Exercise 6 -- Inspection Checklist
From: TECDOC-1526, Inspection of Radiation Sources and Regulatory Enforcement, Supplement to GS-G-1.5

APPENDIX C.

INSPECTION PROCEDURES AND RECORDS OF RADIATION SOURCES IN RADIOTHERAPY

INSPECTION RECORD SUMMARY

RADIOTHERAPY (PART 1)

Inspection number	
Authorization number	

Name of the Facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of the Medical (or Hospital) Physicist	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization	☐
Routine	☐
Investigational	☐
Termination	☐
Recommended Date of NEXT Inspection	_____/_____/_____
Summary of Findings and Actions	
NO items of non-compliance found	☐
Items of non-compliance found	☐
Follow-up on previous non-compliance	☐
Inspector (1) name &signature Date	

Inspector (2) name & signature Date	
Supervisor's signature	
Report approved by supervisor	**Yes** ☐ **No** ☐ Comments (if **No**)

Comments (*to be signed and dated*)

INSPECTION RECORD

RADIOTHERAPY (PART 1)

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 applicable*** *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.

This inspection record/checklist is divided into THREE parts*. The first deals with matters generally common to radiotherapy. The second with specific issues for X ray and electron therapy and cobalt teletherapy and the third with brachytherapy (implants and devices). The officer should use the* ***common*** *first part plus the relevant* ***second or third*** *parts as applicable to the authorized use and each type of radiation source.*

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the operator and approved by the Regulatory Body 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	VIOLATIONS

3. INCIDENT/EVENT HISTORY

Prior to the inspection, list for review any incidents or events reported to the Regulatory Body since the last inspection

4. ORGANIZATION AND SCOPE OF THE PROGRAM

Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)

5. RESPONSIBILITIES

Justification [BSS App. II]

	Yes	No
All treatments authorized by appropriately Qualified Practitioners?		
An appropriately Qualified Practitioner is designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this Qualified Practitioner ensure that procedures are justified?		
If yes, how is this achieved?		

All patient have an individual treatment planning performed by a Medical Physicist?		
If yes, Medical (or hospital) Physicist's name?		
Is always at least one radiotherapist present at the facility while patients are being irradiated?		
Are satisfactory procedures in place to properly identify patients before treatment?		
Does the facility undertake research involving exposure of patients to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		
Are such procedures subject to the advice of an Ethics Committee or similar body within the facility?		
Comments:		

6. 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

	Yes	**No**
All personnel using radiation sources have recognized qualifications?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Supervision of personnel (e.g. technologists) by specialist Medical Practitioners is satisfactory?		
Training records kept for each worker?		
Interviews with workers demonstrate an appropriate knowledge of safe working rules and emergency procedures (e.g. source recovery?)		
Discussion with the RPO demonstrates an appropriate knowledge of the Regulatory Body, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments		

7. INTERNAL AUDITS AND REVIEWS		
	Yes	No
Operator reviews the radiation protection programme at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

8. FACILITIES AND RADIATION SOURCES *Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]*		
	Yes	**No**
FACILITIES		
Facilities are as described in the authorization application?		
Radiation sources are secured so as to prevent unauthorized use and removal?		
Access to controlled areas by unauthorized persons properly supervised?		
Suitable emergency equipment for radioactive source recovery is available?		
Fire protection satisfactory?		
COMPLIANCE, MAINTENANCE, AND REPAIR (Quality Control)		
The design and performance characteristics of radiation devices, whether using radioactive sources or electrically generated radiation, comply with relevant IEC/ISO standards or other requirements of the Regulatory Body?		
Radiation devices are subject to regular QC tests to ensure continued compliance?		
If so, at what frequency; by whom; date of last test?		
Radiation devices are subject to routine maintenance by authorized service agents?		
If so, at what frequency, by whom; date last maintenance		
Records of compliance tests, maintenance, inspection and service maintained?		

OPERATING CHECKS AND CALIBRATION		
Appropriate checks of the performance and functionality of radiation devices and their associated safety equipment have been prescribed by a medical physicist and are carried out daily and at other suitable periods (where relevant to the device)?		
These checks are performed by the Medical Physicist or the results of these checks are reviewed by him/her within the day?		
Radiation devices are calibrated using acceptable protocols?		
A complete calibration of each device is performed		
- before the device is first used for patient treatment?		
- routinely at prescribed intervals acceptable to the Regulatory Body?		
- if routine operating checks show output variations outside established limits?		
- after major repair or modification?		
- using instruments with calibrations traceable to an approved standard?		
- by a Medical Physicist recognized by the Regulatory Body?		
Records of operating checks and calibrations are maintained?		
STORAGE OF RADIOACTIVE SOURCES		
Storage facilities for radioactive sources complies with regulations?		
Control and fire safety satisfactory?		
Warning and notification signs satisfactory?		
Inventory of store contents checked at acceptable intervals?		
RADIATION SOURCES		
Radioactive sources (cobalt unit, sealed sources) at the facility are as authorized?		
X ray equipment (interstitial, superficial, deep X ray therapy), linear accelerators, etc. at the facility are as authorized?		
Leak tests are performed on sealed radioactive sources at prescribed intervals?		
Procedures are in place for appropriate action to be taken in the event of an unacceptable leak test?		
Operator confirms the inventory of radiation sources at acceptable intervals?		
Records of radioactive source leak tests and source inventory maintained?		
Comments:		

9. RECEIPT AND EVENTUAL DISPOSAL OF RADIATION SOURCES		
	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential		

radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required (whether radioactive sources or devices that generate radiation electrically) e.g. disposal only to authorized persons (indicate to whom in "Comments"); notification to the Regulatory Body, etc.?		
Records of packaging surveys, source receipt and disposal maintained?		
Comments		

10. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS - Section I.38]

	Yes	No
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

11. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	No
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		

Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period)*		

12. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No. TS-R-1

	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Transporter's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

13. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; losses; incidents; overexposures; safety-related equipment failures; change in RPO and Medical (or hospital)Physicist, and radiation dose reports to workers [BSS - Section 3.12]

	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the Regulatory Body?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the Regulatory Body? (*If no, list the incidents or accidents in Comments)*		

Have any significant structural or other safety related changes been made to the facilities or the radiation devices without approval of the Regulatory Body?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

14. WARNING SIGNS AND LABELING

Proper warning signs in use areas and labeling of containers with radioactive material [BSS-Section I.23]

	Yes	No
Controlled areas have appropriate warning signs (in the local language)?		
Containers of radioactive sources are properly labeled?		
Notices to workers are displayed in the local language?		
Entry to treatment rooms has appropriate warning signs?		
Comments		

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

	Yes	No
Inspector made area and other measurements for comparison to operators		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

16. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who)*

17. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

Comments:

INSPECTION RECORD

RADIOTHERAPY– X RAYS/TELETHERAPY (PART 2)

This inspection record/checklist deals with matters relevant to superficial X ray therapy, deep X ray therapy, linear accelerators and cobalt teletherapy. Record each device on a separate Inspection Record,

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	
For ^{60}Co teletherapy unit: Total Activity & Activity Calibration Date	
Location on premises	

	Yes	No
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- photon/electron selection and any other beam parameter interlocks?		
- area radiation monitor(s)?		
- beam ON indication?		
- patient viewing and intercom systems?		
OPERATION		
Is the device restricted to particular orientations and/or gantry angles?		
If so, is operation prevented in other orientations?		
OPERATING PROCEDURES		
Operating procedures (in the local language) located at the control console?		
Procedures include response to emergencies or abnormal situations?		
Emergency response telephone numbers clearly displayed?		
Patient is sole occupant in the treatment room during treatment?		
All patients have an individual dosimetric treatment planning performed by the Medical Physicist?		
Qualified staff (Medical Physicist, Radiation Oncologist etc.) physically present throughout all treatments with a gamma stereotactic/radiosurgery devices?		

OPERATIONAL CHECKS AND CALIBRATION		
Were operational checks performed before use today (or when last used)?		
Was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date last fully calibrated?		
Records confirm checks, calibrations and related actions?		

Comments

INSPECTION RECORD

RADIOTHERAPY– BRACHYTHERAPY (PART 3)

This inspection record/checklist deals with matters pertaining to devices which use radioactive sources for brachytherapy, e.g. afterloaders, high dose rate therapy (HDR), etc. Record each on a separate Inspection Record.

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	
Radionuclide, Total Activity, Activity Calibration Date	
Number & Type of Sealed Sources	
Types of Treatments	
Location on premises	

	Yes	No
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- area radiation monitor(s)?		
- source ON indication?		
- patient viewing and intercom systems?		
- appropriate emergency source recovery and storage equipment available?		
PROCEDURES		
For devices containing sources (e.g. afterloaders, HDR, etc) operating procedures (in the local language) are located at or near the control?		
Safe nursing procedures (in the local language) are available and explained to all relevant personnel including controlling patients and visitors, contamination control and the size/appearance of sources, emergency procedures?		
Emergency response telephone numbers clearly displayed?		
Functional survey meter immediately available?		
Survey meter's last calibration date?		
Patient is sole occupant in the treatment room?		
Portal alarm at room entrance?		

Medical Physicist		
- performs patient's individual dosimetric treatment planning?		
- surveys patients immediately after implant completed?		
- surveys patients immediately after removal of implant and confirms source inventory before patient leaves treatment area?		
- is physically present throughout all patient treatments with a gamma stereotactic/radiosurgery devices?		
- is physically present when patient treatment with remote afterloaders initiated?		
OPERATIONAL AND DOSE RATE CHECKS		
If a radiation device,		
- are operational checks performed before use on patients?		
- was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date of dose rate last re-assessment by medical physicist?		
Records confirm checks, dose rate assessment and related actions?		

Comments