Principles of QA, radiation protection and patient safety

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Quality Assurance

Quality Assurance system gives assurance that specific objectives are being met

Quality can only be measured and maintained if the need has been defined

Components in Quality Assurance

1. Policy : the setting of standards
2. Procedures: the means by which these standards are tested
3. Correspondence: are the standards met?

References: National and International guidelines/ recommendations (IAEA/ESTRO/AAPM…)

Quality Assurance: Conditions

- Engagement : Entire staff must be willing to participate/apply (+budgets).

- Feedback/review: Check the functioning of the QA procedures at regular time: are objectives still met? Learn from problems/incidents and implement improvements

Aspects of Quality Assurance in BT

1. Machine related QA:
    1. At commissioning
    2. Regular intervals (source exchange)
    3. Upgrades (software/hardware)
2. Procedure related QA *(Human factor)*

    Verification during each step of the procedure
3. (Treatment related QA)

Aspects of Quality Assurance in BT

- Radiation protection
- Patient safety

=> setting up a safety system

Risk analyses in BT

- Identification of dangers / risk factors / risks

Radioactive sources, radiation…

Malfunctioning, lack of training…

Over- or underdosage, unwanted dose…

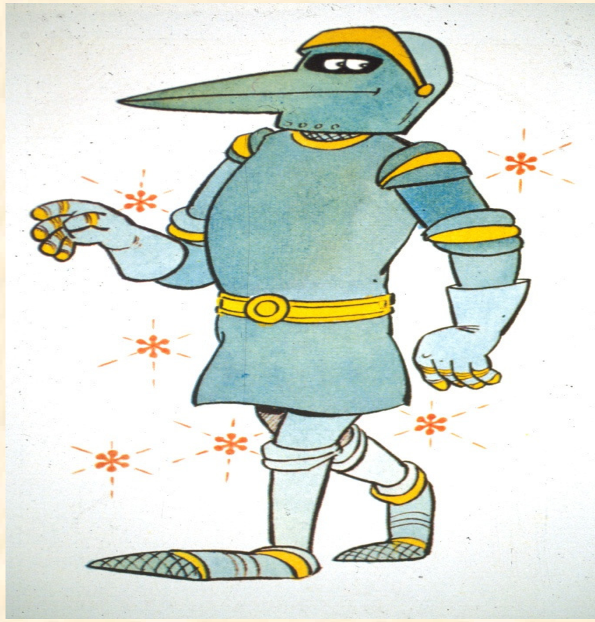
Risk analyses in BT

- HFMEA: (Healthcare) Failure Mode Effect Analyses

Risk analyses

- If the danger cannot be eliminated, there will always be a risk !
- Problem is not the existence of the risk, but the magnitude of the risk

Risk perception !!!



Measures to increase safety

1) Elimination of the danger (?)
2) Collective measures (afterloader, protected treatment room, radiation monitors)
3) Individual measures
4) Measurers to control/maintain damage (training of emergency procedures, personal badge dosimeter)

Radiation Safety in Brachytherapy

- Patient safety
- Staff safety (BT team)
- Nursing Staff safety (other departments)
- Family/Visitors safety
- General Public

Radiation protection: Equivalent Dose (H)

- The biological effects vary in function of the type of radiation and on the dose rate, the time of exposition and the duration of the exposition.
- $H = D \times Q \times N$
- Q = Quality factor(1 for ß, γ , Rx / 10 for fast neutrons)
- N : Factor dose distribution in function of the time.
- SI unit of equivalent dose : **Sievert (Sv)**

Dose limits

• Patient	**N/A**
• Staff (BT team) • Nursing Staff (profess. exposed)	**20 mSv/yr**
• Other Nursing/Hospital Staff • Family/Visitors • General Public	**1 mSv/yr**

But: **Think ALARA**

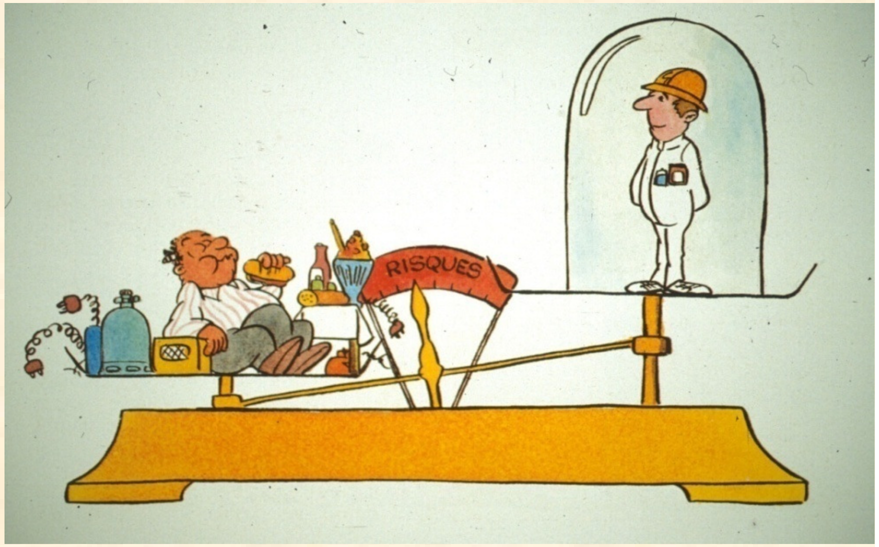
Life reduction (in days)

Activity area	For 1 year of prof. expusure (person of 40 yrs)	For a professional carreer of 35 years
Fishing (open sea)	31,9	923
Carbon mining	3,6	103
Railroad	2,2	63
Construction/building	2,1	62
Industry (average)	0,5	13,5
Professionnel Irradiation (50 mSv/yr)	1,3	32
Professionnel Irradiation (5mSv/yr)	0,1	3

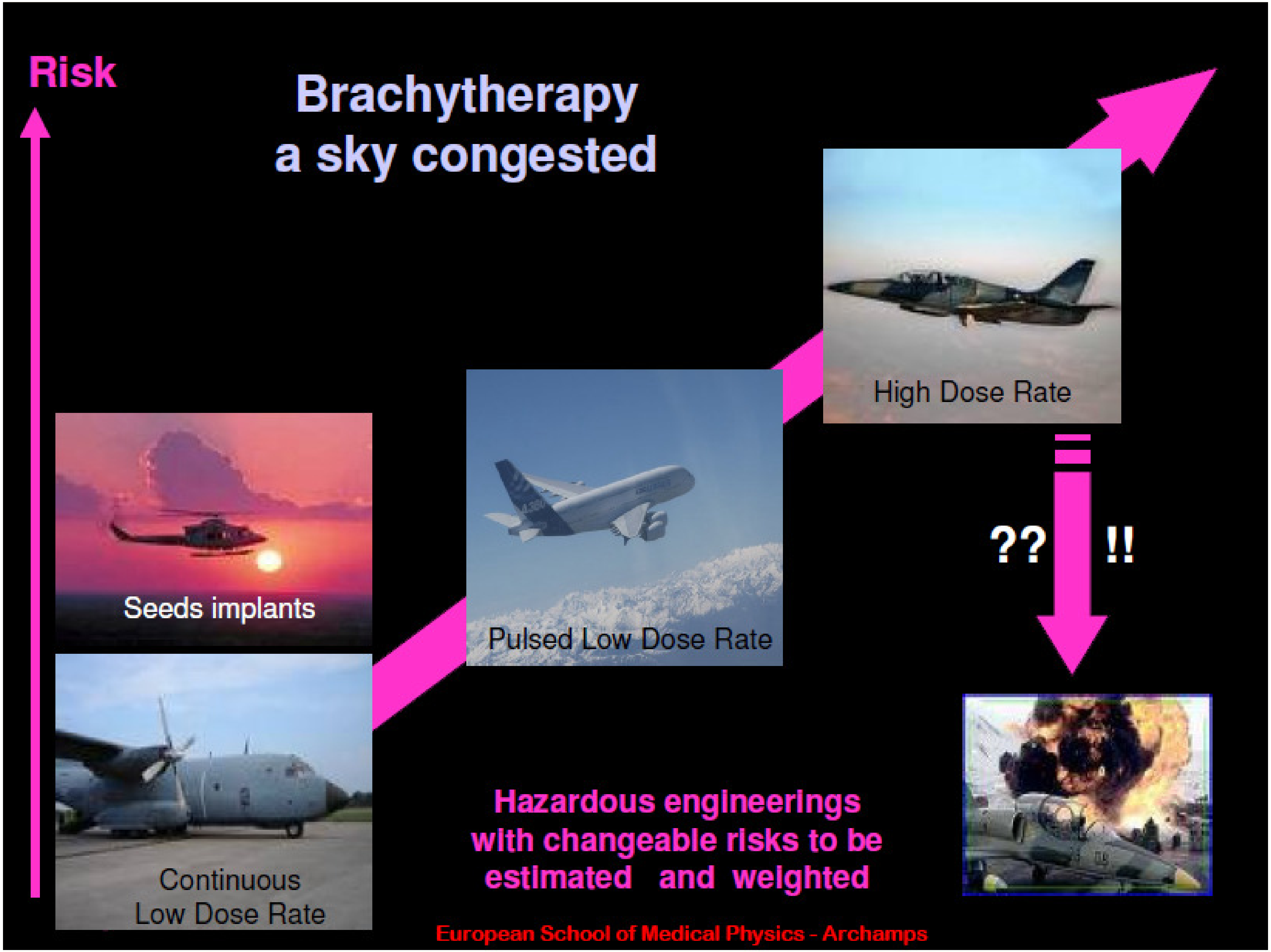
Comparison of the harmfulness

Risk of death: 1 per million :

- **650 km in plane**
- **100 km by car**
- **1,5 minute of climbing**
- **3/4 cigarette**
- **1/3 bottle of wine**
- **Exposure of 0,1 mSv**



=> exposure of 20 mSv/year = 3 cigarettes / week


Risk
Brachytherapy
a sky congested
Seeds implants
Continuous
Low Dose Rate
Pulsed Low Dose Rate
High Dose Rate
??
!!
Hazardous engineerings
with changeable risks to be
estimated and weighted
European School of Medical Physics - Archamps

Patient safety

Dose rate for Ir afterloaders:

LDR: 50-100 cGy/hour

PDR: up to 70 cGy/min at 1 cm from the source

HDR: up to 7 Gy/min at 1cm from the source (30 Gy/min at 0.5 cm from the source)

~~Reaction needed within 1-2 min~~

Source retraction within 1-2 min

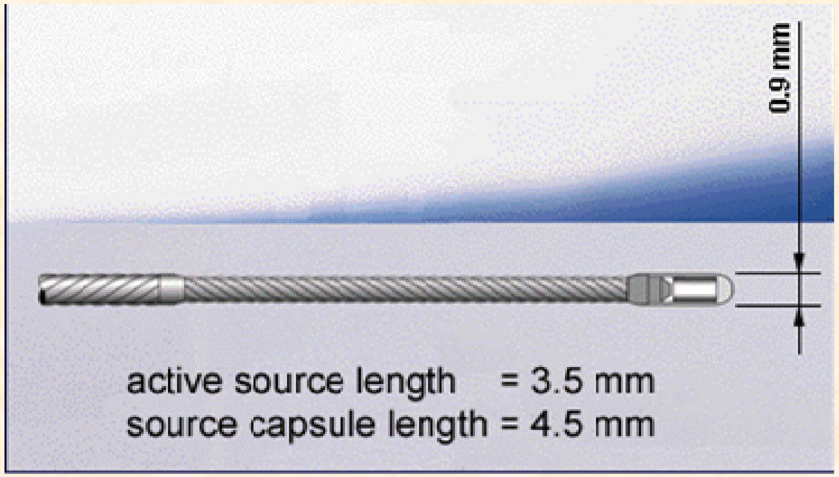
Patient safety

=> In HDR Emergency means:

EMERGENCY

Possible causes for radiological emergency

- Source stuck in applicator/transfer tube
- Electronical/electrical/computer failure
- Source dislodged from source drive wire cable



Emergency procedures in BT

- Probability of an event leading to an emergency situation can seem (very) low, but not negligible
- Risk (consequences) can be extremely high
  - complications, death

Recommendations to install emergency procedures

International authorities : IAEA, ICRP

Scientific organisations : ESTRO, AAPM, …

National legislation, regulations, recommendations

Recommendations : ICRP

An emergency plan should be prepared and practiced with commencement of operations.

A list of emergency procedures (both medical and radiation) should be displayed prominently within the suite.

All necessary emergency equipment items should be readily available.

Training for all personnel should be repeated regularly, especially when new personnel are introduced to the team.

ICRP97, 2005

This reports refers to IAEA TECDOC-1040 (1998) and TECDOC-1257 (2001)

Recommendations : AAPM

Even though the likelihood is extremely low, this report strongly recommends that all HDR BT users *shall* learn and retrain to respond to emergencies.

AAPM TG 59, 1998

Train your team to cope with the most critical conditions

Emergencies: AAPM TG59

- Physical plant emergencies (Fire, physical disasters, power failures)
- Minor emergencies : abnormal performance preventing or interrupting the treatment
  - Interpretation of status lamps, audible alarms, printed or displayed error codes
  - Training on recognizing most frequent problems
  - Complete list available
  - *Can I recover or must I abort treatment ?*

Emergencies: AAPM TG59

- Major emergencies : source retraction failure
  - Written emergency procedure, tested
  - Hands-on training of procedures, repeated at specific intervals
  - Equipment available:
    - Emergency container
    - GM meter, survey meter
    - Forceps, surgical clamps, suture removal kit
    - Flashlamp
  - Specific procedures for specific applications

Recommendations : ESTRO

In case of malfunction of the afterloading machine or breakage of the transport cable or the source there is a high degree of danger for both the patient and the personnel involved. This is the reason that an emergency plan has to be developed

A practical guide to quality control of brachytherapy equipment , ESTRO booklet N°8, 2004

ESTRO booklet N°8, 2004 (cont.)

It is of utmost importance, that all persons are aware of emergency procedures. Failing afterloading equipment may cause great harm to both the patient and the personnel.

The team members should not only be taught in emergency procedures, but these procedures should be practised on a regular basis. In case of an emergency the reaction time is very important, so everyone must have a clear idea of their role in such cases.

ESTRO booklet N°8, 2004 (cont.)

Emergency items
Description of emergency plan
Availability of safety equipment:
• Storage and transport container
• Tools, cable cutter, long forceps
• Radiation monitor
List of error codes available at the treatment unit
List of telephone numbers of responsible and expert persons

Organisational issues

- In HDR : physician, physicist and/or other well trained personal present during treatment
- In PDR : treatment overnight, on a nursing ward, more staff (less informed?) involved

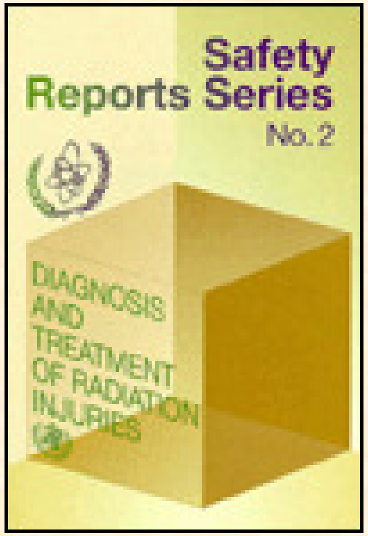
Emergency plan design

1) Don't allow for improvisation, use written plans
2) Test plans, adjust if necessary
3) Equipment available (checked)
4) Training, training, training…

Training aiming at avoiding accidents

Training:

- **Radiographers, nursing staff**
- **Physicians and residents**
- **Patient instructions**



Note: many of the accidents with unintended medical exposures in BT were due to lack of training and procedures (source: IAEA Safety Report Series 2)

Patient safety

However: Patient Safety is not the only issue, treatment quality, performing the treatment to the best actual standard is at least as important!

=> **Comprehensive Quality Assurance program**

End-to-End tests

Radiation protection in practice (neutrons, γ , Rx ,electrons)

- **Time/distance/shielding**

- Individual Protections :
  - Reduce the time of exposition (good preparation of work, training, …)
  - Distance (proper tools/instruments : forceps)
  - Shielding (lead shields/lead glass)

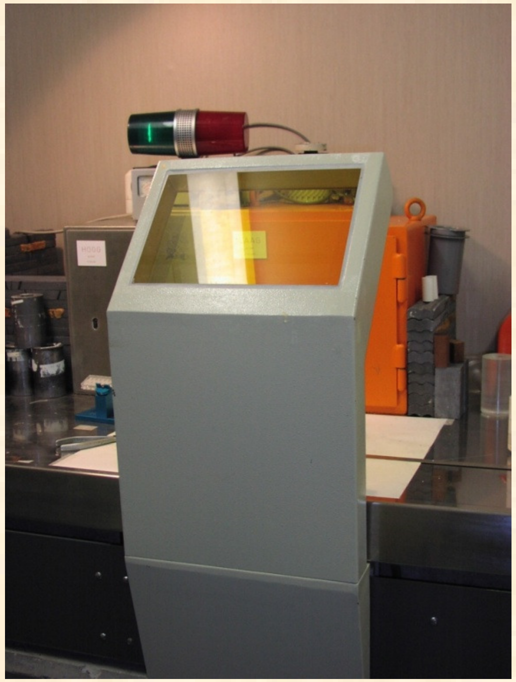
Radiation Safety: source preparation

Distance (Square !) => long forceps

Time => easy and precise tools

Shielding => lead/lead glass shields

Look for optimal solution



Radiation Safety: Source preparation/removal

Source Integrity (wipe test – visual inspection)
Area Survey (clean working areas)
Source Inventory (documented source transfers)
Shielded containers for transfer
Source storage: locked and secured
Clear rules for source acceptance and shipment

Requirements for QC checks

Minimum requirements [NCS Rep. 13, 2000]

Test	Test frequency	
	HDR / PDR	LDR
Leakage radiation	SE	A
Contamination	SE	A

Table taken from: NCS Report 13, The Netherlands Commission on Radiation Dosimetry, November 2000. NCS: Delft, The Netherlands (see www.stralingsdosimetrie.nl)
See also ESTRO Booklet No 8

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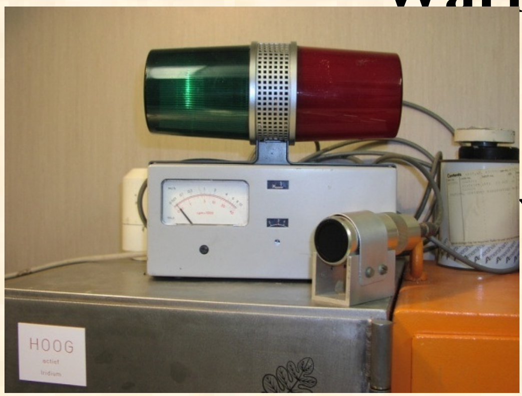
•Warning systems (



interlocks

V system

Safety procedures

Procedures should be set up taking into account type of applications/isotopes/treatment techniques

=> <u>Specific</u> Procedures

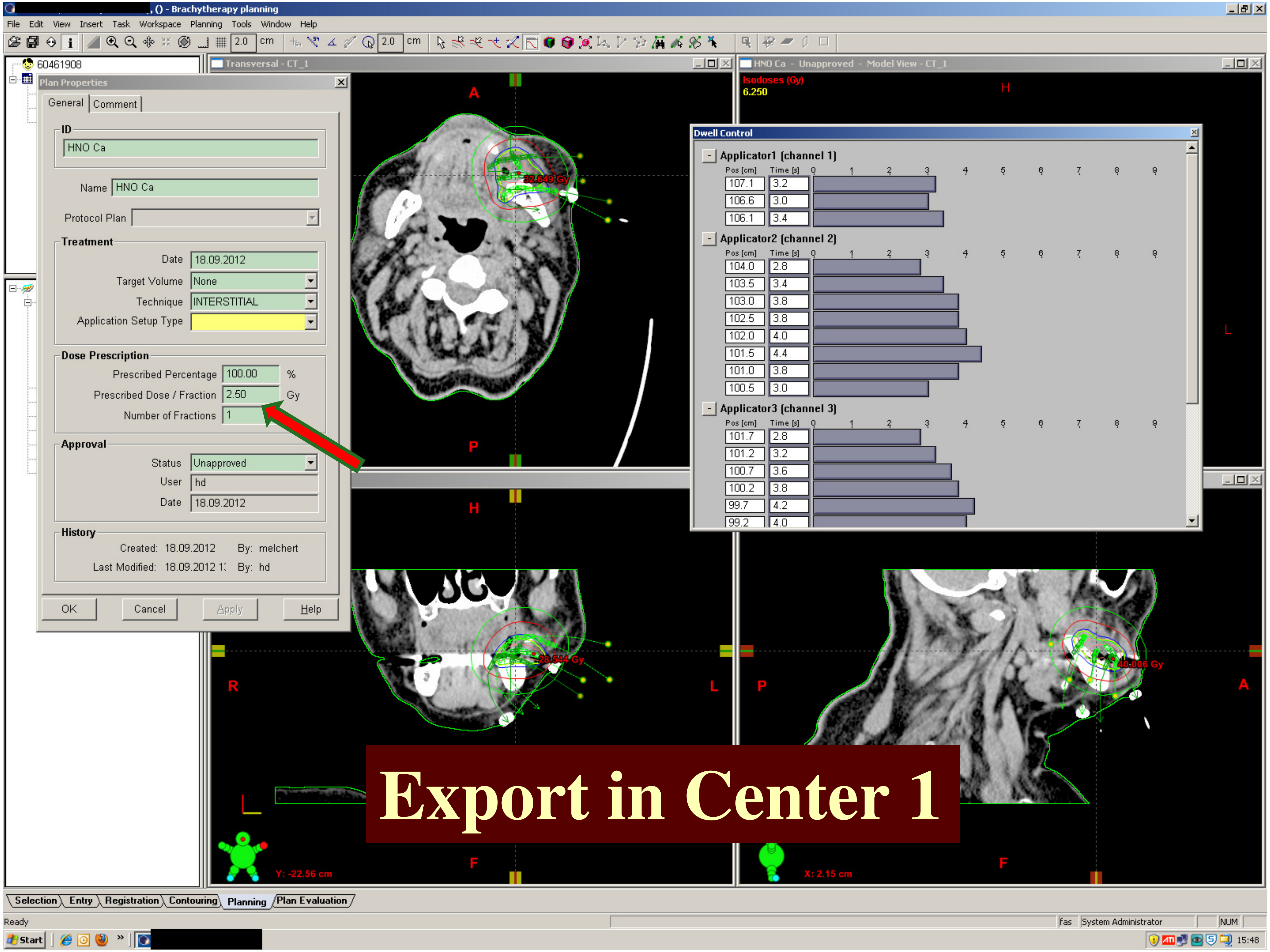
- HDR: high dose rates => fast intervention, continuous guarding

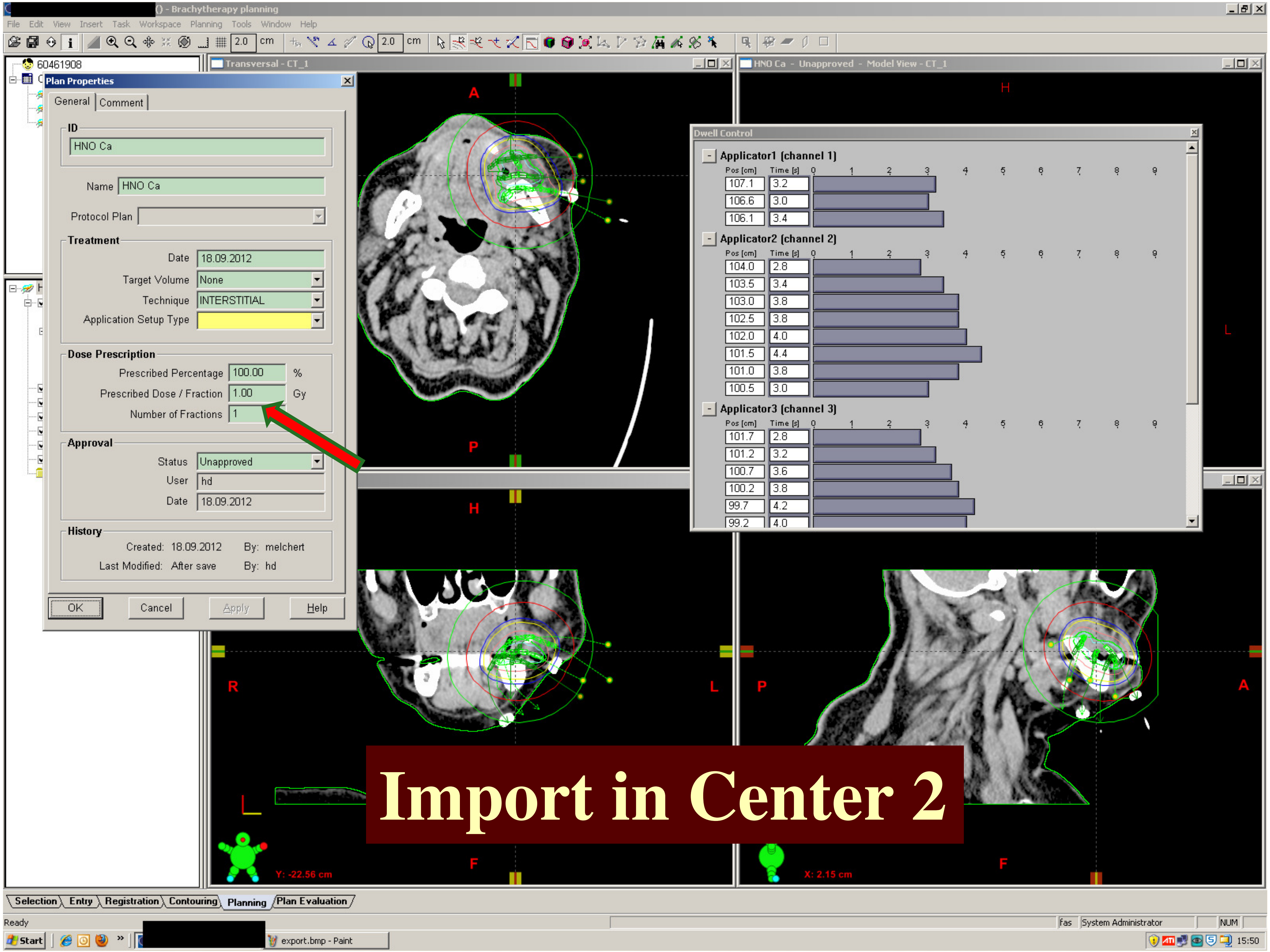
- PDR: applications over several hours/days; what if treatment continues overnight?

- Each treatment technique/treatment site has specific points of attention

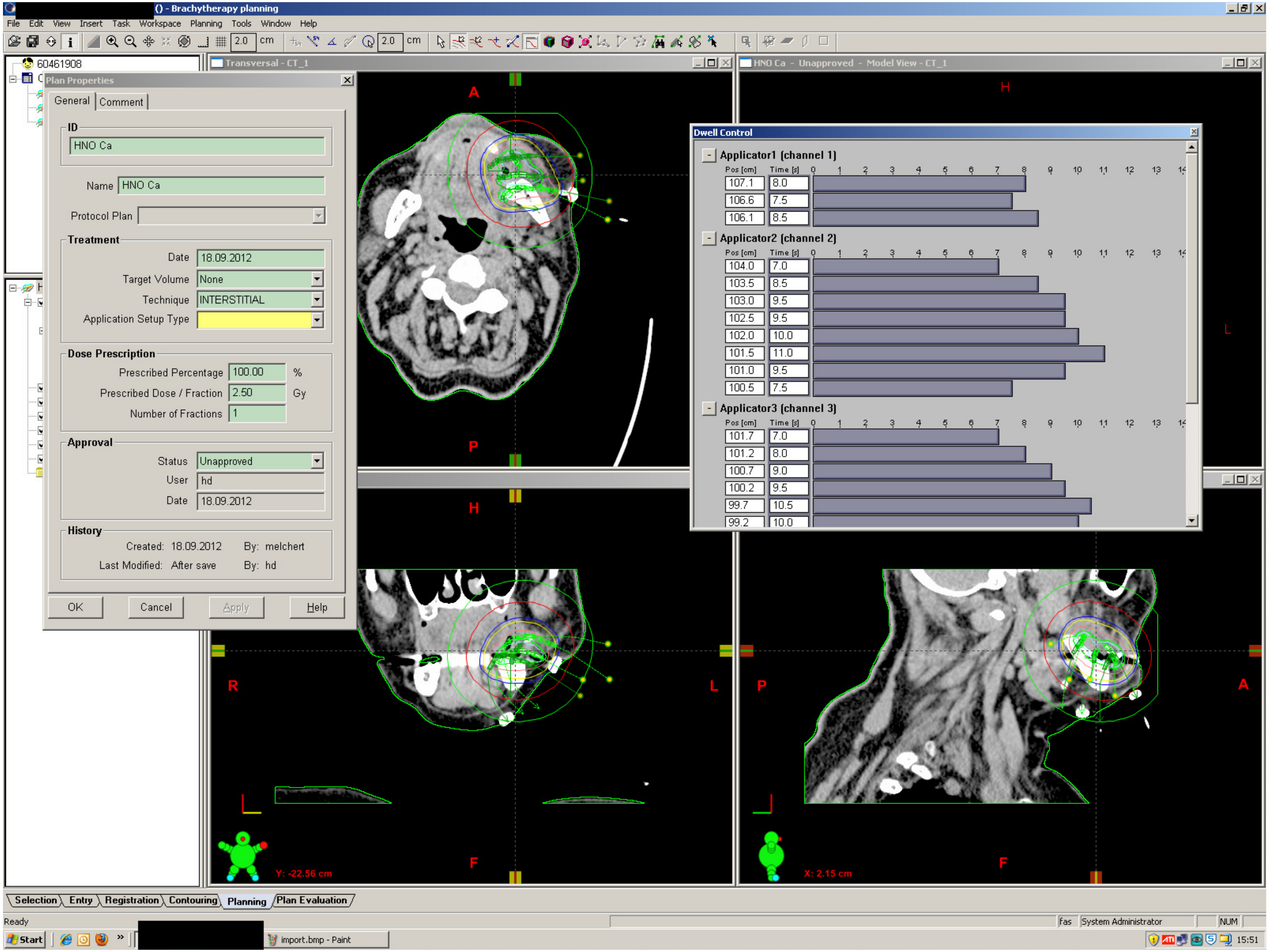
Some examples of what can go wrong

- Source removal at treatment end (1)
- Source removal at treatment end (2)
- PDR unit malfunction
- Incorrect treatment length
- Help! Radioactive patient!
- Help! Radioactive patient! (bis)
- PDR unit malfunction (bis)
- Dicom RT export/import


[redacted] , () - Brachytherapy planning
File Edit View Insert Task Workspace Planning Tools Window Help
60461908
Plan Properties
General
Comment
ID
HNO Ca
Name HNO Ca
Protocol Plan
Treatment
Date 18.09.2012
Target Volume None
Technique INTERSTITIAL
Application Setup Type
Dose Prescription
Prescribed Percentage 100.00 %
Prescribed Dose / Fraction 2.50 Gy
Number of Fractions 1
Approval
Status Unapproved
User hd
Date 18.09.2012
History
Created: 18.09.2012 By: melchert
Last Modified: 18.09.2012 1: By: hd
OK Cancel Apply Help
Transversal - CT_1
HNO Ca - Unapproved - Model View - CT_1
Isodoses (Gy)
6.250
Dwell Control
Applicator1 [channel 1]
Pos [cm] Time [s]
107.1 3.2
106.6 3.0
106.1 3.4
Applicator2 [channel 2]
Pos [cm] Time [s]
104.0 2.8
103.5 3.4
103.0 3.8
102.5 3.8
102.0 4.0
101.5 4.4
101.0 3.8
100.5 3.0
Applicator3 [channel 3]
Pos [cm] Time [s]
101.7 2.8
101.2 3.2
100.7 3.6
100.2 3.8
99.7 4.2
99.2 4.0
32.649 Gy
28.544 Gy
40.006 Gy
Y: -22.56 cm
X: 2.15 cm
Export in Center 1
Selection Entry Registration Contouring Planning Plan Evaluation
Ready
fas System Administrator NUM
Start [redacted]
15:48



Import in Center 2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Number of Fractions 1
Approval
Status Unapproved
User hd
Date 18.09.2012
History
Created: 18.09.2012 By: melchert
Last Modified: After save By: hd
OK
Cancel
Apply
Help
Transversal - CT_1
HNO Ca - Unapproved - Model View - CT_1
Dwell Control
Applicator1 (channel 1)
Pos [cm] Time [s]
107.1 8.0
106.6 7.5
106.1 8.5
Applicator2 (channel 2)
Pos [cm] Time [s]
104.0 7.0
103.5 8.5
103.0 9.5
102.5 9.5
102.0 10.0
101.5 11.0
101.0 9.5
100.5 7.5
Applicator3 (channel 3)
Pos [cm] Time [s]
101.7 7.0
101.2 8.0
100.7 9.0
100.2 9.5
99.7 10.5
99.2 10.0
A
P
H
F
R
L
Y: -22.56 cm
X: 2.15 cm
Selection
Entry
Registration
Contouring
Planning
Plan Evaluation
Ready
fas
System Administrator
NUM
Start
[redacted]
import.bmp - Paint
15:51

Conclusion

Establishment of a good safety program supposes a mixture of:

- Common sense
- Knowledge
- Systematic
- Documentation

And this in balanced quantities