


CCHE-57357 -Policy and Procedure

 مؤسسة مستشفى سرطان الأطفال - مصر Children's Cancer Hospital Foundation - Egypt		Policy Name: Radioactive materials handling	
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1.0 Change in policy:

1.1 no change

2.0 Purpose

2.1 To highlight staff roles & responsibilities regarding proper management of radioactive materials (RAM) inside the hospital.

2.2 To ensure safe handling, preparation, transportation of RAM.

3.0 Policy

3.1 Policy statement

3.1.1 This policy and procedure outline the safe and appropriate preparation and handling of radioactive materials.

3.2 Scope

3.2.1 Cyclotron department.

3.2.2 Nuclear department.

3.3 Responsibilities

3.3.1 All Cyclotron & nuclear department staff.

4.0 Definitions /abbreviations:

4.1 **CCHE:** Children Cancer Hospital – 57357 Egypt.

4.2 **CPID:** Continuous Performance Improvement Department.

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- 4.3 **MMU:** Medication Management & Use.
- 4.4 **MMS:** Medications Management & Safety
- 4.5 **RAM:** radioactive materials
- 4.6 **PET:** positron emission tomography
- 4.7 **ENRRA:** Egyptian Nuclear and Radiological Regulatory Authority

5.0 Procedure:

5.1 Cyclotron Unit is a production facility produces PET radioisotopes contains the following:

5.1.1 Cyclotron Device (PE Trace 16.5 MeV)

5.1.1.1 A cyclotron is a type of particle accelerator accelerates Protons (H-) using a high-frequency, alternating voltage and a perpendicular magnetic field at max energy of 16.5 MeV. These protons will induce a nuclear reaction with stable nuclei to produce new radioactive element.

5.1.2 Production Lab (Hot Lab):

5.1.2.1 Production lab have chemical synthesizer modules kept in clean and radiation shielded cells. These modules execute certain chemical recipes to produce the final form of radiopharmaceuticals.

5.1.3 Quality control lab

5.1.3.1 This lab is responsible for applying specific tests for releasing the final products according to the pharmacopeia instructions.

5.2 Daily routine working:

- 5.2.1 Cyclotron operator starting the cyclotron for approximately 2 hours about 7am.
- 5.2.2 Cyclotron operator automatically transferring the produced radioactive material to production modules.
- 5.2.3 According to specified recipes, daily chemical formulation needs 30 to 60 minutes.
- 5.2.4 Samples from the final product will be sent to the quality control Lab. for analysis tests by quality control chemist.
- 5.2.5 Note: Cyclotron is a controlled area and access will be authorized for cyclotron staff only.

5.3 External and Internal distribution of Radiopharmaceuticals:

- 5.3.1 Inside the cyclotron unit, the radioactivity transferred automatically between different parts of the unit.
- 5.3.2 The last step is the dispensing unit that will give the product packed in multi dose vials.
- 5.3.3 The vials have to be labeled and kept in proper radioactive shield then handled manually to the nuclear medicine (hot lab) inside hospital and received by nuclear medicine technologist (authorized user) upon request.
- 5.3.4 External distribution to our clients covered by the Egyptian Nuclear and Radiological Regulatory Authority (ENRRA) regulations.

6.0 References:

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- 6.1 ENRRA guidelines.
- 6.2 Comecer Theodoric user manual Rev.9
- 6.3 Tracer lab MX operator manual. Version II.
- 6.4 GE cyclotron operational guide manual Rev.7.
- 6.5 Scintomics operational manual (SCI-GRP-091-1).

7.0 Appendices

7.1 Related Forms

7.1.1 N.A.

7.2 Related Policy(S)

7.2.1 Medication Management Program



7.3 Related Standard

7.3.1 JCI standards 7th edition – MMU Chapter. (MMU.5)


7.3.2 GAHAR standard MMS .09

7.4 Attachments

- 7.4.1 Label No.1 for vial
- 7.4.2 Production date and time:
- 7.4.3 Expiry date and time:
- 7.4.4 Activity:
- 7.4.5 Label No.2 for the shield
- 7.4.6 Lot. No.: YYMMDD-FDG-X
- 7.4.7 Activity: _____ mCi
- 7.4.8 Volume _____ ml
- 7.4.9 Calibration time: ____: ____
- 7.4.10 Expires 10 hours after calibration time

FDG (¹⁸F) Solution for IV injection		Radioactive Material 
Production Date and Time: تاريخ وساعة الإنتاج	Administration : Intravenously Expiry time : 10 hours after production hour Storage : at room temperature below 30°C in the lead shield	
Expiry Date and Time: تاريخ وساعة الانتهاء	يحفظ عن طريق الحقن الوريدي . فترة الصلاحية عشرة ساعات بدءاً من ساعة الإنتاج. يتم التخزين في عبوة من الرصاص تحت ثلاثون درجة مئوية	
Activity: _____ mCi النشاط الإشعاعي		
Produced by: Cyclotron Unit Nuclear Medicine Department Children's Cancer Hospital - Egypt (CCHE-57357)	المنتج: وحدة السيكلوترون قسم الطب النووي مستشفى سرطان الأطفال - مصر 57357	

Label No.1 for vial

18F]FDG For IV. injection Lot. No.: YYMMDD-FDG-X Activity: _____ mCi Volume _____ ml Calibration time: ____: ____ Expires 10 hours after calibration time	
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Label No.2 for the shield