National Training Course on Justification & Optimization of Protection in Diagnostic X-ray Imaging & Interventional Radiology

SFDA Role for Radiation Protection

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Outline

• SFDA and Medical Devices Sector background.
• Executive Administration for Radiological Health.
• Radiology Departments Assessment.
• Clearance of Medical Radioactive Materials.
• Radiation Survey at the Borders.
Purpose of Medical Devices Regulation

- Protect and maintain public health within the KSA by the implementation of provisions ensuring a high level of safety and health protection of patients, users and parties with regard to use of medical devices as it relates to their manufacture, supply and use during their lifecycle.
Who Are Regulated?

- The medical devices regulation applies to the following:
  - Manufacturers, authorized representatives, importers and distributors.
  - All medical devices and their accessories that will be supplied to the KSA market.
The Medical Devices Interim Regulation (MDIR) is facilitated through a set of electronic systems to enable Manufacturers, Authorized Representatives, Importers, Distributors, and other parties to communicate efficiently with the MDS.

Electronic Services

- It is a web-based system. All applications for these services shall be made on-line.
Basic purpose of legislation for Radiation Protection

• Radiation is harmful
  – Deterministic effects
    – erythema, sterility, etc.
  – Stochastic effects
    – cancer, hereditary effects

• Protection is needed
  • Workers
  • Members of the public
  • Patients
  • Environment
Causes of Accidents....

Legal Causes identified as contributing to accidents:

• Lack of adequate regulatory framework
  • authorization
  • inspection
  • enforcement

• Lack of safety culture
  • management
  • quality control
  • training and qualification of personnel
Executive Administration for Radiological Health
Executive Administration for Radiological Health

✔ There are two current active Departments:

1- Radiation Protection and Safety Department

2- Radiological Devices Surveillance Department
Executive Administration for Radiological Health

Some of the Responsibilities

- Protect patients, public and users from radiation hazards resulting from radiation emitting medical devices.
- Control the risk from the use of radiation emitting medical devices.
- Implement the roles of Radiation Safety Officer (RSO) in the radiological health institutions.
- Ensure that radiological health institutions and their devices are registered and licensed by SFDA.
Executive Administration for Radiological Health

Some of the Responsibilities

✓ Licensing and registration of radiation emitting medical devices.
✓ Give recommendations and advices for radiological health institutions and related bodies regarding control of radiation hazards.
✓ Establish databases for:
  – National Radiological Health Institutions.
  – Radiation Emitting Medical Devices.
  – Radiation Safety Officers.
✓ Perform testing and calibration of radiation detectors.
Radiological Health Executive Administration's staff with specialists from the Ministry of Interior conduct site visits for radiology departments at health facilities in the Kingdom.

These visits aim to assure the quality and continuity of the radiation protection and safety within the radiology departments.
مخالفات
في أقسام الأشعة بمنشآت صحية
737 زيارة في 83 مدينة

87 مستوصف
104 مركز أسان
319 مستشفى

تصنيف المنشآت
%0.9 مستشفيات جامعية
%2.1 مستشفيات تخصصية
%2.1 مستشفيات عسكرية
%34.2 مستشفيات حكومية
%60.7 مستشفيات خاصة

أبرز المخالفات
11.1% من المنشآت لا يوجد لديها السيرة الواقية من الإشعاع
66% من المنشآت لا تلتزم بشأن التشريعة الإشعاعي
21.9% من المنشآت لا يوجد جهاز إقياس الإشعاع
33.9% من المنشآت لا يوجد عزل للأشعة
38.2% من المنشآت لا يوجد مراقبة جزئية
40.7% من المنشآت لا يوجد جهاز إعلامي

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Radiology Departments Assessment

The assessment covers:

- Staffing
- Service and Maintenance
- Quality Assurance Program
- The Design of Department
- Room Design and Layout
- Structural Shielding Parameters
- Caution Signs, Lights and Locking of Rooms
- Availability of Records
- Emergency Plans
Common findings through site visits

- There are some comments that the assessment team have been met through these visits. It includes, but not limited to:
Common findings through site visits

Staff are working on the site without personal dosimeter
Common findings through site visits

Lack of caution signs on the doors of departments
Common findings through site visits

Inappropriate saving of the lead aprons inside the rooms
The department doesn’t do the lead aprons annual test to ensure the quality of them.
Common findings through site visits

Holes and cracks on the walls and doors of the department rooms
Common findings through site visits

- Department rooms are **not shielded**.
- The department doesn’t do the **annual shielding survey**.
Clearance of Medical Radioactive Materials

Objective:

➢ To ensure the safety and protection of persons, property and the environment from unintended hazards of ionizing radiation during and after the transport of radioactive material and packages at the Saudi customs in the areas of design, manufacture, documentation, use, emergency response, inspection and periodic dose assessments of individuals.

➢ This procedure applies to all consignments of medical-use radioactive material sent by any mode of transport (air, land or water) within, through or into Saudi Arabia. It includes assessment of the choice of packaging, documentation, handling, loading, in-transit storing and receiving of packages containing radioactive material.
Clearance of Medical Radioactive Materials

Each health facility has or intend to acquire Radioactive Materials used for medical applications shall:

1. Fill the forms that are required by Public Security & SFDA.
2. Send a request to police of province for importing/exporting Radioactive Materials.
3. Make sure that all required licenses are valid and provided with the request.
4. Provide the SFDA requirements for clearance of Radioactive Materials with the request.
Clearance of Medical Radioactive Materials

RH Receives a request through the Public Security for technical evaluation

Request reviewed

Contact the applicant to complete the request

NO

Request Complete

YES

Request returned to Public Security with RH recommendations
Radioactive Materials Registration System

عصرًا من الإدارة التنفيذية للصحة الإشعاعية في مجال الأجهزة والمنتجات الطبية بالهيئة العامة للغذاء والدواء ووزارة الداخلية ممثلة بالأمان العام، على إنهاء إجراءات طلبات استيراد ونقل وتصدير المواد المشعة الطبية المستخدمة في التشخيص أو العلاج أو الممارسة الطبية بكل سهولة بما يخدم مصلحة المنشآت الصحية والشركات الناشئة والموردة.

 önemli أكثر...

تعريف النظام | الأسئلة المتكررة | أصل بنا

اسم المستخدم
كلمة المرور
نسيت كلمة المرور؟ دخول

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Radiation Survey at the Borders

**Objective & Scope**

- **aiming to ensure the safety and protection of persons, property and the environment from unintended hazards of ionizing radiation during and after the receipt of medical devices packages at the Saudi customs in the areas of ionizing radiation level and contamination inspections, and periodic dose assessments of individuals.**

- **This procedure applies to all packages of medical devices originating from a Country Suspected for ionizing radiation Contamination (CSC) received at the borders of the KSA.**
Radiation Survey at the Borders

Receives of a request for radiation survey from POE

Assignation and approval of a potential Inspector

Scheduling the inspection time and providing copies of customs information

Filing and final approval of the inspection report

Performing field inspection and preparing an inspection report

Handing proper PPE, personal dosimetry and instrumentation to the Inspector

Returning the request with results to POE.
 Radiation Survey at the Borders

- MDS at SFDA checks any medical device shipments come from Japan to prevent any risk of radiation contamination, due to the Fukushima incident (2011).

- 857 shipments were surveyed by MDS inspectors at the borders.

<table>
<thead>
<tr>
<th>Boarder</th>
<th>KKIA (Riyadh)</th>
<th>Riyadh dry port.</th>
<th>KAIA (Jeddah)</th>
<th>Jeddah Seaport</th>
<th>KFIA (Dammam)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Shipments</td>
<td>88</td>
<td>44</td>
<td>352</td>
<td>282</td>
<td>91</td>
<td>857</td>
</tr>
</tbody>
</table>
Thank You