

Considerations and Issues in Electronic Charting for Brachytherapy

A report from the work group of TG262

Susan Richardson, Ph.D.

Why?

- The American Reinvestment & Recovery Act (ARRA) was enacted in 2009. ARRA includes many measures to modernize our nation's infrastructure, one of which is the "Health Information Technology for Economic and Clinical Health (HITECH) Act". The HITECH Act supports the concept of electronic health records.
- The meaningful use of interoperable electronic health records throughout the United States health care delivery system is a critical national goal.



Electronic Brachytherapy

- Interpretation dependent rules:
 - State/NRC regulations
 - Radiation Safety officer involvement and beliefs
 - Amount of electronic record use for external beam
 - Pressure!
 - Type of brachytherapy administration
- Many clinics are still at the ‘hybrid’ level of electronic records

What tools can help me?



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

[A to Z Index](#) | [Follow FDA](#) | [En Español](#)

SEARCH

[Home](#) [Food](#) [Drugs](#) [Medical Devices](#) [Radiation-Emitting Products](#) [Vaccines, Blood & Biologics](#) [Animal & Veterinary](#) [Cosmetics](#) [Tobacco Products](#)

CFR - Code of Federal Regulations Title 21

[FDA Home](#) [Medical Devices](#) [Databases](#)



New Search

[Help](#) | [More About 21CFR](#)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL

PART 11 [ELECTRONIC RECORDS; ELECTRONIC SIGNATURES](#)



[Subpart A--General Provisions](#)

- [§ 11.1](#) - Scope.
- [§ 11.2](#) - Implementation.
- [§ 11.3](#) - Definitions.

[Subpart B--Electronic Records](#)

- [§ 11.10](#) - Controls for closed systems.
- [§ 11.30](#) - Controls for open systems.
- [§ 11.50](#) - Signature manifestations.
- [§ 11.70](#) - Signature/record linking.

[Subpart C--Electronic Signatures](#)

- [§ 11.100](#) - General requirements.
- [§ 11.200](#) - Electronic signature components and controls.
- [§ 11.300](#) - Controls for identification codes/passwords.

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

Source: 62 FR 13464, Mar. 20, 1997, unless otherwise noted.

Issues with moving electronic

- How will records be accessed when audited?
- Who can access them and when?
- Poor computer skills or comfort levels with computers may be an issue:
 - Staff
 - Auditors
 - Radiation Safety
- Time – it can take *longer* to do it electronically, at least in the short term.

Conversion of paper to electrons

- What paperwork do you need to keep? Look at it critically.
- How long do you need to keep it? Space?
- Options:
 - Scan the paperwork, make a digital copy of the paperwork, print as PDF from TPS or other system, import as a treatment plan? Or document? Etc
- Where is the signature? Where is the time stamp?
- If data is duplicated, which is “official?”

Items to consider

- Much of work flow is checklist driven or paperwork driven
- Electronic charts need electronic triggers*
- Do you have the tools in place to treat your patients safely and efficiently?
- What information do you want in the patient's (auditable and requestable) chart?
- Verbal changes of written directives

An Overview

- *Standalone*
 - These are devices or procedures which do not connect to EMR at all.
- *R&V Connectivity*
 - Typically, they require scheduling in the EMR and a connectivity module, which then makes patient treatment plans available to the machine to deliver. After each delivery, the treated dose is automatically recorded back to the EMR, but not other data such as imaging.
- *Full Connectivity*
 - Device is driven by the EMR similar to current XRT

	Written Directive	Standalone	R&V connectivity	Full connectivity
Prostate seed implant	X	X		
LDR	X	X		
HDR	X	X	X	?
Radiopharmaceutical	X			
Gamma Knife	?	X	X	

Brachytherapy Types

- HDR
 - Integrated R&V (Aria/Brachyvision)
 - Non-integrated R&V (all others)
- LDR
 - Live time prostate implants? Plan is dynamic!
 - Eye plaques
 - Can you get pdfs into your medical record?
- Radiopharmaceutical
 - Spheres/Thyroid/Xofigo/etc

HDR

- Information management issues
 - What happens if computers and systems don't communicate properly?
 - External beam you send them home – not an option for patients with implanted applicators!
- Lack of hard stops (e.g. you can treat without the prescription being approved)
- Timing considerations
 - Plans is verbally approved, why aren't we treating?

HDR

- Process mapping
 - Where can improvements be made?
 - What is the easiest solution?
 - Is everyone on board with the solution?
 - Especially the MD!
 - Is everyone familiar with Plan B (or C?)?
- The process is inherently different than XRT
 - E.g. time outs/face photo verification in Mosaiq

HDR Brachytherapy checklists

Quality Checklist - MR#: 5551212 TESTY, TEST

View: By Patient
Patient: TESTY, TEST 5551212

»	Due	al	Procedure	Req	Resp	»	Attending M	S	ot	Comment
	6/18/2015		Physics- 2nd check	SD			DS			
	6/18/2015		Prescription signed	PHY	PHY		DS			Rx complete and approved by attending
	6/18/2015		Plan Signatures	PHY	PHY		DS			Plan approved by dosimetrist and attending
	6/18/2015		Appl. tip correct	PHY	PHY		DS			Applicators defined correctly; ring offset applied
	6/18/2015		Channels per protocol	PHY	PHY		DS			Channel assignments per departmental protocols
	6/18/2015		Matches template	PHY	PHY		DS			Interstitial: channel assignment matches template
	6/18/2015		Consistent with Rx	PHY	PHY		DS			Planned dose same as Rx dose; point doses & DVH OK
	6/18/2015		Conformance < 10%	PHY	PHY		DS			SAVI: air volume < 10% PTV Eval volume
	6/18/2015		Dwells verified	PHY	PHY		DS			RadCalc performed, within 3%, uploaded as Calc 2nd check
	6/18/2015		Treatment approved	PHY	PHY		DS			Treatment approved in Brachyvision & transfer to console PC

Close
Add
Change
Delete
Complete
Append

Due Date Range
From: 6/15/2015
To: 6/19/2015

Filter By
☐ Complete
☒ Incomplete
☐ All

Document in R&V alternative

Patient Name: Date:
MRN: Site/Technique:
MD: Nurse:
Patient Identification: Fraction # of

Treatment Planning Checks:

Mosaiq Written directive is signed and dated by authorized user:
Brachyvision Treatment plan- number of catheters and lengths correct:
Brachyvision Treatment plan dose matches written directive prescription:
MU check performed if treating from non-standard plan:

Pre-Treatment checks

Daily QA performed:
Brachyvision Treatment plan transferred to GammaMed afterloader correctly:
Patient was connected to afterloader and checked by 2 individuals:
Calculated treatment time matches afterloader:
$$= \text{Decay Factor} \times \text{treatment planning time} = \text{Total Time}$$
$$= \text{} \times \text{} = \text{0$$

GammaMed wheels locked:
Treatment plan approved in Mosaiq by authorized user:

Checklist, cont.

Treatment

Area monitor off prior to treatment: ☐

Area monitor on during treatment: ☐

Area monitor off after treatment: ☐

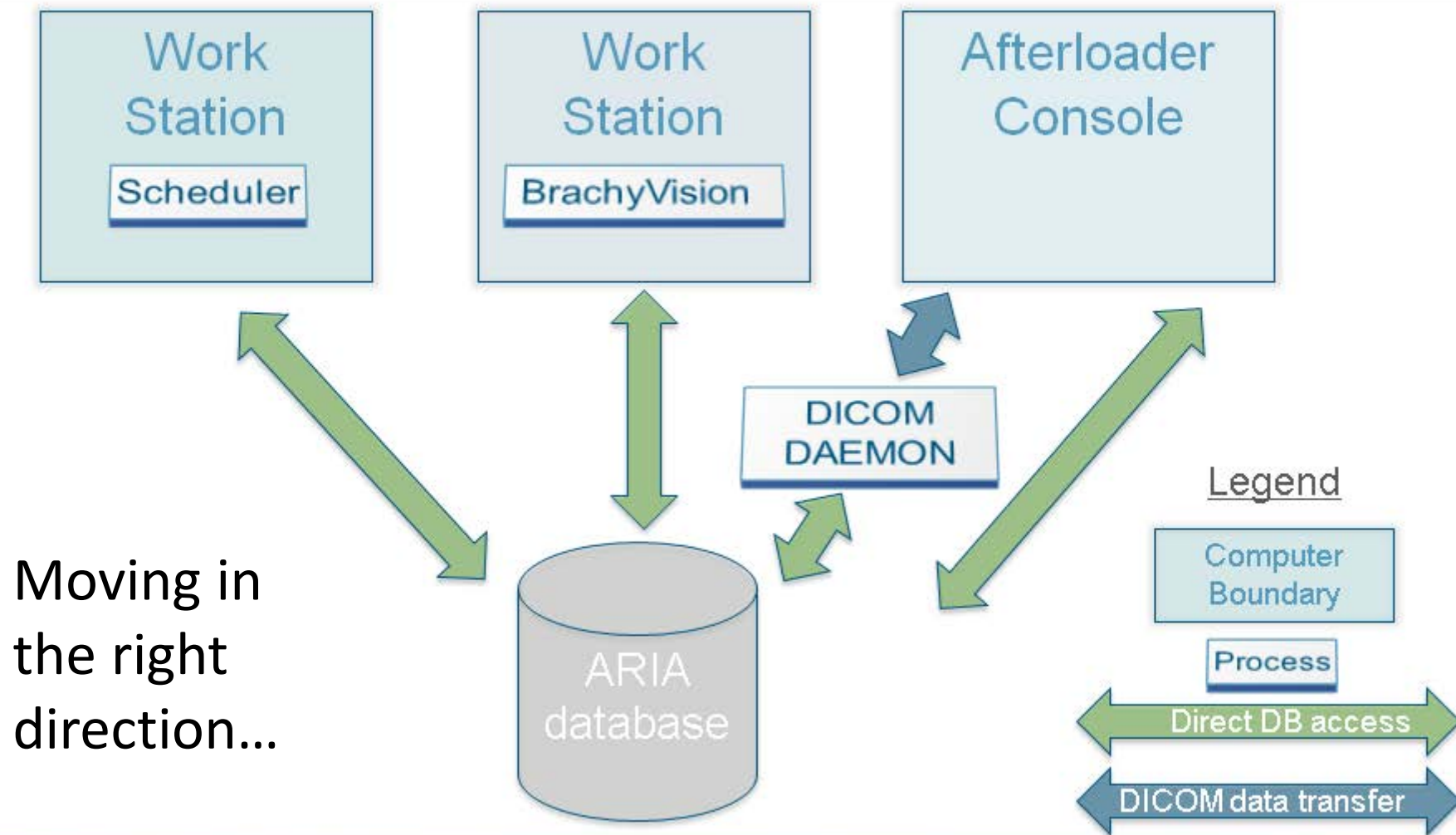
Residual activity in patient checked with survey meter: ☐

GammaMed afterloader secured: ☐

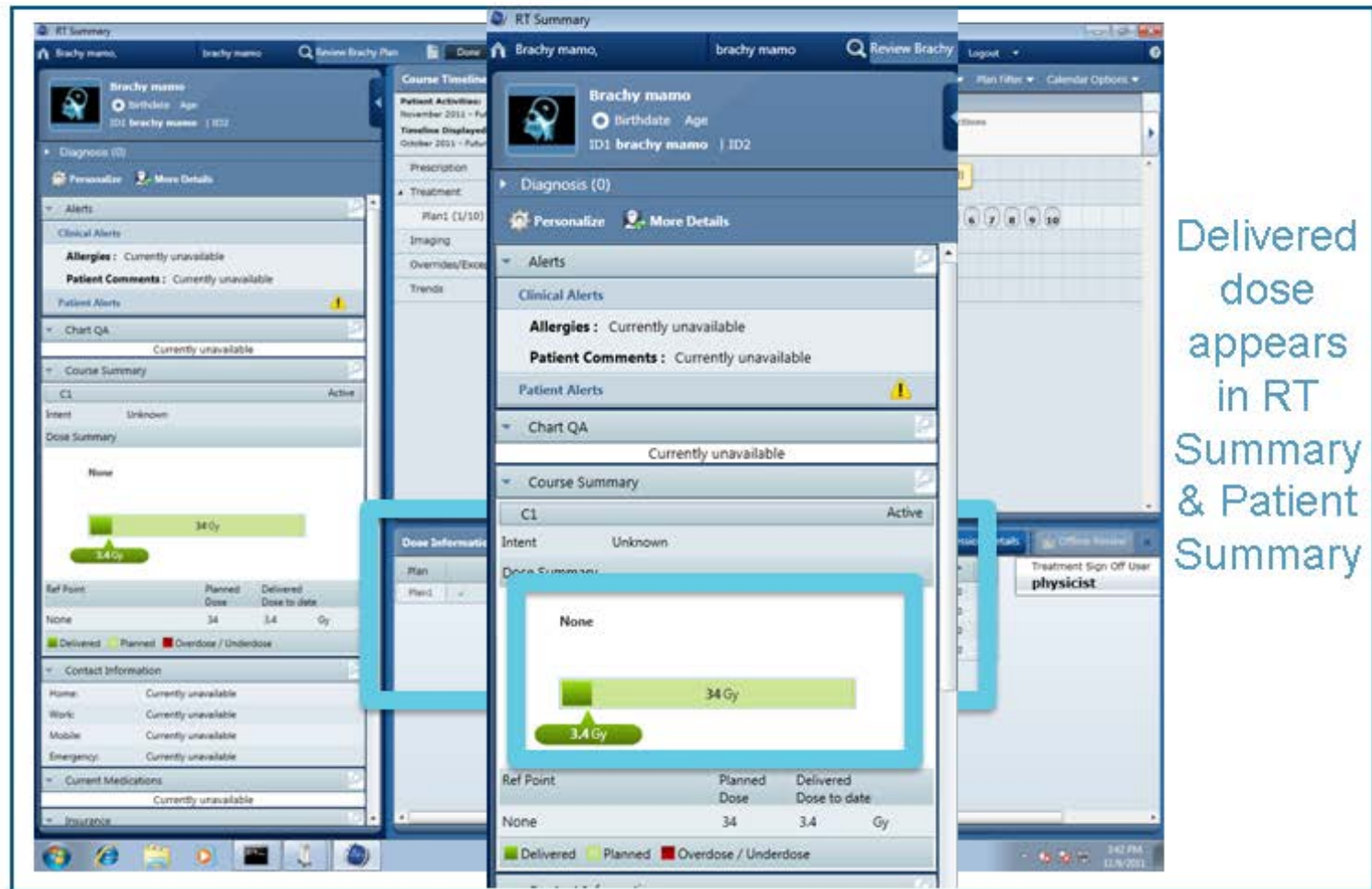
Dosimetrist signature:

Physicist signature: |

iX – ARIA Integration



Brachy HDR Workflow



Use your EMR wisely

Radiation | Medical | Surgery | General | Admin

	Start	Status
Dx: *Corpus Uteri		
Radiation Oncology Course: 1		
Rad Rx: vag cuff - HDR Ir192-Intracav - HDR Dose: 2,100 cGy @ 700 cGy x 3		A 2/24/2014 TPM
Plans		
PLAN VAG Cuff		A 2/24/2014 TPM
Treatment Fields		
HDR - VagCuff - 192 X [HDR]	2/24/2014	A 2/24/2014 PDW

Radiation Prescriptions

Dx: *Corpus Uteri Course: 1

Site	Technique	Modality	Fractions		Rx Dose		Total Dose	
			Act	Rx	Dose	Pattern	Act	Rx
vag cuff	HDR Ir192-Intracav	HDR	3	3	700 cGy	Every 14 Days	2,100 cGy	2,100 cGy

Rx Site: vag cuff Status: Approved TPM 2/24/2014 View Fractions: By Course

Technique: HDR Ir192-Intracav Number Fractions: By Course

Modality: HDR

Dose Spec: Depth 0.5

Rx Dose	Fractional Dose	Number of Fractions	Fractionation Pattern	Status
2,100 cGy	700 cGy	3	Every 14 Days	Fractions Treated

Week	S	M	T	W	T	F	S
1		1					
2							
3		2					
4							
5		3					

Close Add Change Delete Dosimetry

Note Plan Docs Status

Plan Label: PLAN VAG Cuff

Description:

Status: Approved 2/24/2014

Associations: Rx vag cuff

Approvals

Doctor: TPM 2/24/2014

Dosimetrist:

Physicist: SLR 3/18/2014

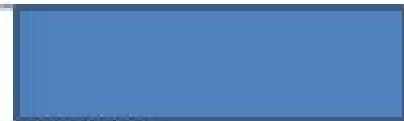
>> View All

BrachyVision

Software version: Brachytherapy Planning 8.9.09

Varian Medical Systems

Plan Report for "Nuc2.5Vag7Gy"



Treatment site:

Total prescription: 700 cGy in 1 fraction.
Dwell times are displayed for a single fraction.
Plan was created: 2/24/2014 3:16:16 PM
Plan was saved: 2/24/2014 3:16:37 PM
Dose calculation medium: Homogeneous

Source wire serial number: 24-01-2466-001-110113-11708-03
Source calibration date: 11/18/2013 12:00:00 AM (nominal)
Source calibrated activity: 10000.00 mCi (nominal)
Source half life: 73.83 d
Treatment date: 2/24/2014 12:00:00 AM
Source treatment activity: 10000.00 mCi (nominal)
Total air kerma strength: 3346.44 cGy cm² (nominal)
Total Curie seconds: 2960.00 (nominal)
Total treatment time: 296.00 s

No attached clinical protocol

Applicator: Applicator1, Channel: 1, Source Model: GMP Ir-192 HDR, Tx Strength: 40700.00 cGy cm² / h (nominal),

Position [cm]	129.80	129.30	128.80	128.30	127.80	127.30	126.80	126.30	125.80	125.30
Time [s]	54.0	35.0	23.0	20.0	13.0	13.0	20.0	23.0	35.0	60.0
Position [cm]										
Time [s]										

No seeds

Reference point:

x [cm]	y [cm]	z [cm]	Total dose [cGy], 1 fraction(s)
pt at TipSurface -0.95	-0.24	6.26	1566.0

8.50 x 11.00 in

GammaMedPlus iX : Treatment History Report

varian / Swedish Cancer Institute / 640351 / 2014-03-10 13:58:51

Patient / Treatment Data

Patient Data

Last name [REDACTED]
 First name [REDACTED]
 Patient ID1 [REDACTED]
 Sex Unspecified
 Birth date Unspecified

Plan Data

Total Planned Fractions .. 3
 Physician
 Treatment site Unspecified
 Applicator
 File name 1455n12m

Treatment Summary

Fraction Number	Matching Fraction	Console Entry Date	Plan Author	Delivery status
1		2014-02-24		Completed
2	1	2014-02-24		Completed
3	1	2014-02-24		Completed

Document Type	Source ID	F	Status	Encounter	By	Approved	By	Review Req	Co-Sign Req	Transcrib
HDR Treatment		S	Approved	3/10/2014	PDW	3/10/2014	SLR	S. Richardsor		3/10/20
Treatment Record		S	Approved	3/10/2014	PDW	3/10/2014	SLR	S. Richardsor		3/10/20
Physics Cont Consul		S	Approved	3/10/2014	SLR	3/10/2014	SLR			3/10/20
HDR Treatment		S	Approved	3/04/2014	PDW	3/10/2014	SLR	S. Richardsor		3/10/20
HDR Treatment		S	Approved	2/24/2014	PDW	3/10/2014	SLR	S. Richardsor		2/24/20
Radiation Consent		S	Approved	2/24/2014	YCF	2/25/2014	YCF			2/25/20

LDR – e.g. prostate

- Timeout may occur in the OR before your team is there! How will you document?
- Intraoperative planning creates a new document
- Change of written directives/seed counts to be incorporated
- Lots of the paperwork will fall to the hands of physicists

Radiopharmaceuticals

	Start	Status
Dx: *Liver		
Radiation Oncology Course: 1		
Rad Rx: RT Lobe - Brachytherapy - Yttrium Dose: 12,050 cGy @ 12,050 cGy x 1		A 6/4/2015 VKM
Dx: *On Clinical Study		

Radiation Prescriptions

Dx: *Liver
Course: 1

Site	Technique	Modality	Fractions				Rx Dose		Total Dose
			Act	Rx	Dose	Pattern	Act	Rx	Act
RT Lobe	Brachytherapy	Yttrium		1	12,050 cGy	Daily		12,050 cGy	

Rx Site: RT Lobe
Technique: Brachytherapy
Modality: Yttrium
Dose Spec: Plan

Status: Approved VKM 6/04/2015
View Fractions: By Course
Number Fractions: By Course

Rx Dose	Fractional Dose	Number of Fractions	Fractionation Pattern	Status
12,050 cGy	12,050 cGy	1	Daily	

Week	S	M	T	W	T	F	S
1		1					

Note
Plan Docs
Status







Radiopharm, cont.

Created: 6/04/2015 VKM Edited: 6/11/2015 SLR Locked:

Subject:

OK

Cancel

F Times New Roman 10 B I U       B

liver brachytherapy

dosi/tx planning:

1. special physics conslut

Radiopharmaceutical: Y-90 TheraSphere; Nordion

Treatment site: RT LOBE

Lung shunt factor: 10%

Planned lung dose: 8.59

Required Y-90 activity: 5 GBQ

Actual Y-90 activity: 5.29 GBQ

Injection date and time: 6/11/2015 11 AM

Delivered target dose: 122.9

Delivered lung dose: 8.76

Total lung dose: 8.76

Maximum allowed lung dose per treatment: 30Gy

Maximum allowed total lung dose: 50Gy

Acknowledgements

- *Data Integrity and Electronic Charting (EBRT and Brachytherapy): Clinical Implementation of Electronic Charting* – Lisa Benedetti 2013 SCM, <https://vimeo.com/90160027>
- Sonja Dietrich
- TGT262 members

A nighttime photograph of the Seattle skyline. The Space Needle is prominently featured on the left, illuminated with white lights. In the background, the dark blue waters of the Puget Sound are visible, with snow-capped mountains rising behind them under a cloudy night sky. In the foreground, the city lights are visible, including the illuminated, undulating roof of the Smith Center for the Performing Arts and a red neon sign on a building to the right.

Thank you!