

Establishing Process Parameters and Process Acceptance

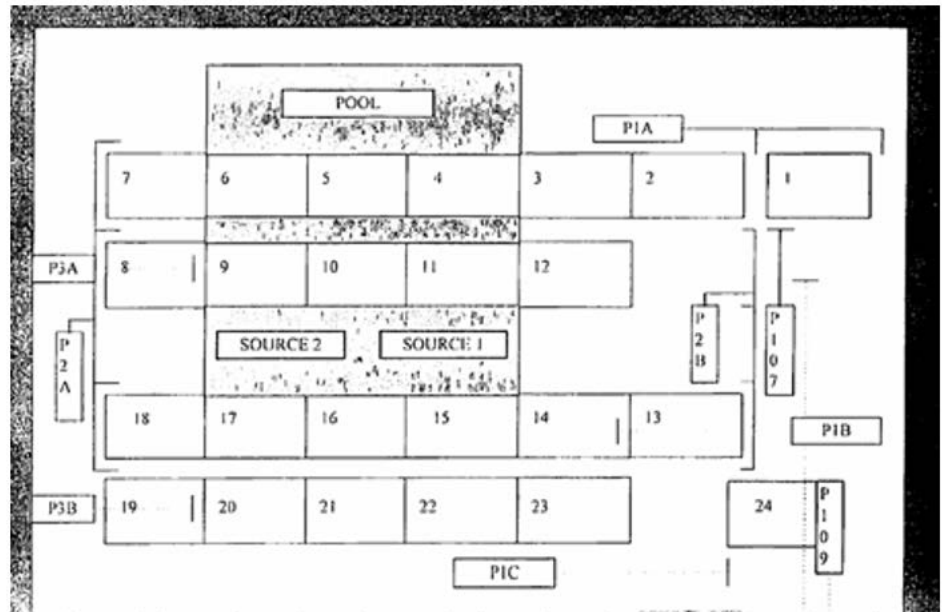
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Agenda

- Gamma irradiator overview
- Operational Qualification (OQ)
- Performance Qualification (PQ, product dose mapping)
- Target dose
- Cycle time calculation
- Processing parameters
- Cycle time setting
- Process acceptance

Gamma Irradiators

- Activity 2MCi – 5MCi
- 2-pass, 4-pass system, 6-pass systems
- Source overlap –carrier length is above and below source rack height
- Product overlap – two levels of carriers.
- Carriers cycle around the source rack in each dwell position
- Contribution of total dose per dwell position



POOL						
7	6	5	4	3	2	1
0.7%	2.9%	4.0%	3.1%	0.8%	0.0%	0.0%
8	9	10	11	12		
1.6%	11.6%	14.7%	9.6%	1.2%		
SOURCE 2 SOURCE 1						
18	17	16	15	14	13	
1.6%	11.6%	14.7%	9.6%	1.2%	0.0%	
19	20	21	22	23	24	
0.7%	2.9%	4.0%	3.1%	0.8%	0.0%	

Data Establishing Process Parameters

- Data used to establish process parameters
 - OQ data from source loading (cycle time calculation)
 - PQ data from product dose maps following loading (cycle time calculation)
 - Historical data (scheduling)
 - Empty to full carrier effects (scheduling)

Establishing Process Parameters

OQ data

Operational qualification data following source loading

- Three densities

- Low, middle, high covering typical routine processing density range

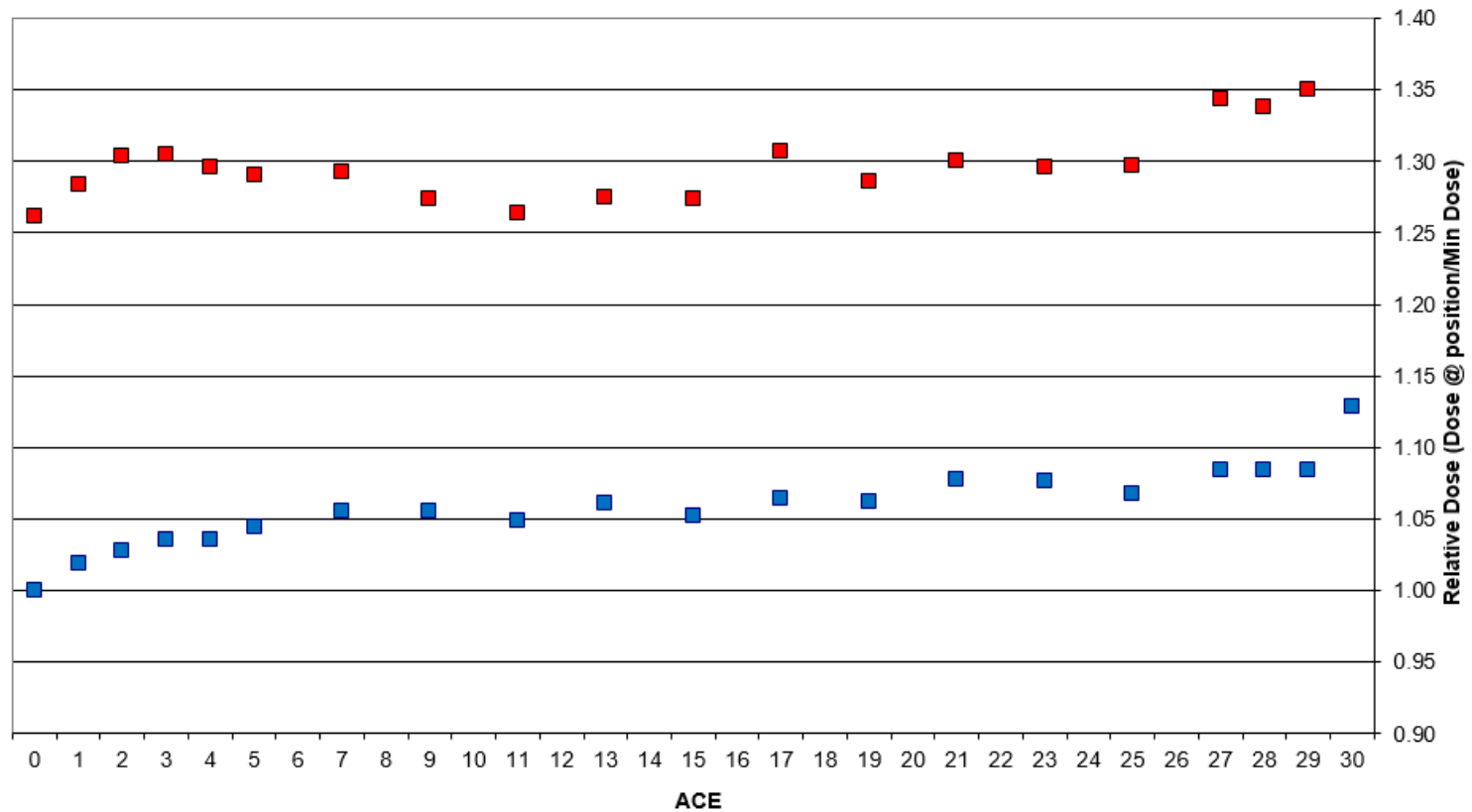
- Three carriers per density

- Use average minimum and maximum dose in initial cycle time calculations

- Data from empty-to-full carrier for low, middle, high density

OQ Profile

Qualification #25 (0.16 g/cc)
2 racks



PQ

Product Dose Map Data

- Products are dose mapped after each source loading

- Each product's data contains placements based on OQ results from the applicable density range

- Product dose specification – starting point for setting process

Customer:		Process Date:	
IR Run #:	27094A	Cycle Time (sec):	630
Family:	NA	Number of Dosimeters per Position :	3
Product Code:	NA		
Load Specification No:	9		
Eff Density (g/cc):	0.12		

DOSE MAP CARRIER NUMBER						
Dose Coordinate	1st	2nd	3rd	Equivalence Zone	Mean at Position	Sum of Squared Differences
0C1	30.2	29.5	28.5	MinZone	29.4	1.462
0C3	30.7	30.8	29.1	MinZone	30.2	1.745
0C7	30.1	30.2	29.3	MinZone	29.8	0.456
0C9	29.8	29.8	28.3	MinZone	29.3	1.641
1C1	30.9	30.7	29.7	MinZone	30.4	0.787
1C9	31.0	30.6	29.8		30.5	0.741
2C1	32.1	31.9	29.7		31.3	3.483
2C9	32.3	32.0	30.7		31.7	1.369
TBC9	33.8	34.0	33.7		33.8	0.042
3A5	39.0	39.1	38.1		38.7	0.581
3E 5	38.5	37.4	36.9		37.6	1.227
4A5	38.2	38.2	37.4		37.9	0.415
4E 5	38.1	37.5	36.8		37.5	0.926
5A5	39.5	39.7	38.9		39.4	0.349
5E 5	37.9	38.2	37.8		38.0	0.110
7A5	40.5	40.4	39.2		40.0	1.067
7E 5	38.4	38.1	36.7		37.7	1.588
9A5	39.2	41.1	39.8		40.1	1.864
9E 5	38.0	38.3	37.6		38.0	0.246
11A5	40.9	40.9	39.0		40.3	2.389
11E 5	38.9	38.2	37.2		38.1	1.427
13A5	41.1	38.7	37.6		39.1	6.293
13E 5	39.9	38.2	37.4		38.5	3.100
15A5	41.6	41.9	40.3	MaxZone	41.3	1.381
15E 5	39.4	40.3	37.5		39.0	3.989
17A5	40.6	39.0	37.6		39.1	4.655
17E 5	39.1	39.4	37.6		38.7	1.817
19A5	42.1	41.6	40.4	MaxZone	41.4	1.399
19E 5	40.2	39.9	39.2		39.8	0.526
21A5	39.8	39.1	38.9		39.3	0.440
21E 5	39.1	38.8	38.5		38.8	0.194
23A5	42.5	41.9	41.6	MaxZone	42.0	0.433
23E 5	39.9	40.2	40.7		40.3	0.374
25A5	39.6	41.3	38.9		39.9	3.185
25E 5	38.7	39.3	38.1		38.7	0.714
27A5	42.4	42.1	41.3	MaxZone	41.9	0.562
27E 5	39.2	39.3	39.4		39.3	0.019
TBA5	38.0	39.5	38.3		38.6	1.329
TBE5	38.0	38.2	38.8		38.4	0.363

Overall Var	0.701
MDD	1.14
Minimum dose	29.3 kGy
Maximum dose	42.0 kGy
Min Position	0C9
Max Position	23A5
DUR	1.43

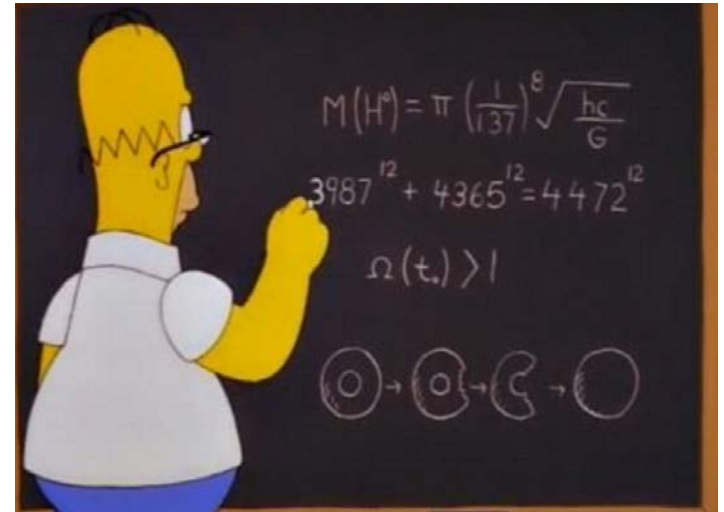
Target Dose



- Spreadsheet allows for a minimum dose buffer
 - Planner will never schedule a run based on the exact minimum dose specification
 - Planners have the ability to add a buffer to the spreadsheet
 - X% over the min dose specification
 - Y% under the max dose specification
 - Target dose = recommended buffer % over minimum dose specification
 - Process variability accounts for measurement response changes of dosimeter, decay change relative to cycle time over 30 days, and variation from PQ data replicates

Cycle Time Calculation

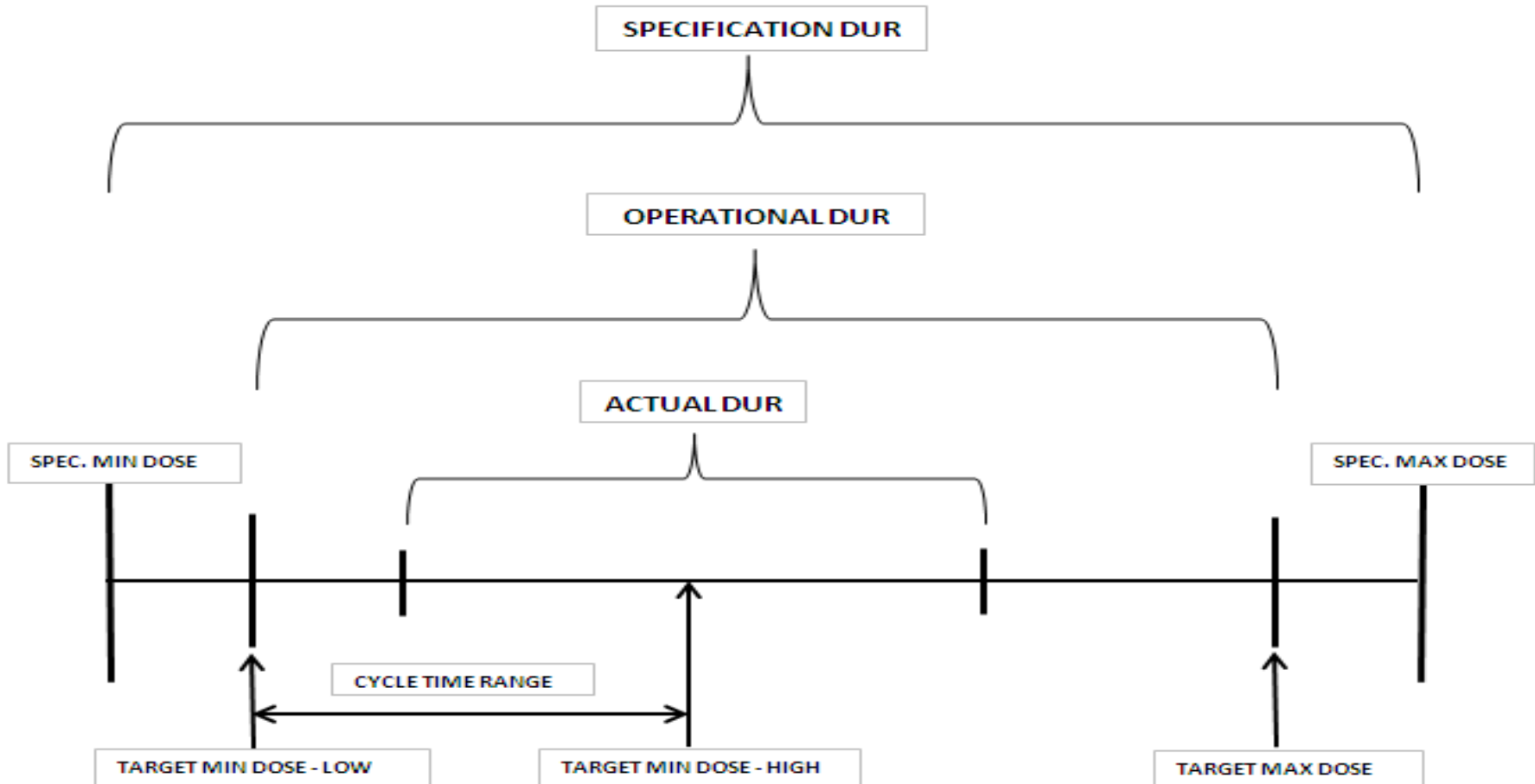
- Cycle time calculation spreadsheet used
- Coming out of a loading, the data inputted into the spreadsheet is OQ data
- Use OQ data for initial runs; typically products with wide dose ranges
- Populate cycle time spreadsheet with product dose map data
- Over time, all PQ results are inputted into the spreadsheet



Cycle Time Calculation

- PQ data has limitations
 - Three middle carriers does not account for phase in/phase out densities
 - Changes in product packaging
 - Changes in product weight
- Calculated cycle time must be adjusted for scheduling
 - Empty-to-full carrier data from OQ
 - Daily production schedule
 - All products processed that day in sequential order
 - Product density, number of carriers, min/max dose from first/middle/last carriers, cycle time
 - Historical data

Establishing Process Parameters



Cycle Time Setting

Customer	Product Code	Bulk Density (g/cc)	Effec. Density (g/cc)	Spec. Min.Dose (kGy)	Spec. Max.Dose (kGy)	Loading Diagram	C O M	Target Min. Dose (kGy)	Today's Cycle Time		Hist Data DUR	Schedule Cycle time (sec/cyc)	Predicted Min. Dose (kGy)	Predicted Max. Dose (kGy)
									Min. (sec/cyc)	Max. (sec/cyc)				
	Med. Devices	0.03	0.02	25.0	35.0	L-08 1BOX	32"	26.0	615	755	1.05	650	27.5	29.0
	Med. Devices	0.13	0.08	25.0	38.0	L-03 4 per		26.0	660	782	1.19	700	27.6	32.7
	Med. Devices	.07/.10	.04/.10	25.0	40.0	L-01/02 9/8 per		26.0	675	835	1.19	715	27.6	32.9
	Med. Devices	0.23	0.22	25.0	40.0	L-23 16 PER		26.0	755	829	1.34	775	26.7	35.9
	Med. Devices	0.08	0.08	25.0	40.0	L-02 8 PER		26.0	665	780	1.26	700	27.4	34.5

Process Verification and Acceptance

- Dosimetry is the indicator of process verification
- Product release is based on the dose value measured on the dosimeter
- There is no adjustment of dose after measurement
- For example, for a product with 25.0 kGy min specification; 24.9 kGy OOS and non-conformity, 25.0 kGy in specification