**Requirements for the treatment of skin cancer using Rhenium-188 unsealed brachytherapy compound**

Management licence condition M1768

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Introduction



The Victorian Radiation Act 2005 (the Act) has the objective of protecting the health and safety of persons and the environment from the harmful effects of radiation. The Department of Health (Department) administers this legislation. The Act seeks to fulfil this objective by establishing a licensing framework to regulate the conduct of radiation practices and the use of radiation sources. Any person who conducts a radiation practice must hold a management licence (unless exempted from that requirement). The management licence holder must comply with every condition of their licence.

Scope

This document describes the obligations of management licence holders where condition M1768 has been imposed in respect of an authority to possess Rhenium-188 unsealed brachytherapy compound for the purpose of skin cancer treatment.

Mandatory requirements

1. The management licence holder must ensure that no treatment using Rhenium-188 is performed unless the treatment is approved in accordance with the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* by a **Radiation Medical Practitioner** that has successfully completed Rhenium-SCT training provided by OncoBeta GmbH.
2. The management licence holder must ensure that no treatment using Rhenium-188 is approved by the Radiation Medical Practitioner unless the treatment is part of an **approved research project**, or the following requirements are satisfied:

2.1 malignancy has been confirmed and melanoma excluded by histological examination; and

2.2 the maximum depth of the lesion is no greater than 3 mm; and

2.3 the necessary treatment diameter is between 15 mm and 80 mm; and

2.4 the malignancy to be treated is on the nose, eyebrow, lip, ear, digit, genitalia, shin, or collarbone, or

in a contiguous area; or

2.5 the patient has comorbidities that prevent surgical excision or external beam radiotherapy; and

2.6 there is a written referral for the treatment that:

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a. has been issued by:

1. a **Specialist Dermatologist**; or
2. a **Radiation Oncologist**; or
3. a **Plastic Surgeon**; or
4. any other professional specified by the Department for the purpose of this condition; and

b. contains the clinical condition that the referrer is seeking to treat; and

c. includes a statement from the referrer confirming that other treatment options have been considered; and

d. contains patient identification information; and

e. provides the referrer’s contact details for consultative purposes.

3. The management licence holder must ensure that sufficient evidence is retained for each treatment to be able to demonstrate, at any time, compliance with the requirements in this document. The evidence must include referrals, histological reports and sufficiently detailed clinical notes.

Definitions

**“Approved research project”** means a research project approved by a Human Research Ethics Committee in accordance with the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005).

**“Radiation Medical Practitioner”** means the medical practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation.

**“Radiation Oncologist”** means a person registered as a medical specialist in the field of Radiation Oncology with the Australian Health Practitioner Regulation Agency (AHPRA).

**“Plastic Surgeon”** means a person registered as a medical specialist in the field of Plastic Surgery with the Australian Health Practitioner Regulation Agency (AHPRA).

**“Specialist Dermatologist”** means a person registered as a medical specialist in the field of Dermatology with the Australian Health Practitioner Regulation Agency (AHPRA).

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