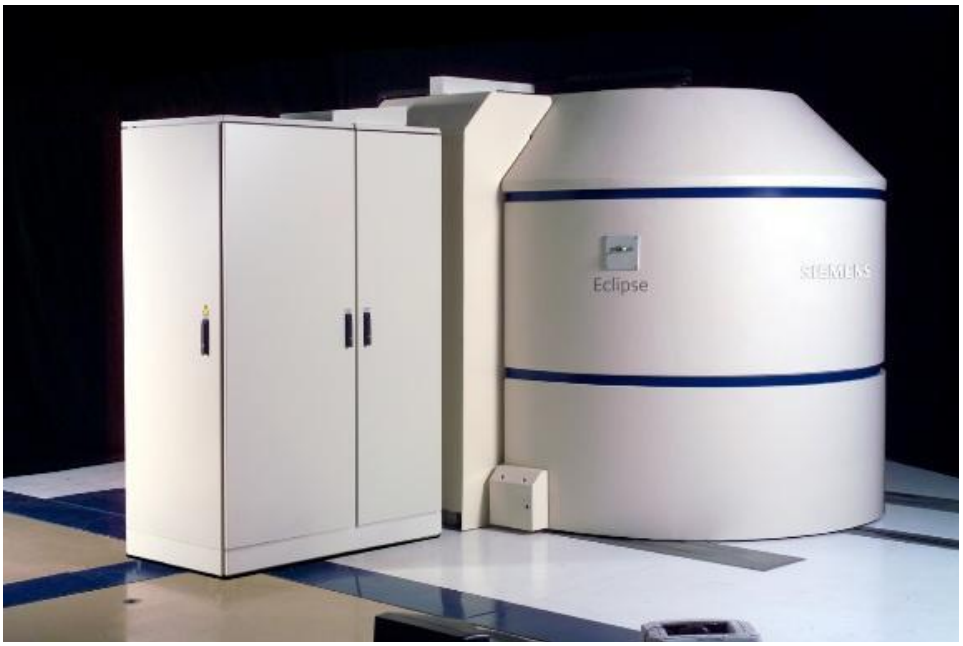
Environmental and Social Impact Assessment Study Report for the Proposed Medical Cyclotron Facility for Cancer Medical Imaging.



Project Proponents

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Falcon Road, Industrial Area
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February 2019

EIA CONDUCTED BY:

UMWELT CONSULTS

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CERTIFICATION

This is to certify that the Environmental Impact Assessment (ESIA) Study report for the proposed refurbishment of existing godown for **ADVANCED MOLECULAR IMAGING LTD,** on LR. No. 12366/2, off Enterprise Road/Falcon Road, Nairobi, was prepared by **UMWELT CONSULTS,** P. O. BOX 575 – 00502 NAIROBI. The Study Report was prepared with full involvement and cooperation from the project proponents, project design architects, concerned stakeholders, interested parties and management staff of the companies in close proximity to the proposed project site.

Name: **JOSEPH NDUNGU.**

……..... ……

Signature Date

EIA & EA Lead Expert. NEMA Reg. No. 916

FOR: UMWELT CONSULTS. (NEMA Reg. 1592).

Designation:……..

……..... ……

Signature Date

FOR: ADVANCED MOLECULAR IMAGING LTD

P.O. BOX 41669 - 00100 NAIROBI.

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ACRONYMS AND ABBREVIATIONS

CPP	Consultation and Public Participation
DIN	*Deutsche Institut für Normung* (German Institute for Standardization).
EMCA	Environmental Management and Coordination Act
EMP	Environmental Management Plan
FDG	Fludeoxyglucose
GOK	Government of Kenya
IAEA	International Atomic Energy Agency
IOP	Institute of Physics
MCF	Medical Cyclotron Facility
NCC	Nairobi City County
NEMA	National Environment Management Authority
NWSC	Nairobi Water and Sewerage Company
OH&S	Occupational Health and Safety
OSHA	Occupational Safety & Health Act
PET-CT	Positron Emission Tomography–Computed Tomography
PPB	Pharmacy and Poisons Board
PPE	Personal Protective Equipment

1 EXECUTIVE SUMMARY

1.1 OBJECTIVE OF THE INITIATIVE

The purpose of this study report is to describe the proposed refurbishment of existing godown to enable the setting-up of a medical cyclotron facility. The facility belongs to ADVANCED MOLECULAR IMAGING LTD, which will be situated off Enterprise Road/Falcon Road, Industrial area in Nairobi County. An ESIA will however be mandatory and issuance of ESIA licence before the setting-up of the medial cyclotron facility.

This is in pursuant to the Legal Notice No. 101 of the Environmental (Impact Assessment and Audit) Regulations of 2003. The Legal Notice states that before any construction work commences, a Study report should be written and submitted to the Authority, NEMA. The report should state the nature of the project, location of the project, activities that shall be undertaken during the project design, construction and decommissioning phases.

The study was undertaken as per the ToR prepared by the client. The ToR later formed the basis of the contract that was entered into by both the project proponent and the consultant.

The broad objective of this study as set out in the TOR was to undertake an independent EIA of proposed project This objective was fulfilled through pursuit of three sub-objectives set out in the TOR as follows: -

- To help establish the baseline data, by having a thorough understanding and presentation of the existing environmental conditions of the area and its surroundings before the any construction work commences.
- Create linkages during the project cycle (construction, operation and decommissioning phase) and try to gain a thorough understanding of some of the emerging impacts on natural and human environment
- Predict the extent of the impacts on the environment by warehouse operations and related activities and propose remedial/mitigation measures.

The project proponent has a budget of Kenya Shillings *Twenty Million, (Kshs. 20,000,000.00)* for the proposed initiative.

1.2 SCOPE OF THE INITIATIVE

ADVANCED MOLECULAR IMAGING LTD, the project proponents, have leased an existing godown from CONSOLIDATED TIMBERS godown and agreed to make the alterations and selective refurbishment to one of the godowns. The godown is currently fitted with office,

stores and sanitary facilities. The godown is within the Consolidated Timbers Ltd godown No. 9, off Enterprise Road/Falcon Road, Industrial area in Nairobi.

As per their binding lease tenancy agreement with the godown Landlord, the project proponents wants to make the following alterations to Godown No. 9, which will include[1]:

a) Setting up of cancer related pharmaceutical production unit. This will include refurbishment, partitioning making fixtures and fittings to the existing godown as to their requirements.
b) Installing the relevant machinery and equipment for their proposed initiative.
c) Production of positron-emitting isotopes suitable for molecular imaging in the refurbished godown[2]
d) Production of ancillary molecules, which will include setting up equipment that would be required for production, testing, quality control, distribution, storage, warehousing and any other related activities.

The main partitioning and rooms will be as follows:

Ground Floor

- Off Loading /Unloading area
- Dispatch area
- Storage area
- Packing
- Hot lab
- Gowning room
- Clan room and Waste material room
- Q. C. Lab
- Cyclotron area, well protected with radiation shielding walls, to required standards and its control room
- Quarantine, incoming material rooms

Further, there will be ample parking place for the vehicles, WC and related facilities.

[1] Refer to details in the copy of the tenancy agreement attached in the appendix of this report.

[2] Positron emission or beta plus decay *(β+ decay)* is a subtype of radioactive decay called beta decay, in which a proton inside a radionuclide nucleus is converted into a neutron while releasing a positron and an electron neutrino (ve). Positron emission is mediated by the weak force. The positron is a type of beta particle (β+).

- The area is sewered with the NWSC sewer line.

Ground Floor

Second floor will mainly be offices, meeting room, training centre and pantry.

The area is secured with a guard gated perimeter wall and within an industrial area where godowns predominates. The area is served with a sewer line from NWSC.

There are no sites of specific scientific or cultural interest situated in close proximity to the proposed project site and the project will be in character with the surrounding establishments, mainly warehouse. It has therefore no major environmental concern.

The refurbishment, mainly internal and extension work of the godown will in character with the surrounding. The area is dominated by godowns.

The Environmental Management Plan (EMP) in the Study report and the impacts monitoring are fairly simple and it shows clearly the mitigation measures and for the identified impacts.

Thus, the proposed project could be allowed to continue provided that the project proponent complies with all the Nairobi City County (Adoptive By-Laws), Building Order, Building Code, National Construction Authority, NEMA EIA conditions, issues raised by interested parties or any other relevant regulations from mandated government agencies.

2 INTRODUCTION

2.1 POLICY AND LEGAL FRAMEWORK FOR EIA

2.1.1 Policy Framework

The Kenya Millennium Development Goals (MDGs) Progress Review (2003), Kenya Vision 2030, Interim Investment Programme for Economic Recovery Strategy for Wealth and Employment Creation 2003 – 2007 (GoK, 2003), Poverty Reduction Strategy Paper (GoK, 2003), the Nairobi District Development Plan 2002 – 2008 as well as the Kenya National Development Plan 2002 – 2008 have addressed various approaches of improving the industrial sector and creating employment. The economic and social pillars in Kenya Vision 2030 emphasises the need to maintain a sustained economic growth of 10% p.a. over the next 25 years as well as having a clean and secure environment. This is also in the Sessional Paper No. 6 on Environment and Development (GoK, 1999) which elaborates a complementary strategy with the objective of harmonizing sustainable management of natural resources and development without harming the environment.

2.1.2 Legal Framework

In Kenya Study report requirement is stipulated in Section 58 (1) and (2) of the Environmental Management and Coordination Act (EMCA) No- 8 of 1999 (Republic of Kenya, 2000). Subsection 58(1) states that, notwithstanding any approval, permit or license granted under this Act or any other law in force in Kenya, any person, being a proponent of a project, shall, before financing, commencing, proceeding with, carrying out, executing or conducting or causing to be financed, commenced, proceeded with, carried out, executed or conducted by another person any undertaking specified in the Second Schedule to this Act, submit a Study report to the Authority.

The law further prescribes that the environmental audit and environmental impact assessment studies and reports should be conducted by individuals or firms of experts who have been registered by the National Environment Management Authority (NEMA). This Study report has been prepared pursuant to the above mentioned legal framework and as

first step in fulfilling the law before the alteration and construction of the proposed warehouse.

2.2 RELEVANT GUIDELINES AND STANDARDS FOR PROPOSED PROJECT

The environmental guidelines and standards in the industrial sector are meant to be a reference point upon which the threshold of impacts can be assessed. The pertinent guidelines/standards governing environmental quality with reference to industrial activities include the following:

2.2.1 Nairobi County Government Guidelines on Structures Standards and Zoning

The guideline outlines the type, nature and size of the building. They are classified into zones, area to be covered by the building, type of development allowed, and minimum area in hectares to be covered by the proposed development.

The area for the proposed project is within Zone 10E of the NCC Zoning schedule[3]. Within this zone, the warehouse/industry ground coverage (GC) and the plot or plinth area ratio (PR) should be 80% and 300 respectively, of the total size of the plot (PR = GR + floor area, 1, 2, 3...). The project proponent has adheres these specifications of CCN. Table 1.2 gives details within this zone.

Table 1.2: Proposed Project Area and the NCC Zoning Schedule

ZONE No.	AREA COVERED (INDUSTRIES)	GC	PR	TYPE OF ALLOWED DEVELOPMENTS	MIN AREA (Ha)	REMARKS/ POLICY ISSUES
9	**Main Industrial Area**	80	300	Industries/Godowns	0.05 (on sewer)	-

Source: NCC Architecture and Planning Dept. Nairobi Zoning Schedule, 2006.

[3] Refer to NCC zoning schedule, Zone No. 10E, 2006 from Architecture and Planning Dept, NCC.

2.2.2 City Planning, Building By-Laws (Adoptive By-Laws) and Regulations

Pursuant to Local Government (Adoptive By-Laws) (Building) Order 1968 L.N. 15/1969, City of Nairobi (Building) By-Law 1948 G. N, 313 / 1949, the proposed project was approved, subject to the following conditions, among others:

- Structural details including lintols and trusses
- Details on management/disposal of excavated materials during site preparation phase.

2.2.3 Physical Planning Act, Cap 286:

Part V of this Act empowers the Local Authority (in this case CCN), to:

- Prohibit or control the use and development of land and buildings in the interests of proper and orderly development of an area.
- Consider and approve all development applications and grant all development permission.
- Regulate zoning in respect of use and density of development.
- Section 36 of the Act provides that an EIA shall be carried out on development activities likely to have injurious impacts to the environment.

2.2.4 National Construction Authority (NCA)

Some of the relevant provisions in this Act are:

- to award certificates of proficiency to contractors, skilled construction workers and construction site supervisors
- Carrying out investigations of any offence or inspection under this Act.
- Notice in writing, ordering the suspension of all or any part of the works in respect of which the provisions of this Act have not been complied with until the time of such compliance.

2.2.5 CCN Building Code

The building proposal that was presented to CCN by the proponent acquired development consent from the County after fulfilling all the building conditions set in the building code

and the physical planning act prior to the project commencement. Some of the specifications are building space stands, panning regulations and requirement for inspections during construction period. Further relevant guidelines are the CCN Development Zones and Rationalization Schedule 2006.

2.2.6 Environmental Management (Waste Management) Regulation 2006

During the construction/refurbishment phase, the project proponent shall ensure that all excavated material and debris is collected, reused where necessary and disposed off as per the regulation in this Environmental Management and Coordination.

2.2.7 Occupational Safety and Health Act (OSHA), No. 15, 2007

The OSHA outlines and explains issues relating to safety, health and welfare of the workers and all persons lawfully present at workplaces. Among others and relevant to the proposed project, it elaborates on:

- Duties of employees
- Prohibition against creation of hazards
- Machinery safety and safety general provisions

2.2.8 Ministry of Works Signboard with NEMA Number

Once the project has been approved, the project proponent will put up a project signboard as per the Ministry of Works Standard indicating the NEMA Approval/Licence reference number among other information.

2.2.9 Noise and Excessive Vibration Pollution Control Regulation 2009

The proponent will adhere to the provisions of Environmental Management and Coordination (Noise and Excessive Vibrations Pollution Control) Regulations of 2009.

2.2.10 National Legislation

- Land Control Act Cap 302
- Land Planning Act Cap. 242
- Physical Planning Act Cap 286
- Factories Act Cap. 514
- Public Health Act Cap. 242
- NEMA Waste Management Regulations 2006, Part II, III on solid and industrial waste management.

2.3 RADIATION PROTECTION ACT, CAP. 243

2.3.1 The Act and the Licensing Provisions

PART IV of the Act, on Licensing Provisions has guidance on application for, and issue of, a licence. It states,

> "(1) A person who owns, purchases, acquires, imports, manufactures, sells or deals in, stores, uses, disposes of or exports any kind of irradiating device or radioactive material or any other source of ionizing radiation shall apply, in the prescribed form, to the Board for an appropriate licence or for a renewal of the licence"

2.3.2 The Radiation Protection Board

The Radiation Protection Board is a statutory body established under the Act of parliament, the Radiation Protection Act, Cap 243, Laws of Kenya as the national competent authority with the responsibility for protecting the health and safety of people and the environment from the harmful effects of ionizing radiation.

RPB regulates the use of ionizing radiation, exportation, importation, distribution and possession of radiation sources. The Board operates under two subsidiary legislations;

- the Radiation Protection (standards) Regulations – LN. 54/1986;
- the Radiation Protection (structural requirements and inspection of buildings) Regulations LN. 55/1986.

To this effect, the RPB further has set conditions for the regulatory approval of the proposed facility in particular emphasising on the following aspects:

2.3.3 Details on Regulatory Approvals from RPB on Setting up MCF

- The project site has to be inspected and approved by RPB.
- Location of the MCF within: Is it within an industrial premise?
- Data on max level of ground water and maximum flood levels for the past 10 years
- The distance of site installation of the MCF from the nearby public utility or residential premises
- Results from soil tests/ground characteristics from a NEMA accredited lab
- Provision of access road to the MCF site.
- Details of the site layout
- Baseline radiation/radiological baseline survey to be done and report provided.

2.3.4 RPB's Design and Construction Requirements for MCF

- Design for the MCF to be carried out by a duly registered architectural and Engineering firm.
- Availability of services from certified Technical Provider (TSP) available? - for baseline radiation studies, radiation protection, shielding calculations, management of radioactive waste etc).
- Architectural designs drawing for the facility with shielding requirements submitted to manufacturer for comments / recommendations.
- Endorsement of the drawing by the final manufacturer of the MCF. Shielding reports and any other related documents to be forwarded to RPB for approval.
- Structural engineer to work on the floor loading of the cyclotron vault during construction putting in mind the gross weight of the cyclotron to be installed.
- RPB to approve any modifications of the MCF, in case there's any.

2.4 PHARMACY AND POISONS BOARD AND RELATED AUTHORITIES

2.4.1 The Drug Regulatory Authority

It was established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and

poisons. The Board offers the following services, among others: Registration of Pharmaceutical Premises/Outlets, Ensuring Good Manufacturing Practice (GMP), Pharmacovigilance and Post-Market Surveillance.

2.4.2 Pharmacy and Poisons Act, (PPA) Cap. 244, Part III A

In Part III A of the Act – Manufacture of Medicinal Substances, Clause 35A. Licence to manufacture medicinal substances, it states that:

(1) No person shall manufacture any medicinal substance unless he has been granted a manufacturing licence by the Board.

(2) Each manufacturing licence shall expire on the 31st December of every year and the renewal thereof shall be subject to compliance with conditions prescribed by the Board.

(3) No person shall manufacture any medicinal substance for sale unless he has applied for and obtained a licence from the Board in respect of each substance intended to be manufactured.

(4) Any person who intends to manufacture a medicinal substance shall make an application in the prescribed form for the licensing of the premises; and the application shall be accompanied by the prescribed fee.

(5) The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him shall have power to enter and sample any medicinal substance under production in any manufacturing premises and certify that the method of manufacture approved by the Board is being followed.

2.4.3 PPA, Cap. 244, Clause 35B: Compliance with Good Manufacturing Practice

The Acts stipulates that very person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board.

3 PROJECT DESCRIPTION

3.1 PROJECT LOCATION

3.1: Project Site, off Enterprise Road/Falcon Road, Industrial Area, Nairobi

Source: Author, Jan, 2019. Aerial view map from Google Earth.

3.2 PROJECT LOCATION AND ITS CLOSE PROXIMITY TO THE AIRPORT

As it has already been established, the FDG shelf life is incredibly small. The site for the Cyclotron therefore should be near the airport (In this case JKIA) to allow for quick transportation to regional PET CT centres. The cyclotron location should also be within close proximity of all major local Hospitals and PET CT sites.

The site should be in Kenya to ensure that the local industry benefits from being the first Cyclotron site in the region, encouraging medical tourism, and also ensuring that we create an opportunity to export the FDGs rather than becoming a target market for importation of the same.

The location required should also be viable from a financial point of view and offer manageable manufacturing and maintenance costs so that the FDG's can be sold at a proce that is affordable to the public.

Taking the above considerations into mind, the godown No. 9 off Fulcon Road stands out as the right choice of location offering both proximity to necessary channels, and offering benefits in optimizing manufacturing costs.

3.2: Project Site and Location of JKIA, Nairobi

Source: Google Earth, 2017.

3.3 PROJECT BUDGET

The proponent intends to spend Kenya Shillings *Ten Million, (Kshs.10, 000,000)*

3.4 POSSIBLE PROJECT ALTERNATIVES

3.4.1 Alternative Godown at the Proposed MCF Site

The range of alternatives required to be evaluated is governed by the "rule of reason," which requires an analysis of only those alternatives necessary to permit a reasoned choice. The project proponents do not consider any other meaningful project site as an alternative to what they have already selected. The FDG shelf life is incredibly small. The site for the Cyclotron therefore should be near the airport

However, in case the neighbours raise issues, an alternative godown, preferably at the farthest end of the godown, adjacent to the road or stand alone (indicated/circled in diagram 3.3) can serve as alternative. The two alternative sites have no immediate neighbours compared to the proposed godown No. 9.

3.3: Project Site and Possible Alternative Godowns

3.4.2 Further Alternative Godowns which were Visited by the RPB

The godowns that were visited by the RPB team and they had no issues to raise in case the project proponent agrees to hire one of them for his proposed initiative can serve as an alternative site for the proposed MCF.

3.5 DETAILS OF THE PROJECT SITE

3.5.1 Ownership and Zoning Approval

The godowns/plot belongs to CONSOLIDATED TIMBERS LTD, (Lessor), from whom ADVANCED MOLECULAR IMAGING LTD (Lessee) has leased, and agreed to make the alterations and selective refurbishment.

Pursuant to the County Government of Nairobi Guidelines on Structures Standards and Zoning (2006), the area for the proposed project is within Zone 9 (main Industrial area) of the CCN Zoning schedule. Within this zone, the godowns ground coverage (GC) and the plot or plinth area ratio (PR) should be 80% and 300 respectively, of the total size of the plot (1.15917 Acre). (PR = GR + floor area, 1, 2, 3...). The project proponent has adheres these specifications of CCN.

3.5.2 Architectural Design Details and Elevations Of The Project

A description of the warehouse design is based on information obtained from the detailed architectural drawings provided by the architects, consultations held with the civil, structural, electrical and mechanical engineers, planners, and site visits. Detailed architectural design drawings are attached herewith[4].

A Structural Plan Approach has been employed in the overall design of the proposed development. The warehouse, store and shed will be having the following facilities:

The Warehouse

It will be used solely for:

- Setting up of cancer relate pharma production unit
- Production of positron-emitting isotopes suitable for molecular imaging
- Production of ancillary molecules, which will include setting up equipments that would be required for production, testing, quality control, distribution, storage, warehousing and any other related activities.
- Make partitioning, fixtures and fittings to the godown as to their requirements

3.6 PICTORIAL DETAILS OF THE PROJECT SITE

3.1: Details of the Proposed Godown and its Neighbourhood

[4] See attached site plan.

The Company will occupy godown No. 9. (marked above). There are a total of various godowns, with various business related activities.

Left: Inside the proposed

Source: Author, Jan. 2019.

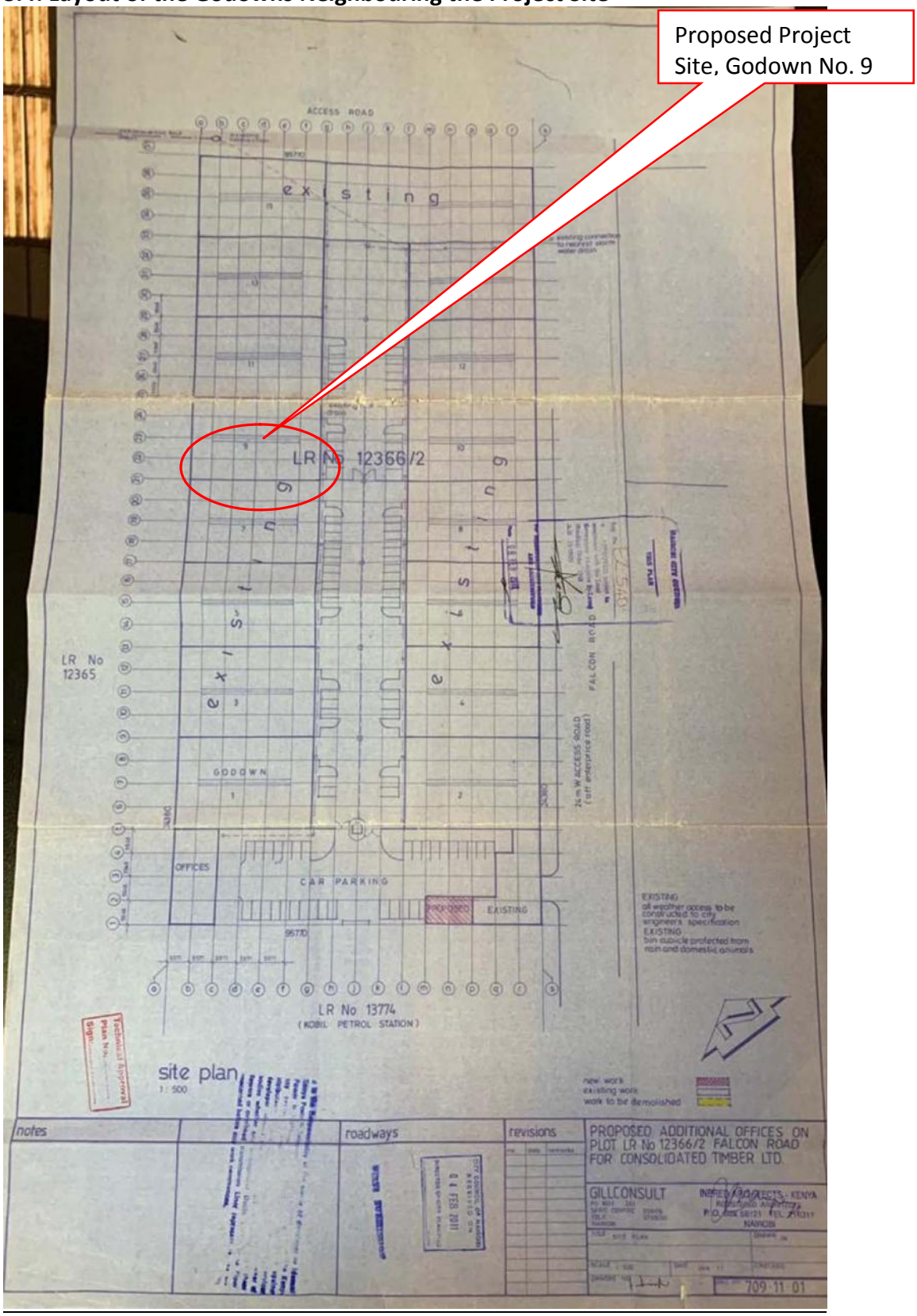
There are various manufacturing industries neighbouring godwn No. 9.

3.2: Adjacent Godowns to the Project Site

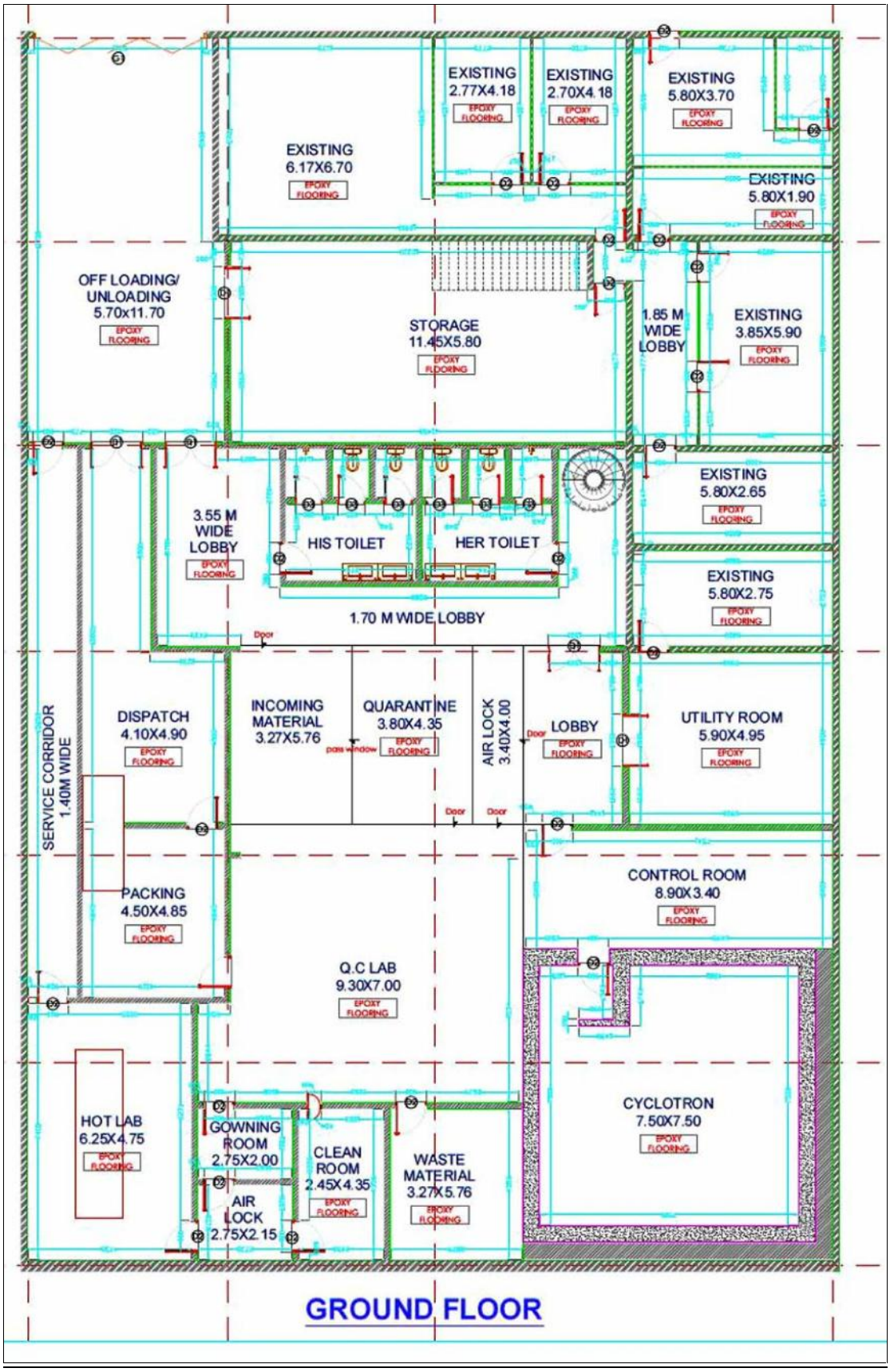
The backside and neighbour to Godown No. 9 No.

3.7 The Project Site and the Immediate Godowns at Fulcon Road Godowns

3.4: Layout of the Godowns Neighbouring the Project Site



3.8 Design Details of the Dcyclotron Godown and its Partitions



3.9 The Project Site and its Immediate Surroundings

3.5: Establishments within a Radius of 1km from the Project Site

The godowns immediate neighbourhood are mainly godowns carrying out various industrial activities or serving as stores for industrial materials and equipment.

To the north, approx. 950 meters from the project site, along Falcon/Ricky Road are the Mukuru kwa Reuben slums. They're almost a km away from the project site, and therefore no possible impacts to the residents.

4 PROJEC T JUSTIFICATION

In Kenya the state of public health poses a severe challenge to health care providers for multiple reasons. One of the main challenges includes Medical Infrastructure for diagnosis of Cancer Management across the country. Since couple of years now the cancer management in Kenya has been phenomenally improved and the private health care providers are playing a major role for improves the quality life of cancer patients however the infrastructure resource is a major constraints for the country in terms of PET-CT scanner facilities.

For the earlier cancer detection, the PET-CT scan examinations is an advance diagnosis tool, for which FGD Isotope is injected into the cancer affected patient. To produce of FGD Isotope injection, the CYCLOTRON facility is must. With a view to establish a CYCLOTRON facility and ADVANCED MOLECULAR IMAGING LIMITED initiating this medical infrastructure in Nairobi, it will improve cancer diagnosis and management in the country.

Radiation during the project's operation phase can be an issue of concern. However, the design of the entire cyclotron facility, including safety considerations for staff and the general public, will have to be reviewed and approved by the relevant and mandated government agencies, among them Pharmacy and Poisons Board, Public Health Department in the Ministry of Health among others before its commissioning.

Further, to mitigate radiation, the facility will be having multiple levels of shielding, protection, and monitoring to ensure safe operation.

The cyclotron itself has several built-in safety interlock systems that prevent the cyclotron from operating if all safety systems are not operational or engaged.

All cyclotron safety systems will be tested on a regular basis to ensure they are functioning according to design.

It will be therefore be of paramount importance to set up and operate the PET-CT scanner facility to address cancer medical related issues.

4.1 INTRODUCING MEDICAL CYCLOTRON TO ADDRESS CANCER ISSUES

Advanced Molecular Imaging Limited is setting up a Medical Cyclotron in Nairobi. A cyclotron is used to produce the pharmaceutical radioactive biomarker units which are used with PET-CT SCANS for the proper diagnosis and management of cancer.

4.1: CT Scan Equipment

PET CT scan is an advanced nuclear imaging technique combines positron emission tomography (PET) and computed tomography (CT) into one machine.

A PET/CT scan reveals information about both the structure and function of cells and tissues in the body during a single imaging session

This unique initiative will give patients access to better cancer care treatment locally, establish Kenya as a medical tourism country, create an export market for FDG radioactive biomarkers to neighbouring countries, and increase the skill levels of workers within the industry.

4.2 NEED OF SETTING UP A MEDICAL CYCLOTRON FACILITY IN NAIROBI

Every year, an estimated eight million people die from cancer globally. Of these deaths, 70 percent occur in developing countries, majority of which are in Africa1. Cancer is the 3rd highest cause of death in Kenya. It is estimated that there are 40,000 new cases per year. It is further estimated that there are at least 30,000 cancer related deaths per annum due to late, incorrect, and/or no diagnosis. 70%-80% of cancer cases in Kenya are diagnosed at late stages largely due to the lack of awareness, inadequate diagnostic facilities, lack of treatment facilities, high cost of treatment, and a high poverty Index.

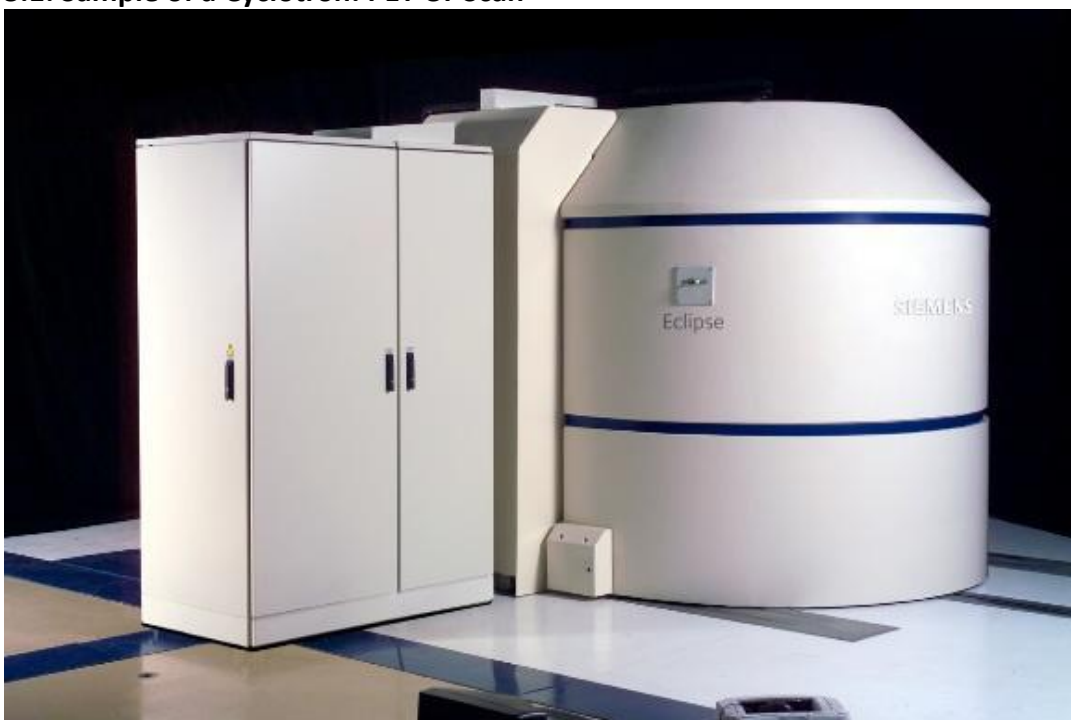
5 OUTLINE OF TECHNICAL ASPECTS IN PET-CT SCANS

5.1 POSITRON EMISSION TOMOGRAPHY–COMPUTED TOMOGRAPHY

The PET-CT scanners are essentially full ring coincidence detectors, the P.E.T. portion, physically mounted together with CT systems of various types. The PET tomographs are fitted with various crystals (BGO, LSO, GSO) that are used to detect the emission photons and convert them to light signals. This scintillation event is converted to an electric signal that can be displayed on a monitor.

Photons that originate from structures deeper in the body are more highly attenuated by the intervening soft tissue than those originating closer to the surface. This effect of attenuation is not accounted for in the non-attenuation corrected images, which appear to show high activity toward the surface and relatively low activity toward the centre.

5.1: Sample of a Cyclotron. PET CT Scan



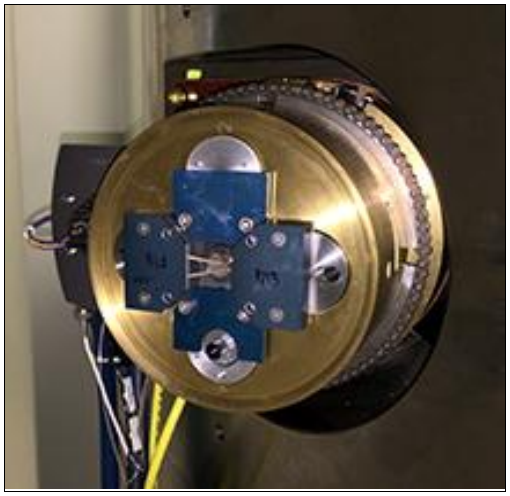
5.2 HOW THE CYCLOTRON WILL WORK

The cyclotron is a particle accelerator that features a vacuum chamber and a strong magnet. The vacuum chamber is heavily shielded, with operations conducted from a

separate room. There also is a "clean lab" where the original isotopes produced by the cyclotron are converted into the trace sugars used with the PET / CT scanners.

In the cyclotron, a high-frequency alternating voltage applied across the "D" electrodes alternately attracts and repels charged particles. The particles, injected near the centre of the magnetic field, accelerate only when passing through the gap between the electrodes. The perpendicular magnetic field, combined with the increasing energy of the particles, forces the particles to travel in a spiral path.

5.2: Details of a Cyclotron. PET CT Scan



The spiral beam of particles widens and hits one of the two targets located on either side of the vacuum chamber. The cyclotron at HSC Winnipeg contains eight such targets in two carousels. Cyclotron beams are used to bombard other atoms to produce short-lived positron-emitting medical isotopes suitable for use with the PET scanner.

The main isotope produced by our cyclotron is Fluorine-18 (F-18). F-18 has a half-life of approximately 110 minutes. Once produced in the cyclotron, the material is transferred to a shielded "hot cell" where it is run through sophisticated chemistry modules to produce the required biological tracers.

5.3 HOW CYCLOTRON PRODUCTS ARE USED

The Positron Emission Tomography (PET) scanner is a nuclear medicine imaging technique which produces three-dimensional images of processes inside the body. The system detects pairs of gamma rays which are emitted indirectly by the positron-emitting tracer. A

radiotracer called Fluorodeoxyglucose (FDG) which is fluorinated glucose is produced in the cyclotron, and this FDG sugar is injected into patients to help identify the presence of cancer.

The accumulation of these tracers shown in the PET scan provides a look at metabolic activity in the tissues. As cancer cells generally use more energy than normal tissue, they take in the FDG sugar tracers as a form of energy, and that contrast is shown by the scans.

Most patients undergo their PET scan at the same time as a CT scan. Computer tomography (CT) generates a 3-D image of the inside of the body from a large series of two-dimensional X-rays taken around a single axis of rotation. By combining the two scans (CT for anatomy and PET for metabolic activity) the areas of abnormality in the PET scan can be pinpointed to the anatomy shown in the CT scan.

5.4 EFFECTIVENESS OF PET-CT SCANS IN CANCER DIAGNOSIS

PET-CTs are the more effective way to diagnose, stage, and evaluate the treatment of cancer with better sensitivity and accuracy compared to conventional CT and/or MRI.
It is suggested that 80 - 90% of all cancer patients should undergo PET-CT scans for diagnosis, during treatment and follow-up. Further usefulness of PET– CT scans include:

- Cancer diagnosis
- To assess tumor aggressiveness
- To monitor success of therapy (surgical, chemotherapy or radiotherapy)
- To detect early any recurrent tumors
- To provide a whole-body survey for cancer that may have spread
- To identify benign and malignant growths
- Used for radio guided surgery
- Used for PET guided radiotherapy

5.5 ITEMS TO BE USED AND THEIR QUANTITY

ITEM	ITEM DESCRIPTION	QTY
ECLIPSE HP CYCLOTRON		
1	System - Eclipse HP Cyclotron	1
2	Cyclotron Shields (standard room)	1
3	Shielded Cyclotron Preinstall kit	1
4	Second Beamline Eclipse HP	1
5	18F Tantalum Target - HP	1
6	13N Target - HP	2
7	Option - Switching Valves	1
8	Option - Remote Diagnostics	1
9	Cyclotron Shipping	1
10	Cyclotron Shipping kit	1
11	Eclipse cyclotron installation	1
12	Project management services	1
13	On-site cyclotron Orientation	1
14	Cyclotron 3-Phase Transformer	1
TARGETRY		
20	PEEK MANIFOLD REBUILD KIT	1
21	Check Valve, In-line 1/16"SS	2
22	FERRULE 1/16""ZFI"	20
23	NUT 1/16""ZNI"	10
24	O-RING REPLACEMENT KIT #	1
TARGET REBUILD KITS		
25	ASM KIT REBLD ECLIPSE F18	4
26	ASSEMBLY KIT, REBUILD, ECLIPSE N-1	2
VACUUM SYSTEM		
27	O-RING 36.79"ID X. 210"CROSS SECT,	1
28	ASSEMBLY, RF GASKET	1
29	HEATER, PUMP VARIAN VHS-4	1
30	HEATER WIRE NICKEL	1
31	OIL MECH PUMP EDWARDS ULTRAGRADE 1	2
32	KIT, FILAMENT, REPLACEMENT, UHV-24	1
33	GREASE HIGH VACUUM IN TU	1
34	GREASE L HIGH VACUUM API	1
35	OIL DIFFUSION PUMP SANTOV	1

Source: Various Sources.

6 POSSISIBLE IMPACTS AND MITIGATION MEASURES

6.1 ENVIRONMENTAL HEALTH CARE CONCERNS AND MITIGATIONS MEASURES

6.1.1 Cyclotron Room, Exhausts and Control Measures

Air conditioning and exhaust serving the cyclotron room is required 24 hours/day, 7 Days / week. Ventilation and air changes shall be in accordance with DIN 6844, Part 1 or in accordance with national or local regulations[5]. The cyclotron room pressure shall be maintained at negative pressure relative to the surrounding areas.

Prior to discharge, all exhaust from cyclotron and chemistry enclosures must pass through a proper filtration and monitoring system to meet national and local safety code requirements. It is the responsibility of the customer to ensure that the exhaust control and monitoring system complies with applicable national and local regulations.

When the configuration of the equipment allows, the cyclotron exhaust may be combined with the exhaust from the chemistry enclosures in the radio pharmacy area to help minimize the number of monitoring systems required in the facility.

The project proponent shall provide an appropriate visual temperature and humidity monitor at the cyclotron control station to ensure that the specified temperature and humidity levels are maintained during daily operation.

6.1.2 Gases

The standard cyclotron requires six compressed gas cylinders. Installation of an approved compressed gas cylinder mounting system is the responsibility of the customer[6]. There should be enclosures that may be required by local safety codes for flammable gases.

Included in the cyclotron shipment are gas bottle regulators and a bottle farm interface box. During the time of mechanical installation, the gas bottle regulators will be provided to the customer for fitting to the gas bottles in advance of the site readiness inspection. The regulators themselves come with CGA fittings. Appropriate adapters should be obtained by the customer in order to fit these to non-CGA bottles.

[5] DIN 6844-1. Part 1: Rules for the construction and equipping of facilities for ambulatory use of unsealed radioactive materials for diagnosis and treatment. *Deutsche Institut für Normung*

[6] A cylinder of hydrogen gas is required for the system.

The Bottle farm Interface box will be mounted by the Test and Commissioning Engineers in the cyclotron room at the time of commissioning. However, gas lines must be run from the gas bottles to the interface box inside the cyclotron room and terminated at the location where the bottle farm interface box will be located

6.1.3 Compressed Air

The cyclotron requires a source of compressed air. This can be in the form of a compressor with air drier or a compressed air bottle. Drops for compressed air will be at the bottle farm and the workbench. For facilities having an available source of compressed air, one of the gas bottles can be eliminated. Note: ¼ inch Female NPT fittings required for installations.

- Required pressure: 7.0 Bar +/- 0.7 Bar (100 psig ± 10 psig)
- Peak flow (Cyclotron Only) 1L/min (0.04 cfm)

At the point of discharge, compressed air servicing the cyclotron shall meet or exceed a Class 2 quality standard as set forth in ISO/DIS8573-2. Within this quality standard, the oil content shall be limited to 0.1 ppm, the water dew point shall be held to -40ºC (-40ºF) and the size of dirt particulates shall be no greater than 1µ.

6.1.4 Radiation Protection

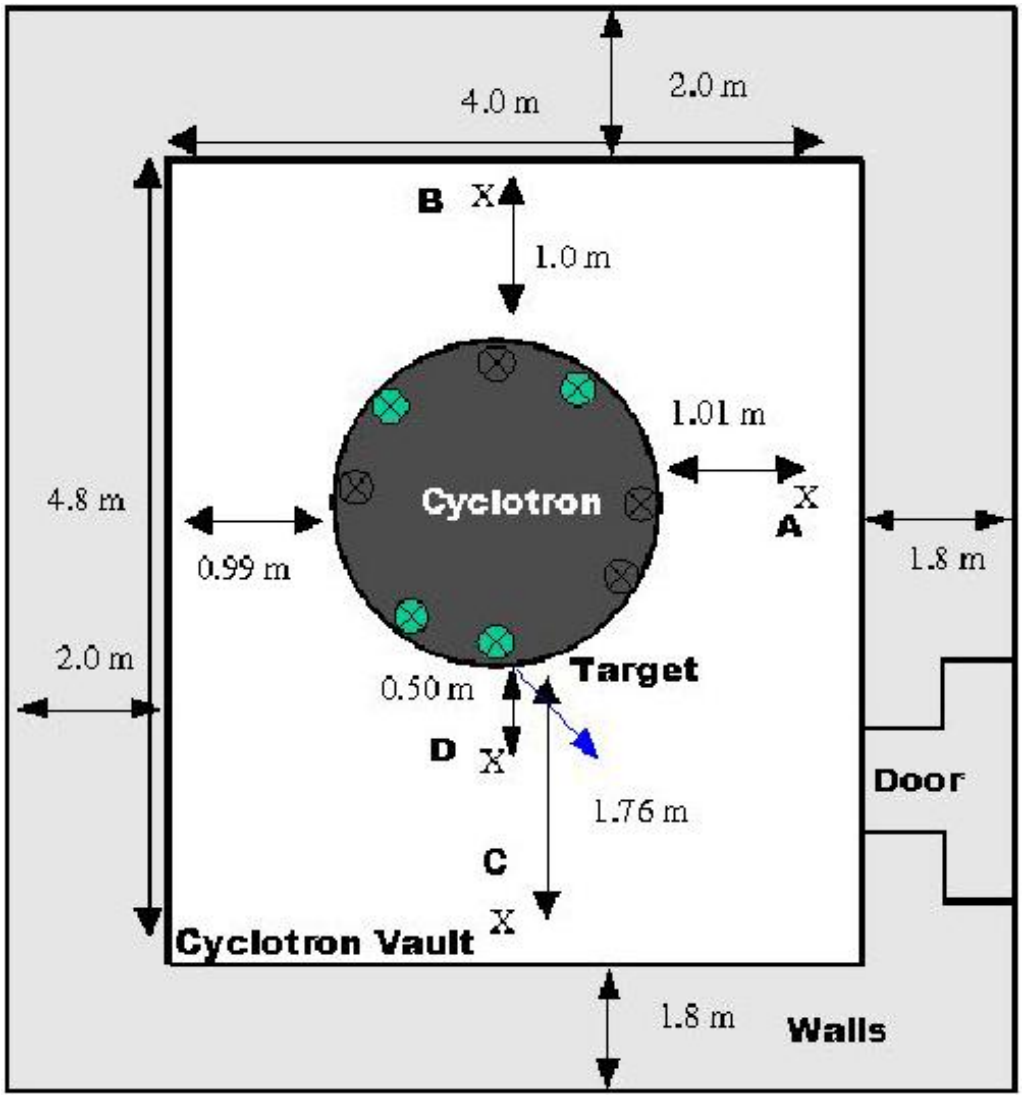
Radiation exposure calculations are prepared by Siemens Implementation Project Management and provided to our customers as a part of the project design drawings to be utilized as guidelines in the final design of the cyclotron room. These guidelines are utilized by the planners in the development of appropriate secondary containment shielding thickness for the cyclotron room relative to the space utilization of the adjacent areas. It is responsibility of the customer to secure the services of an independent, certified third-party to review, verify and certify the calculations and design so the design meets applicable code requirements and radiation safety regulations for the facility.

6.1.5 Secondary Containment and the Cyclotron Room

For the basis of the initial cyclotron room design, the secondary containment thickness of the walls will be planned at 45-60cm (18-24 in) of concrete with a density of 2.35 g/cm³. If there is occupied space directly above the cyclotron room, the initial allowance for

secondary containment will be planned at 45-60cm (18-24 in) of concrete with a density of 2.35 g/cm³. If there is no occupied space directly above the cyclotron room, it is possible that no additional secondary containment material will be required.

6.1.6 Details on Design and Safety in the Cyclotron Room



The walls to the Cyclotron are two meters thick. They will be constructed as per the required professional guidelines. Further the Cyclotron will be at least one meter from the walls. Radiation effects will therefore be minimised

6.1.7 Radiation Emitted, Monitoring and Exposure Warning/Prevention

Since a radiation field and irradiated materials are being generated by the operation of the cyclotron, the facility shall be equipped with radiation survey monitoring equipment (fixed

and portable), to provide immediate feedback or warning of exposure levels in the facility. This system of monitors shall be provided by the customer as part of the equipping of the facility prior to commissioning of the cyclotron.

6.1.8 Radiation Safety within PET Cyclotron's Immediate Environment

The MCF area shall be equipped with radiation detectors that will continuously monitor radiation dose rates and trigger alarms at dose rates above normal expected operating conditions. Areas that shall have radiation include:

a) Cyclotron room
b) Synthesis (Hot) Cell room
c) Processing (Dispensing) Cell room
d) Ventilation Systems (stack)

In maintaining the radiation safety protection procedures:

- All radiation monitors shall be maintained according to manufacturer specifications.
- Radiation monitors shall be calibrated annually as part of a regular preventive maintenance schedule. This can be done on a rotational basis as long as all are calibrated annually.

6.1: Project Site and Immediate Neighbourhood

The project neighbourhood is dominated by godowns. There are no residential houses close to the project road.

The nearest settlement is approx. one kilometre away, the Mukuru kwa Reuben slums. There are no possible radiation related impacts as a result of settlement; they are far away from the project site.

6.1.9 Isotopes Produced by the Cyclotron and Safety Concerns

The isotopes produced by the cyclotron have a relatively short half-life and quickly decay to products that are not radioactive. The volume of radioactivity regularly produced by the cyclotron is relatively small in scale. A typical production run of F-18 amounts to less than 3mL of F-18. Once processed into FDG, the final volume is 15mL

The design of the entire cyclotron facility, including safety considerations for staff and the general public, should be reviewed by the mandated government agency or any other applicable international body.

6.1.10 Project's Compliance Status with Radiation Protection Board's Requirements

Table 6-1: Compliance Checklist for the Medical Cyclotron Facility

	Checklist Item	Compliance		Comments
		Yes	No	
REGULATORY APPROVALS BY RADIATION PROTECTION BOARD (RPB)				
A	**Site Assessment and Approval**			
1	Has the project site been inspected and approved by RPB?	✓		*Site inspected and approved by RPB officers. Approval letter is attached in the addendum of ESIA report.*
2	Is the location of the MCF within an industrial premise?	✓		The site is within Industrial area, dominated by godowns
3	Data on max level of ground water and maximum flood levels for the past 10 years	✓		*Data obtained from the Kenya Meteorological Department*
4	What's the distance of site installation of the MCF from the nearby public utility or residential premises?	✓		Nearest residential area (slums) is one kilometre away.
5	Are results from soil tests/ground characteristics from a NEMA accredited / mandated government laboratory available?	✓		*Results available and attached in the addendum of ESIA report.*
6	Provision of access road to the MCF site.	✓		Site is easily accessible through Enterprise Road /Falcon Road.
7	Details of the site layout	✓		*Architectural site layout drawing available with all the main partitioning and rooms.*

8	Has the baseline radiation/radiological baseline survey done and report provided?	✓		*Survey carried out.*
B	**Design and Construction Requirements**			
9	Was the design for the MCF carried out by a duly registered architectural and Engineering firm?	✓		A duly registered architectural and Engineering firm has carried out the design.
10	Are services of certified Technical Provider (TSP) available? - for baseline radiation studies, radiation protection, shielding calculations, management of radioactive waste etc).	✓		TSP available
11	Has the structural engineer worked on the floor loading of the cyclotron vault during construction putting in mind the gross weight of the cyclotron to be installed?	✓		
12	Has the RPB approved any modifications of the MCF, in case there's any?	n/a	n/a	No modifications

6.1.11 Noise levels

The noise levels in the room can be quite high, especially with the air compressor running. Hearing protection is often required. At a minimum, the area should be surveyed for noise levels and the noise levels posted if necessary. Noise levels above 85dbA require some hearing protection in order to avoid hearing loss.

6.1.12 Ventilation facility

Entry inside the vault is restricted for several minutes after the high voltage has been shut off. Airflow in the facility is a decreasing pressure gradient with the lowest air pressure in the cyclotron room. Contaminated air from the cyclotron system is passed through the HEPA (High-Efficiency Particulate Air) filters and then through the carbon filters and finally connected to the stack facility.

The contaminated air thus collected is released after 10 half-life decay through an exhaust. The ventilation duct radiation monitor also monitors exhaust air. The radiation detector is installed inside the duct system to monitor the activity constantly irrespective whether beam is ON or OFF.

The ducts of the ventilation system remain open during or after beam operation. Potentially contaminated air from the cyclotron is monitored to ensure exposure rates below country's permissible limit as per regulatory guidelines and is disseminated in the environment through a chimney on the roof of the building.

The ventilation safety functions have been tested prior to the facility start-up. The ventilation power supply is protected to avoid any ventilation loss during the cyclotron operation.

The exhaust for the cyclotron, hot cell is separate from the facility HVAC equipment. Exhaust from the hot cell are filtered and then combined with the exhaust from the cyclotron. The combined exhaust, which includes the cyclotron and hot cell exhaust, is monitored for radioactivity through a stack monitor and then released through a stack located on the building roof.

6.1.13 Gaseous by- Product Emission and Storage

Air Compression system has been created in order to extract potentially radioactive air from the hot cells, arising from various gaseous by-products (viz. $CF_3SO_2{}^{18}F$, $H^{18}F$, $^{13}NO_x$ etc.) during the radiochemical synthesis of FDG and to send it to low pressure tanks for stocking and decay. Air is compressed by means of a diaphragm compressor, which also acts as a vacuum pump, being able to compress air in the delivery phase and to generate negative pressure in the suction phase. The system sets automatically in action whenever the Geiger counter in the air output from one or more cells measures a radioactivity value higher than the preset value, or if the operator manually pushes the start button of a cell. As a result, the cell shifts from the "stand-by ventilation rate" to the "production ventilation rate" configuration in the following way:

- Air input and output is simultaneously blocked by means of special automatic valves;
- The air output fan of the selected cell(s) is stopped;
- The electro valve connecting the air output ducting of the box with the suction plenum chamber is activated (the valve opens only when the box minimum negative pressure threshold value has been attained and it closes when the negative pressure reaches the maximum value). Since the vacuum tank (plenum chamber) is characterized by a high negative pressure (inside it, vacuum is generated by means of a compressor), when a contamination is recorded, the air exchange is immediately closed and the accumulation device is activated. The cell is isolated and kept at a vacuum level (negative pressure) varying from –50Pa to –150Pa.

This takes place by opening (in the ON/OFF way) a 2/2 NC solenoid valve throttled by an unidirectional flow regulator. This solenoid valve connects the cell to the vacuum tank and is opened and closed according to the two threshold values set on the controlling gauge of the cell itself. It should be noted that in order to make a 1000-litre box attain the corresponding value of -200 Pa, it is enough to extract approximately 2 ambient liters. When the plenum chamber is full (that is, the negative pressure of the plenum chamber falls below the set value), the compressor transferring air from the plenum chamber to a stocking tank is activated.

6.1.14 Air Compression system (ACS)

The system performs the extraction of potentially radioactive air from inside of the hot cells during the production or following a malfunction of the synthesis modules. The extracted air is then sent to a compressing station, which stocks it in cylinders until its decay. Once decayed, the air, which is no more contaminated, is vented out (through the output ducting of the general ventilation of the lab) after being monitored by a Geiger probe placed inside a Marinelli system shielded with Pb 20 mm.

6.1.15 Cyclotron Emergency Procedures

The manufacturers' ob-site technicians of the Cyclotron will have identified all aspects of the safe operation of radiation devices. Device operators shall conduct all start-up and shut-down procedures as well as preventive maintenance checks according to the manufacturer guidelines. The following procedures are in addition to the general emergency procedures.

The following procedures should be followed:

- Immediately shut down the cyclotron using the software, if possible, or press the emergency stop button.
- Note: if electrical power is lost the cyclotron will shut down completely.
- Ensure no personnel are in the cyclotron room or other affected rooms and shut the doors.
- Inform all workers in the facility about the accident and evacuate the affected areas.
- Inform the site security officer about the incident.
- Close off areas and identify access points with radiation warning signs.
- Inform the service provider

6.1.16 Best Practices for Controlling Vehicular/Pedestrian Traffic

The Prime contractor or owner will:

- Develop a traffic management plan for the project that meets all the traffic requirements and addresses the control of and safe movement of all traffic that enters/exits Enterprise Road/Falcon road junction into the Consolidated Timber yard godowns site.

- Secure traffic management signage/materials near the construction site, e.g. warning sign "Heavy Traffic Turning" etc.
- Conduct a hazard assessment in relation to the vehicular/pedestrian traffic that both enters/exits the work site, and traffic that utilizes the road adjacent to the project.
- Appoint qualified persons to supervise traffic control procedures (when lorries entering or exit project site) to ensure they are in accordance with the traffic management plan.
- Provide all necessary traffic signage at strategic locations that warns motorists of changes to traffic patterns at Enterprise Road/Falcon road junction.
- Ensure regular inspections as required on installed mitigation measures.
- Install signage that gives the driver and public enough advanced notice of the closure / delay / detour so other routes can be planned.

6.2 WASTE MANAGEMENT DURING THE PROJECT'S OPERATION PHASE

6.2.1 NEMA's Provisions in Disposal of Radioactive Waste

Pursuant to the Waste Management Regulations 2006, Clause 49, Protection Act Cap 243, Part VII, on Radioactive Substances, *"No person shall dispose of any radioactive substance or waste other than at a designated site or plant approved by the Authority*".

6.2.2 Disposal of Radioactive Waste from the Cyclotron

To this effect,

- Radioactivity waste will be disposed off in accordance with regulatory requirements. No radioactive material will be released into the sanitary sewers, or disposed off through incineration.
- Radioactive waste materials with half-lives of less than or equal to 120 days will be disposed by decay-in-storage [DIS]. The minimum holding period for decay is ten half- lives of the longest-lives of the longest-lived radioisotope in the waste. Adequate space and facilities will be available for the storage of such waste. Procedures for management of waste by DIS include methods of segregation, surveys prior to disposal, and maintenance of records of disposal. Segregation of

waste will be accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods of time, freeing storage space.

- Waste for DIS is stored in properly shielded storage to decay for half-lives. After the decay period, surveys will be performed on the waste. If the surveys indicate that the waste is not above background, the waste will be disposed in normal trash. If surveys indicate activity above background, the waste will be held longer to decay until surveys indicate no activity above background.
- All radioactive signs and labels on the outside of the container will be removed or defaced prior to disposal of the waste. Long-lived radioactive wastes (e.g. activation products) with half-lives greater than 120 days are stored for further off-site disposal. Shielded space is available inside the cyclotron room for radioactive waste storage.

6.2.3 Management of Waste Gases produced in the Cyclotron Room

For the exhaust system, the waste gases produced in the cyclotron room are sucked from the room, and are compressed in the waste gas system (consisting of cylinders) till it decays to background level. The gas is subsequently released into a ventilation exhaust duct system. A ventilation duct radiation monitor monitors the exhaust pipe and a display of the same is viewed in the control room.

6.2.4 Cyclotronic Waste in the Typical Characteristics of Radioactive Waste Classes

It is necessary to classify waste into different categories. The categories are related to the hazards and risks to humans and the environment. Different waste materials present different degrees of hazard. Some types of material contain short lived radionuclides, while other types contain very long lived radionuclides.

	WASTE CLASS	TYPICAL CHARACTERISTICS	DISPOSAL OPTIONS
1	Exempt waste (EW)	Activity levels at or below No radiological restrictions clearance levels that are based on an annual dose to members of the public of less than0.01 mSv	No radiological restrictions.
2	Low and intermediate level waste (LILW)	Activity levels above clearance levels and thermal power below about 2 kW/m^3	
2.1	Short lived waste (LILW–SL)	Restricted long lived radionuclide concentrations (limitation of long lived alpha emitting radionuclides to 4000 Bq/g in individual waste packages and to an overall average of 400 Bq/g per waste package)	Near surface or geological disposal facilities.
2.2	Long lived waste (LILW–LL)	Long lived radionuclide concentrations exceeding the limitations for short lived waste.	Geological disposal facilities.
3	High level waste (HLW)	Thermal power above about 2 kW/m^3 and long lived radionuclide concentrations exceeding the limitations for short lived waste	Geological disposal facilities

Source: IAEA, 2013.

6.2.5 Further General Waste Management Measures

Pursuant to Environmental Management and Co-ordination Act, (Waste Management Regulations 2006, Part II, Solid Waste), the hereby general provisions of solid waste management during the project cycle should be adhered to.

Solid Waste Management Issues		Waste Management and Disposal Methods / Provisions
1	Responsibility of the constructors, the main waste generators during the project cycle.	• Dispose waste in designated waste receptacles only. • Waste generated shall be collected, segregated at the source and disposed off in designated waste receptacles only. • The constructors (waste generators) to ensure that waste is transported to a person who is licensed to transport and dispose off waste in designated waste facilities.

2	Segregation of waste by generators	• Use the 3R Waste Management Approach, i.e. *Reduce, Reuse and Recycle* whereby waste shall be segregated - plastics, glass, tins, papers, wood, metals etc (later to be re-used or recycled).
4	Waste Transportation	• During the construction, operation and decommissioning , all the waste transport vehicles from the proposed project shall be approved by the Authority upon recommendation from Lead Agency.

Source: Adopted from NEMA Waste Management Regulations, Part II, Solid Waste, 2006.

7 OCCUPATIONAL SAFETY AND HEALTH FOR THE WORKERS.

During construction/refurbishment and operation stages of the proposed warehouse, the project proponent and the contractor should develop an environmental occupational health and safety policy. The policy should:

- Include a commitment to continual improvement.
- Show commitment to comply with applicable occupational OH&S regulations.
- Be communicated to all employees so that they know their OH&S obligations.
- Be reviewed periodically to ensure that it remains relevant.

7.1 OH&S MEASURES FOR THE WORKERS AND GENERAL PUBLIC

During construction phase, accidents, occupational diseases, ill health and damage of property can occur if precautionary measures are not observed. Some of the precautionary measures are described below.

Personal Protective Equipment (PPE)

- Use of appropriate PPE (helmet, gloves, protective boots, etc) to be mandatory for all site workers during preparation and construction period.
- Workers to be trained on proper use of personal protective equipment (PPE) regardless of their prior working experience elsewhere.
- Workers to be informed and sensitized on the relevance of using PPE.
- First Aid Box to be provided with necessary medicines and equipment.
- Construction working team to have at least one trained First Aider.

Noise and Vibrations

- Workers near machines producing high noise to use ear muffs to deaden noise.
- Machines, tools or equipment producing excessive vibrations to be noted.
- Machines producing high noise to be properly maintained.

7.2 WORKPLACE SAFETY DURING ALTERATIONS OF THE GODOWN

7.2.1 Construction Safety

- Metallic or wooden scaffold to be set up by professionals and to be inspected before use and regularly during construction period.
- Working platforms planks and guardrails to be firmly fixed and inspected regularly.
- Ladders and other access facilities to be constantly inspected to assess if they are in good conditions. Damaged ladders and access facilities to be repaired or replaced
- Warning signs to be fixed at strategic places.

7.2.2 Machinery Safety

- All the machines and equipment used should be in good conditions.
- Safeguards should be provided for each machine or equipment to be used.
- All the portable tools and appliances in use should be in good condition.
- All the safety conditions and instructions issued in regards to machines and equipment used should be clear to the workers.
- Faulty machines or equipment to be repaired before being used.
- Machines must be repaired or maintained only by professionals but not informal artisans.

8 CONSULTATIVE PUBLIC PARTICIPATION (CPP)

8.1 RELEVANCE OF CPP

The purposes of consultative public participation in this EIA study were mainly to gain views from the public, concern and value in regards of possible impacts due to the activities that will be carried within the site for the proposed work at the godown. Through this, it was anticipated that transparency and accountability in the final study report would be achieved. Possible conflicts between the proponents, stakeholders and community members living in close proximity to the project site would be addressed and solved at an earlier stage.

8.2 ISSUES OF CONCERN FROM STAKEHOLDERS AND THE NEIGHBOURHOOD[7]

Most of the participants were of the opinion that jobs will be created, though for professionals. They were however concerned on the exposure to radiation during the operation phase of the proposed initiative.

8.2.1 Consultative Meetings during the Design Stage of the Cyclotron Facility.

[7] See filled in questionnaires in the appendix.

8.2.2 Issues of Concern Raised by the Management of Site Owners (Lessees).

Management of the company was apprehensive about the proposed initiative. However, they noted that if all the safety procedures are followed, there will be no significant impacts. Specific issues raised included:

- Safety to the project neighbours
- Waste disposal, - how will it be done?
- Will the project be constantly inspected by mandated government officers, -NEMA, Pharmacy and Poisons Board

8.2.3 Recommendations from Clinical Oncologists, Pallative Medicine Specialists

The following list of doctors have all recommended the necessity of addressing cancer related problem through the introduction of a FDG Cyclotron facility in Nairobi. All their input has been attached in the appendix of this report.

i. Dr. Manoj Shah (HSC). Chair, Social Service League, M. P. Shah Hospital, Nairobi.
ii. Dr. N. Adamali. Medical Director, Cancer Care Kenya.
iii. Dr. Alfred Odhiambo, Neuroradiologist, University of Nairobi/Plaza MRI.
iv. Dr. Catherine Nyongesa. Chair, Kenya Society of Hemato-oncology
v. Dr. Eliud Njuguna. Specialist in Clinical Oncology and Pallative Medicine.
vi. Health Care Global (Kenya)
vii. Meditecs System Ltd. (Partner of SIEMENS Healthineers, East Africa).

8.2.4 Recommendations from Oncology Related Interested Parties

The chair to the following listed interested parties wrote down their concerns in support of he proposed initiative. Their concerns are attached in the appendix of this report.

- Kenya Cancer Association (KENCASA)
- Kenya Cancer Organisations Network
- Environmental Radiation Surveillance and Baseline Radiation surveyors, Nairobi.

8.2.5 Observations by Neighbours to the Proposed Project Site

Comments from management staff to the godown neighbours are attached in the appendix of this report.

8.2.6 Concerns of Radiation Protection Board after Visiting the Site

The Team had no objection of the godown/site being fitted with the necessary equipment, machinery and tools for the medical cyclotron facility. They however instructed that an EIA must be done. A copy of the letter on their consent is attached in the appendix of this report.

8.2.7 Issues of Concern Raised by further Project Neighbours

The neighbours were of the opinion that all:

- All the activities should be done in the godown but not outside
- NEMA regulations should be followed
- Before the start of the work, they should be assured that all the necessary conditions have been met.

8.2.8 Issues of Concern Public Health Officer, Nairobi County

The officer will visit the premises during its preparation phase and operation phase.

9 PROPOSED EMP FOR THE PLANNED WAREHOUSE REFURBISHMENT AND EQUIPPING

The proposed EMP will identify feasible and cost effective measures to reduce potentially significant adverse environmental and social impacts to an acceptable level. The EMP identifies impacts, mitigation measures and action plans for the impacts. Through this, possible public resentment will be identified and mitigated.

Project Activities/ Impact Sources	Proposed Mitigation and Action Plans	Monitoring /Inspection Type and Responsibility	Cost Estimates	Targets to Achieve	Timeframe and Monitorial Indicators
SITE PREPARATION					
Road accidents along Enterprise Road/Falcon Road junction during delivery of equipment and machines	• Secure traffic management signage near the godown site, e.g. warning sign "Heavy Traffic Turning" etc. • Appoint qualified persons to supervise traffic control procedures (when lorries entering or exit project site) • Provide all necessary traffic signage at strategic locations that warns motorists of changes to traffic patterns/diverting • Ensure regular inspections as required on installed mitigation measures.	**Verification inspection by:** Contractor. **Technical and planned Inspections by:** Site Engineer Contractor	To be specified in the BoQ	No accidents. Complaints from the community.	**Timeframe:** Monitoring to be done during site preparation.
Haulage of materials	• Ensure on site speed regulations for haulage trucks.	**Verification inspections by**: • Contractor	To be specified in the BoQ document.	To avoid dust and dust	**Timeframe:** Monitoring to be done during site preparation
Selection of non-skilled workers from the neighbourhood to work at the refurbishing site.	• Employ locals with the consultations with area elder with the objective of achieving project acceptance within the neighbourhood. • Area elder to liaise with the contractor in agreeing on the modality of employing locals in low skilled jobs at the godown	**Inspection / monitor on:** • Number of local youngsters employed at the site.	Variable costs to be set up by contractor.	Project acceptance harmony with the neighbouring community	**Timeframe:** Monitoring to be carried out during construction phase.

REFURBISHMENT PHASE OF THE EXISTING GODOWN					
Presence of workers at the godown gate and not area residents	• Put up a clear message of "NO JOB VACANCIES" at the gate.	**Spontaneous inspection:** • Company management team.	Costs not applicable.		**Timeframe:** Monitoring to be done during site preparation
Anti-social behaviour from the workers (social ills), permanent and casuals.	• Contractor and area chief to allow persons of good conduct only to work at the site.	**Verification inspections by**: • Contractor • Community elder (chief) living close to haulage route, especially the nearby the road.	n/a	No cases/issues of anti social behaviours.	**Timeframe:** Monitoring to be done during site preparation
PROJECT OPERATION (GENERAL OPERATIONS)					
• General Occupational Health and Safety Concerns.	• Provide and enforce use of appropriate protective gear, -dust masks, protective shoes etc. • The godowns construction site to be out of bounds to unauthorized intruders, food vendors or job seekers. • Constructor at the godowns to have at least one trained First Aider, aware of firefighting techniques, precautions etc. • Develop liaison with health provision arms for emergency response. • Provide security services within the godowns. • All firefighting equipment to be constantly inspected by authorized agents for continual operability. • Management staff of the godowns to have at least one trained First Aider, aware of firefighting techniques, precautions etc.	**Scheduled and verification inspection by:** • Safety Health and Environment (SHE) advisor to the project proponent **Supervision by:** • Workshop supervisor	To be specified in the BoQ document.	No occupational accidents.	Number of affected people.
Air pollution	• Maintenance of plant and equipment and sensitize workforce. • Sensitize vehicle owners in the godown	**Scheduled and verification inspection by:** • Safety Health and		No air pollution related to workshop operations.	Airborne related diseases.

	parking/passage area not to leave their vehicles; engine running while inside the Industrial Park. • Operations to be done during the day only. • Work equipment and engines to be switched off when not in use.	Environment (SHE) advisor to the project proponent **Supervision by:** •Workshop supervisor			
Waste Management	• Provide appropriate options for waste management. • Assess opportunities for reducing solid waste generation in particular of hazardous and undesirable materials • Dispose all unwanted structures, wastes and unused materials in accordance to NEMA Waste Management Regulations.	**Spontaneous and general inspection by:** • Public Health Officers, Nairobi County	Variable costs to be included in the BoQ.	Minimal negative impacts on the natural and human environment	**Timeframe:** Monitoring and inspection to be carried out during construction phase. **Monitorial Indicators:** • Constituents of generated waste. • Housekeeping status of camp.
Accumulation of solid waste	• Workers to be encouraged to segregate waste from the source, use the 3R Management Approach: Reduce, Reuse and Recycle. • Limit waste quantity by proper planning. • Godowns management to be carrying out inspections within and around the building (general, spontaneous and verification types of inspections) to monitor waste, cleanliness and housekeeping status. • Improvised waste management systems not to be encouraged • Godowns management staff to have a functional waste management system. • Waste disposal bins to be placed in all departments in the godowns.	**Scheduled and verification inspection by:** • Safety Health and Environment (SHE) advisor to the project proponent **Supervision by:** •Workshop supervisor	Variable costs to be included in the BoQ	No accumulation waste	**Timeframe:** Monitoring and inspection to be carried out during construction phase. **Monitorial Indicators:** • Constituents of generated waste. Housekeeping status of camp.

Fire Precautions/ Environmental Incidents Emergency Procedures	• Hoses and fire extinguishers are checked and maintained on schedule for continued operability. • Necessary fire related training, certificates available. • Implement monitoring programs, parameters and procedures for control and corrective actions in case of emergencies, e.g. fire and workplace accidents. • Fire training sessions for all employees are carried out, with practical demonstrations on how to combat fire.	**inspection by:** • Safety Health and Environment (SHE) advisor to the project proponent **Supervision by:** •Workshop supervisor	Variable costs to be included in the BoQ	Variable costs to be included in the BoQ	**Timeframe:** Monitoring and inspection to be carried out during construction phase. **Monitorial Indicators:** • Filling/checking fire equipment and schedule • Training schedule for workers
Ergonomic risks during construction and operation.	• Train workers on appropriate methods of manual lifting of heavy equipment and materials to avoid occupational health complaints such as musculoskeletal disorders of the back which can lead to the damaging the spinal cord, among other negative health impacts.	**Spontaneous inspection by:** • Contractor • Contractor/Factory supervisor.	Variable costs.	To avoid any noted substandard working practice with the objective of protecting the workers.	**Timeframe:** Monitoring and inspection to be carried out during construction and operation phase. **Monitorial Indicators:** • Frequency and causes of accidents.
OPERATION PHASE OF THE MEDICAL CYCLOTRON PHARMACEUTICAL WORKS					
Operations in the Cyclotron Room	• Strict adherence to the set standards in radiation exposure levels in and around the cyclotron room. • The radiation exposure levels outside the shielded area of the cyclotron should be minimal, in accordance to PPB standards/any other international accepted standard. This will	**Spontaneous inspection by:** • Contractor. • Contractor/ supervisor. • Experts contracted with the task.	Variable costs	Avoid any shortfalls at the Cyclotron room	**Timeframe:** Monitoring and inspection to be carried out during construction and operation phase. **Monitorial Indicators:** • Frequency and

	include: ionization chamber, vault door/wall, console and outer wall of the Cyclotron • There should be no leakage of the radiation outside the vault and all the values are to be below the recommended levels of exposure in accordance to PPB standards or any other international accepted standard. • The exposure values should be noted before operation, during and after operation of the cyclotron.				causes of accidents.
Cyclotron Room and possible Exhausts.	• Ventilation and air changes shall be in accordance with DIN 6844, Pt 1 • The cyclotron room pressure shall be maintained at negative pressure relative to the surrounding areas • all exhaust from cyclotron and chemistry enclosures must pass through a proper filtration • monitoring system to meet national and local safety code requirements • Specified temperature and humidity levels are maintained during daily operation.	**Spontaneous inspection by:** • Contractor • Contractor/ supervisor. • Experts contracted with the task	Variable costs	Avoid any shortfalls at the Cyclotron room	**Timeframe:** Monitoring and inspection to be carried out during construction and operation phase. **Monitorial Indicators:** • Frequency and causes of accidents.
Radiological Safety	• Workers to wear radiation badge while in the building only. • Workers should not bring food, drinks, chewing gum, makeup or their packaging in the working area, especially cyclotron room.	**Spontaneous inspection by:** • Contractor/ supervisor. • Experts contracted with the task.	Variable costs	Avoid any shortfalls at the Cyclotron room	**Timeframe:** Monitoring and inspection to be carried out during operation phase. **Monitorial Indicators:**

	• Workers to wear disposable gloves while working with irradiated materials and • Used gloves to be put in the container dedicated to potentially radioactive waste. • irradiated material should not be taken outside of the restricted area				• Frequency and causes of accidents.
Workers Safety and Exposure to Radiation	• Work attire to be strongly adhered to, including workers 'long pants and closed-toe shoes. • Conducts regular inspections of the facility's radiation safety program to ensure safety and compliance with federal safety regulations.	**Spontaneous inspection by:** • Contractor/ supervisor. • Experts contracted with the task.	Variable costs	Avoid any shortfalls at the Cyclotron room	**Timeframe:** Monitoring and inspection to be carried out during operation phase. **Monitorial Indicators:** • Frequency and causes of accidents.
DECOMMISSIONING PHASE OF THE MEDICAL CYCLOTRON PHARMACEUTICAL WORKS GODOWN NO. 7					
Closure of the godowns	• All the unwanted materials to be removed from the site.	**Supervision by:** •Workshop supervisor	Variable costs	To avoid scrap metal and garbage at the site.	**Timeframe:** Monitoring and inspection to be carried out during construction and operation phase. **Monitorial Indicators:** Frequency and causes of accidents
Dismantling of the equipment and removal of machinery	• Dismantling and decommissioning activities to adhere to NEMA's Waste Management Guidelines (2006) and other international recognised body, e.g. IAEA, DIN etc	**Technical and scheduled** **Supervision by:** • Mandated government Agent. Contractor PHO	Variable costs	To avoid scrap metal and garbage at the site.	**Timeframe:** To be carried out during construction and operation phase. **Monitorial Indicators:** Frequency and causes of accidents

10 ENVIRONMENTAL PERFORMANCE MONITORING PLAN

10.1 OBJECTIVES OF THE MONITORING PLAN

Monitoring shall be conducted to ensure that the predicted project impacts are within the environmental acceptable limits. Further objectives of the environmental monitoring program will be to ensure that:

- The mitigation measures are implemented.
- The mitigation measures have the intended results.
- Those remedial measures are undertaken if mitigation measures are inadequate or the impacts were underestimated.

10.2 MONITORING AND ACTION PLAN FOR PREDICTED IMPACTS

In order to exercise effective monitoring control of the impacts arising from the proposed project and thus protecting the environment, a monitoring plan was proposed. Monitoring will take place after the refurbishment/partitioning and operational phases of the project.

11 DECOMMISSIONING PHASE

Decommission is to dismantle or remove something that had been operating from service. This is the last phase in a project cycle after design, construction and operation. In the eventuality that company closes down its operations, it will contract a decommissioning audit team to assist it in the following issues:

11.1 SAFETY DECOMMISSIONING OF THE MEDICAL FRACILITY[8]

NEMA and IAEA have guidelines of management of toxic waste. In the IAEA, the following provisions have been provided for decommissioning, and which the project proponent must adhere to.

- During all phases of decommissioning, workers, the public and the environment should be properly protected from hazards resulting from the decommissioning activities. A thorough safety assessment of the hazards involved during decommissioning (including accident analysis, where necessary) should be conducted to define protective measures, part of a defence in depth system that takes into account the specifics of decommissioning
- Safety assessment to be done after decommissioning.
- Activities such as decontamination and the progressive dismantling or removal of some existing safety systems are also of importance. These activities have the potential for creating new hazards. An important objective during decommissioning is, therefore, that the safety aspects of such activities are adequately assessed and managed so as to minimize the impact on safety.
- In the course of decommissioning, consideration should be given to the radiation protection of both workers engaged inthe decommissioning operations and the public who may be exposed to radiation from discharges to the environment, from the release of solid materials, and as a result of any subsequent occupancy of the decommissioned site.

[8] Decommissioning concerns extracted from IAEA, Vienna, in *Decommissioning of Small Medical, Industrial and Research Facilities*, page 46-47.

Dismantling of plant machinery, equipment and any unwanted material will be sold to authorized and licensed dealers. The disposing method should not have any negative effects to the environment and disused equipment should not be left on site. The management will also organize the time frame when various operations within the company should stop. The time frame will also include restoration of the company building for the next use.

11.2 SAFETY NET FOR THE WORKERS

The management should provide safety net for workers who will be declared redundant so that possible increase of poverty due to loss of employment will be mitigated.

12 CONCLUSIONS AND RECOMMENDATIONS

The proposed warehouse will not affect any environmentally sensitive area and its present issues are well defined and understood. It has therefore no major environmental concern. The Environmental Management Plan (EMP) and the impacts monitoring are fairly simple and it shows clearly the mitigation measures and action plans for the identified impacts. Thus, the proposed project could be allowed to continue provided that the proponent complies with all the relevant regulations, NEMA conditions for approval and Nairobi City County By-Laws or any other issues of concerns from mandated government agencies.

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14 APPENDIX

REPUBLIC OF KENYA

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Our Ref: **RPB/NRB/628/ (33)**

Date: **22nd January 2019**

The Director
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AUTHORIZATION TO CARRY OUT EIA FOR CYCLOTRON FACILITY

Thank you for your letter of 14th January 2019 regarding the above subject.

Preliminary findings from the site visit (Godown No.9, Consolidated Timber Limited, off Enterprise Road, Nairobi) by our officers and interrogation of the scientific and technical information provided in your write-up, provide sound basis for a detailed and informed EIA for the proposed medical cyclotron facility.

In particular, aspects of radiation safety, environmental protection and nuclear security should be elaborated to the required depth and detail within such an EIA with other sector regulatory requirements equally applying.

We note the effort by AMIL in identifying a candidate industrial site for the proposed cyclotron facility. However, we do respectfully insist on the fulfillment of Part I of the cyclotron facility guidelines issued by the Board with emphasis on nuclear security (threat assessment). This is also particularly highlighted in the letter by PS-Health Ref.No.MoH/DNCD/CB/1/1 VOL.I of 7th December 2018.

J A W Maina
CEO/BOARD SECRETARY