

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

EXTERNAL BEAM & BRACHYTHERAPY
QUALITY ASSURANCE PROGRAM AUDIT FORM

Purpose: To provide licensees and registrants with a standard form for documenting compliance with the audit requirements contained in 10 NYCRR 16, Section 16.24.

Background: The New York State Sanitary Code, Chapter I, Part 16, Ionizing Radiation, requires New York State Department of Health Licensees to conduct audits of their radiation therapy quality assurance programs (10 NYCRR 16.24). Specifically, 16.24(a)(4) states the required frequency and type of audits which are to be conducted. Licensees have two options: 1) external audits must be conducted every 12 months by radiation therapy physicists possessing the qualifications specified in 10 NYCRR 16.122 and physicians who are active in the practice and type of radiation therapy conducted by the licensee or registrant, or, 2) the licensee or registrant can conduct internal audits at intervals not to exceed 12 months and have an audit performed by the American College of Radiology or, a program found equivalent by the Department, at intervals not to exceed five years.

For all types of audits, the licensee or registrant shall promptly review the audit findings, address the need for modification or improvements, and document action taken. If recommendations are not acted on, the reasons for this will also be documented.

The attached audit format may be used for both internal and external audits. The scope of this package contains the minimum expectations of a 16.24 audit. Licensees and registrants may need to expand and/or focus on more specific facets of their program.

Documentation: Licensees and registrants are required to maintain written records for review by the department which document quality assurance and audit activities [10 NYCRR 16.24 (a)(5)].

DOH will review these audits during inspections. For licensees and registrants who use this format, the inspectors will limit their 16.24(a)(4&5) review to: dates of audits, qualifications of auditors, auditor's recommendations, and the documentation for the implementation of recommendations or explanation for not implementing the recommendations.

Instructions: The audit form is divided into four sections. Section A contains general questions about the facility including therapy modalities, facility and staffing. Section B, review of patient charts and films, must be completed by a physician who is active in the practice and type of radiation therapy conducted by the licensee or registrant. The Radiation Therapy Physicist must complete Section C, the physics component. For external audits the Radiation Therapy Physicist must possess the qualifications specified in 10 NYCRR 16.122. Section D contains the audit summary/recommendations and the facility's response.

BRACHYTHERAPY AND EXTERNAL BEAM ANNUAL QA AUDIT

A. General Information Section			
Facility Name			
Type of Audit: Internal <input type="checkbox"/> External <input type="checkbox"/>			
Auditor Name(s)			
Period Reviewed	From: / / To: / /		
Modalities - Type of Unit(s)	Workload	Comments	
Linear Accelerator <input type="checkbox"/> w/Electrons <input type="checkbox"/>			
Superficial Units <input type="checkbox"/>			
HDR <input type="checkbox"/>			
Co-60 Teletherapy <input type="checkbox"/>			
Brachytherapy Cs-137, <input type="checkbox"/> I-125, Ir-192, Sr-90 <input type="checkbox"/> Other _____ <input type="checkbox"/>			
I. Facility/Physical Plant			
1.	Is the facility adequate for the number of patients treated? yes <input type="checkbox"/> no <input type="checkbox"/> Comments:		
2.	Emergency Equipment, "Crash Cart" <input type="checkbox"/> Oxygen <input type="checkbox"/> Suction <input type="checkbox"/>		
3.	Do therapy rooms have functioning: Door interlocks <input type="checkbox"/> Visual monitors <input type="checkbox"/> Audio monitors <input type="checkbox"/>		
4.	Do HDR rooms have separate: Interlocks <input type="checkbox"/> Radiation monitors <input type="checkbox"/>		
5.	Other observations:		
II. Staffing			
1.	Number of Radiation Oncologists (certified/eligible)		
2.	Number & Type of physics staff (full time/part time, certified/eligible)		
3.	Number of RTTs _____ Number Licensed _____		
4.	Number of nurses _____ Number of Dosimetrists _____		
5.	Number of patients seen annually _____		
6.	Number of daily patients _____ Curative % ___ Palliative % ___		
7.	Is there a weekly chart review? _____		
8.	Comments:		

III. Quality Assurance

		Yes	No
1.	Is there a written QA manual?	9	9
2.	Is there a Procedures Manual?	9	9
3.	Are there specific policies regarding: a)HDR?	9	9
	b) emergency procedures?	9	9
	c) isotopes?	9	9
4.	Is there an annual focused review?	9	9

Comments: _____

B. Patient Chart and Film Review Section

I. Individual Patient Chart and Film Review Form

Reviewer is to select 6 charts from patients treated during the past year with different curative sites, and 9 charts from patients currently being treated. If possible the latter should include 3 curative cases, 3 palliative cases and 3 brachytherapy cases. Thus a total of 15 charts and port films should be reviewed. If brachytherapy is not performed, 3 other curative cases should be reviewed. This is to be completed by a physician who is active in the practice and type of radiation performed by the licensee of registrant. (Please note that 15 charts is the minimum number to be reviewed.)

Instructions: Complete one form for each patient chart reviewed. Attach these reviews to the summary form (Summary of chart and film reviews).

Treatment – Curative⁹ or Palliative⁹, Treatment completed⁹ or current⁹, Brachy.⁹ or Beam⁹

		Yes	No	Comments
1.	Is there a history and physical on the chart?	9	9	
2.	Are tumors staged?	9	9	
a.	Is there a pathology report?	9	9	
b.	Are there appropriate x-ray reports?	9	9	
4.	Is there a <u>signed prescription</u> that includes the area to be treated, technique, energy, dose fractionation and the total dose plus limits to critical structures (if applicable)?	9	9	
5.	Is the plan appropriate for tumor stage & type	9	9	
6.	Do the treatment fields adequately cover the tumor?	9	9	
7.	Is there a signed informed consent?	9	9	
8.	Are there ID photos and field photos?	9	9	
9.	Are there periodic progress notes?	9	9	
10.	Is there a completion note?	9	9	

Comments: _____

Instructions: Enter the summary of the individual patient chart reviews and attach the individual patient chart reviews.

II. Summary of Chart and Film Reviews

		Reviewed Items Acceptable?
Past Patients	Disease Site	Yes No Comments
#1		9 9
#2		9 9
#3		9 9
#4		9 9
#5		9 9
#6		9 9
Current-Curative		
#1		9 9
#2		9 9
#3		9 9
Current-Palliative		
#1		9 9
#2		9 9
#3		9 9
Current-Brachytherapy		
#1		9 9
#2		9 9
#3		9 9

III. Other Observations: _____

IV. Summary and Recommendations: _____

Physician Reviewer's Signature _____ Date: _____

Print Name _____

This section is to be completed by a radiation therapy physicist. If this is an external audit the radiation therapy physicist must possess the qualifications specified in 10 NYCRR 16.122.

I.	General Items	Yes	No
1.	Does a qualified medical physicist periodically review the Physics Q.A. program? Frequency?_____	9	9
2.	Is the Q.A. program adequately documented including:		
		a. procedure for performing the test?	9 9
		b. frequency of the test?	9 9
		c. acceptable deviation?	9 9
		d. corrective actions to be taken?	9 9
		e. who performs the test?	9 9
3.	TG-40 Protocol		9 9
4.	Comments:		
II.	Measurement Equipment	Yes	No
1.	Are dosimeters used for linear accelerators and cobalt-60 sources calibrated according to current approved protocols?	9	9
2.	Are survey instruments and external beam calibration instruments calibrated according to current approved protocols?	9	9
3.	Comments:		

III.	External Beam Treatment and Simulators Equipment	Yes	No
1.	Are all external beam therapy units calibrated according to current approved protocols?	9	9
2.	Do the frequencies and tolerances of and data of the Q.A. tests conform to the specification so of the Institution's Q.A. manual? TG-40?	9 9	9 9
3.	Are Q.A. tests followed by proper corrective actions and is this documented?	9	9
4.	Are corrective actions taken at the action levels specified on the Q.A. manual and is this clearly documented?	9	9
5.	Comments:		
IV.	Treatment Planning	Yes	No
1.	Is the method used for computation to the treatment time or monitor units clearly documented?	9	9
2.	Are monitor units and time calculations confirmed by data measured for relevant cases (benchmark data)?	9	9
3.	Has dose distribution data used by the treatment planning system been measured? If the answer is "No", has the library data been verified by measurements?	9	9
4.	Are computer algorithms verified against the appropriate measured of published data (benchmark data)?	9	9
5.	Is there a Q.A. program for the computer treatment planning system?	9	9
6.	Is this Q.A. program followed?	9	9
7.	Are all manual and computer generated calculations checked independently by a medical physicist of his/her designee?	9	9
8.	Is there a chart check protocol? Is this protocol being followed?	9 9	9 9
9.	Comments:		

V.	Brachytherapy	Yes	No
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1.	Are brachytherapy sources calibrated according to current approved protocols?	9	9
2.	Have dose and time calculations been confirmed by bench mark data?	9	9
3.	Have dose distributions been confirmed by bench mark data?	9	9
4.	Have computer algorithms used for brachytherapy dose distribution calculation been measured and/or verified against bench mark data?	9	9
5.	Is there a Q.A. program for the computer brachytherapy treatment planning system?	9	9
6.	Is this brachytherapy Q.A. program followed?	9	9
7.	Are all manual or computer generated calculations to a single point of interest checked independently by a medical physicist or his/her designee?	9	9
8.	Is the computation of radioactive implant treatment times based on: a. acceptable source calibration procedure? b. correct source data c. acceptable computational algorithm.	9 9 9	9 9 9
9.	Is there a brachytherapy chart check protocol according to acceptable standards?	9	9
10.	Is this protocol being followed?	9	9
11.	Comments:		
VI.	Mechanical and Electrical Safety	Yes	No
1.	Does the protocol properly address mechanical and safety operation for external beam therapy units? Is this protocol being followed?	9 9	9 9
2.	Does the protocol properly address mechanical and safety operation for brachytherapy units and sources? Is this protocol being followed?	9 9	9 9
3.	Comments:		

Other Observations: _____

Medical Physics Summary and Recommendations: _____

Reviewers Signature _____ Date: _____

