RESPONSIBILITIES AND JUSTIFICATION IN MEDICAL EXPOSURES (PAKISTAN’s PERSPECTIVE)

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Background

PNRA Regulatory Framework

Topical Area for Pakistan (Medical Exposure)

Identified Implementation Issues

Responsibilities of the Government

Requirement: 3.147

Responsibilities of Registrants and Licensees

Requirement: 3.150 (d); 3.151; 3.153 (c & e)

Justification of Medical Exposure

Requirement: 3.155 & 3.156

Conclusion
Pakistan has adopted and implemented IAEA Safety Standards ever since the inception of nuclear energy in the country.

In 1990, these Safety Standards became part of our national regulatory framework with the promulgation of “Pakistan Nuclear Safety and Radiation Protection Regulations, 1990” and were updated in view of the requirements as specified in BSS-115, in 2004.

In 2001, Federal Government discharged its responsibility of ensuring safety to PNRA through promulgation of PNRA Ordinance.

PNRA has gained tremendous advantage from application of the IAEA Safety Standards in developing national regulations for regulating nuclear and radiation facilities in the country.

Licensees of nuclear & radiation facilities are obliged to follow these regulatory requirements for demonstration of safety as overriding priority.
PNRA REGULATORY FRAMEWORK

Act/Ordinance:
- PNRA Ordinance issued by the Federal Government
- Presents objectives, structure, functions & responsibilities and powers of the Authority

Regulations:
- Issued by PNRA; obligatory in nature;
- Specify basic requirements that must be fulfilled to ensure safety
- Of administrative and technical nature

Regulatory Guides:
- Issued by PNRA,
- Of a non mandatory nature
- Provide guidance for implementation of regulations
Document: GSR Part 3 (Interim); Revised BSS
Section – 3: Planned Exposure Situations
Medical Exposure:
  - Applicable Requirements: 34 – 37
  - Applicable Paras: (3.144 – 3.160)

These requirements are related to “Responsibilities & Justification in Medical Exposures”.
Most of these requirements have already been addressed in national regulations and are being implemented effectively.
However, a few of them appear to have challenges in their implementation.
Requirement 34: Responsibilities of the Government

- 3.147: The government shall ensure that a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures.

  **Explanation:** PNRA promulgated diagnostic reference levels (adopted from IAEA) for medical exposures through its regulations on Radiation Protection - PAK/904 in 2004.

- A study on “Radiological Protection of Patients” for verification of these reference levels was undertaken. Optimized reference level determined/established as a result of this study may be included in the revised regulations PAK/904.

  **Implementation Issue:** Diagnostic reference levels set by IAEA are generic in nature; applicable to adult patients only.

- Do not include separate DRLs for patients of various age groups (specially infants); Difficult to implement.

- Implementation would require lot of time and resources to determine optimized reference levels for patients of various age groups.
Requirement 36:
Responsibilities of Registrants and Licensees

- **3.150:** Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:
  - (d) The patient or the patient’s legal authorized representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

- **Explanation:** Section–12(f) Annex-IV of PNRA regulations on Radiation Protection-PAK/904 establishes this regulatory requirement.

- Patients are generally informed about benefits & risks associated with interventional/therapeutic procedures (involving high doses); however, this may not be ensured during conventional diagnostic procedures (involving low doses).

- **Implementation Issue:** Due to heavy work load in conventional diagnostic procedures; this practice is hard to follow.
Requirement 36: Responsibilities of Registrants and Licensees

3.151. Registrants and licensees shall ensure that no individual incurs a medical exposure as part of a program of biomedical research unless the exposure has been approved by an ethics committee; and that the requirements for optimization of protection and safety for persons subject to exposure as part of a program of biomedical research are met.

Explanation: There is no such program of biomedical research in Pakistan based on human exposures, therefore, no experience can be shared, at present. However, this requirement may be considered for inclusion in revised regulations on Radiation Protection - PAK/904, as per our national policy.

Implementation Issue: This requirement will be adopted during the revision of national regulations on Radiation Protection – PAK/904.
3.153. Registrants and licensees shall ensure that

- (c) **Sufficient** medical personnel and paramedical personnel are available as specified by the health authority;

**Explanation:** PNRA in consultation with Ministry of Health has established the criteria for qualified medical professionals for medical facilities; and their availability commensurate with the requirement is periodically verified during regulatory inspections.

**Implementation Issue:** Though the criteria for qualified medical professionals (RPO/HP/MP) is defined; however, its implementation is not effective in conventional diagnostic radiology mainly due to the fact that a large number of such centers are operating throughout the country.

Moreover, all of these units are still not in PNRA licensing network due to certain reasons.
Requirement 36:
Responsibilities of Registrants and Licensees

- 3.153. Registrants and licensees shall ensure that
  - (e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;

- Explanation: PNRA has defined this requirement under Section-9 & 40 of its regulations PAK/904. Medical Physicist (refer to as RPO/Health Physicist/Medical Professional) are generally available at big medical centers with therapeutic & interventional radiology.
  - However, small setups with conventional diagnostic equipments only; may not fulfill this requirement.

- Implementation Issue: It is generally not possible for small conventional diagnostic radiology facilities to implement this requirement.
  - They do not have RPO/HP/MP and can not perform QA testing at their own.
  - Effort is however being made by PNRA in providing QA testing services to such facilities during regulatory inspections and by providing instructions (leaflets, brochures, articles in news papers) and lectures for safety of radiation workers, patients and public.
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.

**Explanation:** Justification of medical exposure has been imposed as a generic regulatory requirement under Section-36 of regulations on Radiation Protection- PAK/904. PNRA is not specifically involved in justification of such radiological procedures, however, induction of all new radiological procedures generally undergo through generic justification by the health authority.

**Implementation Issue:** Structured R&D work based on knowledge advancement and technological developments needs to be initiated by the relevant parties which may serve as basis for review of such procedures.
Requirement 37: Justification of Medical Exposures

3.156. The justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or paediatric, of:

- (a) The appropriateness of the request;
- (b) The urgency of the procedure;
- (c) The characteristics of the medical exposure;
- (d) The characteristics of the individual patient;
- (e) Relevant information from patient’s previous radiological procedures.

Explanation: In most of the radiological procedures, justification of medical exposure is carried out through consultation, however, it is not documented.

If not consulted with referring medical practitioner; the radiological medical practitioner may obtain such information directly from the patient or his representative, informally.

Implementation Issue: This requirement is generally implemented for therapeutic and interventional radiology procedures, however, it is difficult to implement for conventional diagnostic procedures.
Conclusion

Following is concluded/proposed for the purpose of improvement and effective implementation of IAEA Safety Standards:

- Separate diagnostic reference levels for patients of specific age group should be established e.g. for infants.

- Administrative and technical requirements related to conventional diagnostic radiological procedures/facilities should be separated from therapeutic and interventional radiology. This is proposed because these are large in number and their regulatory control is generally a weaker area.

- The requirement of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment may not be implemented by licensees with small setups. Therefore, it should be implemented and controlled by an accredited third party (relevant professional body) under regulatory oversight.
THANK YOU