Radiation Processing Management Facility

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Pelatihan Penyegaran Petugas Iradiator

Direktorat Pengembangan Kompetensi BRIN - 2025

PROFILE

- Bimo Saputro

- Sarjana – Fisika Nuklir, Politeknik Teknologi Nuklir Indonesia (STTN-BATAN) 2012-2016
- Magister – Fisika, Universitas Indonesia 2023-2024

- Honda Motor Ltd. 2016-2017
- BATAN 2018-2021
- BRIN 2021-Current

- Fellowship on Gamma Radiation Facility at Vinca, Belgrade, Serbia 2019
- Online Training Course by IAEA Expert (Andras Kovacs, Hungary) on Radiation Dosimetry 2020
- Fellowship on Radiation Dosimetry at Aerial CRT, Strasbourg, France 2021
- Scientific Visit on Radiation Processing Technology at KAERI, Jeungup, Korea 2022
- Workshop Accelerating the Adoption of eBeam/X-ray technologies in Asia and the Pacific Daejeon, Korea 2022
- Regional Project on eBeam Application in Asia-Pacific. Daejeon, Korea 2023
- IAEA Research Project on Dosimetry at Aerial CRT Strasbourg, France 2023

- Speaker on International Conference on Applications of Radiation Science and Technology at IAEA Vienna, Austria 2022
- Speaker on International Meeting on Radiation Processing IMRP at TINT Bangkok, Thailand 2022
- Speaker on International Meeting on Radiation Processing IMRP at San Jose, Costa Rica 2024
- Speaker on Regional Workshop on eBeam Application at Ho Chi Min, Vietnam 2024

What is your basic document in operations management?

- ISO 9001:2015 Quality management systems — Requirements
- ISO 11137-1:2006 Sterilization of health care products — Radiation

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

- ISO 11137-2:2013 Sterilization of health care products — Radiation

Part 2: Establishing the sterilization dose

- ISO 11137-3:2017 Sterilization of health care products — Radiation

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

- ISO/TS 11137-4:2020 Sterilization of health care products — Radiation

Part 4: Guidance on process control

- ISO 14470:2011 Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

HIGHLIGHT AGENDA

1. ISO 9001

2. ISO 11137-1-2-3 (ISO 13485)

3. Perka BPOM 3 TAHUN 2018 dan Perka BAPETEN 6 TAHUN 2023

1 ISO 9001

ISO 9001

4 Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the quality management system
4.4 Quality management system and its processes

5 Leadership
5.1 Leadership and commitment
5.2 Policy
5.3 Organizational roles, responsibilities and authorities

6 Planning
6.1 Actions to address risks and opportunities
6.2 Quality objectives and planning to achieve them
6.3 Planning of changes

7 Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information

8 Operation
8.1 Operational planning and control
8.2 Requirements for products and services
8.3 Design and development of products and services
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products and services
8.7 Control of nonconforming outputs

ISO 9001

9 Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation
9.2 Internal audit
9.3 Management review

10 Improvement
10.1 General
10.2 Nonconformity and corrective action
10.3 Continual improvement

KEY POINT

7.1.5.2 Measurement Traceability
When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing conficence in the validity of measurement result: (a) calibrated, or verified; (b) identified

8.1 Operational Planning and Control
(a) Determining requirement for the product and services; (b) establishing criteria; (c) determining the resources needed to achieve conformity

2 ISO 11137 Part 1

Content of Document

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

Content of ISO 11137-1

4 Quality Management

4 Quality Management System Elements

Major reference for quality systems:
ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes

4.3 Product realization
4.3.4 Dosimetry used in the development, validation and routine control of the sterilization process **shall have measurement traceability** to national or international standards and **shall have a known level of uncertainty**

5 Sterilizing Agent

5 Sterilizing agent characterization
Sterilizing agent characterization - not needed for radiation

However: Radiation Energy

5.1.1 The type of radiation to be used in sterilization processing shall be specified.

5.1.2 For electrons or X-rays, the energy level of the electron beam shall be specified. If the energy level **for electrons exceeds 10 MeV** or the energy level for electrons used to generate **X-rays exceeds 5 MeV**, the potential for induced radioactivity in product shall be assessed. The outcome of the assessment and the rationale for decisions reached shall be documented.

Note: US FDA is unconcerned with x-ray **energy up to 7.5 MeV, for medical** devices. For food, the limit **remains at 5 MeV**

7 Product Definition

7 Product definition

7.1 Product to be sterilized, including packaging materials, shall be specified.

7.4 Introducing ”product family” Group of produts based on microbiological properties. For example, tested together for sterilisation dose establishment, and having the same sterilisation dose.

7.5 – 7.6 Introducing ”processing category” Group of products that can be processed together. Can be based on, for instance, composition, density or dose requirements.

9 Validation

9 Validation

Definition EN ISO 11137-1
3.47 validation

- documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.
- These conditions include sterilization dose and maximum acceptable dose.

9.1 Installation qualification
3.16 - installation qualification - IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. Whether or not data are “in accordance with their specification” depends on agreement between supplier and user

Operational Qualification

9.2 Operational qualification

3.22 Operational qualification - OQ
Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

9.2.2 OQ shall be carried out by irradiating appropriate test material to demonstrate the capability of the equipment to deliver the sterilization process that has been defined. provides baseline data to show consistent operation of the facility

9.2.4 Dose maps must be made with fully loaded irradiation chamber

9.2.5 OQ dose mapping shall be carried out on a sufficient number of
irradiation containers to allow determination of the distribution and variability of dose between containers.

Operational Qualification

12.4.1 Requalification of a sterilization process shall be carried out for defined product and specified equipment; it shall be performed at defined intervals and after the assessment of any change (see 12.5). The extent to which requalification is carried out shall be justified.

12.5.1 Any change in the irradiator which could affect dose or dose distribution shall be assessed. If one or both of these is judged to be affected, then a repeat of part or all of IQ, OQ and/or PQ shall be carried out.

Peformance Qualification

9.3.1 Concerns dose mapping of real product
to identify the location and magnitude of minimum and maximum doses and to determine the relationship between the min and max doses and the routine monitoring dose

It is impossible to measure dose everywhere in/on an irradiated product. Where to measure?
Strategies for dose mapping based on:

- OQ measurements
- Inhomogeneous product distribution, orientation, voids, interfaces.
- Monte Carlo calculations of dose distributions can help choosing measurement locations and might in the future replace (at least some) measurements

3 ISO 11137 Part 2

11137- Part 2

Part 2: Establishing the sterilization dose

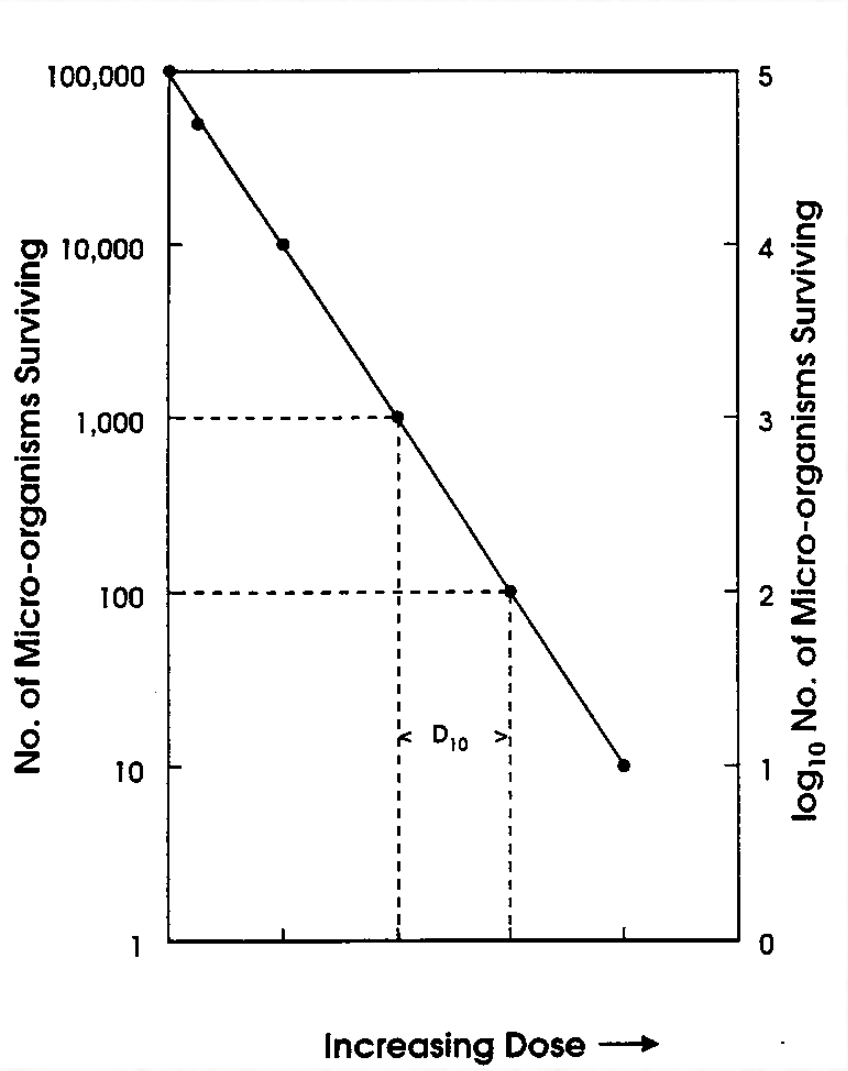
One of two approaches, as described in a) and b) below, shall be taken in establishing the sterilization dose:

- ❑ a knowledge of the number and/or resistance to radiation of the bioburden is obtained and used to set the sterilization dose; or
- ❑ a sterilization dose of 25 kGy or 15 kGy is selected and substantiated. In substantiating a sterilization dose of 25 kGy or 15 kGy (ISO 11137-2) or to other doses (ISO TS 13004), the primary manufacturer shall have evidence that the selected sterilization dose is capable of achieving the specified requirements for sterility

11137- Part 2

Sterilization
Logarithmic plot of typical bacterial survival curve

“Sterile”: Probability of finding one viable microorganism per product item less than or equal to 10e-6.
i.e. Sterility Assurance Level (SAL) ≤ 10e-6



11137- Part 2

Method 1

1. Determine the bioburden (EN ISO 11737-1)
2. Find the verification dose in table 5, ISO 11137-2, for SAL = 10^{-2} for the bioburden.
3. Irradiate 100 product units with the verification dose.
4. Test each of the irradiated product units for sterility (ISO 11737-2).
5. If there are no more than 2 positives (2 non-sterile) of the 100 product units, read from table 5 the dose for sterilization (SAL = 10^{-6}).

If Method 1 fails:

Obtain measurement of resistance of microbial contamination → Method 2.

Or, substantiate the sterilizing dose → Method VD_{max}.

11137- Part 2

Sterilization

Method 2:

Based on tests of sterility for samples irradiated with increasing doses.

Total of 840 samples to be tested.

2 points on the survival curve are found:

1) 3 cfu per item
2) SAL = 10^{-2}

Extrapolation to SAL = 10^{-6} for finding sterilization dose

Method VD_{max}^{25}

Substantiate 25 kGy

Max bioburden: 1000 cfu/unit

Method VD_{max}^{15}

Substantiate 15 kGy

Max bioburden: 1.5 cfu/unit

11137- Part 2

Aspect	Method 1	Method 2
Approach	Bioburden-based with verification dose	Incremental dose-response testing
Complexity	Simpler, fewer steps	More complex, requires multiple dose steps
Time Required	Shorter validation period	Longer due to multiple dose assessments
Dose Optimization	No optimization, relies on pre-set dose	Can optimize dose to minimize material degradation

Vdmax 25
•Used to verify a **sterilization dose of 25 kGy**.
•Requires demonstrating that a **verification dose (≤10.1 kGy)** results in a microbial survival probability consistent with a **Sterility Assurance Level (SAL) of 10^{-6}**.
•If the product passes the verification dose test, the **25 kGy dose is validated** for routine sterilization.

Vdmax 15
•Used to verify a **lower sterilization dose of 15 kGy** (typically for radiation-sensitive materials).
•Requires demonstrating that a **verification dose (≤7.1 kGy)** achieves the required microbial inactivation level.
•If successful, the **15 kGy dose is validated**, allowing for **reduced radiation exposure** to prevent material degradation.

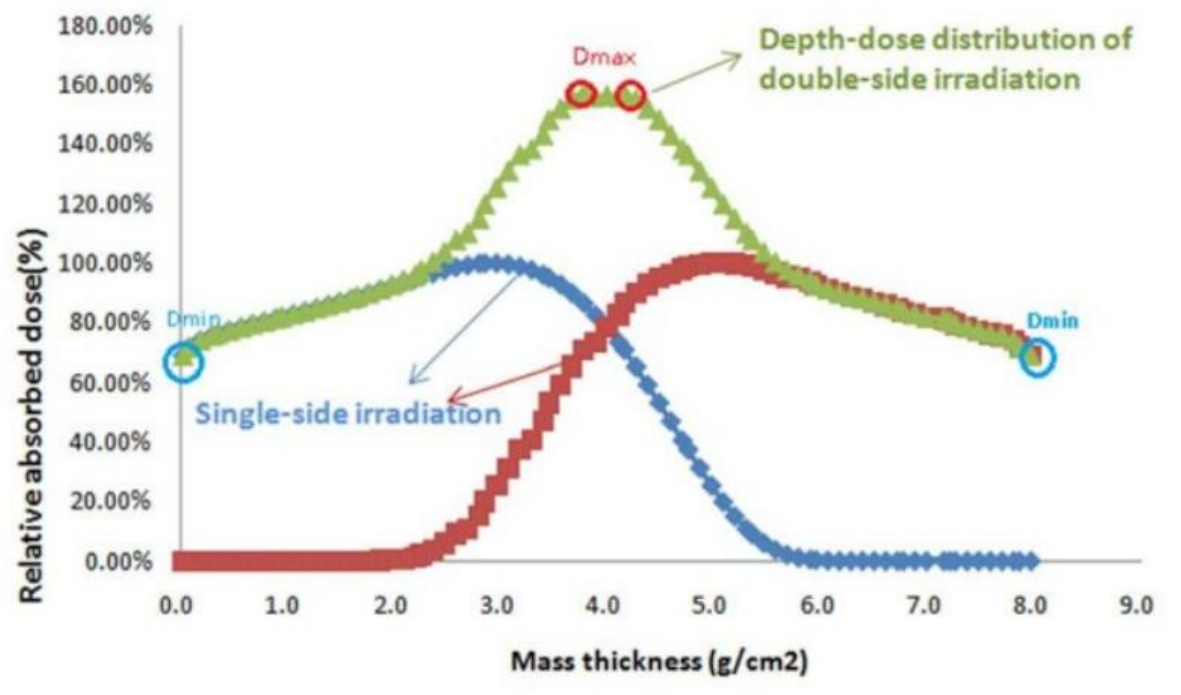
4 ISO 11137 Part 3

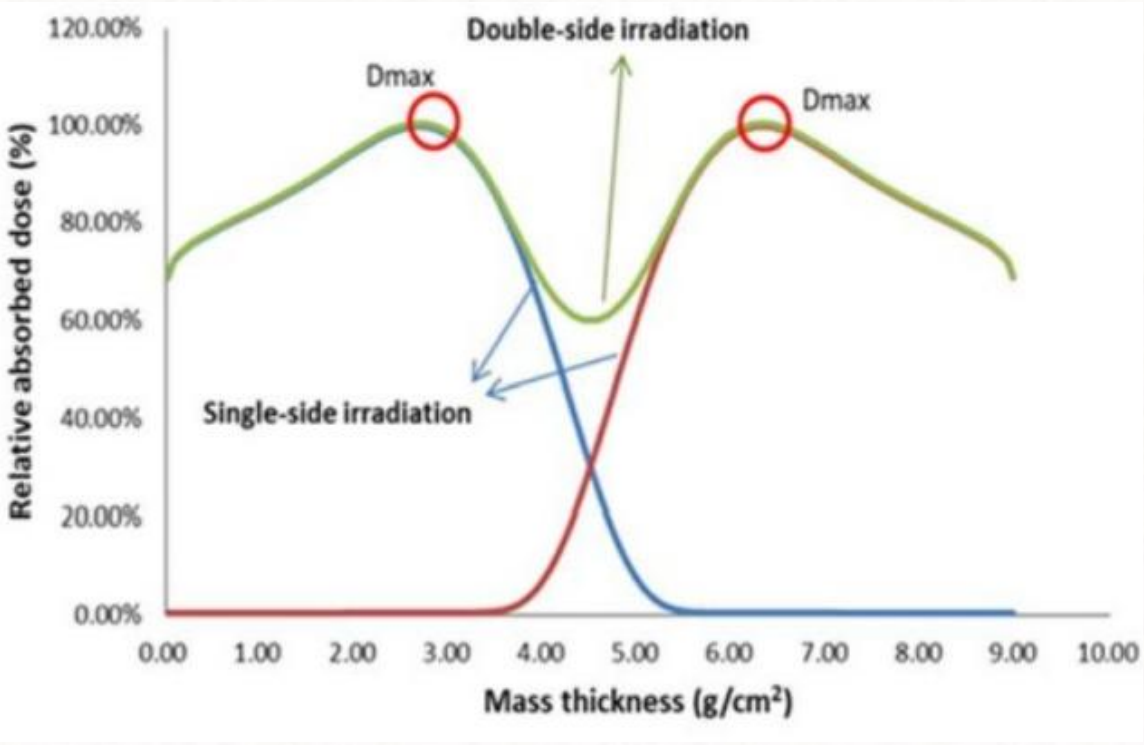
ISO 11137 Part 3

3.1.5
dose uniformity ratio
ratio of the maximum to the minimum *absorbed dose* (3.1.1) within the irradiation container

3.1.6
dosimetry system
interrelated elements used for determining *absorbed dose* (3.1.1), including dosimeters, instruments, associated reference standards and procedures for their use

ISO 11137 Part 3





ISO 11137 Part 3

3.1.4
direct dose measurement
measurement of *absorbed dose* (3.1.1) with a dosimeter at the location of interest
Note 1 to entry: For example, a direct measurement of minimum dose is made with a dosimeter at the minimum dose location in an irradiation container.

3.1.8
indirect dose measurement
measurement of *absorbed dose* (3.1.1) at a location remote from a directly measured dosimeter, calculated by the application of factors
Note 1 to entry: For example, where the minimum dose in an irradiation container cannot easily be measured directly, a dosimeter placed in a remote location may be measured and factors applied to that measurement to calculate the minimum dose.

ISO 11137 Part 3

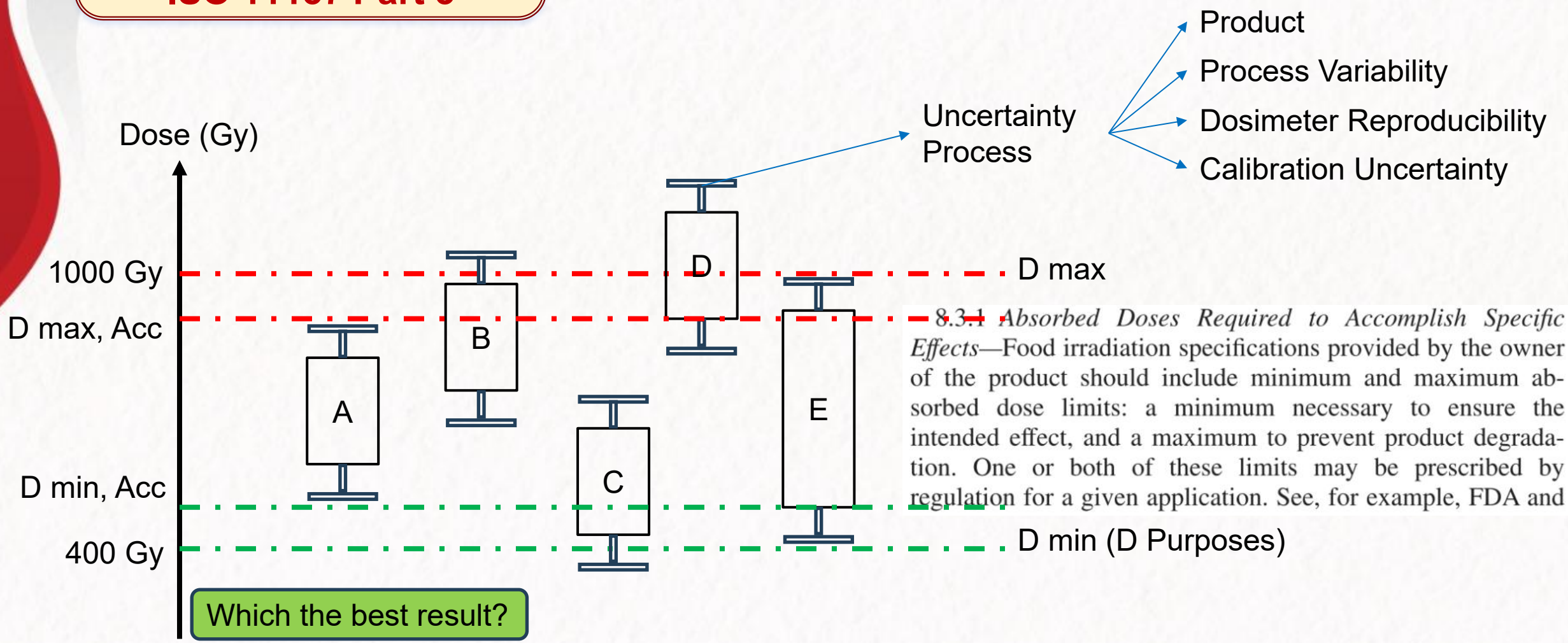
The uncertainty components associated with direct or indirect measurement of dose in an irradiation container can be subdivided as given below:

— the uncertainty reported by the calibration standards laboratory;
— the uncertainty due to mathematical fitting of the calibration function;
— the uncertainty related to the effect of environmental influence quantities on dosimeters during calibration and use;
— the uncertainty related to the reproducibility of the monitoring dosimeter;
— the uncertainty, for indirect measurements, in dose ratios derived from dose mapping;
— the uncertainty, if applicable, for indirect measurements, arising from variations in irradiator dose delivery between the irradiation of the monitoring dosimeter and the irradiation of the container in which it is required to estimate the dose.

ISO 11137 Part 3

ISO 11137 Part 3

ISO 11137 Part 3



8.3.1 *Absorbed Doses Required to Accomplish Specific Effects*—Food irradiation specifications provided by the owner of the product should include minimum and maximum absorbed dose limits: a minimum necessary to ensure the intended effect, and a maximum to prevent product degradation. One or both of these limits may be prescribed by regulation for a given application. See, for example, FDA and

ISO 11137 Part 3

Experimental

- GEX Windose B3 and alanine were used for dose mapping
- 10 MeV E-Beam double sided irradiation along the Z axis
- Dosimeters placed at suspected minimum and maximum dose zones

Organized box

- DUR (alanine)= 1.55
- DUR (B3) = 1.57

Unorganized box

- DUR (alanine) = 1.76
- DUR (B3) = 1.79

Monte Carlo

Organized box

- DUR = 1.67

Monte Carlo

Unorganized box

- DUR = 1.88

5 ISO 11137 Part 4

ISO 11137 Part 4

3.1.9
process target dose
D_{target}
dose, at a specified monitoring location, which the irradiation process parameters are set to deliver

3.1.10
process variability
measure of factors that result in a random distribution of data around the average that provides information on how well the process can perform when all special cause variation is removed

3.1.11
Statistical Process Control
SPC
set of techniques for improving the quality of process output by reducing variability through the use of one or more control charts and a corrective action strategy used to bring the process back into a state of statistical control

ISO 11137 Part 4

4.2.2 D_{mon} as an indirect measurement of dose to product

In an indirect measurement, the maximum and minimum doses to product **are calculated from the monitoring dose measurement**. The calculated doses have uncertainties associated with the dose at the monitoring location as well as the uncertainty associated with the dose at maximum or minimum locations and associated ratios, plus any other applicable components of uncertainty. A combination of these components can be used to determine the maximum and minimum targets for the routine monitoring dose

ISO 11137 Part 4

4 Principles applied in validating and controlling an irradiation process

4.2 Use of the dose measurement at the monitoring location.

4.3 Monitoring of critical process parameters

Parameter	Effect	Monitoring	Gamma	Elec-tron	X-ray
Radiation field					
Radioisotope decay	Over time the radiation intensity is reduced	Source decay occurs based on the half-life of the isotope; date of irradiation is recorded	✓		
Electron energy	Energy affects the penetration depth of electrons, scan width, and also X-ray conversion efficiency	Irradiator parameters associated with input power and beam current are monitored; indirect measurements using beam penetration profiles are made periodically as part of a quality control check		✓	✓
Beam current	A change in beam current will lead to a change in the radiation intensity and possibly of the beam energy	Can be monitored indirectly during operation; indirect monitors can be calibrated		✓	✓
Beam scan width	For scanned system, width will affect the size of the radiation field and a reduction in width will increase the radiation intensity	Monitored indirectly by feedback of scanning system, or directly through interception of the beam, or through periodic dosimetric tests		✓	✓

ISO 11137 Part 4

Parameter	Effect	Monitoring	Gamma	Elec-tron	X-ray
Exposure time					
Cycle time	Dose is directly proportional to cycle time. An increase in cycle time equals an increase in dose.	Cycle time is set by operator, recorded as part of the pro-cess and associated timers are calibrated	✓		✓
Conveyor speed	Dose is inversely proportional to speed of product travelling through an irradiation field	Feedback from convey-or speed monitors; direct measurements made during periodic tests	✓	✓	✓
Product influence					
Loading pattern	Changes to loading pattern including product orientation inside a carton and/or carton loading into an irradiation container can affect dose delivery	Defined product loading patterns and procedures to ensure products are loaded according to specification	✓	✓	✓
Density and loading pattern of surrounding materials	Materials surrounding prod-uct during irradiation can affect dose delivered through attenuation or scattering of radiation	Appropriate scheduling of process loads; defined criteria resulting from OQ for materials surrounding product during irradiation are documented	✓	✓	✓

ISO 11137 Part 4

5 Establishing process target dos

5.1 Inputs and steps in establishing a process target dose

5.1.4 Determine $\sigma_{process}$

The standard deviation to be used in setting process target doses is designated $\sigma_{process}$ and can be derived by quantifying individual components of measurement uncertainty and process variability or by quantifying a combination of components obtained during qualification exercises and by the use of historical data for a given irradiator.

ISO 11137 Part 4

5.1.2 Process validation inputs (installation, operational and performance qualification)

The results of process validation that can be used to provide input into establishing process target doses include the following:

a) the magnitude of minimum dose to product D_{min} for a given loading configuration and set of operating parameters and its relationship to the routine monitoring dose D_{mon};

b) the magnitude of maximum dose to product D_{max} for a given loading configuration and set of operating parameters and its relationship to the routine monitoring dose D_{mon};

c) the variability associated with D_{min}, D_{max} and D_{mon}, and the uncertainty associated with their ratios (if used); and if applicable the effects of

d) process interruptions;

e) transitions between different product;

f) partially filled irradiation containers.

ISO 11137 Part 4

5.2 Performance qualification outputs

5.2.2 Experimental design for PQ

There are a number of factors that go into the design of a PQ study which will provide enough information to set up a process that when in a state of control renders product that is irradiated within its dose specifications D_{ster} and $D_{max,acc}$. This can include the determination of the relationship between maximum, minimum and monitoring doses as well as information on the variability of the process. Factors which can influence the number of dosimeters used and the number of replicate dose maps include, but are not limited to, the following considerations:

a) radiation type (gamma, electron beam, or X-ray);
b) complexity of the product;
c) historic dose mapping data from similar products;
d) information gained from OQ;
e) output of mathematical models.

6 Perka BPOM 3 TAHUN 2018 dan Perka BAPETEN 6 TAHUN 2023

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

Pasal 6

Bahan kontak Pangan dan Dosis Serap maksimumnya harus sesuai dengan Dosis Serap maksimum jenis Pangan yang diiradiasi.

Pasal 7

(1) Pangan Iradiasi dilarang diiradiasi ulang.

(2) Dikecualikan dari larangan iradiasi ulang sebagaimana dimaksud pada ayat (1) untuk Pangan berkadar air rendah yang diiradiasi untuk membasmi serangga.

(3) Total Dosis Serap pada Pangan yang diiradiasi ulang sebagaimana dimaksud pada ayat (2) tidak boleh melebihi Dosis Serap maksimum sebagaimana dimaksud dalam Pasal 4.

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

Pasal 8

(1) Iradiasi ulang tidak termasuk:

a. Iradiasi pada Pangan yang mengandung bahan pangan yang telah diiradiasi pada dosis rendah

untuk tujuan perlakuan karantina, menghambat pertunasan selama penyimpanan, atau menunda pematangan;

b. Iradiasi pada Pangan yang mengandung bahan pangan yang telah diiradiasi kurang dari 5% (lima perseratus); atau

c. Iradiasi yang dilakukan lebih dari satu kali untuk mencapai dosis serap maksimum yang diinginkan, sebagai bagian dari proses untuk tujuan teknologi tertentu.

Pasal 11

(5) Pelaporan hasil pencatatan sebagaimana dimaksud pada ayat (3) dan ayat (4) dilakukan setiap 6 (enam) bulan dengan menggunakan format tercantum dalam Lampiran

PERATURAN BADAN PENGAWAS TENAGA NUKLIR REPUBLIK INDONESIA NOMOR 6 TAHUN 2023 TENTANG SISTEM MANAJEMEN FASILITAS DAN KEGIATAN PEMANFAATAN TENAGA NUKLIR

Pasal 3

Peraturan Badan ini berlaku untuk:

a. instalasi nuklir;

b. pertambangan bahan galian nuklir; dan

c. pemanfaatan sumber radiasi pengion.

Pasal 4

(1) Pemegang Izin menyusun, menetapkan, mengembangkan, menerapkan, mengevaluasi, dan meningkatkan Sistem Manajemen secara berkelanjutan untuk memastikan tujuan keselamatan tercapai.

(2) Sistem Manajemen sebagaimana dimaksud pada ayat (1) mencakup:

a. budaya keselamatan dan budaya keamanan;

b. penerapan pendekatan bertingkat persyaratan Sistem Manajemen;

c. Dokumentasi Sistem Manajemen;

d. kebijakan dan perencanaan;

e. tanggung jawab manajemen;

f. manajemen sumber daya;

g. pelaksanaan Proses; dan

h. pengukuran efektivitas, penilaian, dan peluang perbaikan.

PERATURAN BADAN PENGAWAS TENAGA NUKLIR REPUBLIK INDONESIA NOMOR 6 TAHUN 2023 TENTANG SISTEM MANAJEMEN FASILITAS DAN KEGIATAN PEMANFAATAN TENAGA NUKLIR

Pasal 8

Pemegang Izin menjamin semua personel dalam kegiatan organisasi sebagaimana dimaksud dalam Pasal 7 ayat (1):

a. memberikan kontribusi untuk membina dan mempertahankan budaya keselamatan dan budaya keamanan;

b. mempunyai pemahaman yang sama tentang aspek utama budaya keselamatan dan budaya keamanan;

c. memperoleh pelatihan secara sistematis untuk memberikan pemahaman yang komprehensif tentang keselamatan dan keamanan;

d. melaksanakan tugas dengan mempertimbangkan interaksi antara personel, teknologi, dan organisasi;

Terima Kasih

THANK YOU

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