Responsibilities and Justification in Medical Exposure

REGIONAL WORKSHOP ON THE IAEA GENERAL SAFETY REQUIREMENTS: GRS PART 3

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April 2012
1) Radioactive Substance Act 1968
   - First legislation regulating the use of ionising radiation.

2) Atomic Energy Licensing Act 1984 (Act 304)
   - Replaces and supersedes the Radioactive Substance Act 1968.
Introduction

Malaysian Legislations: Regulations

1) Radiation Protection (Licensing) Regulations 1986


   15 February 2010

3) Radiation Protection (Transports) Regulations 1989

Medical Exposure

Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a programme of biomedical research. – GSR Part 3 - Definitions

Means the exposure incurred by:

(a) a patient as part of his medical or dental investigative or diagnostic procedures or treatment;

(b) a person who knowingly assists in the support and comfort of patients, other than a person who is occupationally exposed; or

(c) a volunteer in a medical research programme that involves radiation exposure;  

BSRP 2010, Reg. 3
Requirement 34: Responsibilities of the government specific to medical exposure

- The government shall ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.

BSRP – Reg. 41 - Responsibilities of licensee or employer

BSRP – Subreg. 48. (1)(c) the relevant guidance levels as specified in the Sixth Schedule is taken into account.

Reg. 54 - Guidance levels
Requirement 34: Responsibilities of the government specific to medical exposure – cont’d

- The government shall ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.

BSRP – Reg. 55- **Dose constraints**

- **55(1)** Medical research
- **55(2)** Person who knowingly assists in the support of a patient undergoing medical diagnosis or treatment
Requirement 35: Responsibilities of the regulatory body specific to medical exposure

- The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty.

Act 304 – Sub-Reg. 12 (1)- Without prejudice to the requirements of any other law, no person shall-
(a) site, construct or operate a nuclear installation;
(b) deal in, possess or dispose of any radioactive material, nuclear material, prescribed substance or irradiating apparatus,
unless he is the holder of a valid licence issued under section 16 (5) by the appropriate authority for such purpose and as specified in the licence.
Requirement 36: Responsibilities of registrants and licensees specific to medical exposure

- Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.

BSRP – Reg. 41 - Responsibilities of licensee or employer

(a) no patient is administered with a diagnostic or therapeutic medical exposure unless the exposure is prescribed by an approved registered medical practitioner;

(b) …obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of,…
Requirement 36: Responsibilities of registrants and licensees specific to medical exposure

- Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.
Requirement 37: Justification of medical exposures

- Relevant parties shall ensure that medical exposures are justified.

BSRP – Reg. 42- Justification of medical exposure

42(1) The medical exposure shall be justified by weighing the diagnostic or therapeutic benefits produced by the exposure against the radiation detriment caused, taking into account the benefits and risks of other available techniques that do not involve medical exposure.

42(3) and 42(4) - Mass screening of population

42 (5) Medical exposure of humans for medical research.
Requirement 37: Justification of medical exposures

3.155. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.
Summary

• In general, GSR Part 3 (Responsibilities and justification in medical exposure) requirements are in line with current regulations requirements in this country.

• Issues:
  o Generic justification (req. 3.155)
  o Req. 3.157 - Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure—suggested documents???

• Assistance is required, amongst others, in strengthening medical physics services such as through medical physics residency program.
Thank you