CHECKLIST FOR REGULATORY INSPECTION OF MEDICAL CYCLOTRON FACILITY

RADIATION PROTECTION BOARD

INSPECTION CHECKLIST FOR A MEDICAL CYCLOTRON FACILITY

	Inspection number	
	Registration Number	
Name of the facility		
Address (include location of the facility)		
Telephone Number		
Radiation Safety Officer		
Licencee's representative for the inspection		
Date of last Inspection		____/____/_____
Date of this Inspection		____/____/_____
Starting time:		**Exit time:**
Type of Inspection	Pre-authorization	☐
	Planned	☐
	Investigation	☐
	Termination	☐
Recommended Date of NEXT Inspection		____/____/_____
Summary of Findings and Actions		
No items of non-compliance found		☐
Items of non-compliance found		☐ (to be detailed in Comments)
Follow-up on previous non-compliance		☐
Inspector (1) Name & Signature		
Date		
Inspector (2) Name & Signature		
Date		
Inspector (3) Name & Signature		
Date		
Report approved by supervisor		**Yes** ☐ **No** ☐ Comments (if **No)**
Supervisor's signature		
Comments (*to be signed and dated*)		

This inspection record/checklist is to be used by the inspector to assist with the performance of the inspection. Note that all areas will not necessarily be applicable to each authorized facility. In addition, with supervisory approval, the inspector may choose not to review a particular program area during each inspection. However, for those areas ***not examined*** *or* ***not relevant*** *during the inspection a notation such as "Not Reviewed" or "Not Applicable" should be made in the relevant section and a brief explanation as to why the area was not reviewed should be provided, where applicable.*

All areas investigated during the inspection should be documented in sufficient detail to describe the activities and procedures observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the operator demonstrates any work practices at the inspector's request, describe those demonstrations. The observations and demonstrations described in this report, along with measurements and the records reviewed, should substantiate your inspection findings. Attach copies of all relevant documents and records required to support item(s) of non-compliance

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the facility and approved by the Board since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non- compliance identified during previous 2-3 inspections

DATE	**INSPECTOR(S)**	**VIOLATIONS**

3. IMPLEMENTATION OF THE PREVIOUS INSPECTION RECOMMENDATIONS

Prior to the inspection, check in the file for any correspondence from the facility on implementation

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4. INCIDENT / EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported by the facility to the Board since the last inspection*

5. ON-SITE VERIFICATION OF LICENCES/AUTHORIZATIONS ISSUED		
Is the licence for operation is valid?	☐ Yes	☐ No
Is layout approval available?	☐ Yes	☐ No
s the RSO licence/certificate valid	☐ Yes	☐ No
Is RSO (licensee) the same as mentioned in the licence ?	☐ Yes	☐ No
Comments:		

6. OPERATING PERSONNEL

During inspection list all operating personnel employed by the facility, their qualification and experience (a separate sheet can be used)

No.	Type of Personnel	Name	Qualifications
1			
2			
3			
4			
5			
6			
7			
8			

7. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; and emergency response

All personnel responsible for the operation/maintenance of the facility and production of F-18 have prescribed qualifications and/or training?	☐Yes	☐No
All occupationally exposed personnel have undertaken a radiation safety course?	☐Yes	☐No
Refresher radiation safety training is provided periodically?	☐Yes	☐No
Training records maintained for each worker?	☐Yes	☐No
Interviews with personnel demonstrate an adequate level of understanding regarding safe working procedures?	☐Yes	☐No
Discussion with the RSO demonstrates an appropriate knowledge of the Act and subsidiary legislations, the licence requirements, the licence conditions, safe working	☐Yes	☐No
Does the RSO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?	☐Yes	☐No
Comments:		

8. PERSONNEL RADIATION MONITORING *Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers*		
Operator provides personal dosimeters to all radiation workers?	☐Yes	☐No
Dosimetry Service Provideris an authorized provider?	☐Yes	☐No
Name of dosimetry service provider:		
Dosimeters provided are appropriate for the radiation type and energy?	☐Yes	☐No
Dosimeters are exchanged at the prescribed period?	☐Yes	☐No
Dosimetry reports are promptly reviewed by the RSO?	☐Yes	☐No
Is it evident that personal dosimeters are being worn by workers?	☐Yes	☐No
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?	☐Yes	☐No
Personnel monitoring records are maintained?	☐Yes	☐No
Are pocket dosimeters (active dosimeters) available? Are they used by radiation workers?	☐Yes	☐No
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period)*		

9. DETAILS OF CYCLOTRON			
Cyclotron Unit make:			
Cyclotron Unit Model:			
Cyclotron Unit Serial No.			
Type of shielding:	☐Unshielded	☐Self-shielded	
Beam Type:	☐Protons	☐Deuterons	☐Both
Nominal Beam Energy:	Protons:.....MeV	Deuterons:.....MeV	
Maximum Beam Current	Protons:.....μA	Deuterons:.....μA	
Number of target ports available for radioisotopes production:			
Number of target ports used at the time for radioisotopes production:			
Radioisotopes produced:			
Comments			

10. INTERLOCKS, ACCESS CONTROL AND OTHER SAFETY FEATURES			
Tally			
(i)	Control console access password/key is working and secured	☐Yes	☐No
		Provided	**Working**
(ii)	Cyclotron vault door interlock	☐Yes ☐ No	☐Yes ☐ No
(iii)	Emergency switch "off" on control console	☐Yes ☐ No	☐Yes ☐ No
(iv)	Cyclotron vault door interlock	☐Yes ☐ No	☐Yes ☐ No
(v)	Shelf Shielding interlock	☐Yes ☐ No	☐Yes ☐ No
(vi)	Uninterrupted power supply/standby power supply	☐Yes ☐ No	☐Yes ☐ No
(vii)	Provision for safe "STANDBY' mode for cyclotron in case of power failure	☐Yes ☐ No	☐Yes ☐ No
(viii)	Provision of emergency power for ventilation system, access control system and radiation monitoring system	☐Yes ☐ No	☐Yes ☐ No
(ix)	Interlock for access prevention into cyclotron vault, if residual radiation dose inside the vault is high	☐Yes ☐ No	☐Yes ☐ No
(x)	Beam 'ON' alarm/signal warning light at the entrance of vault	☐Yes ☐ No	☐Yes ☐ No
(xi)	Cooling System/vacuum system/compressed air system interlock	☐Yes ☐ No	☐Yes ☐ No
(xii)	Area monitors inside the vault with audible warning set to a threshold radiation level	☐Yes ☐ No	☐Yes ☐ No
(xiii)	Area monitors in console room, hot lab, chemistry module and other rooms set to a threshold radiation dose level	☐Yes ☐ No	☐Yes ☐ No
(xiv)	Portable contamination monitors/area survey meters (neutron and gamma)/pocket dosimeter are available	☐Yes ☐ No	☐Yes ☐ No
Comments			

11. INDICATION OF VARIOUS PARAMETER ON THE CONTROL CONSOLE DISPLAY			
Tally			
(i)	Various interlock position	☐Yes	☐No
(ii)	Beam parameter	☐Yes	☐No
(iii)	Beam current	☐Yes	☐No
(iv)	Target selection	☐Yes	☐No
(v)	Utility parameter (temperature, water level, cooling agents, compressed air pressure, nitrogen, helium, vacuum etc)	☐Yes	☐No
(vi)	Beam ON/OFF indication	☐Yes	☐No
(vii)	Ventilation/exhaust control system	☐Yes	☐No
(viii)	Transfer of radionuclide status	☐Yes	☐No
(ix)	Interlock for access prevention into cyclotron vault, if residual radiation dose inside the vault is high	☐Yes	☐No
(x)	Beam 'ON' alarm/signal warning light at the entrance of vault	☐Yes	☐No
(xi)	Beam ON time display	☐Yes	☐No

12. CONTROL OF AIRBONE ACTIVITY				
Tally				
(i)	Cyclotron vault ventilation interlock	Provided	☐Yes	☐No
		Working	☐Yes	☐No
(ii)	Provision for negative pressure inside cyclotron vault and other room?		☐Yes	☐No
(iii)	Standby exhaust pump/fan at the end of ventilation duct?		☐Yes	☐No
(vi)	HEPA/charcoal filter/other high efficiency filter provided?		☐Yes	☐No
(vii)	Provision of decontamination and containment of used air filter?		☐Yes	☐No
(viii)	Ventilation/exhaust control system		☐Yes	☐No

13. EMERGENCY PREPAREDNESS AND RESPONSE			
(i)	Has the facility prepared it radiological emergency preparedness (REPR) and response plan?	☐Yes	☐No
(ii)	Has the facility submitted a copy of its REPR to the Board?	☐Yes	☐No
(iii)	Has the REPR been ever exercised?	☐Yes	☐No
(iv)	Has the facility documented the emergency procedures?	☐Yes	☐No
(v)	***Are the following response procedures displayed in controlled and supervised area:***		
	Target foils rupture	☐Yes	☐No
	Radioactive source stuck in transfer line	☐Yes	☐No
	Power failure	☐Yes	☐No
	Containment rapture in chemistry hot cell	☐Yes	☐No
	Vial break in the QC lab	☐Yes	☐No
	Fire breakout	☐Yes	☐No
	Failure of ventilation system	☐Yes	☐No
	Spillage in controlled/ supervised areas	☐Yes	☐No
(vi)	Is fire alarm system available?	☐Yes	☐No
Comments			

14. NOTIFICATIONS AND REPORTS *Reporting and follow-up of t heft; loss; incidents; overexposures; safety-related equipment failures; change in RSO, and radiation dose reports to workers.*		
Have any notifiable incidents or accidents occurred since the last inspection?	☐Yes	☐No
If yes, have they been reported to the Board? (*If no, list the incidents or accidents in Comments)*	☐Yes	☐No
Actions taken to prevent recurrence:		
Comments		

15. TRANSPORT OF F-18		
Name of transport company:		
Is the transport company certified by the Board?	☐Yes	☐No
Maximum Activity per shipment by company:		
Shielding, packaging and transporting in accordance with Board's regulations and guidance, and IAEA SSR-6 (2012) regulations?	☐Yes	☐No
Company's declaration papers have correct details and used when shipping sources?	☐Yes	☐No
Any Radioactive material Shipments transported, by other than above Company? *(If the answer is yes, give details of the company in the comments section)*	☐Yes	☐No
Are vials checked for contamination prior to packing?	☐Yes	☐No
Comments		

16. DELIVERY OF F-18 AT CUSTOMERS' PREMISES		
Are there documented procedures for delivery/receipt?	☐Yes	☐No
Are there accurate records of shipments?	☐Yes	☐No
What are the security measures during delivery?		
What happens if no one is present to accept delivery?		
Comments		

17. WASTE MANAGEMENT		
Overview (types of solid/liquid/contaminated wastes, any disposal through sink to sewer):		
Location of waste:		
Is the waste labelled:	☐Yes	☐No
Records of storage/disposal:	☐Yes	☐No
Monitoring:	☐Yes	☐No
Comments		

18. RECORDS			
Is the following information recorded and maintained?			
(i)	Authorizations from the Radiation Protection Board	☐Yes	☐No
(ii)	Staff access and visits to the facility and irradiation room	☐Yes	☐No
(iii)	Discharges and evaluation of doses to the public	☐Yes	☐No
(iv)	Results of radiation monitoring of areas	☐Yes	☐No
(v)	Inventory of radiation protection equipment	☐Yes	☐No
(vi)	Results of tests and checks of safety systems (annual, biannual, monthly, daily and special)	☐Yes	☐No
(vii)	Calibration certificates for measuring instruments	☐Yes	☐No
(viii)	Schedules for and results of maintenance and repairs	☐Yes	☐No
(ix)	Reports on internal audits and inspections, etc	☐Yes	☐No
(x)	Information on waste management	☐Yes	☐No
(xi)	Reports on investigations of incidents and accidents	☐Yes	☐No
Comments			

19. INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
Inspector made area and other measurements for comparison to operator's	☐Yes	☐No
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		