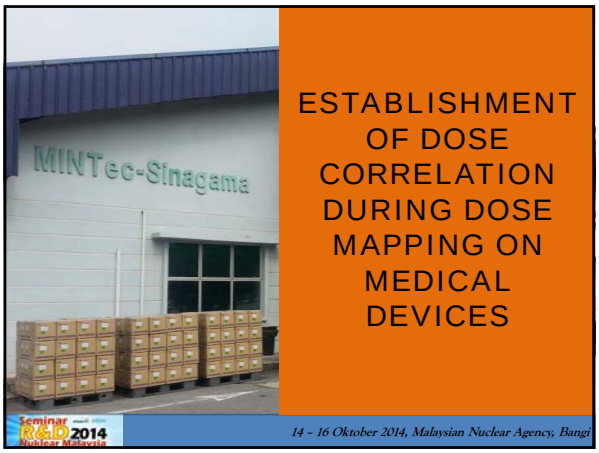


ESTABLISHMENT OF DOSE CORRELATION DURING DOSE MAPPING ON MEDICAL DEVICES

Ruzalina Baharin[1], Hasan Sham[2], Ahsanulkhaliqin A. Wahab[1], Jamilah Karim[1], Cosmos George[1], Zarina M. Nor[1], Mohd K. Azfar[1], Sofian Ibrahim[3] & Mohd Sidek Othman

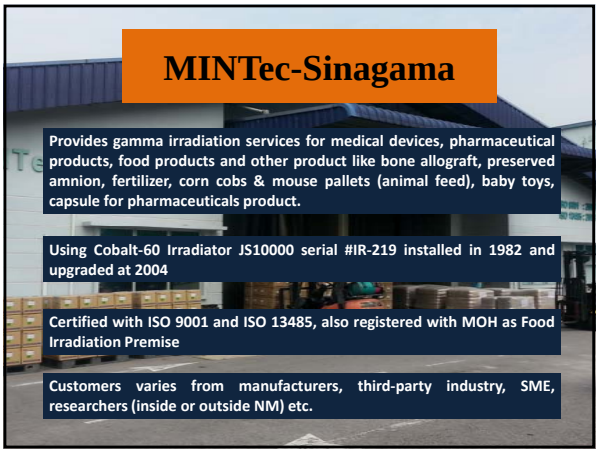
[1]MINTec-Sinagama, [2]SSDL, [3]Raymintex

Seminar R&D 2014 Nuklear Malaysia
14 – 16 Oktober 2014, Malaysian Nuclear Agency, Bangi

CONTENT

- Phase 1: Business nature of MINTec-Sinagama
- Phase 2: Works on Dose Mapping
- Phase 3: Output from Dose Mapping work

Phase 1
Business nature of MINTec-Sinagama



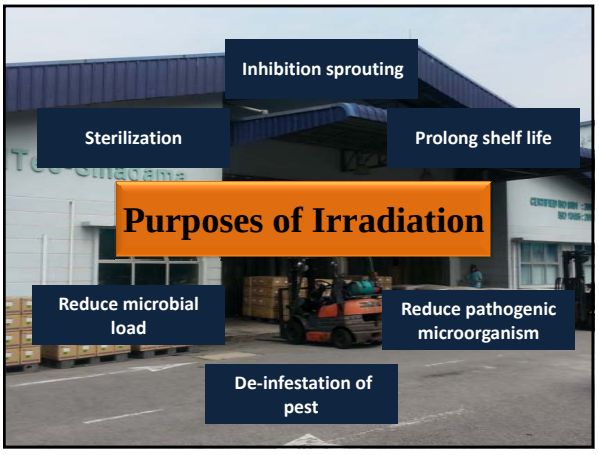
MINTec-Sinagama

Provides gamma irradiation services for medical devices, pharmaceutical products, food products and other product like bone allograft, preserved amnion, fertilizer, corn cobs & mouse pallets (animal feed), baby toys, capsule for pharmaceuticals product.

Using Cobalt-60 Irradiator JS10000 serial #IR-219 installed in 1982 and upgraded at 2004

Certified with ISO 9001 and ISO 13485, also registered with MOH as Food Irradiation Premise

Customers varies from manufacturers, third-party industry, SME, researchers (inside or outside NM) etc.



Purposes of Irradiation

- Inhibition sprouting
- Sterilization
- Prolong shelf life
- Reduce microbial load
- Reduce pathogenic microorganism
- De-infestation of pest

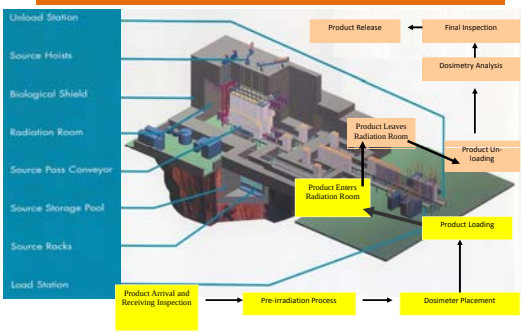
Medical devices

Medical devices like gloves, petri dish, vaginal speculum, catheter and clean room garments (jumpsuits)

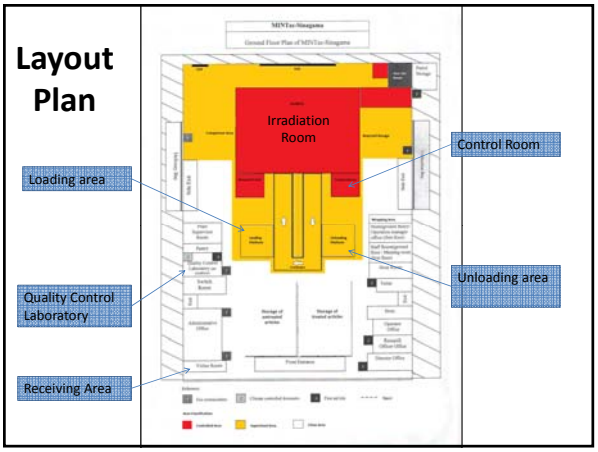
Food

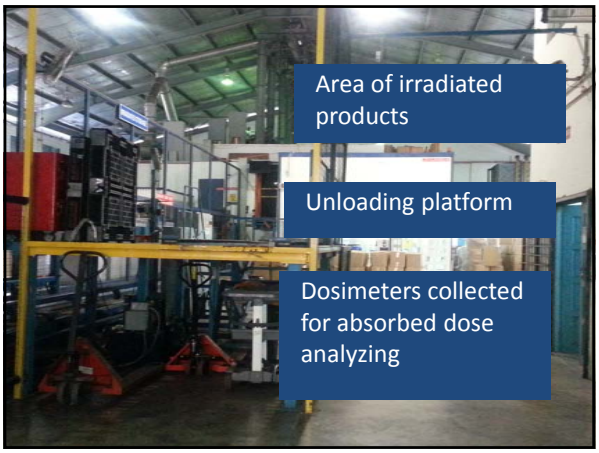
Herbs, spices, oat, cereal, tea, cocoa, frozen durian, curry leaves, fresh fruit (rambutan, pineapple) – coming next year

Process flow



Layout Plan





Radiation Facility

1. Define the process
2. Validate the process
3. Monitor & control the process

1 Define the Process

Minimum Dose

Establishment of minimum dose by looking into intended effect to achieve

Maximum Dose

Dose that absorbed by product that not abuses the quality and functionality of the product

2 Validate the Process

3 qualifications needed:

Installation Qualification (IQ)
First time installation of plant

Operational Qualification (OQ)
Sources replenishment

Performance Qualification (PQ)
For specific product

2 Validate the Process

Installation Qualification (IQ)

To confirm that installation is correct

To obtain and document the evidence

2 Validate the Process

Operational Qualification (OQ)

- To ensure that plant is operated within the predetermined specifications
- To obtain and document the evidence
- To determine dose distributions through dose mapping

2 Validate the Process

Operational Qualification (OQ)

*Poster presented at Seminar R&D 2014

2 Validate the Process

Performance Qualification (PQ)

- To ensure, obtain and document the evidence that plant is consistently operated
- To determine the appropriate process parameters (time, PLP) for specific product through dose mapping
- To get correlation factor for dose at reference monitoring position

Questions to be asked

1. What is product dose mapping?
2. Why we need product dose mapping?
3. When we do product dose mapping?
4. How does product dose mapping performed?
5. Results of product dose mapping?

Objectives

1. To ensure the correct dose is delivered
2. To ensure the effect of irradiation is achieved

1 What is product dose mapping?

From ISO 11137-1:2006,

Dose mapping is a measurement of dose distribution and variability in material irradiated under defined conditions

- Co-60 replenishment to increase strength
- Irradiator dose mapping to determine area of minimum and maximum dose inside the tote
- Product dose mapping for specific product and its configuration

1 What is product dose mapping?

- § To determine the distribution of minimum and maximum doses
- § to ensure plant is well operated

Co-60 replenishment to increase strength

↓

Irradiator dose mapping to determine area of minimum and maximum dose inside the tote

↓

Product dose mapping for specific product and its configuration

- § To determine the absorbed dose and dose correlation
- § To get product loading patern

1 What is product dose mapping?

Co-60 replenishment to increase strength

↓

Irradiator dose mapping to determine area of minimum and maximum dose inside the tote

↓

Product dose mapping for specific product and its configuration

Irradiator Dose Mapping

Product Dose Mapping

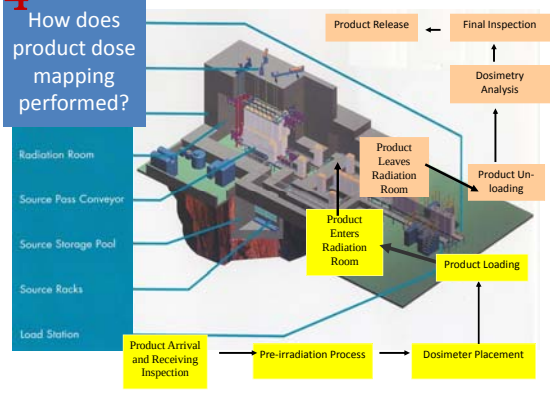
2 Why we need product dose mapping?

- § Confirm the zones of minimum and maximum dose distribution within the product load
- § Validate the set cycle timer
- § Assess the reproducibility of the irradiation process

3 When we should do product dose mapping?

- § When the product is sent for processing for the first time
- § When there are any changes in the product or packaging specifications that will effect tote density
- § When there are any changes to the irradiator system that may affect dose distribution and irradiator performance
- § For monitoring purpose, or official instruction by the management

4 How does product dose mapping performed?



4 How does product dose mapping performed?

IMPORTANT

- Should be performed for specific products and loading configurations
- May be performed using actual product or dummy
- Similar density throughout the products
- Three totes

4 How does product dose mapping performed?

IMPORTANT

- Should be performed for specific products and loading configurations
- May be performed using actual product or dummy
- Similar density throughout the products
- Three totes

Measure the product's; weight	Get the product's; dimension	Count the product
11.10 kg	41.0 (L) x 34.0 (W) x 28.5 (H)	48 cartons

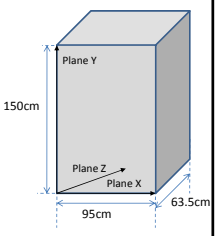
4 How does product dose mapping performed?

** Dosimeters placements are based on the specific coordinate; X, Y and Z*

*** Routine monitoring position; Coordinate 38 is a closest point to the source on the first pass.*

Zone	X (cm)	Y (cm)	Z (cm)
1	0.0	150.0	32.0
2	23.8	150.0	32.0
3	48.0	150.0	32.0
4	71.3	150.0	32.0
5	95.0	150.0	32.0
6	0.0	130.0	32.0
7	23.8	130.0	32.0
8	48.0	130.0	32.0
9	23.8	100.0	32.0
10	48.0	100.0	32.0
11	71.3	100.0	32.0
12	23.8	90.0	32.0
13	48.0	90.0	32.0
14	71.3	90.0	32.0
15	23.8	80.0	32.0
16	48.0	80.0	32.0
17	71.3	80.0	32.0
18	0.0	50.0	63.5
19	23.8	50.0	63.5
20	0.0	50.0	32.0
21	23.8	50.0	32.0
22	23.8	30.0	63.5
23	48.0	30.0	63.5
24	0.0	30.0	0.0
25	23.8	30.0	0.0
26	48.0	30.0	0.0
27	23.8	20.0	0.0
28	48.0	20.0	0.0
29	71.3	20.0	0.0
30	48.0	10.0	0.0
31	48.0	10.0	32.0
32	48.0	10.0	63.5
33	0.0	0.0	32.0
34	23.8	0.0	32.0
35	48.0	0.0	32.0
36	71.3	0.0	32.0
37	95.0	0.0	32.0
*38	95.0	0.0	63.5

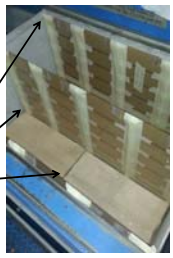
Tote size:
150H x 95L x 63.5W



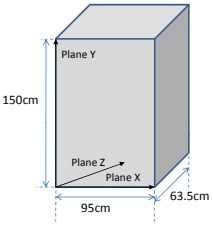
Direction of tote movement

4 How does product dose mapping performed?

*** 3 planes; front, centre, back*



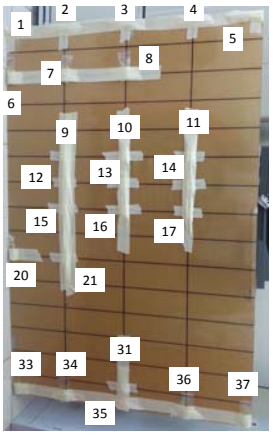
Tote size:
150H x 95L x 63.5W



Direction of tote movement

Zone	X (cm)	Y (cm)	Z (cm)
1	0.0	150.0	32.0
2	23.8	150.0	32.0
3	48.0	150.0	32.0
4	71.3	150.0	32.0
5	95.0	150.0	32.0
6	0.0	130.0	32.0
7	23.8	130.0	32.0
8	48.0	130.0	32.0
9	23.8	100.0	32.0
10	48.0	100.0	32.0
11	71.3	100.0	32.0
12	23.8	90.0	32.0
13	48.0	90.0	32.0
14	71.3	90.0	32.0
15	23.8	80.0	32.0
16	48.0	80.0	32.0
17	71.3	80.0	32.0
18	0.0	50.0	63.5
19	23.8	50.0	63.5
20	0.0	50.0	32.0
21	23.8	50.0	32.0
22	23.8	30.0	63.5
23	48.0	30.0	63.5
24	0.0	30.0	0.0
25	23.8	30.0	0.0
26	48.0	30.0	0.0
27	23.8	20.0	0.0
28	48.0	20.0	0.0
29	71.3	20.0	0.0
30	48.0	10.0	0.0
31	48.0	10.0	32.0
32	48.0	10.0	63.5
33	0.0	0.0	32.0
34	23.8	0.0	32.0
35	48.0	0.0	32.0
36	71.3	0.0	32.0
37	95.0	0.0	32.0
*38	95.0	0.0	63.5

Plan at Z=32.0 cm



4 How does product dose mapping performed?

Best loading configuration

Three totes

Three planes per tote with one dosimeter per location

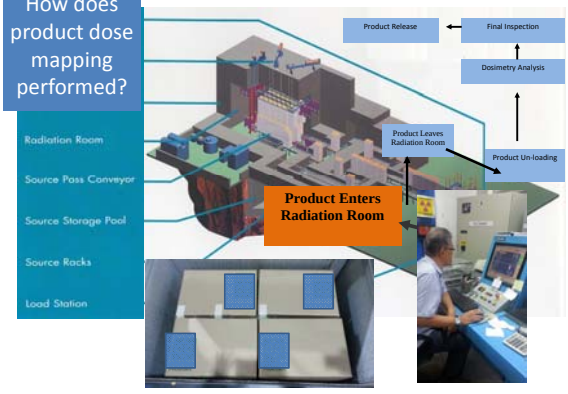
Three dosimeters at dose routine monitoring

150 kg per tote,
So ≈ 150kg/11.1kg ≈ 13.5 ctns

By dimension, per tote for 12 cartons

12 cartons x three totes = 36 cartons

4 How does product dose mapping performed?



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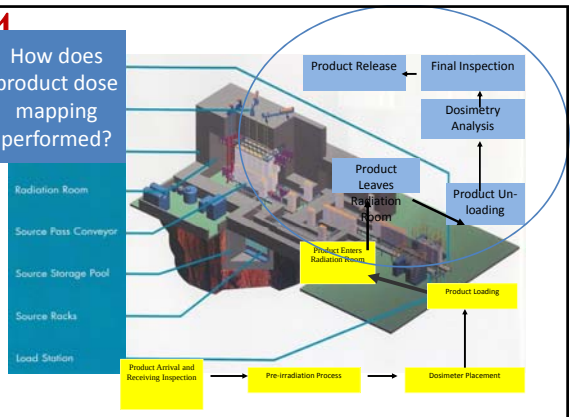
How does product dose mapping performed?



5

Results of product dose mapping?

	Dose (Gy)								
	Average	SD	Actual			Reference			
			Tote 1	Tote 2	Tote 3	Tote 1	Tote 2	Tote 3
D_{min}	**10.8**	**0.42**	10.3	10.1	10.4	13.8	13.8	13.8
			Average = 10.3					
D_{max}	**14.2**	**0.36**	14.9	14.8	15.1	**Average = 13.8**		
			Average = 14.9					
Uniformity (U)			1.45	1.47	1.45			
			Average = 1.46					

Calculation

$D_{r\,m}$ position, Dosimeter No. 28 = 13.8

Actual D_{min} position = Tote 1 (No. 23); Tote 2 (No. 24); Tote 3 (No. 23)

$a = D_{min} / D_{r\,m}$ (actual) = 10.3 /13.8 = **0.75**

Actual D_{max} position = Tote 1 (No. 18); Tote 2 (No. 18); Tote 3 (No. 18)

$b = D_{max} / D_{r\,m}$ (actual) = 14.9 / 13.8 = **1.08**

Correction factor: a = 0.75 b = 1.08

3 Monitor & Control the Process

- Dosimetry
- Documentation & Recordkeeping

3 Monitor & Control the Process

Dosimetry System

Absorbed Dose

- Relies on dose-response function
  - Must be calibrated
  - Measure dose and get the response-dose relationship
- Different dosimeters sensitive to differences in dose rate/radiation quality
  - Need to choose suitable dosimetry system depending on processing conditions
  - Parameters are stabilize

3 Monitor & Control the Process

Dosimetry System

Traceability and Accuracy

- Dosimetry used is traceable to national and international standards
  - International Dose Assurance Service (IDAS) of IAEA
- Statement of accuracy
  - Need to provide summary statement; error, statistical confidence

3 Monitor & Control the Process

Documentation & Recordkeeping

- Auditing the facility
  - By authorities and inspection services
  - Rely on record
- Auditing the process
- Compliance with Customer and Legal Requirements
- Inventory Control and Product Release

3 Monitor & Control the Process

Dosimetry Report
Customer: [redacted] BHD.
Irradiation Lot No: **130116**
Dosimeter Batch No: **B03/2013**

Tote Position in	Dosimeter Position	Potential Difference (mV) 1	2	3	Dose (kGy) 1	2	3	Average Dose (kGy)
First	0-E-5	20.4	20.5	R	14.3	14.4	-	14.4
Middle 1	0-E-5							
Middle 2	0-E-5							
Middle 3	0-E-5							
Middle 4	0-E-5							
Middle 5	0-E-5							
Last	0-E-5							

Process complete? Yes/No
Dose meet customer's requirement? Yes/No
Ref. Maximum Dose at 0-E-5 (kGy) : 14.4

Remarks :
a = 0.75
b = 1.08

Actual Minimum Dose (kGy) : 10.8
Actual Maximum Dose (kGy) : 15.6

Verified by: _____ (QA Personnel)

_____ (Date of Evaluation)

Correction factor:
a = 0.75
b = 1.08

Phase 3
Output from Dose Mapping work

Certificate of Irradiation

Certificate No.

RSP-6
Issue#: 5
Date: 1 Nov 2011

MINTec-Sinagama
Agensi Nuklear Malaysia
(Formerly known as Malaysian Institute for Nuclear Technology Research -MINT)
Bangi 43000 Kajang, Selangor, MALAYSIA
Tel:603 8920 2057/E-mail:sgama@nuclearmalaysia.gov.my/ Fax:603 8920 1099

CERTIFICATE OF IRRADIATION

Customer :
Address :
Order No. :
Total No. of Product Unit :
Total Volume (m^3) /Weight (kg):
Dose Requested (kGy) : Minimum ..... kGy; Maximum ..... kGy
Irradiation Date :
Product Unit Serial Numbers :
Purpose of Treatment :
Type of Treatment given :
Radiation Source :

Product Description	Catalog No./ Product Code	Quantity	Batch No.

Dose Delivered (kGy): Minimum ___ kGy
Maximum ___ kGy

Approved by : _____
Title : _____
Date Issued : _____

From Product Dose Mapping Report

ACCEPTANCE OF LIMITS
To the Manager of MINTec-Sinagama,

According to the Dose Mapping Report, Certificate No. **130047** and PLP No. **9P115/13**, our product has been validated between **10.3 kGy** and **15.1 kGy**. Due to practical reasons, we accept that the recommended range for the routine sterilization of this product to be in the range of **10.0 kGy** and **15.0 kGy.**

Signature _____
Name _____
Designation _____
Company _____

Thank you