

Teori Sistem Dosimetri

Pusat Pendidikan dan Pelatihan



Badan Tenaga Nuklir Nasional



Biodata



1.	Name	Bimo Saputro
2.	Education	Bachelor Nuclear Engineering
3.	Birth Day	Yogyakarta, October 13, 1993
4.	Specialist	Gamma Irradiator, Accelerator and Dosimetry
5.	Mail Address	bimo-saputra@batan.go.id
6.	Phone Number / WA	0813 1941 7800

Training Experience

Num	Year	Training Title	Time and Place
1.	2018	ESR Spectrometers	September, Indonesia
2.	2019	Gamma Irradiator Facility	November to December, Serbia
3.	2020	Irradiator Officer	July, Indonesia

Research Experience

Num	Year	Title
1.	2019	Dosimetry Intercomparison Performance
2.	2020	Radiation Application for PPE Sterilization



Latar Belakang



- Latar

Pemahaman dasar teknologi iradiator dan jaminan kualitas proses diperlukan sebuah pemahaman. Pemahaman ini menjadi dasar melakukan proses iradiasi sesuai standar, sehingga dapat menciptakan kepuasan bagi pelanggan iradiasi.

- Manfaat -

1. Mampu memahami prinsip kerja iradiator gamma
2. Mampu mengaplikasi standar kualitas proses

- Tujuan

1. Mampu menjelaskan prinsip kerja iradiator gamma
2. Mampu menerapkan teknik dosimetri sesuai standar



Pokok Bahasan



- Jenis

1. Kategori Iradiator Gamma
2. Perbedaan Fungsi Berdasarkan Kategori Iradiator Gamma

- Aplikasi -

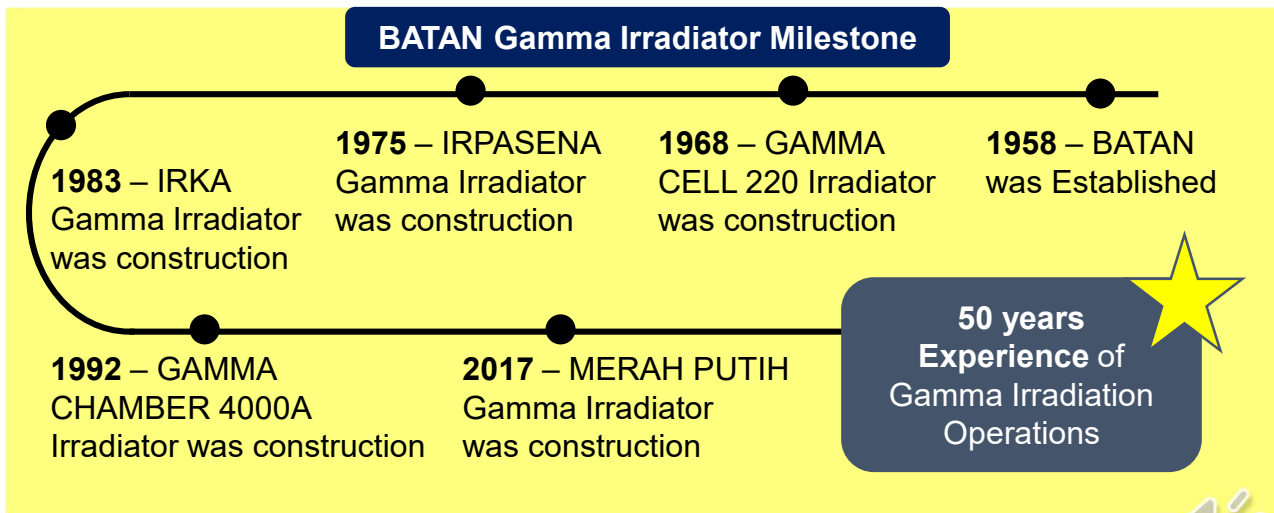
1. Definisi dan Prinsip Dosimetri
2. Standar Dosimetri Primer, Acuan, Transfer dan Rutin

- Macam

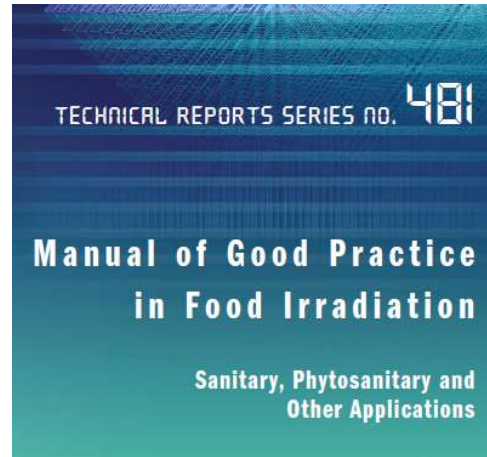
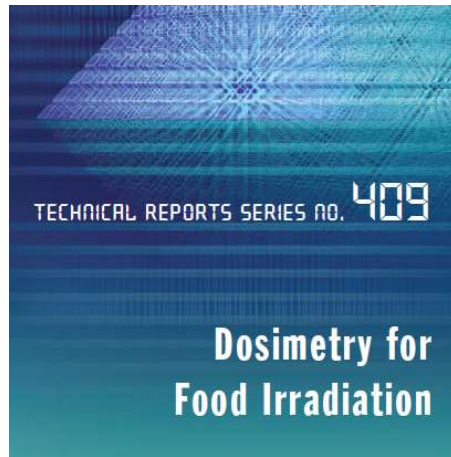
1. Definisi dan Prinsip Dosimetri
2. Standar Dosimetri Primer, Acuan, Transfer dan Rutin



Fasilitas Irradiator BATAN



Standar Iradiasi



INTERNATIONAL
STANDARD

ISO
14470

First edition
2011-12-01

Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

INTERNATIONAL
STANDARD

ISO
11137-3

Second edition
2017-06

INTERNATIONAL
STANDARD

ISO
11137-1

First edition
2006-04-15

Sterilization of health care products — Radiation —

Part 3:
Guidance on dosimetric aspects of development, validation and routine control

Sterilization of health care products — Radiation —

Part 2:
Establishing the sterilization dose

Stérilisation des produits de santé — Irradiation —

Partie 2: Établissement de la dose stérilisante

Sterilization of health care products — Radiation —

Part 1:
Requirements for development, validation and routine control of a sterilization process for medical devices



BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA



PERATURAN BADAN PENGAWAS OBAT DAN MAKANAN
NOMOR 3 TAHUN 2018
TENTANG
PANGAN IRADIASI

KEPUTUSAN KEPALA BADAN PENGAWAS TENAGA NUKLIR

NOMOR : 11/Ka-BAPETEN/VI-99

TENTANG

IZIN KONSTRUKSI DAN OPERASI IRADIATOR

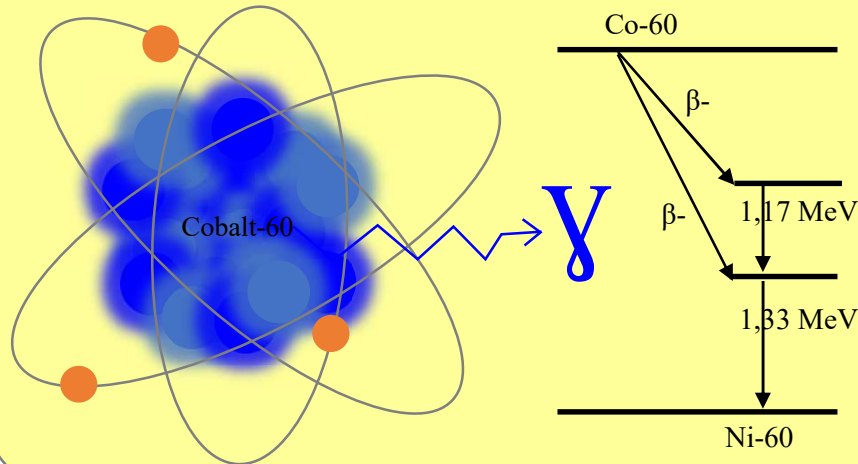
KEPALA BADAN PENGAWAS TENAGA NUKLIR,



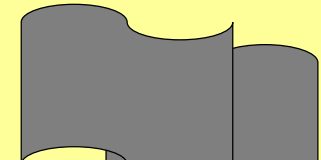
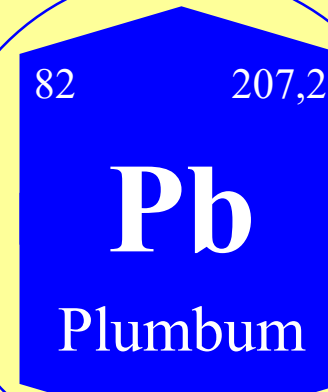
Komponen Utama Iradiator



Sumber Cobalt



Shielding (Timbal)

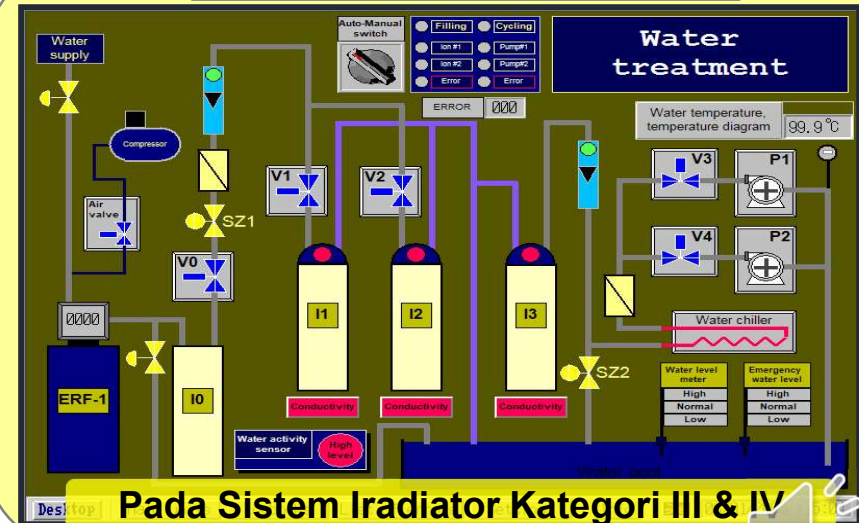


Pada Sistem Iradiator Kategori I & II

Sistem Kontrol



Demineralizer Water Sistem



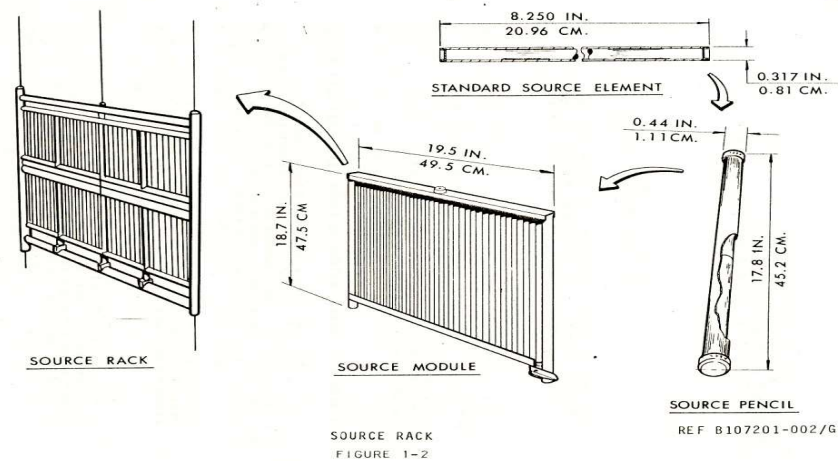
Pada Sistem Iradiator Kategori III & IV

Gamma Facilities: Radiation Sources

^{60}Co :



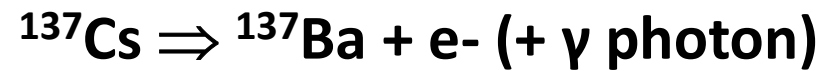
Half life: 5.26 years;



Photon energy: 1.17 MeV and 1.33 MeV;

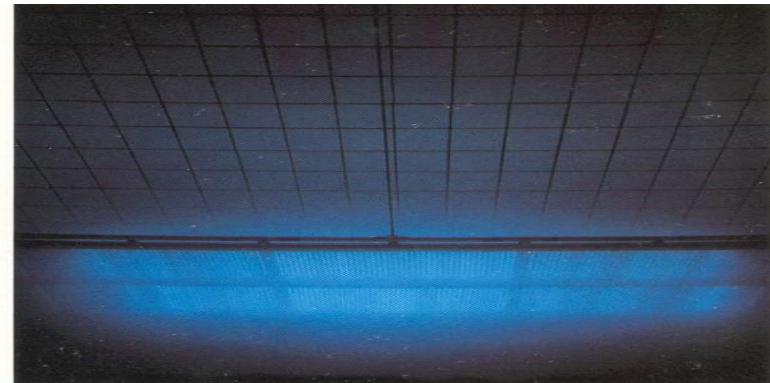
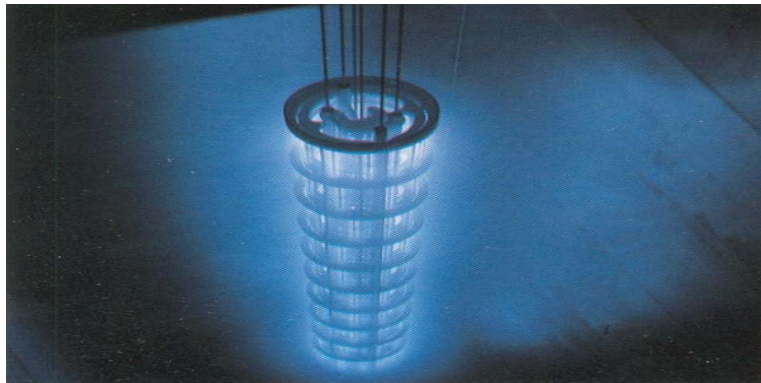
Radiation sources

^{137}Cs :



Half life: 30 years;

Photon energy: 0.662 MeV;

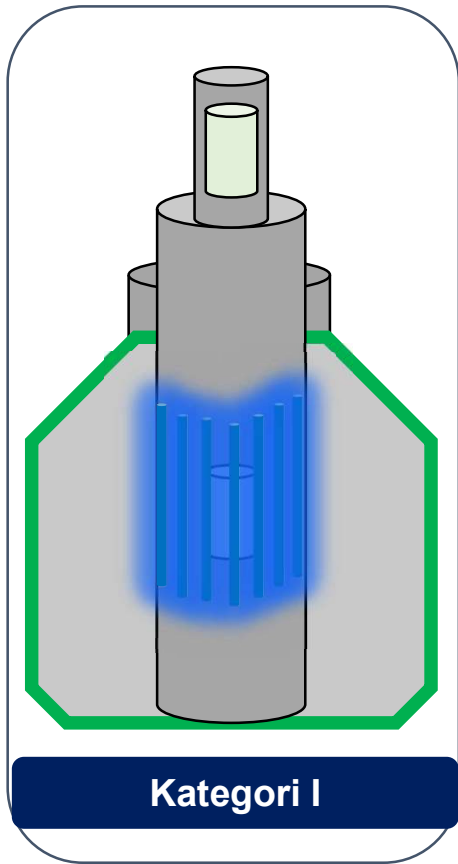




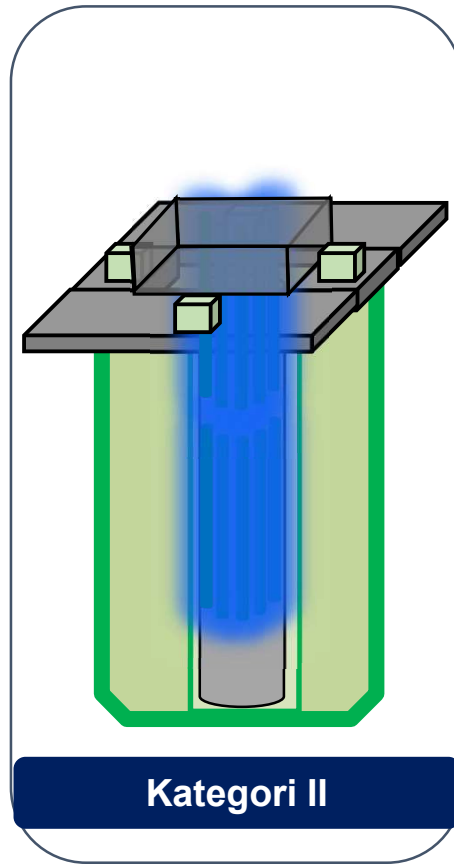
Kategori Irradiator Gamma



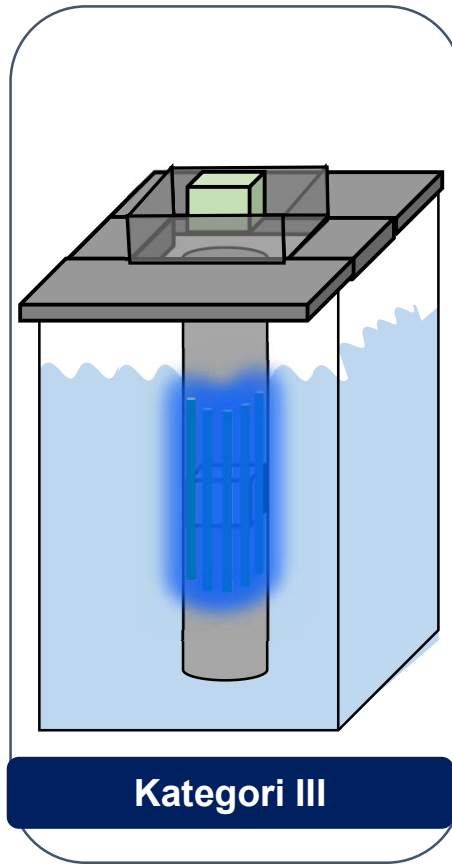
Kontainer kering,
sumber diam,
sampel bergerak



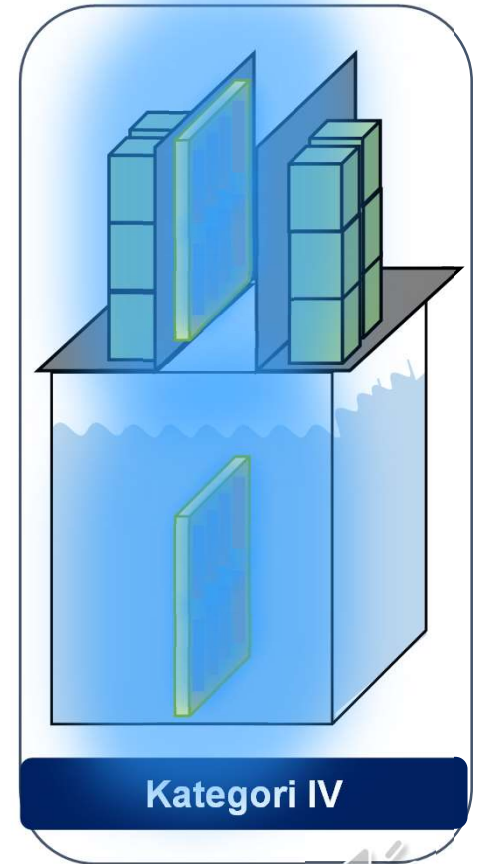
Kontainer kering,
sumber bergerak,
sampel diam



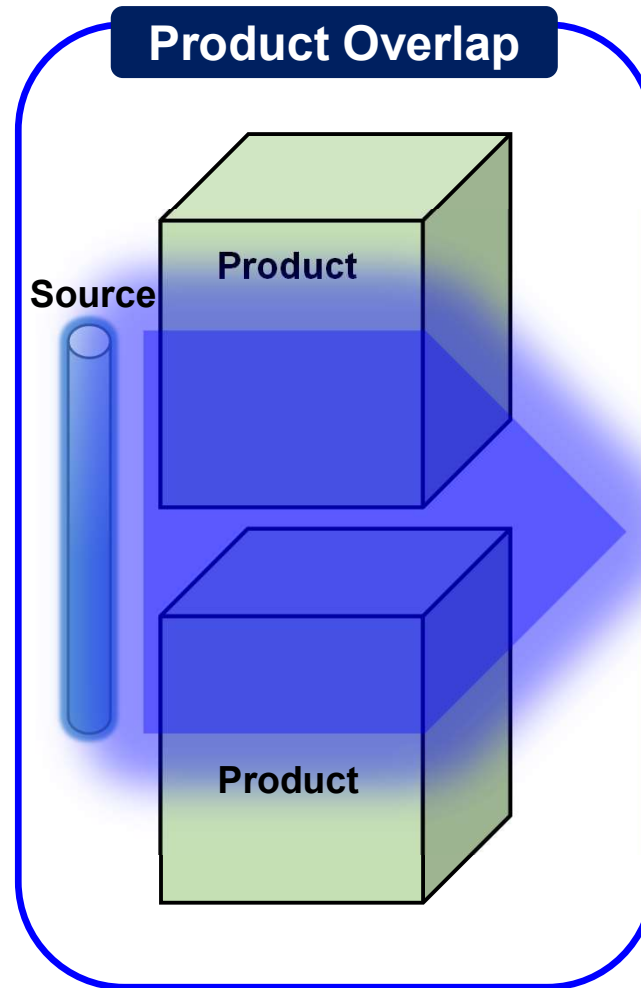
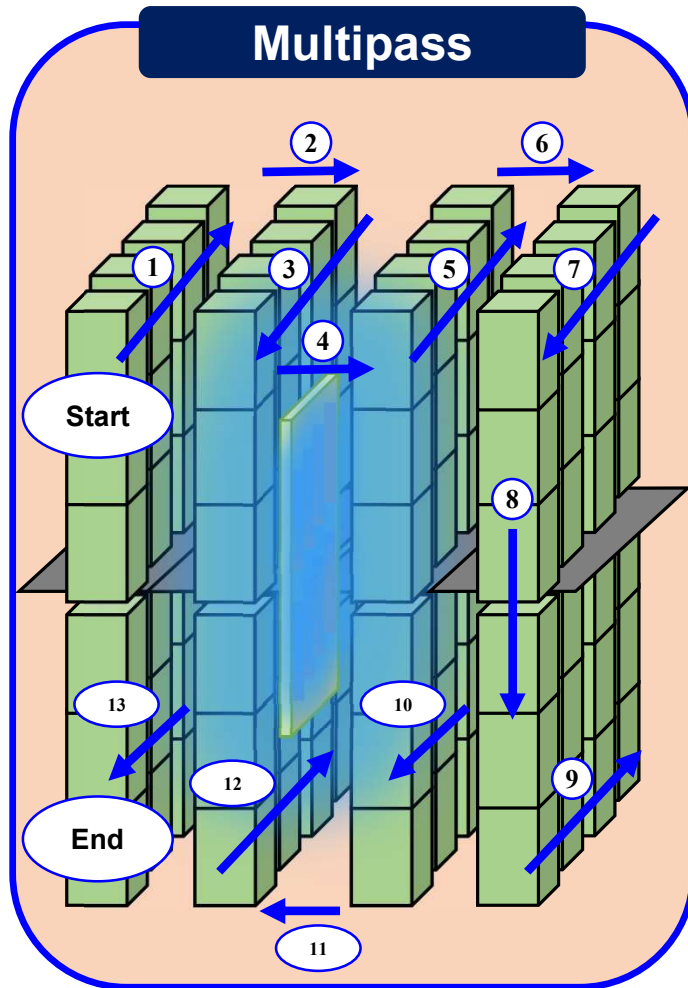
Kontainer basah,
sumber diam,
sampel bergerak



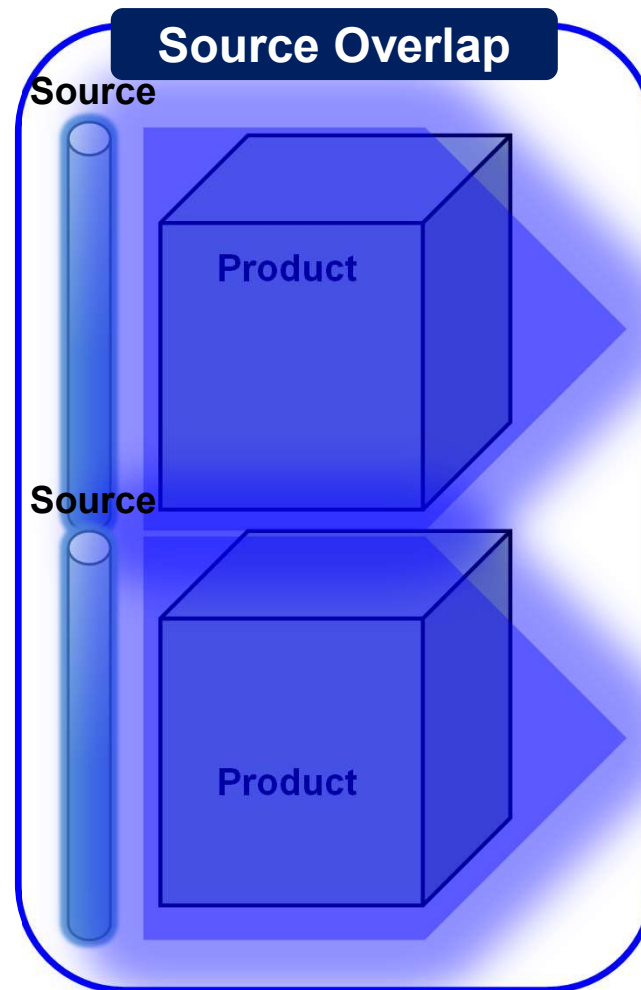
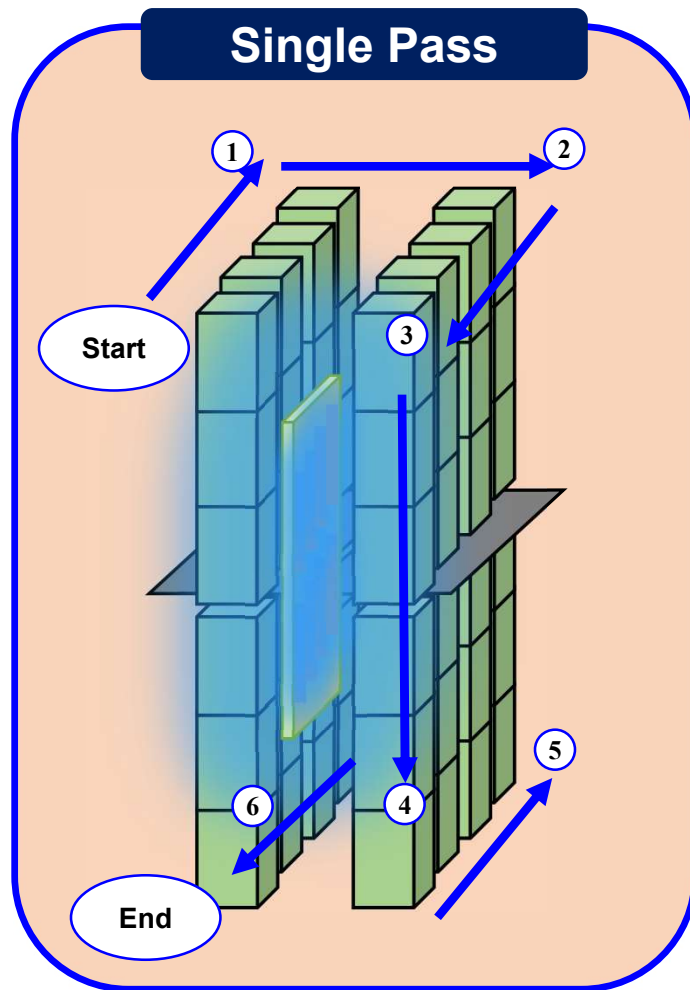
Kontainer basah,
sumber bergerak,
sampel diam



Karakteristik Iradiator Gamma



Karakteristik Iradiator Gamma



Fasilitas Iradiator Gamma di PAIR



1. Iradiator Gamma Cell 220 Upgrade



- Dibangun : Tahun 1968 - Upgrade Tahun 2017
- Kategori : Kategori I
- Sumber : Cobalt-60
- Kap. Maks : 11 kCi
- Komisioning : 7 kCi per April 2018
- Aplikasi : Penelitian

2. Iradiator Gamma Chamber



Aktivitas Sumber Radiasi Rendah

- Dibangun : Tahun 1992
- Kategori : Kategori I
- Sumber : Cobalt-60
- Kap. Maks : 10 kCi
- Komisioning : 0,37 kCi per April 2018
- Aplikasi : Penelitian

Fasilitas Irradiator Gamma di PAIR



3. Irradiator Karet Alam (IRKA)



- Dibangun : Tahun 1983
- Kategori : Kategori IV
- Sumber : Cobalt-60
- Kap. Maks : 300 kCi
- Komisioning : 70 kCi per April 2018
- Aplikasi : Industri dan Penelitian

4. Irradiator Panoramic Serbaguna (IRPASENA)



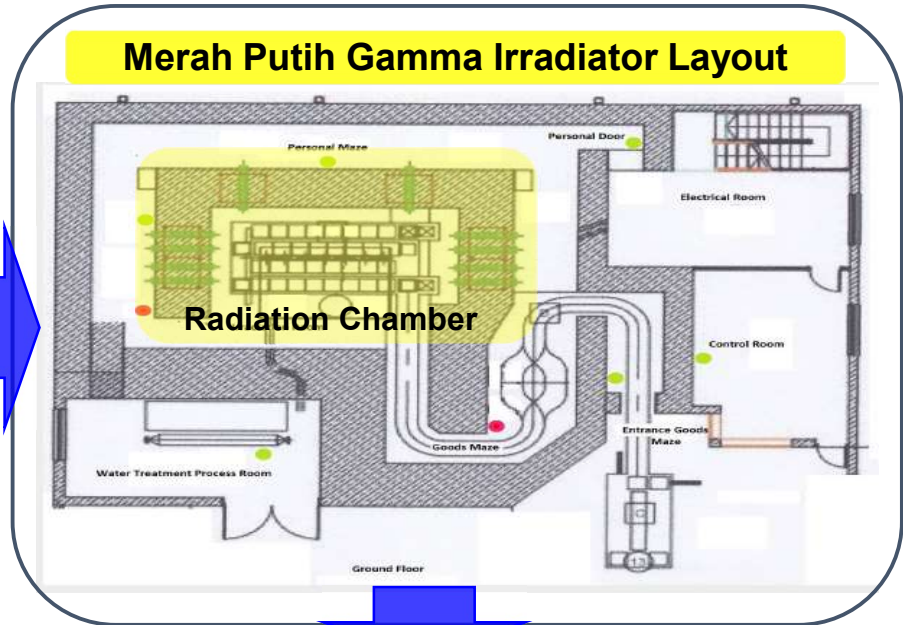
- Dibangun : Tahun 1975
- Kategori : Kategori II
- Sumber : Cobalt-60
- Kap. Maks : 80 kCi
- Komisioning : 10 kCi per April 2018
- Aplikasi : Industri dan Penelitian



Fasilitas Irradiator Gamma di PAIR



Merah Putih Gamma Irradiator Building



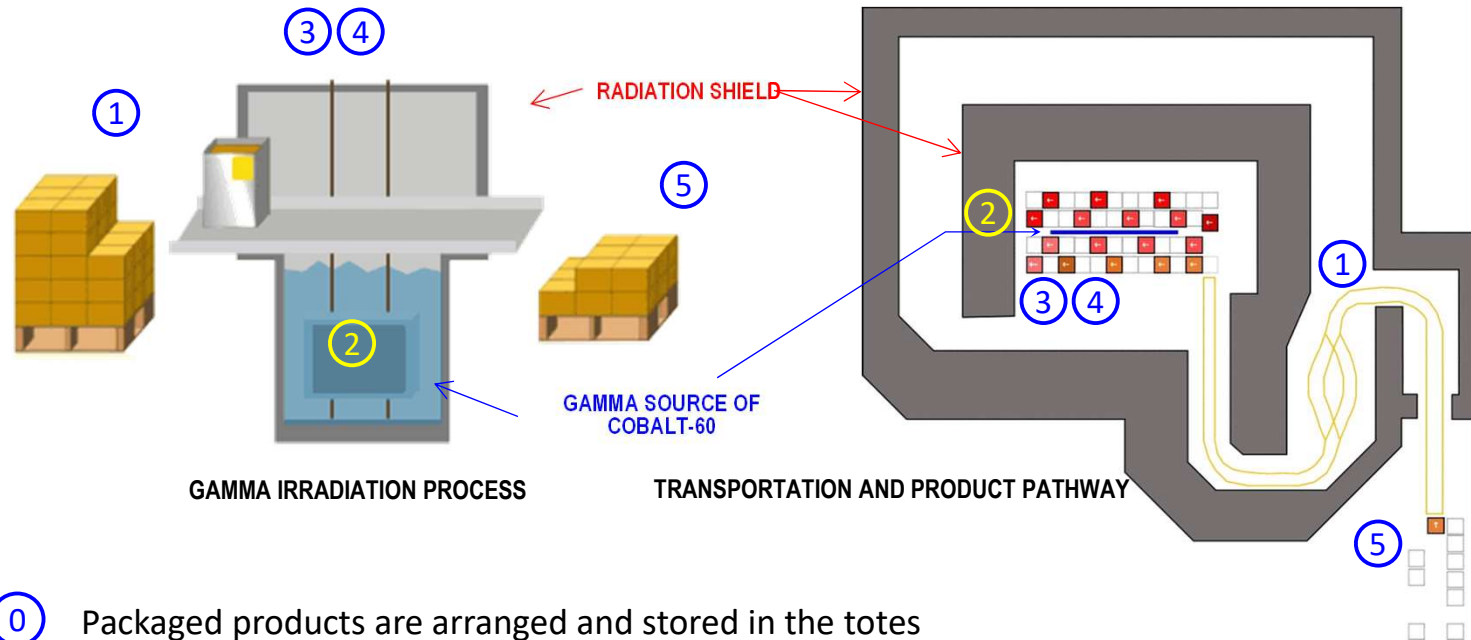
Facility

- Utility and Generator System
- Water Treatment System
- Main Control Panel System
- Product Transport System

Specification

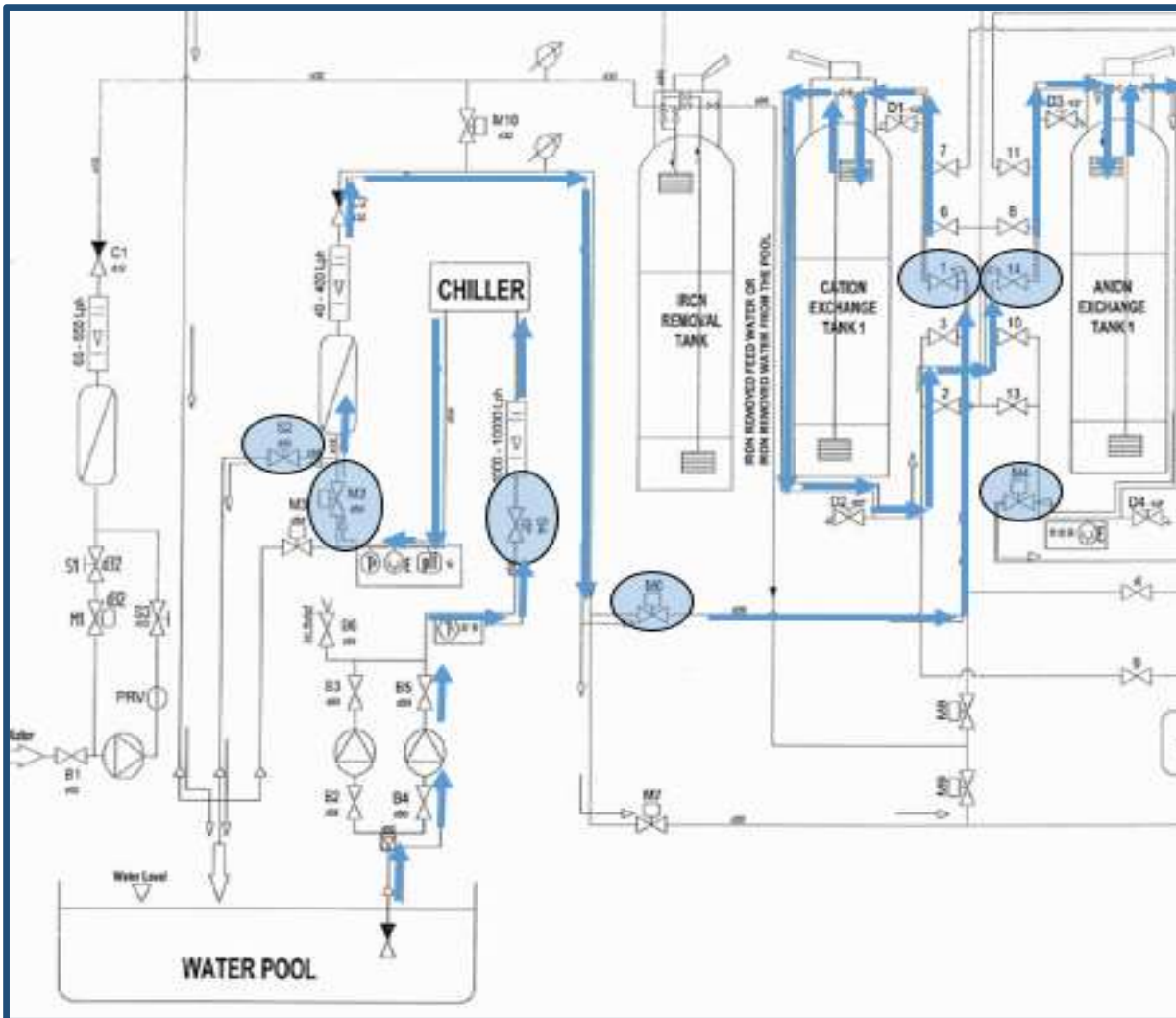
- Construction : **November 2017**
- Category : **Category IV**
- Radioactive Source : **Cobalt-60**
- Max Capacity : **2000 kCi**
- **Source Activity** : **250 kCi per Feb 2019**
- Applications : **Multipurpose**

Fasilitas Irradiator Gamma di PAIR



- 0 Packaged products are arranged and stored in the totes
- 1 Totes enter the irradiation chamber (bunker).
- 2 Gamma source of Cobalt-60 are ascended from the water pool for irradiation process.
- 3 Totes undergo the specific pathway to achieve the uniform irradiation dose.
- 4 Irradiation time is determined by the product type.
- 5 Post-irradiation: products are still intact with the initial packaging, ready to be distributed to the market.

Water Treatment System



1. Menjaga Konduktivitas dibawah 10 micro siemens

2. WTS memiliki 2 sistem Anion dan Kation

3. Anion untuk menarik unsur mineral negatif

4. Kation untuk menarik unsur mineral positif



Pemanfaatan Iradiator



Penelitian

- Modifikasi Bahan (Crosslinking, Degradasi, Grafting, & Polimerisasi)
- Mutasi/ Pemuliaan tanaman
- Fitosanitari

Tanaman Utuh



Plantlet/Kallus



Benih



Kitosan



Super Absorban



Industri

- Pateurisasi
- Sterilisasi

Kapsul herbal



Seasoning



Bahan baku kosmetik



Alat Kesehatan



Pangan



Pemanfaatan Iradiator



KASA



IUD



CATHETER

PASTEURISASI



CABE BUBUK



TEH MURBAI



PACEKAP



APA ITU DOSIMETRI?

Bagian dari sistem kualitas total dengan memberikan jaminan kualitas dan dokumentasi, bahwa prosedur iradiasi telah dilakukan sesuai dengan spesifikasi.



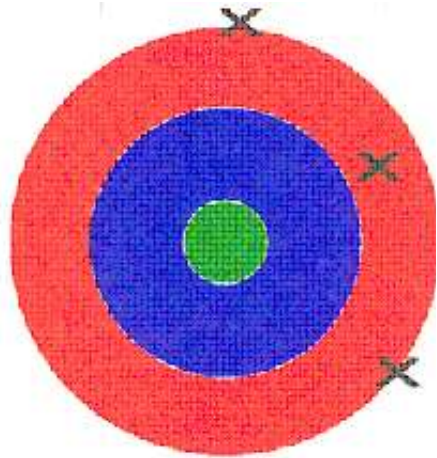
01 Dalam proses radiasi, validasi dan kontrol proses tergantung pada pengukuran dosis yang diserap.

02 Pengukuran dosis serap menggunakan sistem dosimetri atau sistem yang memiliki tingkat akurasi dan presisi yang diketahui.

03 Kalibrasi setiap sistem dosimetrik harus dapat tertelusur ke standar nasional yang sesuai.

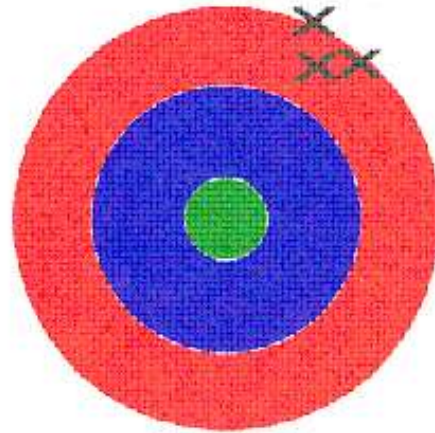


Accuracy and Precision



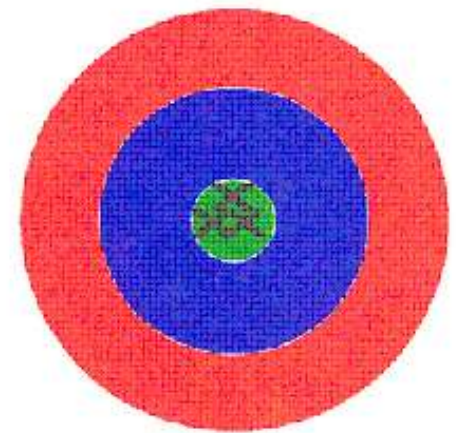
poor accuracy
poor precision

improved
measurement
technic →



poor accuracy
good precision

calibration →



good accuracy
good precision

ISO/ASTM Standards



- 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing*
- 51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System*
- 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*
- 51275 Practice for the Use of a Radiochromic Film Dosimetry System*
- 51276 Practice for the Use of a Polymethylmethacrylate Dosimetry System*
- 51310 Practice for the Use of a Radiochromic Optical Waveguide Dosimetry System*
- 51401 Practice for Use of a Dichromatic Dosimetry System*
- 51431 Practice for Dosimetry in Electron Beam and X-Ray (Bremsstrahlung)
Irradiation Facilities for Food Processing*
- 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System*
- 51540 Practice for Use of a Radiochromic Liquid Dosimetry System*
- 51607 Practice for Use of the Alanine-EPR Dosim System*
- 51608 Practice for Dosimetry in an X-Ray (Bremmstrahlung) Facility for Radiation
Processing*

Dosimetry – Sistem Penerapan



○ Aplikasi:

- installation qualification;
- operational qualification;
- performance qualification;
- process control;

○ Sistem dokumentasi

- Pengukuran traceable to a national standard or international standard,
- Mengetahui nilai ketidakpastian dosimetri.

○ Strata dosimeter:

- primary-, secondary-, transfer standards;
- routine systems;

- 1. Irradiation conditions are different from calibration conditions:**
 - temperature, dose rate, relative humidity, energy spectrum, irradiation geometry, etc.
- 2. Storage conditions:**
 - before and after irradiation;
- 3. Instrumental errors:**
 - absorbance and wavelength scale, scattered light, transfer of calibration curve from one instrument to another one, etc.

Environmental effects on dosimetry systems



Dosimeter	Measurement time after irr.	Humidity	Dose rate (Gy s ⁻¹)	Irradiation temp. coeff., (°C) ⁻¹
Alanine	24 hours	yes	< 10 ⁸	+ 0.25 %
Dichromate	24 hours	no	0.7 – 5x10 ²	- 0.2 %
Ceric-cerous	immediately	no	< 10 ⁶	conc. dep.
ECB	immediately	no	< 10 ⁸	+ 0.05 %
Calorimeters	immediately	no	< 10 ⁸	-
Perspex	24 hours	yes	< 10 ⁵	+ 1 %
FWT-60	5 min/60 °C	yes	< 10 ¹³	+ 0.2 %
B3	5 min/60 °C	yes	< 10 ¹³	+ 0.3 %
Sunna	20 min/70 °C	no	< 10 ¹³	+ 0.2 %

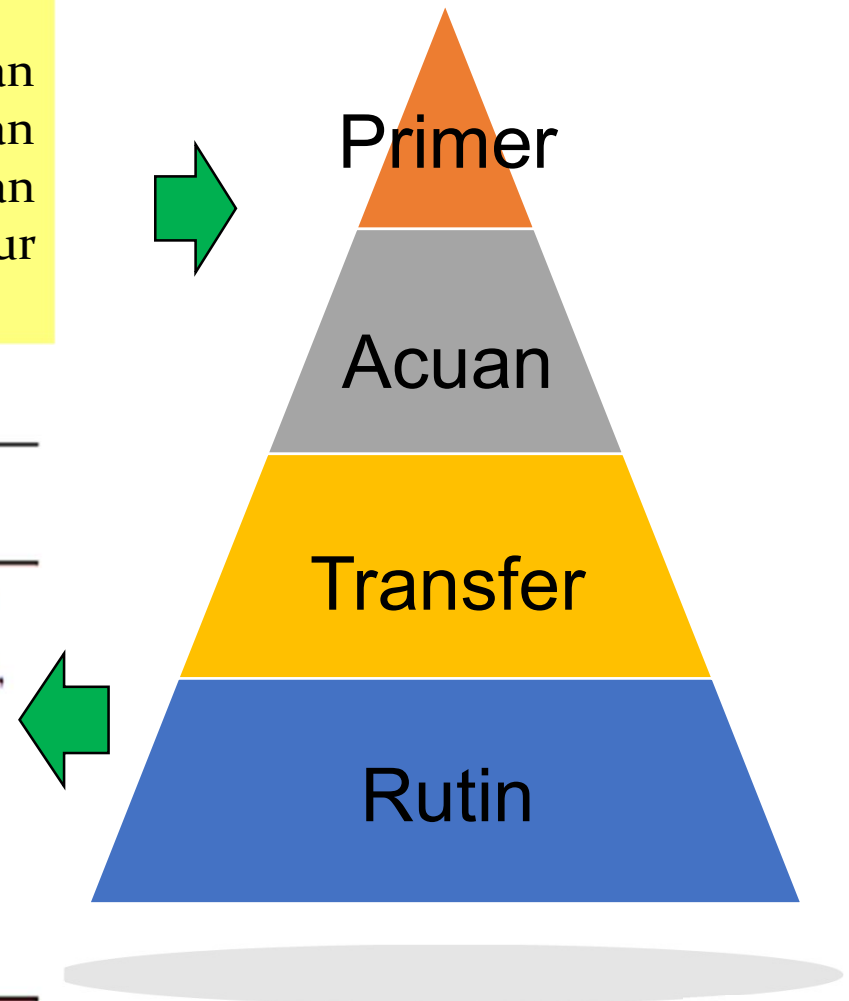
Dosimeter dan Jenisnya



APA ITU DOSIMETER?

Perangkat yang ketika diiradiasi, menunjukkan perubahan kuantitatif yang dapat dikaitkan dengan dosis yang diserap dalam suatu bahan menggunakan instrumen dan prosedur pengukuran yang tepat.

Class	Calibration necessary?	Uncertainty ($k = 1$)	Examples
Primary	No	1%	Calorimeter, ionization chamber
Reference	Yes	2-3%	Calorimeter, alanine, dichromate, ceric-cerous, ECB, Fricke,
Transfer	Yes	3-5%	Alanine, Fricke, dichromate, ceric-cerous, ECB
Routine	Yes	$\approx 5\%$	PMMA, radiochromic films, CTA, ceric-cerous, ECB



Dosimeter dan Standarnya



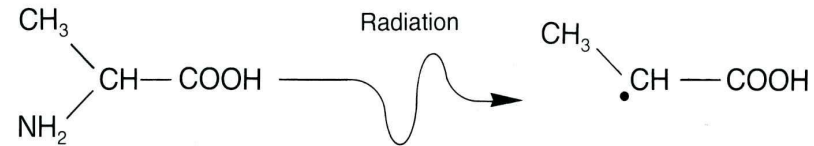
Dosimeter system	Method of analysis	Useful dose range, Gy	Nominal precision limits	References
Fricke solution	UV – spectro- photometry	$3 \times 10^{-2} - 4 \times 10^2$	1 %	ASTM E 1026 - 04
Ceric – cerous sulphate	UV – spectro- photometry	$10^3 - 10^6$	3 %	ISO/ASTM 51205
Potassium dichromate	UV-VIS spectrophotometry	$5 \times 10^3 - 4 \times 10^4$	1 %	ISO/ASTM 51401
Ethanol-mono- chlorobenzene	Titration, or HF oscillometry	$4 \times 10^2 - 3 \times 10^5$	3 %	ISO/ASTM 51538
L - alanine	EPR	$1 - 10^5$	0.5 %	ISO/ASTM 51607
Perspex systems	VIS - spectro- photometry	$10^3 - 5 \times 10^4$	4 %	ISO/ASTM 51276
FWT – 60 film	VIS - spectro- photometry	$10^3 - 10^5$	3 %	ISO/ASTM 51275
B 3 film	VIS - spectro- photometry	$10^3 - 10^5$	3 %	ISO/ASTM 51275
Cellulose triacetate	UV – spectro- photometry	$10^4 - 10^6$	3 %	ISO/ASTM 51650
Calorimetry	Resistance/ temperature	$1.5 \times 10^3 -$ 5×10^4	2 %	ISO/ASTM 51631

Prinsip Dosimeter



Pengukuran Dosis berdasarkan variasi metode:

- Peningkatan Temperatur (Kalorimeter)
- Perubahan Warna (Radiochromic, PMMA)
- Konsentrasi Radikal Bebas (Alanine)
- Perubahan Konduktivitas (ECB)
- Oksidasi Kimia Radiasi (Fricke)
- Pengurangan Kimia Radiasi (ceric-cerous, dichromate)



Primary standard dosimeters
• 1 Kali kalibrasi



Reference standard dosimeters
• Kalibrasi oleh Lab nasional atau Lab terakreditasi



Transfer standard dosimeters
• Kalibrasi oleh Lab nasional atau Lab terakreditasi



Routine dosimeters
• Kalibrasi fasilitas / *in-plant*



Dosimeter Standar Primer



01

Dosimeter dengan kualitas metrologi tertinggi, ditetapkan dan dipelihara sebagai standar dosis serap oleh organisasi standar nasional atau internasional untuk kalibrasi lingkungan radiasi

02

Aplikasi berdasarkan pengukuran kuantitas fisika dasar

03

Contoh : Kalorimeter Rentang dosis 1,5 – 50 kGy

ISO/ASTM 51631:2003 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Routine Dosimeter Calibrations



Dosimeter Standar Acuan



Dosimeter dengan kualitas metrologi tinggi, digunakan sebagai standar untuk memberikan pengukuran yang dapat ditelusur ke pengukuran yang dilakukan oleh dosimeter standar primer



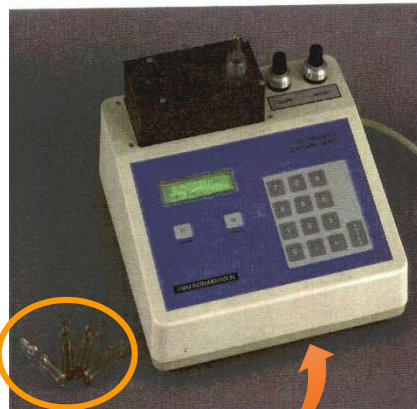
Membutuhkan kalibrasi dan digunakan untuk mengkalibrasi lingkungan radiasi dan dosimeter rutin

Contoh :

- Fricke
- Potassium dichromate



Fase Cairan



Fase Padatan

Contoh : Alanine



- ethanol-monochlorobenzene
- ceric-cerous



Dosimeter Standar Acuan



Dosimeter Fricke

- Rentang dosis pengukuran = 40 – 400 Gy
- Alat Ukur = UV-Vis Spektrofotometer
- Pembacaan Panjang Gelombang = 305 nm



Dosimeter Alanine

- Rentang Dosis pengukuran = 10 Gy – 100 kGy
- Alat Ukur = Electron Spin Resonance (ESR)



Dosimeter Standar Transfer



Sistem perantara dengan kualitas metrologi yang tinggi, digunakan untuk mentransfer informasi dosis dari laboratorium standar ke fasilitas iradiasi untuk ketertelusuran

Membutuhkan kalibrasi

Contoh dosimeter transfer



- Alanine
- Ethanol-Monochlorobenzene (ECB)
- Potassium dichromate
- Ceric-cerous



Dosimeter Rutin



01

Digunakan untuk pemetaan dosis serap dan kontrol rutin proses iradiasi



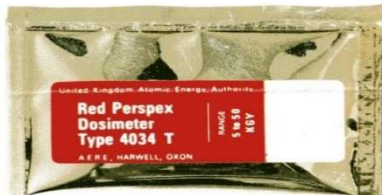
02

Mebutuhkan kalibrasi terhadap dosimeter acuan



03

Contoh dosimeter rutin:



Perspex
(Red dan Amber)



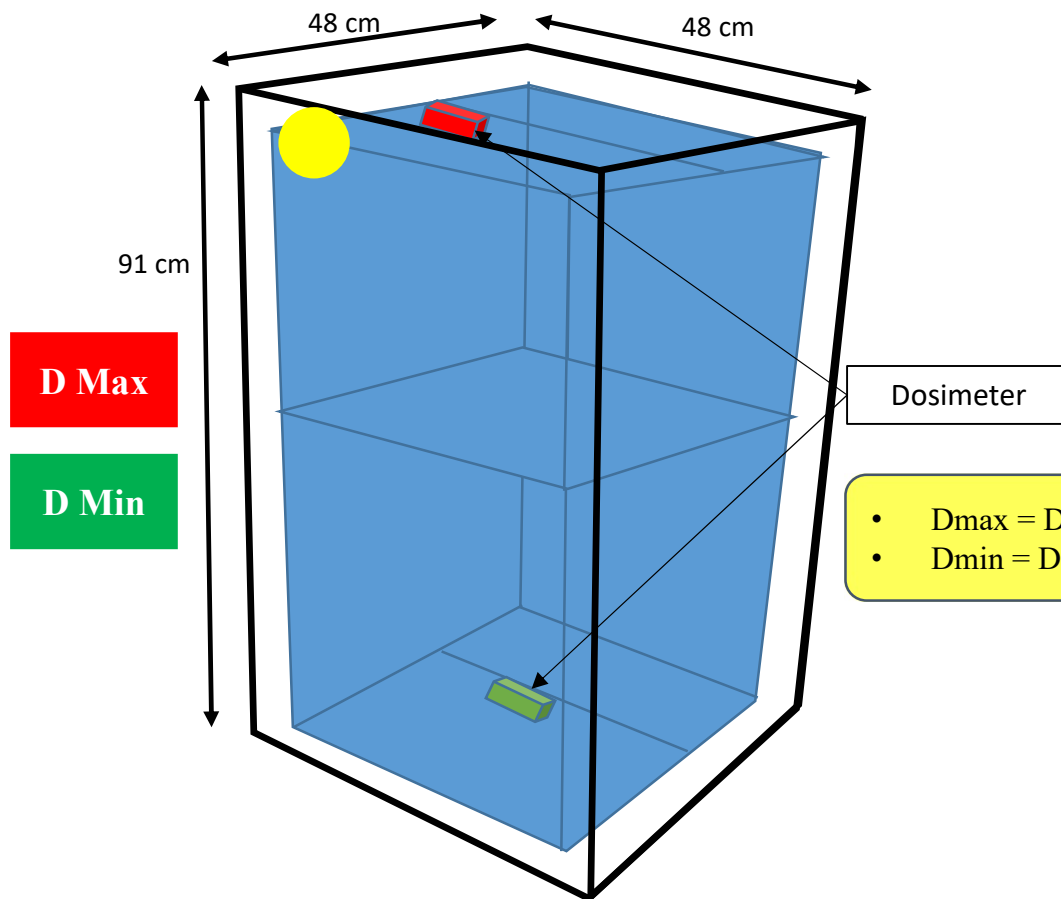
Radiochromic film (B3, FWT, Gafchromic)



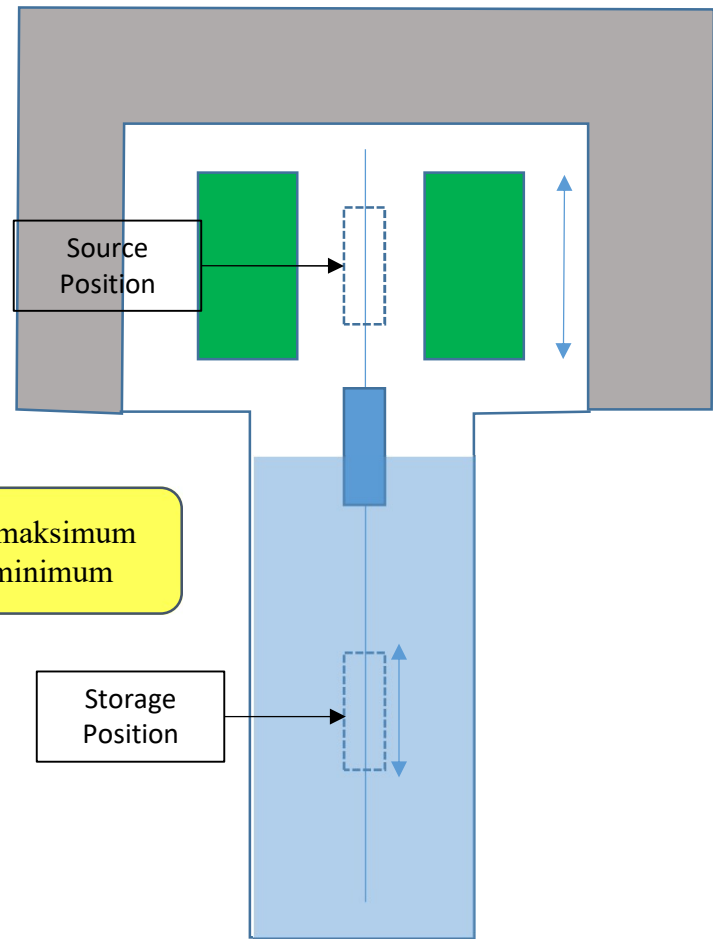
Macam Dosimeter Rutin

NO	DOSIMETER	PERALATAN	RANGE DOSIS (kGy)
1.	Clear perspex	Spectrophotometer	1 - 100
2.	Dyed perspex	Spectrophotometer	1 - 50
3.	Ceric cerous sulphate	Potentiometry Spectrophotometer	or 1 - 100
4.	Ferrous-cupric dosimeter	Spectrophotometer	1 - 30
5.	Cellulose triasetate	Spectrophotometer	10 - 400
6.	Radiochromic dye films, solution, optical wave guide	Spectrophotometer	0.001 - 100

3. Kontrol Rutin



- Dmax = Dosis maksimum
- Dmin = Dosis minimum



- Posisi sumber tampak atas

- Kalibrasi dosis dilakukan setiap 3 bulan sekali
- Untuk kontrol rutin, dosimeter dipasang pada setiap batch proses

1. Kalibrasi Laju Dosis



2. Pemetaan Distribusi Dosis Serap



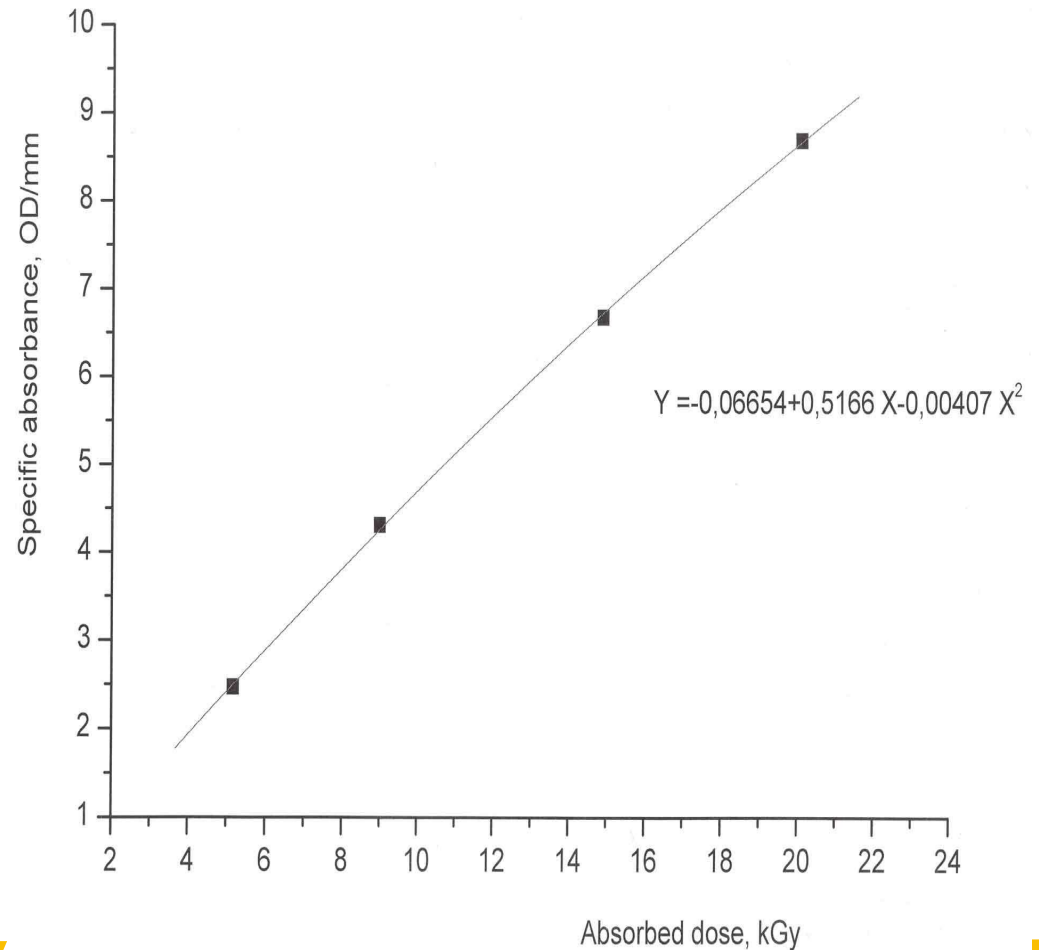
3. Kontrol Rutin Dosis



Tujuan Kalibrasi



- **Memastikan respon dosimeter dan dosis serap.**
- **Influence factors:**
 - dose rate
 - temperature
 - storage (time, conditions)
 - humidity
 - light
- **Meminimalisir efek dari faktor pengaruh melalui optimalisasi kondisi kalibrasi**



Kalibrasi



○ Calibration of dosimeter

• Calibration of equipment



Kalibrasi



- - **Spectrophotometer:**
- **absorbance and wavelength scale with calibrated optical filters;**

- - **Thickness gauge:**
- **calibrated gauge blocks;**

- - **Thermometers:**
- **calibrated thermometers;**

- - **Resistance measurement (Ohm-meter for calorimeters):**
- **calibrated reference resistor;**

- - **Humidity meters:**
- **saturated salt solutions;**

Kalibrasi



- - **Dose range:**
- **Larger dose range than intended use;**

- **Number of dose points: (4 dosimeters at each point)**
- **Dose range less than one decade: 5 points (at least)**
- - **arithmetically (10 - 20 - 30 - 40 - 50 kGy);**
- **Dose range greater than one decade: 5 points (at least) per decade**
- - **geometrically (1 - 1.5 - 2.3 - 3.4 - 5.1 - 7.6 - 11.4 - 17 - 26 - 38 - 58 - 87 kGy);**

- - **Batch calibration:**
- **Each new batch must be calibrated (annual checks);**
- **Don't use manufacturers's calibration curve - unless verified;**

1. Kalibrasi Laju Dosis



Tujuan :
Mendapatkan hubungan antara respons dosimeter dengan dosis aktual



Dosimeter diukur pada Lab Standar kemudian hasilnya dikirim ke fasilitas

01

Dosimeter standar (Alanine) dari Lab standar sekunder di kirim ke fasilitas

02

Dosimeter dikembalikan ke Lab standar sekunder

03

04

Verifikasi laju dosis pada fasilitas

05

1. Kalibrasi Laju Dosis

Dose Range : 20 Gy – 887 Gy



HDRL 19C-109A
Page 4 of 6

HDRL

Riso High Dose Reference Laboratory
Technical University of Denmark
DTU Nutech, Bld. 201
DK 4000 Roskilde
Denmark

Tel +45 4677 4224
Fax +45 4677 4050
e-mail arni@dtu.dk

Riso High Dose Reference Laboratory is
accredited by *DANAK - Danish Accreditation*

Irradiation data (information provided by user)

Facility: Gamma Cell 220 Upgrade BATAN

Date of irradiation [yyyy.mm.dd]	Serial no. BK616	Approx. Dose [Gy]	Temp. (start) [°C]	Temp. (end) [°C]
2019.10.15	892	20.0	30.8	33.4
2019.10.15	893	30.5	30.9	32.8
2019.10.15	894	46.5	33.5	34.7
2019.10.15	895	70.8	32.6	33.5
2019.10.15	896	107.9	30.2	33.3
2019.10.15	897	164.5	30.3	33.6
2019.10.15	898	250.7	33.2	34.6
2019.10.15	899	382.0	32.7	35.4
2019.10.15	900	582.2	33.8	35.9
2019.10.15	901	887.3	31.1	36.8
Control	0	0	--	--
Irr. control	BK158	10	25	25



Measurement data

Received at Riso: 2019
Measured: 2019
Instrument: Bruk
Environment: Tem
Rel.

Results (dose to water, kGy)

Serial no. BK616	Irr. Temp., T_{20} [°C]	Dose [Gy]	Overall uncertainty ($k=2$)	
			[Gy]	[%]
892	32.9	28	0.9	3.3
893	32.2	38	1.3	3.3
894	34.3	54	1.7	3.2
895	33.2	77	2.5	3.2
896	32.3	116	3.7	3.2
897	32.5	174	5.6	3.2
898	34.1	264	8.5	3.2
899	34.5	400	12.9	3.2
900	35.2	603	19.5	3.2
901	34.9	918	29.6	3.2
BK158	The irradiated control dosimeter was measured before and after shipment: No change observed within measurement uncertainty ($k=2$)			

Reference Dosimeter Certificate

Certificate no.: 19C-109A

Measurement with **alanine reference** dosimeters irradiated at the customer's facility
according to HDRL instruction HDRL-I-15 and HDRL-I-16.

Customer: National Nuclear Energy Agency of Indonesia
Centre for Isotope and Radiation Application
Lebak Bulus Raya Street No.49
Pasar Jumat, South Jakarta
Indonesia 7002 JKSL

Order no.-reference: 266/PO/September 19 DTU - Mrs. Irmawati

File 19C-109A Batan
Date 2019.11.07

Signature

Arne Miller
Head of Riso HDRL

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1. Kalibrasi Laju Dosis

Dose Range : 1,35 K Gy – 60 K Gy



HDRL 19C-109B
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HDRL

Riso High Dose Reference Laboratory
Technical University of Denmark
DTU Nutech, Bld. 201
DK 4000 Roskilde
Denmark

Tel +45 4677 4224
Fax +45 4677 4959
e-mail armi@dtu.dk

Riso High Dose Reference Laboratory is
accredited by DANAK - Danish Accreditation

Reference Dosimeter Certificate

Certificate no.: 19C-109A

Measurement with **alanine reference** dosimeters irradiated at the customer's facility
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Signature

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Head of Riso HDRL

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Irradiation data (information provided by user)

Facility: Gamma Cell 220 Upgrade BATAN

Date of irradiation [yyyy.mm.dd]	Serial no. BK616	Approx. Dose [Gy]	Temp. (start) [°C]	Temp. (end) [°C]
2019.10.15	902	1352.4	33.6	36.9
2019.10.15	903	2061.6	32.4	37.1
2019.10.16	904	3141.3	32.1	35.3
2019.10.16	905	4787.5	33.8	36.6
2019.10.16	906	7296.6	31.8	36.6
2019.10.16	907	11120.5	31.6	36.1
2019.10.17	908	16948.5	30.8	36.2
2019.10.17	909	25830.8	32.0	37.6
2019.10.18	910	39368.1	30.3	37.1
2019.10.18	911	60000.0	33.8	44.7
Control	0	0	--	--
Irr. control	BK159	10	25	25



Measurement data

Received at Riso:

Measured:

Instrument:

Environment:

Results (dose to water, kGy)

Serial no. BK616	Irr. Temp., T_{eff} [°C]	Dose [kGy]	Overall uncertainty ($k=2$)	
			[Gy]	[%]
902	35.8	1.39	0.05	3.2
903	35.5	2.12	0.07	3.2
904	34.2	3.22	0.10	3.2
905	35.7	4.93	0.16	3.2
906	35.0	7.58	0.24	3.2
907	34.6	11.5	0.37	3.2
908	34.4	17.5	0.56	3.2
909	35.7	26.7	0.86	3.2
910	34.8	40.9	1.3	3.2
911	41.1	63.0	2.0	3.2
BK159	The irradiated control dosimeter was measured before and after shipment: No change observed within measurement uncertainty ($k=2$)			



Dosimeter fricke diiradiasi pada beberapa titik waktu tertentu dengan pengulangan 3x



Mengukur absorbansi menggunakan spektrofotometer



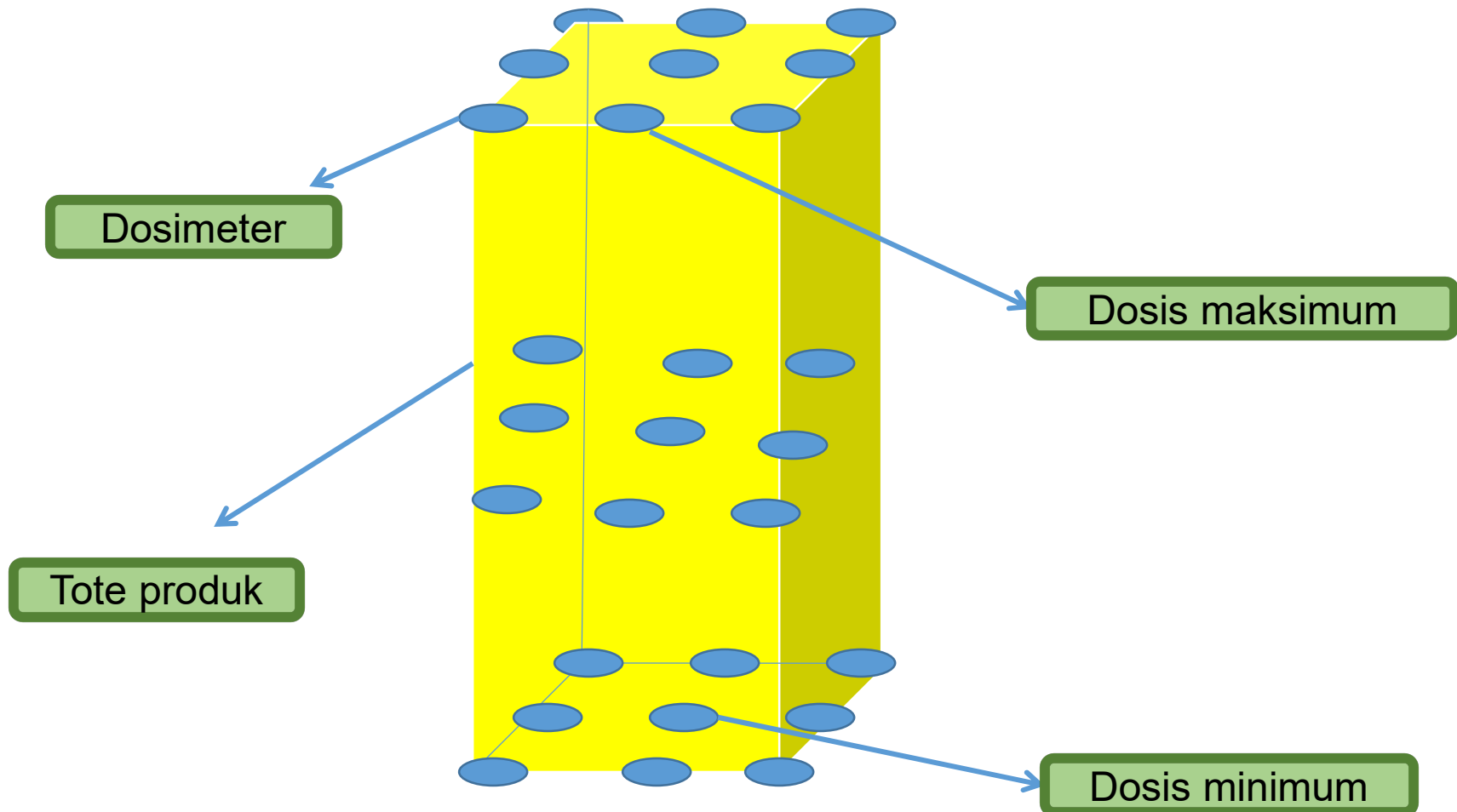
Didapatkan laju dosis sebagai acuan iradiasi rutin/kontrol



Didapatkan kurva kalibrasi dan persamaan fungsi

2. Pemetaan Distribusi Dosis

- 27 Dosimeter ditempatkan pada 27 titik dalam tote
- Didapatkan posisi untuk dosis maksimum dan minimum



Verifikasi Fasilitas Iradiator



1. Food Irradiation Facility and Operator Details

- 1.1. What are the name and address of the facility?
- 1.2. What is the general layout of the irradiation facility, what conveyor system is used (if appropriate) and what is the size and type of irradiation container?
- 1.3. Is the facility designed to irradiate products continuously or batch-wise?
- 1.4. What is the legislation that the organization needs to comply with? [For example, national and international]⁴
- 1.5. What is the management structure at the facility?

3. Regulatory Authority Control

These questions may only be necessary when the auditors are in facilities which are not in their home countries.

- 3.1. Which national regulatory authority(s) (including national plant protection organizations) are responsible for the following:
 - Licensing the irradiation facility?
 - Prior approval to irradiate food?
 - Official control and audit of the facility?

[Useful information to gather includes: dates of regulatory visits, people met, time spent at the facility, any non-compliance found, written reports, reported remarks, deadlines for correction, corrective actions implemented and follow-up visits]
- 3.2. Which licences or permits have been issued for the irradiation of food? [It may be useful to obtain a copy of the licence, permit or official documentation relating to the official approval to irradiate food]
- 3.3. What official control and supervision does the regulatory authority perform?

2. Product Information

- 2.1. What type of food is irradiated?
- 2.2. What is the purpose of irradiation?
- 2.3. Is it unprocessed (raw) food, or has it been processed or manufactured?
- 2.4. Is any other treatment combined with irradiation of the product?

4. Radiation Source

- 4.1. What type of ionizing radiation is used to process the food? [For example, gamma ray, electron beam and X ray]

For radionuclide sources

- 4.2. Which radionuclide is used? [For example, ¹³⁷Cs or ⁶⁰Co]
- 4.3. What is the current activity of the radionuclide source (in Bq or Ci)?
- 4.4. When was the last replenishment, when and how much was the loading?
- 4.5. How is the radiation source stored when not in operation (e.g. water pool or dry store)?
- 4.6. Is there a positive indication of the correct operational and the correct safe position of the radiation source, and is it interlocked with the product movement system?



5. Dosimetry

- 5.1. What types of dosimeter are used for dose validation and routine dose measurements?
[Are the dosimeters suitable for the application, and has the impact of environmental conditions (e.g. low temperature for frozen foods) on dose reading been accounted for?]
- 5.2. How are dosimeters calibrated, and is the dose traceable to a national standard?
- 5.3. What is the uncertainty in the dose measurement?
- 5.4. Are reference dosimeters used to verify the calibration of dosimeters?
- 5.5. What procedure is used for dose validation?
- 5.6. What is the position and magnitude of minimum and maximum dose in the product to be irradiated?

6. Food Irradiation Process Control

Product

- 6.1. Have all the process variables been identified?
- 6.2. Is the product to be treated fit for irradiation?
- 6.3. Is the food product prepacked, or is it treated in bulk?
- 6.4. What are the characteristics of the packaging material (suitability, hygienic condition, transport and handling)?
- 6.5. Are there standard operating procedures and quality assurance procedures in place to control the irradiation of food?
[Are they up to date, accurate and cover all relevant aspects? Are they used by the operator? What evidence is there that people use these procedures? It may be useful to obtain copies of these documents]
- 6.6. What measures have been taken to ensure that treated and untreated foods are separated at all times?

7. Records and Documentation

Product traceability

- 7.1. What is the format and content of records kept for each batch of treated food?
[For example, nature and type of product being treated, packaging identification marks or shipping details, bulk density, type of source or electron machine, dosimetry, dosimeters used (calibration details) and date of treatment]
- 7.2. How long are records kept and in what form?
- 7.3. What documentation accompanies irradiated food destined for export?
- 7.4. What are the details of labelling used to identify the product or details of shipping documentation?

Process control

- 7.5. What records are maintained for each irradiation batch of food?

Dosimetry

- 7.6. What records are kept of dosimetry measurements?
[For example, archives, calibration log, calibration schedule and other records]

Personnel training

- 7.7. What are the qualifications of those responsible for validation, routine control, operation and maintenance of the facility?
[For example, academic qualifications, formal training and work experience]

8. Packaging and Labelling

- 8.1. What is the labelling of the prepackaged foodstuffs?
[For example, are they labelled as 'irradiated' or 'treated with ionizing radiation'? Are any special logos used (e.g. Radura)? Is the name of the food clear, is there a list of ingredients, a date of minimum durability, the name and address of the manufacturer/packager? Are there any special storage instructions or any instructions for use?]
- 8.2. What shipping documents are used?
[Do these documents state that the food is irradiated? Do they identify the irradiation facility in some way, do they include the date of irradiation treatment, do the papers identify the food and the lot or batch number of the food products?]

- Soal -

1. Berapa kategori iradiator gamma?
2. Sumber bergerak, penyimpanan kolam. Kategori berapakah iradiator tersebut?
3. Berapa jenis klasifikasi dosimetri? Sebutkan!
4. Sebutkan 3 jenis dosimeter Acuan!
5. Sebutkan 2 Jenis dosimeter Rutin!

- Kesimpulan -

1. Terdapat 4 kategori iradiator gamma, yaitu kategori I, II, III, IV.
2. Terdapat 4 klasifikasi dosimeter, yaitu primer, acuan, transfer dan rutin
3. Dosimeter primer hanya perlu dikalibrasi 1 kali.
4. Kalibrasi dosimeter acuan harus mengacu pada laboratorium standar nasional atau internasional
5. Dosimeter rutin harus mengacu pada hasil kalibrasi dosimeter acuan

Terima Kasih



BADAN TENAGA NUKLIR NASIONAL



Jl. Kuningan Barat, Mampang Prapatan Jakarta, 12710



(021) 525 1109 | Fax. (021) 525 1110



humas@batan.go.id



Humas Batan



@humasbatan



badan_tenaga_nuklir_nasional



Humas Batan

Phone Number / WA

0813 1941 7800

