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12 Jun 2011

Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

Pemegang Lesen Kelas A dan Kelas A&C berkenaan di bawah
Akta Perlesenan Tenaga Atom 1984 (Akta 304) Untuk Maksud Perubatan

Y. Bhg Datuk/Dato'/Datin/Tuan/Puan,

**GUIDELINES FOR MANAGEMENT OF BRACHYTHERAPY FOR PROSTATE CANCER
USING PERMANENTLY IMPLANTED RADIOACTIVE SOURCES**

Adalah saya dengan hormatnya merujuk kepada perkara yang tersebut di atas.

2. Bersama-sama ini dikemukakan *Guidelines for Management of Brachytherapy for Prostate Cancer using Permanently Implanted Radioactive Sources* sebagai panduan untuk memastikan penggunaan sinaran mengion bagi rawatan kanser prostat adalah memenuhi keperluan di bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304). Ini juga bagi memastikan tahap keselamatan pesakit, pekerja dan orang ramai daripada risiko yang mungkin timbul akibat penggunaan *radioactive seeds* tersebut.

3. Untuk makluman Y. Bhg. Datuk/Dato'/Datin/Tuan/Puan, garis panduan ini telah disediakan oleh Jawatankuasa Teknikal yang dikendalikan oleh Kementerian Kesihatan Malaysia (KKM). Ahli Jawatankuasa Teknikal terdiri daripada pakar-pakar perubatan dalam bidang radioterapi dan onkologi, urologi, forensik dan patologi serta ahli fizik perubatan, pegawai penyelidik dan penasihat undang-undang.

4. Adalah diharapkan komuniti perubatan yang terlibat dalam memberikan perkhidmatan rawatan kanser prostat tidak mengangap keperluan ini hanya bertujuan untuk memenuhi keperluan perundangan sahaja, malahan yang lebih penting daripada itu ianya bertujuan untuk meningkatkan kualiti perkhidmatan yang diberikan, demi menjaga keselamatan orang awam.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Yang ikhlas,

(DATO' DR. HASAN BIN ABDUL RAHMAN)
Ketua Pengarah Kesihatan Malaysia



KEMENTERIAN KESIHATAN MALAYSIA

Guidelines for Management of Brachytherapy for Prostate Cancer Using Permanently Implanted Radioactive Sources

Malaysian Guidelines on Radiation Protection in Prostate Brachytherapy

OBJECTIVE :

The purpose of this guide is to define the roles and responsibilities of the personnel from various departments involved in permanent brachytherapy implants and to specify the radiation safety procedures to be carried out at a brachytherapy centre in order to comply with the licensing conditions and regulations, under the Atomic Energy Licensing Act 1984 (Act 304).

The guidelines will be effectively implemented at all treatment centres in Malaysia using permanent prostate brachytherapy implants.

INTRODUCTION:

Permanent prostate brachytherapy is an established option for the treatment of patients with clinically localised prostate cancer using iodine (^{125}I), palladium (^{103}Pd) or other radioactive seeds. The radiation dose is then delivered continuously over the lifetime of the source to a complete decay (permanent implants).

This kind of treatment needs the specific input from the doctor in order to ensure the patient understands the risks and benefits of this option.

ACKNOWLEDGEMENT:

The following guidelines were developed by clinical/radiation oncologists and urologists, in cooperation with the forensic pathologist, the legal advisor, research personnel, medical physicist and the secretariat to the appropriate authority under the Act 304 (Director-General of Health).

1.0 Responsibilities of Personnel

- 1.1 The patient selection shall be jointly decided by the Clinical and/or Radiation Oncologist (thereafter referred to as Oncologist) and Urologist.
- 1.2 The procedure must be jointly carried out by the Oncology and Urology teams.
- 1.3 The Radiation Protection Officer shall ensure that the regulations are adhered to at all stages of the implant programme.

2.0 Consent

- 2.1 The implant procedure, potential side effects and implications/obligations must be explained to the patient and next of kin by the Oncologist and Urologist and must be followed by a written consent obtained from the patient and next of kin. The consent shall include safety instructions.
- 2.2 It must be clearly explained to the patient and the next of kin that in case the patient passes away within one year of the implant for ^{125}I seeds (three months for ^{103}Pd seeds) and the body is to be cremated, there will be a need for post-mortem removal of the prostate in order to decrease the risk of radiation exposure to the public. If the patient and the next of kin do not agree to this, then other treatment modalities must be considered.

3.0 Patient Surveillance and Auditing

- 3.1 A record of patients who have undergone radioactive implants, including contact details of the patient's next of kin, shall be kept, continuously updated and monitored by a coordinator.
- 3.2 The record shall be the responsibility of the urology team with the support of the oncology team.

4.0 Acquisition of Radioactive Materials

- 4.1 The procurement, storage and use of radioactive seeds shall be under the licence of the Oncologist managing the patient.
- 4.2 Compliance to the regulations under the Act 304 that are related to the purchase, storage, usage and disposal of radioactive seeds shall be under the purview of the Oncologist.

5.0 Implantation Procedure

- 5.1 Pre-operative assessment, imaging and ultrasound of the prostate, insertion of the applicators, catheterisation and post-operative management shall be the joint responsibility of the Urologist and Oncologist.
- 5.2 Cystoscopy and any other related endoscopy procedures shall be under the responsibility of the Urologist.
- 5.3 Planning and computation of the isodose distribution and acceptance of the radiotherapy treatment plans shall be the responsibility of the Oncology team.
- 5.4 Radiation protection shall be under the purview of the Oncology team.
- 5.5 Compliance to the regulations under the Act 304 that are related to the use of radiation in medicine will be under the purview of the Oncologist.
- 5.6 The Urology and Oncology teams shall undertake the responsibility of ensuring that arrangements are made for post mortem removal of the prostate should the patient pass away within one year of the implant for ^{125}I seeds (three months for ^{103}Pd seeds), and if the body is to be cremated.

6.0 Safety Instructions for Patients and Next of Kin with Permanent Implants

- 6.1 The patient and the next of kin shall be given written instructions on radiation safety issues after the implant. These instructions shall be reinforced verbally.
- 6.2 These instructions shall include minimising contact with pregnant ladies and children within two months of the implants, instructions on how to deal with expelled seeds through urine, semen or gastrointestinal tract, subsequent pelvic or abdominal surgery, sexual activity, possible triggering of security monitors and cremation.
- 6.3 The written instructions shall include the contact details of the Urology and Oncology teams (**repeated below in 8.2**).
- 6.4 The patient must be given a Medic Alert Card or equivalent to be carried by the patient at all times.

7.0 Discharge of Patients After Permanent Implant

- 7.1 A patient undergoing prostate brachytherapy may be discharged from the hospital if:
 - a) the measured dose rate from the patient is less than 50 μSv per hour at 1 meter; and
 - b) the Oncologist and Urologist have authorised the discharge.

8.0 Instructions to Next of Kin in Case of Death of Patient within a Year of Implantation

- 8.1 The written instructions shall be provided by the Urologist and Oncologist. A copy of these instructions shall be attached to the patient's hospital notes.
- 8.2 The written instructions shall be given to the patient, next of kin and referring doctor, and includes the necessary actions to be taken and officers to contact (Urologist, Oncologist and Radiation Protection Officer) in the event of death of a patient.
- 8.3 It shall be the responsibility of the next of kin to notify the contact persons as soon as possible in the event of death of the patient within one year of the implant for ¹²⁵I seeds (three months for ¹⁰³Pd seeds).

9.0 Death of a Patient Within a Year of Permanent Radioactive Implant

- 9.1 If the deceased is not to be cremated, then it is safe to bury the deceased with an intact prostate as the risk of radiation exposure to those preparing the deceased for burial will be negligible. In this case, the post-mortem removal of the prostate is not necessary.
- 9.2 If the deceased is to be cremated, consent by the next of kin to allow post-mortem removal of the prostate shall be taken by the Urologist, Pathologist and/or Medical Officer.
- 9.3 Prior to the post-mortem removal of the prostate, the Radiation Protection Officer will measure the radiation dose rate. A permanent implant is a radiation hazard if the ambient dose equivalent rate is more than 25 µSv per hour at 1 metre from the body.
- 9.4 The post-mortem removal of the prostate will be conducted by the Urologist, Pathologist and/or Medical Officer at a mortuary facility. The Radiation Protection Officer shall advise the Urologist, Pathologist and/or Medical Officer regarding radiation safety precautions.
- 9.5 The prostate will be removed and disposed off as clinical radioactive waste. The body will then be monitored for any remaining radiation prior to cremation.

10.0 Disposal of Prostate with Radioactive Seeds Intact

- 10.1 The prostate with the implanted radioactive seeds must be stored inside a shielded container and sent to the National Radioactive Waste Management Facility for the purpose of safe disposal.
- 10.2 The appropriate authority must be informed prior to the disposal of the prostate tissue with the embedded permanent radioactive seeds.



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Date : 6 June 2011