

EPA Guidelines

Hand-held dental X-ray apparatus

October 2006

EPA 647/06: This guideline discusses the sale, registration and use of hand-held dental X-ray apparatus within South Australia.

Introduction

Use of dental X-ray apparatus in a hand-held manner is not permitted under South Australian legislation. Such apparatus requires remote operation. Under some limited circumstances, apparatus capable of being used in a hand-held manner may be justified, and exemptions from the Regulations granted to permit this, subject to:

- justification acceptable to the Environment Protection Authority (EPA)
- controls specified by the EPA
- the unit achieving compliance with standards for apparatus specified in the regulations.

Relevant legislation

The registration and use of dental X-ray apparatus in South Australia is governed by the *Radiation Protection and Control Act 1982* (the Act) and the *Radiation Protection and Control (Ionising Radiation) Regulations 2000* (the Regulations). The Act and the Regulations are administered by the Radiation Protection Division of the EPA.

Regulation 91(10) for *apparatus used for dental radiography with extra oral X-ray tube*, requires the exposure control switch to be arranged so that the operator can remain at least two metres from the X-ray tube. Without an exemption from this regulation, the owner of dental X-ray apparatus capable of being used in a hand-held manner would be committing an offence.

Exemptions from regulatory requirements may be granted if the EPA is satisfied that, should the exemption were granted subject to appropriate conditions, the activity would not endanger the health or safety of any person.

Whether or not this exemption is granted, apparatus must meet all other standards specified in regulation 91.



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Obligations on apparatus sellers

Sellers of ionising radiation apparatus do not require a licence to sell in South Australia. However, the regulations require sellers to provide notification of sales in writing to the EPA. regulations 47, 48 and 49 describe the information that must be provided.

The Regulations also require sellers to provide the purchaser with an application form to register the apparatus.

Prior to sale, sellers are advised to inform the purchaser of the EPA's requirements for owners and users of hand-held apparatus, as the purchaser will have to justify to the EPA why they should be granted the necessary exemptions from the Regulations. The EPA will impose conditions on the exemptions, and these should be acknowledged prior to sale. The EPA may also require the purchaser to provide test results before registering apparatus.

Obligations on apparatus purchasers

Under the Act all ionising radiation apparatus must be registered in the name of the owner of the apparatus. Regulation 61 gives the registration requirements. If it is not so registered, the owner is guilty of an offence with a maximum penalty of \$10,000.

The EPA will not register noncompliant apparatus. The owner should therefore resolve the exemption from the Regulations issue prior to taking possession.

The owner is responsible for demonstrating to the EPA why the use justifies the additional radiation dose that an operator of a hand-held unit would incur over a fixed or remotely operated portable unit. This should be done by written application to the EPA. The application should demonstrate what benefits will be achieved, why these benefits justify additional operator dose, and why the outcome cannot be achieved with remotely operated equipment.

The EPA may require the purchaser to provide test results demonstrating compliance with the regulatory standards for apparatus.

Once an application is approved, the owner is then responsible for ensuring that any conditions imposed by the EPA are implemented.

Justification for use of hand-held X-ray apparatus

The EPA does not guarantee that any particular apparatus or use will be granted an exemption from the Regulations. The EPA is bound by the objective of ensuring that the exposure of persons to ionising radiation is kept as low as reasonably achievable, social and economic factors being taken into account.

The EPA recognises that in some circumstances there may be beneficial outcomes, such as improved healthcare, if use of dental X-ray apparatus in a hand-held manner is permitted. However, where an equivalent outcome can be achieved with fixed or portable equipment that is compliant with the regulations, then hand-held use is unlikely to be justified.

The EPA is likely to seek the advice of the statutory Radiation Protection Committee regarding an application to grant an exemption for hand-held X-ray apparatus.

It is possible that once a specific type of use has been justified, the exemptions may be granted for that category of users or type of use, rather than on a user-by-user basis.

Conditions that the EPA may impose

If an exemption is granted then conditions are likely to be imposed. Conditions will depend on the equipment and how it is used, but may include:

- that only digital imaging receptors or equivalent fast-speed film be used with the unit
- operators must wear an appropriate radiation monitoring badge
- the protective shield must not be detachable from the edge of the collimator
- appropriate degree of instruction and training in the safe use and handling of the unit, and a verification by the EPA of the competence of the user
- use restricted to a specified principal trained user (likely to be the qualified dentist)
- a radiation management plan to ensure that proper use is assured, including prevention of unauthorised use
- dose optimisation measures including restriction of access, and in some circumstances, a requirement to wear shielded aprons.

The EPA will review the apparatus test results in light of the intended use. For example, leakage standards in the Regulations assume remote operation; if leakage is not substantially better than the minimum standard for fixed apparatus, then additional conditions may be imposed.

FURTHER INFORMATION

Legislation:

Legislation may be viewed on the internet at: <www.parliament.sa.gov.au/dbsearch/legsearch.htm>

Copies of legislation are available for purchase from:

Government Information Centre	Telephone:	13 23 24
Lands Titles Office, 101 Grenfell Street	Internet:	< shop.service.sa.gov.au >
Adelaide SA 5000		

For general information please contact:

Environment Protection Authority	Telephone:	(08) 8130 0700
Radiation Protection Division	Facsimile:	(08) 8124 4671
PO Box 721	Internet:	< www.epa.sa.gov.au >
Kent Town SA 5071	E-mail:	< radiationprotection@epa.sa.gov.au >
