") in a forward direction[1]. The radiation levels are most intense at the beam aperture at the front end of the equipment and reduce in intensity with increasing distance. If unshielded, the radiation in the main beam can be measured several metres to tens of metres from the equipment. When X-rays strike a material some are absorbed and some are scattered back in a different direction. Consequently, when the unit is in use (i.e. directed at an object), scattered radiation can also be measured outside of the main beam.

If hand-held devices are used properly the radiation risks to operators and other persons should be minimal. However, if the equipment is incorrectly set-up or misused there is the potential for unacceptable radiation exposures. An employer and the manufacturer must ensure restriction of exposures firstly by means of engineering controls and design features, and then by the provision and use of safety features and warning devices, and finally by the

[1] Hand-held devices containing radioactive sources also exist. They generally present similar radiation hazards as the hand-held X-ray devices and most radiation protection measures and safety design features mentioned below are also applicable to them.

provision of safe systems of work. Advice on these matters must be sought from a suitable radiation protection expert.

2. Regulatory requirements

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
Article 78(1): Information on equipment

Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level which is as low as reasonably achievable.

All suppliers (including hirers) must therefore provide adequate health and safety information. However HERCA recognises that this is not always adequate, particularly in relation to some second-hand equipment and equipment purchased from overseas such as via the Internet.

Particular care should be taken when obtaining second-hand equipment to ensure that appropriate information is passed on and that all the safety features are fitted and working.

3. Recommendations

The Heads of European Radiological protection Competent Authorities address the following recommendations to European regulatory authorities:

Regardless of the level of dose of ionising radiation and in accordance with the basic safety standards internationally applied in radiation protection, the three principles of justification, optimization and dose limitation must fully apply to these technologies using ionising radiation.

1. **Justification of exposures** is one of the basic principles of radiation protection. No use of radiation is permitted unless the benefits outweigh the disadvantages and in particular the possible radiation detriment:
   - Justification is specific to both the purpose and the environment within which the technology is being applied. Therefore a generic justification decision cannot be made for use of hand-held equipment using X-rays over remotely operated equipment.
   - A decision to use hand-held X-ray equipment requires an evaluation of the expected benefits. *In most cases it is not justified as the use of non-hand-held equipment is a reasonable alternative.*

2. **The optimization process should be given careful consideration:**
   - In many European countries a specific authorisation from a competent authority for the use and/or the supply of such devices is required.
   - Radiation doses to operators using hand-held X-ray equipment depend on the type of equipment, maintenance standards, and operational procedures.
   - Operators should be educated and trained so that they are able to take care of their own radiation protection as well as that of other persons. This education and training

should include both normal operating conditions and incidents/ accidents/ equipment malfunction.

- A risk assessment has to be performed prior to the use of the equipment.
- Occupational exposure may have to be assessed and documented.
- Operator's procedures need to be available.
- A safety perimeter may have to be established to minimise the exposure of people and to avoid the exposure of parts of the body. A procedure to check the absence of people within the safety perimeter has to be established.
- Proper use of safety measures (like audiovisual signals)
- Equipment should conform to a technical equipment specification and quality assurance standard that includes the prevention of accidental exposure, the optimisation of equipment parameters, and the methods to test the performance and safety of the device.

  IEC 62495 edition 1.0 2011-04 could serve as a basis.

3. **To respect the he dose limitation principle**: Operators must be able to demonstrate to the relevant competent authority that annual doses to the workers and to the public are below the respective statutory annual dose limits and constraints and as low as reasonably achievable.

End.

Appendix: Safety requirements for hand-held X-ray equipment

A. Engineering controls and design features

X-ray equipment has a number of design features to prevent misuse of the equipment and reduce operator exposure. Actual features may vary between equipment and manufacturers but those listed below represent the best standards of engineering controls. This may be used as a checklist by which to compare available devices.

- A clear warning on the equipment to indicate that it is capable of emitting X-radiation.
- Key-operated or password-protected to prevent unauthorised operation.
- A housing designed to shield against leakage of X-rays.
- An exposure control which must be pressed continuously to generate X-rays. Hand-held units should be designed for two-handed operation (to keep both hands away from the beam).
- A fail-to-safety warning light to indicate when X-rays are being generated.
- A proximity sensor which prevents X-rays being generated without a sample held against the aperture. Where this is not practical, a low-count (backscatter) interlock should be fitted. Ideally, both safety systems should be fitted.

Some devices provide all of the above engineering controls but it should always be confirmed that they are properly activated and working. It may be a requirement that this type of equipment is used within a local enclosure, wherever this is reasonably practicable, for example where the subject of the exposure can be taken to the X-ray equipment.

Enclosures should provide:

- Adequate shielding, i.e. such that the dose rate outside surfaces of the enclosure is below 1 µSv/h.
- A safety system will prevent X-rays being emitted while the hands are inserted into the enclosure.

B. Safe Working Procedures

The key elements Safe working procedures **for hand-held equipment** are:

- The main beam must never be pointed at any parts of the body. Samples should not be held in the hand during measurements.

- The main beam should be fully intercepted by the subject. If a subject is too small to completely cover the aperture then this should be taken to a test stand within a local enclosure.
- All persons should be excluded from the immediate area when the X-rays are on.
- The battery pack should be removed from the instrument when work has finished and only attached when all preparations have been satisfactorily completed and the operator is ready to start.
- Specification of a radiation protection programme to monitor exposures by the use of personal dosimetry devices and/or other suitable means and to set an investigation level to ensure exposures are as low as reasonable achievable. A programme utilising finger dosimeters for an initial period is often recommended.
- Radiation exposures should be minimised. (e.g. exposure times should be as short as possible.)
- The risk assessment will identify the area where personnel should not be allowed within in front of the primary beam and to each front side, unless there is a solid barrier blocking the entire useful beam, such as floor or wall.

Additional key elements for safe working procedures **for hand-held equipment and use within enclosures** are:

- Measurements on small work pieces/samples (which can easily be transported) should be made within a shielded and interlocked enclosure.
- The equipment should only be repaired/maintained by properly trained and authorised persons. Equipment should be immediately taken out of use if it is suspected of being damaged or any of the safety and warning systems are not working.
- Operators should be the only ones allowed access to keys and/or passwords to minimise potential misuse.
- Enclosures should be designed to provide adequate shielding and should be interlocked to prevent accidental exposures.
- The equipment should be securely stored when not in use to prevent unauthorised use.
- Only trained personnel should be approved for using this equipment. They should ensure that they have been appropriately trained and have read and understood the instructions for use.
- Use of a suitable radiation monitor may be required to carry out radiation measurements (e.g. check dose rates around the enclosure) as recommended by the radiation protection expert.
- Visual inspection of equipment before use should always be carried out by the operator to inspect for any damage.

- Secure storage when not in use which should ensure control of the device in terms of its location on every working day and who has responsibility for the device when removed from storage. The equipment should be made secure, when not in use, to ensure that unauthorised users do not have access to the equipment.

The radiation employer should periodically check to ensure that the above matters are adhered to and prompt action taken where these measures break down.

C. Emergency Response Plans

Emergency response plans to deal with an unintended exposure must be produced in order to restrict any exposure that arises from an accident or incident. Typically emergency response plans should address events such as:

- Dropped X-ray equipment
- Physical damage
- Theft and loss
- Exposure not terminating
- Malfunctioning equipment
- Overexposure or unintended exposure
- Unauthorised use of X-ray equipment

Emergency response plans must be included or at least be referenced in the operator's procedures and all relevant employees must receive training in the required actions.