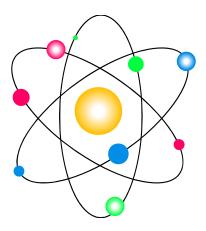


RADIOACTIVE MATERIALS REGULATORY GUIDE



ANNUAL AUDIT CHECKLIST FOR MEDICAL FACILITIES



Radioactive Materials Unit 625 Robert Street North PO Box 64975 St. Paul, Minnesota 55164-0975

TABLE OF CONTENTS

	AUDIT HISTORY	
	ORGANIZATION AND SCOPE OF PROGRAM	3
	RADIATION SAFETY PROGRAM	3
	LICENSED MATERIAL	3
	USE BY AUTHORIZED INDIVIDUALS	4
	FACILITIES	
	RADIATION PROTECTION AND CONTROL OF RADIOACTIVE MATERIAL	5
	POSTING AND LABELING.	6
	Public Dose	
	Personnel Radiation Protection	6
	NOTIFICATION AND REPORTS	
	TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS	7
	RADIATION SURVEY INSTRUMENTS	
	Area Surveys	8
	CONFIRMATORY MEASUREMENTS	
	UNSEALED RADIOACTIVE MATERIALS FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED	
	TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED	
	RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL	9
	RADIOACTIVE WASTE	10
	Transportation	
	RECORDKEEPING FOR DECOMMISSIONING	12
	AMENDMENTS SINCE LAST AUDIT	
	NOTIFICATIONS SINCE LAST AUDIT	
	BULLETINS AND INFORMATION NOTICES	12
Т	HERAPY	13
-		
	TRAINING FOR USE OF MANUAL BRACHYTHERAPY AND USE OF UNSEALED RADIOACTIVE MATERIAL FOR	
	WHICH A WRITTEN DIRECTIVE IS REQUIRED	
	USE BY AUTHORIZED INDIVIDUALS	
	PATIENT RELEASE	
	BRACHYTHERAPY	
	TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY SERVICING	
	FULL CALIBRATION - THERAPEUTIC MEDICAL DEVICES	
	PERIODIC SPOT CHECKS FOR THERAPEUTIC DEVICES	
	FACILITIES	
	MEDICAL EVENTS	16
V	OBILE MEDICAL SERVICE	17
Δ	UDIT SUMMARY AND SIGNATURE	10
~	ODIT ODINIMAN I AND DIGNATON	10

This guide contains model procedures that are only a suggested guide and are one way to meet this requirement. Some sections may not be pertinent to every licensee or to each review or audit. For example, licensees do not need to address areas that do not apply to their activities and activities that have not occurred since the last audit need not be reviewed at the next audit. Reviews or audits of the content and implementation of the radiation protection program must be conducted at least annually.

MODEL ANNUAL AUDIT CHECKLIST

Audit History	4731	N/A	Yes	No
Were previous audits conducted annually?	2010	IN/A	l es	
Are records of previous audits maintained?	2500			
Deficiencies identified?	2300			
Were the deficiencies corrected?				
Organization and Scope of Program	4731	N/A	Yes	No
Radiation Safety Officer				
If the RSO was changed, was license amended?	4403			
Does new RSO meet MDH training requirements?	4411 4414 4415			
Is RSO fulfilling all duties?	4405			
Is the written agreement in place for a new RSO?	4405			
Are there multiple locations of use?				
Are all locations listed on the license?				
If multiple locations authorized, list locations audited.				
Were annual audits performed at each location? If no, explain.				
Radiation Safety Program	4731	N/A	Yes	No
Minor changes to program?	4405			
Records of changes maintained for five years?	4500			
Content and implementation reviewed annually by the licensee?	2020			
Records of reviews maintained?				
Licensed Material	4724	N/A	Vaa	Na
Isotope, chemical form, quantity and use as authorized?	4731	N/A	Yes	No
	3080			
Does total amount of radioactive material possessed require financial assurance? If so, is financial assurance adequate?	3000			
·				
Calibration, transmission, and reference sources Sealed sources manufactured and distributed by a person licensed pursuant to 4731.3400 or equivalent NRC or Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources and sources do not exceed 30 millicuries?	4423			

Any radioactive material with a half life of less than 120 days in individual amounts not to exceed 15 millicuries?	4423			
Any radioactive material with a half life of greater than 120 days in individual amounts not to exceed 200 microcuries or 1000 times the quantities in 4731.3260?	4423			
Technetium-99 ^m in individual amounts as needed?	4423			
Unsealed materials used in 4731.4432, 4731.4434, and 4731.4440 are:				
Obtained from a manufacturer or preparer licensed under 4731.3395? or				
Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of a physician authorized user or authorized nuclear pharmacist? or				
Obtained and prepared for research in accordance with 4731.4432, 4731.4434, and 4731.4440, as applicable?				
Are sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate?	4450 4460 4463			
Are copies of the SSDR Certificates possessed or accessible?				
Are manufacturer's manuals for operation of medical devices possessed?				
Are the actual uses of the medical devices consistent with the authorized uses listed on the license?				
If places of use changed, was the license amended?				
If control of license was transferred, was MDH consent obtained prior to the transfer?				
Use by Authorized Individuals	4731	N/A	Yes	No
Use by Authorized Individuals Authorized Users	4731	N/A	Yes	No
	4731	N/A	Yes	No
Authorized Users	4731	N/A	Yes	No
Authorized Users New Authorized User since last audit?	4731	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements?	4731 4414	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended?	4414 4415	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users	4414 4415 4433	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board	4414 4415 4433 4436 4443	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License	4414 4415 4433 4436 4443 4444 4445	N/A	Yes	No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license	4414 4415 4433 4436 4443 4444			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license Authorized Nuclear Pharmacists	4414 4415 4433 4436 4443 4444 4445 4446			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license	4414 4415 4433 4436 4443 4444 4445 4446			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license Authorized Nuclear Pharmacists Certified by specialty board	4414 4415 4433 4436 4443 4444 4445 4446			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license Authorized Nuclear Pharmacists Certified by specialty board Identified on MDH, NRC or other Agreement State License	4414 4415 4433 4436 4443 4444 4445 4446			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license Authorized Nuclear Pharmacists Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license	4414 4415 4433 4436 4443 4444 4445 4446			No
Authorized Users New Authorized User since last audit? Does the new Authorized User meet MDH training requirements? If a new Authorized User was added, or was the MDH license amended? Authorized Users Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license Authorized Nuclear Pharmacists Certified by specialty board Identified on MDH, NRC or other Agreement State License Identified on permit issued by a broad scope or NRC master materials license Identified on permit issued by a broad scope or NRC master materials license Listed on a facility license	4414 4415 4433 4436 4443 4444 4445 4446 4413 4414 4415			No

Identified on permit issued by a broad scope or NRC master materials license				
Listed on a facility license				
Facilities				
1 acinices	4731	N/A	Yes	No
Facilities are as described in the license application?				
Storage areas:				
Materials secured from unauthorized removal or access?	2290			
Licensee controls and maintains constant surveillance of licensed material not in storage?	2290			
Dose Calibrator:				
Constancy checked daily?				
Linearity tested at intervals not to exceed 3 months?				
Accuracy tested at intervals not to exceed 12 months?				
Geometry dependence test?				
Readings mathematically corrected if linearity error is greater than 10%?				
Records maintained and include required information?	4502			
Determination of dosages of unsealed radioactive material:				
Each dosage determined and recorded prior to medical use?				
Measurement of unit dosages made by direct measurement or by decay correction?	4422			
For other than unit dosages, dose determined by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation?				
Licensee uses generators?				
First eluate after receipt is tested for Molybdenum-99 breakthrough?	4509			
No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μ Ci per mCi of Tc-99 ^m ?				
Records maintained?				
Radiation Protection And Control Of Radioactive Material				
	4731	N/A	Yes	No
Use of radiopharmaceuticals				
Protective clothing worn?				
Personnel routinely monitor their hands?				
No eating/drinking in use/storage areas?				
No food, drink, or personal effects kept in use/storage areas?				
Proper dosimetry worn?				
Radioactive waste disposed of in proper receptacles?				
Syringe shields and vial shields used?				
Leak tests of sealed sources performed at appropriate intervals?	4424			
Leak test records in units of microcuries?				
Leak test records signed by RSO?				

Records of leak tests kept for three years?				
Inventories				
Are sealed sources inventoried?				
Are records of leak tests and inventories maintained?				
Posting and Labeling	4731	N/A	Yes	No
MDH Form, "Notice to Workers" is posted?	1010			
Other posting and labeling per 4731.2310, 4731.2330 and not exempted by 4731.2320, 4731.2340?				
Public Dose	4731	N/A	Yes	No
Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year?	2090			
Has a survey or evaluation been performed?	2200			
Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?				
Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?	2090			
Is licensed material used or stored in a manner that would prevent unauthorized access or removal?	2290			
Records maintained?				
Personnel Radiation Protection	4731	N/A	Yes	No
Exposure evaluation performed?	2200	П	П	П
ALARA program implemented?	2010			
External Dosimetry:				
Monitors workers per 4731.2210?				
External exposures account for contributions from airborne activity?	2040			
Supplier Frequency				
Supplier is NVLAP-approved?	2200			
Dosimeters exchanged at required frequency?				
Internal Dosimetry				
Monitors workers per 4731.2210?				
Briefly describe program for monitoring and controlling internal exposures?	2240			
Monitoring/controlling program implemented (includes bioassays)?				
Respiratory protection equipment [20.1703]?				
Review of Records and Reports				
Reviewed by Frequency				
Auditeureuriaus de managen et en entre vier en anagen fan manie et ta				
Auditor reviewed personnel monitoring records for period to				
Prior dose determined for individuals likely to receive doses?	2520			

Maximum CDEs Organs				
Maximum CEDE				
Internal and external summed?	2030			
Were occupational limits met?	2020			
MDH Form 5 or equivalent provided to all monitored employees (including nursing staff)?	2520 2540			
If a worker declared her pregnancy during the audit period, then was the dose in compliance and were the records maintained?	2030 2540			
Who performed any planned special exposures at this facility (number of people involved and doses received)?	2060 2520 2530 2630			
Records of exposures, surveys, monitoring, and evaluations maintained?	2500 2510 2540			
Notification and Reports	4731	N/A	Yes	No
In compliance with 4731.1030, 4731.3110 (reports to individuals, public and occupational, monitored to show compliance)?				
In compliance with 4731.2600, 4731.3110 (theft or loss)?				
In compliance with 4731.2610, 4731.3110 (incidents)?				
In compliance with 4731.2620, 4731.3110 (overexposures and high radiation levels)?				
Aware of MDH phone number?				
In compliance with 4731.2620 (Constraint on air emissions)?				
Training, Retraining, and Instruction to Workers	4731	N/A	Yes	No
Have workers been provided with required instructions?	1020 4407 4441 4453 4466			
Is the individual's understanding of current procedures and regulations adequate?				
Training program implemented?	4407 4441 4453 4466			
Operating procedures?				
Emergency procedures?				
Periodic training required and implemented?				
Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed?	1020			
Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate?	4407			
protection procedures and administration of whiten directives, as appropriate?				

Additional therapy device instructions and training:				
Unit operation, inspection, associated equipment, survey instruments?				
License conditions applicable to the use of the equipment?				
Emergency drills?	4466			
Workers cognizant of requirements for:				
Radiation Safety Program?	2010 4405			
Annual dose limits?	2020 2090209 5			
10% monitoring threshold?	2210			
Dose limits to embryo/fetus and declared pregnant worker?	2080			
Grave danger posting?	2310			
Procedures for opening packages?	2350			
Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 4731.4407?				
Radiation Survey Instruments	4731	N/A	Yes	No
Appropriate, operable survey instruments possessed or available?	4421			
Calibrations completed before first use?				
Instrument calibrated annually (intervals not to exceed 12 months)?				
Calibrations within 20 percent on each scale or decade of interest?				
Calibration records maintained?				
Area Surveys	4731	N/A	Yes	No
Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements?	2200 4426			
Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms)?	4426			
Weekly in all areas where radiopharmaceuticals or waste is stored?				
Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?				
Trigger levels established?				
Corrective action taken and documented if trigger level exceeded?				
Techniques can detect 0.1 mR/hr, 2000dpm?				
Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry and records maintained? After new source installation?				
Aitel Hew Source Installation:				

Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?				
 Survey records include the following: A diagram of the area surveyed or a list of items and equipment surveyed Specific locations on the survey diagram where wipes test were taken Radiation or contamination levels with appropriate units Date of survey Manufacturer's name, model number, and serial number of each instrument used Name or initials of the person making the evaluation and recording the results. 	2510			
Confirmatory Measurements	4731	N/A	Yes	No
Detail location and results of confirmatory measurements.				
Unsealed Radioactive Material For Which A Written Directive Is Required	4731	N/A	Yes	No
Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls?	4442			
RSO and AU promptly notified if patient died or had a medical emergency?				
Training For Use Of Unsealed Radioactive Material For Which A Written Directive Is Required	4731	N/A	Yes	No
Safety instruction to personnel provided include	4441			
Control of patient and visitors?				
Routine visitation to patients in accordance with 4731.2090?				
Contamination control and size/appearance of sources?				
Safe handling and shielding instructions?				
Waste control?				
RSO and Authorized User notification in emergency or death?				
Records retained?	4510			
Receipt And Transfer of Radioactive Material	4731	N/A	Yes	No
Describe how packages are received and by whom.				
Written package opening procedures established and followed?				
All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form)?	2350			
Incoming packages surveyed?				
Monitoring in (C) and (D) performed within time specified?				
Transfer(s) performed per?	3105			
All sources surveyed before shipment and transfer?	2200			

Records of surveys and receipt/transfer maintained?	2510 3115			
Package receipt/distribution activities evaluated for compliance with 4731.2090?				
Radioactive Waste	4731	N/A	Yes	No
Disposal:		П	П	П
Decay-in-storage	4429			
Procedures followed?				
Labels removed or defaced?	2330 4429			
Special procedures performed as required?	-	П	П	П
Authorized disposals?	2400			
Records maintained?	2510 2560			
Effluents:				
Release to sanitary sewer?	2420			
Material is readily soluble or readily dispersible?	2420			
Monthly average release concentrations do not exceed 2750 Subpart 4?				
No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year?	2420			
Procedures to ensure representative sampling and analysis implemented?	2200			
Release to septic tanks? (Note: Release to septic tanks is not authorized.)				
Waste incinerated?				
License authorizes?	2430			
Directly monitor exhaust?				
Airborne releases evaluated and controlled?	2095 2200			
Air effluents and ashes controlled?	2010 2020 2090 2200 2400			
Air effluent less than 10 mrem constraint limit?	2010			
If no, reported appropriate information to MDH.				
Corrective actions implemented and on schedule?				
Description of effluent program:				
Monitoring system hardware adequate?				
Equipment calibrated, as appropriate?				
Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?				
Waste storage				
Protection from elements and fire?				

Control of waste maintained?	2290			
Containers properly labeled and area properly posted?	2310 2320			
Package integrity adequately maintained?				
Waste disposal:				
 Records for Decay-in-storage include: the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed with the longest half-life; the manufacturer's name, model number, and serial number of the survey instrument used, or a unique meter identification that can be cross-referenced to a specific manufacturer, model, and serial number; the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. 	2405			
Sources transferred to authorized individuals?	2400 2450 3105			
Name of organization:				
Records of surveys and material accountability are maintained?	2510 2560			
Transportation (10 CFR 71.5(a) and 49 CFR 171-189)	4731	N/A	Yes	No
Transportation (10 CFR 71.5(a) and 49 CFR 171-189) Shipments are:	4731	N/A	Yes	No
	4731	N/A	Yes	No
Shipments are:	4731	N/A	Yes	No
Shipments are: delivered to common carriers;	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle;	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both;	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit.	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources?	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages:	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages: Authorized packages used?	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages: Authorized packages used? Performance test records on file?	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages: Authorized packages used? Performance test records on file? DOT-7A packages	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages: Authorized packages used? Performance test records on file? DOT-7A packages Special form sources Two labels (White-I, Yellow-III, Yellow-III) with TI, Nuclide, Activity, and Hazard	4731	N/A	Yes	No
Shipments are: delivered to common carriers; transported in own private vehicle; both; no shipments since last audit. Return radiopharmacy doses or sealed sources? Licensee assumes shipping responsibility? If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities: Packages: Authorized packages used? Performance test records on file? DOT-7A packages Special form sources Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class? Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End	4731	N/A	Yes	No

Prepared and used?		Ιп	П	
Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)?				
Readily accessible during transport?				
Recordkeeping for Decommissioning	4731	N/A	Yes	No
Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination?	3080			
Records include all information outlined in?	3080			
Amendments Since Last Audit				
	4731	N/A	Yes	No
Any Amendments since last audit?	4403			
Notifications Since Last Audit	4731	N/A	Yes	No
Any Notifications since last audit?	4403			
Appropriate documentation provided to MDH for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work?	4403			
MDH notified within 30 days after any of the following stops work or changes name:				
Authorized User;				
Authorized Nuclear Pharmacist;				
Authorized Medical Physicist; or				
Radiation Safety Officer (RSO)				
MDH notified within 30 days after:				
licensee's mailing address changes;				
licensee's name changes without a transfer of control of the license; or				
licensee has added to or changed an area of use for 4731.4432 or 4731.4434 use?				
Bulletins and Information Notices	4731	N/A	Yes	No
Bulletins, Information Notices, etc., received?				
Appropriate action in response to Bulletins, Information Notices, Generic Letters, etc.?				

Therapy

Safety instruction to personnel provided include Control of patient and visitors? Routine visitation to patients in accordance with 4731.2090? Contamination control and size/appearance of sources?	4441 🔲 🔲
Routine visitation to patients in accordance with 4731.2090?	4510
Routine visitation to patients in accordance with 4731.2090?	4510
Contamination control and size/appearance of sources?	4510
	4510
Safe handling and shielding instructions?	4510
Waste control?	4510
RSO and Authorized User notification in emergency or death?	4510
Use by Authorized Individuals	4731 N/A Yes No
Authorized User 4444	4444
4445	
4446	
4458	4458
4459	4459
4461	
4479	4479
Certified by specialty board	
Identified on MDH, NRC or other Agreement State License	
Identified on permit issued by a broad scope or NRC master materials	ls
Listed on a facility license	
Authorized Nuclear Physicist 4412 4414 4415	4414
Certified by specialty board	
Identified on MDH, NRC or other Agreement State License	
Identified on permit issued by a broad scope or NRC master materials	ils 🔲 🗎 🗆
license	
Listed on a facility license	
Individuals released when TEDE less than 0.5 rem?	
Instructions to the released individual, including breast-feeding women, include required information?	iclude
Release records maintained?	
Records of instructions given to breast-feeding women maintained, if required?	uired?
Brachytherapy 4731 N/A Yes No	4731 N/A Yes No
Safety precautions implemented to include patient facilities, posting, stay times, 4454	
and emergency response equipment?	
Survey immediately after implant?	4451
Patients surveyed immediately after removing the last temporary implant source? 4451	
RSO and AU promptly notified if patient died or had a medical emergency 4454	

[35.415(c)]?				
Records maintained [35.2404]?	4411			
Teletherapy and Gamma Stereotactic Radiosurgery Servicing				
	4731	N/A	Yes	No
Inspection and servicing performed following source replacement or at intervals	4477			
not to exceed five years?				
Needed service arranged for as identified during the inspection?				
Service performed by persons specifically authorized to do so?	4477			
Full Calibration-Therapeutic Medical Devices				
	4731	N/A	Yes	No
Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?		П		П
Performed prior to first patient use?	4469			百
F	4470	-		
	4471			
At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR		ΙП		П
remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and		_	_	
PDR remote afterloaders?				
Whenever spot-checks indicate output differs from expected by ±5 percent?				
After source exchange, relocation, and major repair or modification?				
Performed with properly calibrated instrument?				
For teletherapy:				
Output measured within ±3 percent of expected for the range of field				
sizes, range of distances?	4469			
Coincidence of radiation field and field light localizer?				
Uniformity of radiation field and beam angle dependence?		╁╫		H
Timer accuracy and linearity over the range of use?		+ =	H	H
On-off error?		+ =	H	H
Accuracy of all measuring and localization devices?		+H		H
For remote afterloaders:	4470			H
Output measured within ±5percent of expected?	4470	 		\vdash
Source positioning accuracy within ±1 millimeter?		+H	H	H
Source retraction with backup battery upon power failure?		+		H
Length of source transfer tubes?				H
ů .		 		
Timer accuracy and linearity over the typical range of use?		 		
Length of the applicators?		 		
Function of source transfer tubes, applicators, and transfer tube- applicator interfaces?				ΙШ
Autoradiograph quarterly of the LDR source(s) to verify source(s)				
arrangement and inventory?				
For gamma stereotactic radiosurgery:	4.474			
Output measured within ±3 percent of expected [35.635(b)(1)]?	4471	 		
Helmet factors [35.635(b)(2)]?		 		\vdash
Isocenter coincidence [35.635(b)(3)]?		 		
Timer accuracy and linearity over the range of use [35.635(b)(4)]?		 	⊢井	⊢뷰
On-off error [35.635(b)(5)]?		 		
Trunnion centricity [35.635(b)(6)]?		 		
Treatment table retraction mechanism, using backup battery power or				\sqcup
hydraulic backups with the unit off [35.635(b)(7)]?		 		
Helmet microswitches [35.635(b)(8)]?		\perp \sqcup	igsqcut	$\sqcup \sqcup$
Emergency timing circuit [35.635(b)(9)]?				
Stereotactic frames and localizing devices (trunnions)?				
Output corrected mathematically for decay]?				

Records maintained?	4518			
Periodic Spot Checks For Therapeutic Devices	4731	N/A	Yes	No
Performed at required frequency?	4472			
T chamba at required nequency:	4473			
	4474			
Procedures established by authorized medical physicist?				
Procedures followed?				
Medical physicist reviews results within 15 days?				
Performed with properly calibrated instrument?	4472			
	4474			
Output and safety spot checks include:				
For teletherapy:				
Timer accuracy and linearity over the range of use?	4472			
On-off error?				
Coincidence of radiation field and field light localized?				
Accuracy of all measuring and localization devices?				
The output for one typical set of operating conditions?				
Difference between measured and expected output?	4472			
Interlock systems?				
Beam stops?				
Source exposure indicator lights?				
Viewing and intercom systems?				
Treatment room doors, inside and out?				
Electrical treatment doors with power shut off?				
For remote afterloaders:				
Interlock systems?	4473			
Source exposure indicator lights?				
Viewing and intercom systems, except for LDR?				
Emergency response equipment?				
Radiation monitors used to indicate source position				
Timer accuracy?				
Clock (date and time) in the unit's computer?				
Decayed source(s) activity in the unit's computer?				
For gamma stereotactic radiosurgery:				
Treatment table retraction mechanism?	4474			
Helmet microswitches?				
Emergency timing circuits?				
Stereotactic frames and localizing devices?				
The output for one typical set of operating conditions?				
Difference between measured and expected output?				
Source output compared against computer calculation of output?				
Timer accuracy and linearity over the range of use?				
On-off error?				
Trunnion centricity?				
Interlock systems?				
Facilities	4731	N/A	Yes	No
Therapy device facilities provided with:		T		1
Electrical interlock system?				\Box
Viewing system?		 		╁
				. —

Radiation monitor?				
		 	- -	片片
Source retraction mechanism?		<u> </u>		
Source indicator lights?			<u> </u>	
Emergency source recovery equipment available?	4454			
	4467			
Therapy unit operation:				
Unit, console, console keys, and treatment room controlled adequately?	2290			
	4466			
Restricted to certain source orientations and/or gantry angles?				
Ceases to operate in restricted orientation(s)?		П		
Only one radiation device can be operated at a time within the treatment	4466			
room?				
Therapy dosimetry equipment:				
Calibrated system available for use?	4468	П		
Calibrated by a NIST or an AAPM-accredited lab within previous two years and	1.00	Ħ	Ħ	H
after servicing or calibrated by inter-comparison?				
Calibrated within the previous four years?		П		
Licensee has a dosimetry system available for use for spot check				
measurements?				
Record of each calibration, inter-comparison, and comparison maintained?				
Record of each campation, inter-companson, and companson maintained:				
Medical Events				
Medical Events	4731	N/A	Yes	No
		IVA	163	NO
If medical events have occurred since the last audit, evaluate the incident(s) and	4525		Ш	
procedures for implementing and administering written directives using the				
existing guidance.				
Event date		\Box		
Information Source		<u> </u>		
Notifications				
MDH				
Referring Physician Patient				
In writing/By telephone				
If notification did not occur, why not?				
Written Reports Submitted to MDH within 15 days?	4525			

Mobile Medical Service	4731	N/A	Yes	No
Operates services per 4731.4428 and 4731.4475?				
Compliance with 4731.2090 evaluated and met?				
Letter signed by management of each client?	4428			
Licensed material was not delivered to client's address (unless client was authorized)?	4428			
Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent?	4428			
Survey instruments checked for proper operation before used at each address of use?	4428			
Survey of all areas of use prior to leaving each client address?	4428			
Additional technical requirements for mobile remote afterloaders per 4731.4475?				

Audit Summary and Signature

Special license conditions or issues to be reviewed:	
Evaluation:	
Audits and Findings	
Summary of findings:	
Corrective and preventive actions:	
Audit conducted by:	Date: