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[1] DRAFT Revision of ISPM 18: Requirements for the use of irradiation as a phytosanitary measure (2014-007)

[2] Status box

[3]	This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.
[4] Date of this document	[5] 2021-05-21
[6] Document category	[7] Draft revision of ISPM
[8] Current document stage	[9] To first consultation
[10] Major stages	[11] 2014-05 IPPC Secretariat, supported by the Technical Panel on Phytosanitary Treatments (TPPT), developed the generic specification (2014-008) for the development of five standards; Standard Committees (SC) agreed to this approach. [12] 2014-03 CPM-09 added topic <i>Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18) (2014-007)</i> to the work programme with priority 2 (subsequently changed to priority 3 by CPM-10 (2015) and to priority 1 by SC (e-decision 2020_eSC_Nov_02)). [13] 2015-05 SC approved Specification 62 (<i>Requirements for the use of phytosanitary treatments as phytosanitary measures</i>). [14] 2020-12 TPPT started the revision. [15] 2021-02 (two meetings) TPPT revised the draft. [16] 2021-05 SC revised and approved for first consultation.
[17] Steward history	[18] 2016-11 David OPATOWSKI (IL, Steward) [19] 2020-10 Guy HALLMAN (US, Assistant Steward)
[20] Notes	[21] 2021-03 Edited [22] 2021-05 Edited

[23] CONTENTS [to be inserted]

[24] Adoption [to be revised following adoption]

[25] This standard was adopted by the [Fifth] Session of the Commission on Phytosanitary Measures in [April 2003].

[26] INTRODUCTION

[27] Scope

[28] This standard provides technical guidance on the application of ionizing radiation as a phytosanitary measure. This standard does not provide details on specific irradiation treatments, such as specific schedules for specific regulated pests on specific commodities, or treatments used for the production of sterile organisms for pest control.

[29] References

[30] The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispm>.

[31] APPPC (Asia and Pacific Plant Protection Commission). 2014. *Approval of irradiation facilities*. Regional Standard for Phytosanitary Measures (RSPM) 9. Bangkok, APPPC, FAO Regional Office for Asia and the Pacific. 20 pp.

[32]IAEA (International Atomic Energy Agency). 2015. *Manual of good practice in food irradiation: Sanitary, phytosanitary and other applications*. Technical Reports Series No. 481. Vienna, IAEA. 85 pp.

[33]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*. Geneva, International Organization for Standardization.

[34]ISO/ASTM 51261:2013. *Practice for calibration of routine dosimetry systems for radiation processing*, 2nd edn. United States of America, International Organization for Standardization and ASTM International.

[35]Definitions

[36]Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

[37]Outline of requirements

[38]This standard provides guidance on how irradiation treatments may be used for pest management to comply with phytosanitary import requirements.

[39]The roles and responsibilities of parties involved in phytosanitary irradiation are described. Guidance is provided to national plant protection organizations (NPPOs) on responsibilities for approving treatment facilities, and for monitoring and auditing treatment facilities and providers.

[40]The NPPO is responsible for ensuring that the minimum absorbed dose has reached the required level to achieve the stated efficacy.

[41]Application of the treatment requires dosimetry and dose mapping to ensure that the treatment is effective with specific commodity configurations.

[42]The NPPO is responsible for ensuring that treatment facilities are appropriately designed for phytosanitary treatments. Procedures should be in place to ensure that the treatment can be conducted properly and consistently. Systems should be implemented to prevent the infestation or contamination of the irradiated commodity, including accidental mixing with untreated commodities.

[43]Record keeping and documentation requirements should be met to enable auditing and trace-back.

[44]BACKGROUND

[45]The purpose of this standard is to provide generic requirements for the application of ionizing radiation as a phytosanitary measure, specifically for those treatments adopted under ISPM 28 (*Phytosanitary treatments for regulated pests*).

[46]ISPM 28 was adopted to harmonize effective phytosanitary treatments over a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may facilitate trade. ISPM 28 provides requirements for submission and evaluation of efficacy data and other relevant information on phytosanitary treatments, and annexes with specific irradiation treatments that have been evaluated and adopted by the Commission on Phytosanitary Measures.

[47]Irradiation is considered to be effective when the phytosanitary treatment dose of ionizing radiation (hereafter referred to as the “phytosanitary treatment dose”) required by the treatment schedule is absorbed at the location in the process load (as defined in ISPM 5) that receives the lowest dose of radiation. Therefore, process control relies on identifying the minimum dose location for a specific commodity configuration and routinely delivering to this location a dose of ionizing radiation (a minimum dose) that is equal to or greater than the required phytosanitary treatment dose. The effectiveness of the treatment process as a whole also includes measures applied to prevent infestation or contamination after irradiation.

[48] IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[49] The use of irradiation as a phytosanitary measure has a beneficial impact on biodiversity and the environment by preventing the introduction and spread of regulated pests with the trade of plants and plant products.

[50] REQUIREMENTS

[51] 1. Irradiation objective

[52] The objective of using irradiation as a phytosanitary measure is to achieve at a specified efficacy certain pest responses, such as:

- [53] mortality;
- [54] inability to develop successfully (e.g. non-emergence of adults);
- [55] inability to reproduce (e.g. sterility);
- [56] inactivation; or
- [57] devitalization of plants as pests (e.g. seeds may germinate but seedlings do not grow; or tubers, bulbs or cuttings do not sprout).

[58] A range of specific options may be specified where the required response is the inability of the pest to reproduce. These may include:

- [59] complete sterility;
- [60] limited fertility of only one sex;
- [61] egg laying or hatching without further development;
- [62] sterility of F₁ generation.

[63] 2. Irradiation application

[64] Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or caesium-137), electrons (up to 10 MeV) or X-rays (up to 7.5 MeV) generated from machine sources. The unit of measurement for absorbed dose is the gray (Gy).

[65] The phytosanitary treatment dose is the minimum dose required to achieve pest management at a specified efficacy. The treatment is entirely dependent upon the understanding of dose distribution within the commodity configuration and consistent presentation of the process load to the ionizing radiation. Factors that may alter the effectiveness of the treatment may include erratic commodity configurations in the process load and variable levels of oxygen (O₂).

[66] To ensure that the phytosanitary treatment dose has been attained throughout the process load, treatment procedures should ensure that the minimum absorbed dose (D_{\min}) is at least equal to the required phytosanitary treatment dose. The intended use of the commodity should be considered. For example, although appropriate for foods and agricultural products for processing or consumption, irradiation may not be appropriate for plants for planting as it may devitalize them.

[67] In irradiation treatments, it is rare that mortality is technically justified as the required response. It is therefore possible that live, though non-viable target pests may be found in correctly treated commodities. This does not imply a failure of the treatment. It does mean, however, that it is essential for the treatment to be applied correctly to ensure that any live target-pests are unable to complete development or otherwise reproduce. In addition, it is preferable that such pests are unable to escape into the environment unless they can be distinguished from non-irradiated pests.

[68] Irradiation may be applied:

- [69] as an integral part of packing operations;
- [70] to bulk unpackaged commodities;

- [71]to packaged or palletized commodities.

[72]Irradiation may take place where the commodity originates. When it is operationally feasible to prevent the escape of any pests during transport of the untreated commodity, treatment may alternatively be conducted at:

- [73]the point of entry;
- [74]a designated location in a third country;
- [75]a designated location within the country of final destination.

[76]Treated commodities should be certified and released only after dosimetry measurements confirm that D_{\min} was equal to, or above, the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load. Where a pest species requiring a higher dose is found upon inspection and that dose requirement has not been met, consignments may be re-treated, provided the maximum absorbed dose (D_{\max}) total from all treatments is within the limits allowed by the importing country.

[77]Depending on the pest risk to be addressed, the tolerance of the commodity to treatment, and the availability of other pest risk management options, irradiation may be used either as a single treatment or combined with other measures as part of a systems approach to meet the efficacy required (see ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*)).

[78]3. Dosimetry

[79]Irradiation does not deliver a uniform dose throughout a process load but a continuum of doses. The dose range may increase as the size or density of the treated material increases. Therefore, it is important that an accurate measurement of the absorbed dose in a process load can be readily determined to ensure that D_{\min} is greater than or equal to the phytosanitary treatment dose required.

[80]Dosimetry provides assurance that D_{\min} is equal to, or above, the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load. Properly designed systems for treatment delivery and protection against infestation and contamination, together with continual checking and regular monitoring of those systems, provide assurance that treatments are properly conducted. Dosimetry is highly specialized. National plant protection organizations unfamiliar with phytosanitary irradiation should collaborate with technical experts from their national nuclear agencies when approving facilities to be used for phytosanitary irradiation.

[81]Dosimetry should be performed on a routine basis to ensure that for each batch of process loads treated the doses delivered equal or exceed the required D_{\min} .

[82]3.1 Dosimetry systems

[83]A dosimetry system consists of dosimeters, instruments that read dosimeters and procedures. A dosimeter is a device with a reproducible response to irradiation that can be used to measure the absorbed dose. The dosimeter responds to the radiation and the response is measured by instruments to calculate the amount of ionizing radiation that the product has absorbed (expressed as absorbed dose).

[84]The selection and use of specific dosimetry systems should be appropriate for both the dose range and the type of radiation. It should take into account the influence of factors such as dose rates, the minimum level of uncertainty deemed to be acceptable and the required spatial resolution. Examples of dosimetry systems that can be used for gamma ray, electron beam and X-ray facilities can be found in ISO/ASTM 51261:2013.

[85]3.2 Dose mapping

[86]Dose mapping is performed by placing dosimeters throughout the process load, irradiating the process load and reading the dosimeter values. Further information on the practices used for electron beams and X-rays are described in ISO 14470:2011 and ISO/ASTM 51261:2013.

[87]The objectives of dose mapping are:

- [88]to determine the dose distribution throughout the process load and in particular where D_{\min} and D_{\max} are found;
- [89]to demonstrate that the required dose range can be attained for the process load;
- [90]to establish the process parameters that will lead to doses within the required range;
- [91]to assess the variability of the particular process;
- [92]to establish how routine dose measurements will be made.

[93]The dose distribution in a process load is specific to the irradiator, the product path (the path that the commodity takes through the irradiator), the process load and the characteristics of the commodity. If any of these change, dose mapping should be repeated, as such changes affect dose distribution.

[94]3.3 Routine dosimetry

[95]Accurate measurements of absorbed dose in a process load are critical for determining the effectiveness of the treatment and are part of the validation process. The required number, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.

[96]When the position of D_{\min} or D_{\max} is inside the process load and it is not practical to place dosimeters there routinely, a dosimeter may be placed in a reference location on the surface of the process load or on the irradiation container in a location that is readily accessible and easily reproducible for the operator (see Appendix 1). For a given load configuration, a given path through the irradiator or given machine settings, the relationship between the dose measured at the reference location (D_{ref}) and D_{\min} and D_{\max} is arithmetic and constant. The coefficient representing this relationship should be established by dose mapping and may then be used to calculate D_{\min} and D_{\max} from D_{ref} during routine dosimetry.

[97]4. Validation

[98]Validation encompasses a series of checks designed to verify that a treatment facility meets its installation requirements (installation qualification), operates to its design specification (operational qualification) and will consistently deliver the required dose to a given process load within predetermined tolerances (performance qualification).

[99]Installation qualification and operational qualification validate the irradiator and may be performed by the treatment provider with the technology suppliers. National plant protection organizations are typically not involved with installation- or operational-qualification activities, but the treatment provider should inform the NPPO if major changes have been made to the facility that would require dose mapping to be repeated (e.g. replenishment of gamma sources or major changes to conveyor-belt systems or speeds).

[100]The way in which the commodity is loaded and irradiated is based on the results of the performance qualification. Therefore, the NPPO should review the performance-qualification activities that are undertaken with the actual commodity and commercial-product configuration (e.g. full pallet or half pallet). The objective of performance qualification is to demonstrate that the equipment, as installed and properly operated, consistently performs as expected and that the treatment schedule can be met. Dose mapping of the actual commodity to define the configuration of the process load is a key activity to ensure that D_{\min} is achieved.

[101]5. Adequate systems for treatment facilities

[102]Confidence in the adequacy of an irradiation treatment as a phytosanitary measure is primarily based on assurance that the treatment is effective against the target pests under specific conditions and the treatment has been properly applied. Systems for treatment delivery should be designed, used and monitored to ensure that treatments are properly conducted and commodities are protected from infestation and contamination after treatment.

[103]The NPPO of the country in which the treatment facility is located is responsible for ensuring that the facility system requirements are met.

[104]**5.1 Approval of facilities and authorization of treatment providers**

[105]Treatment facilities should be approved by the NPPO of the country in which the facility is located before phytosanitary treatments are applied there, such approval thereby authorizing the treatment provider responsible for the facility (APPPC, 2014). This approval should be subsequent to authorization from competent authorities for safety (e.g. radiation safety authority, nuclear regulatory authority) where appropriate and be based on a set of criteria that include both criteria common to all irradiation facilities and those that are specific to the site and commodity (see Annex 1).

[106]Phytosanitary re-approval should be done by the NPPO on a regular basis at appropriate intervals.

[107]**5.2 Prevention of infestation and contamination after treatment**

[108]At the treatment facility, the necessary measures should be implemented to prevent possible infestation or contamination of the commodity after treatment. The following measures may be required:

- [109]keeping the commodity in a pest free enclosure under conditions that protect it from infestation and contamination;
- [110]packing the commodity immediately after irradiation;
- [111]identifying irradiated commodities to prevent mixing with non-irradiated commodities;
- [112]ensuring that irradiated commodities are separated from non-irradiated commodities;
- [113]dispatching the commodity as soon as possible after irradiation.

[114]The use of pest-proof packaging before irradiation may help to prevent possible infestation or contamination if irradiation is done before export, or to prevent the accidental escape of the target pest if the treatment is done at the destination.

[115]**5.3 Labelling**

[116]Commodities should be labelled with treatment lot numbers or other identifying features allowing trace-back for non-compliant consignments. The labels should be easily identifiable and placed on visible locations.

[117]**5.4 Monitoring and auditing**

[118]The NPPO of the country in which the irradiation is conducted is responsible for the monitoring and auditing of treatment facilities and providers. The NPPO should maintain an audit schedule and ensure that such audits are conducted by appropriately trained personnel. Continuous supervision of irradiation should not be necessary, provided treatment procedures are properly designed and can be verified to ensure a high degree of system integrity for the facility, process and commodity in question. The monitoring and auditing should be sufficient to detect and correct deficiencies promptly.

[119]Treatment providers should meet monitoring and auditing requirements set by the NPPO. These requirements may include:

- [120]access for the NPPO to conduct audits, including unannounced visits;
- [121]a system to maintain and archive treatment records and provide the NPPO with access to these;
- [122]corrective action to be taken in the event of nonconformity.

[123]The NPPO of the importing country may establish approval and audit procedures with the NPPO of the exporting country to verify conformity with requirements.

[124]6. Documentation

[125]The NPPO of the country in which the irradiation is conducted is responsible for ensuring that treatment providers keep appropriate records, such as raw data on dosimetry readings recorded during treatments. Accurate record keeping is essential to enable auditing and trace-back.

[126]6.1 Documentation of procedures

[127]Procedures should be documented to ensure that commodities are consistently treated as required. Process controls and operational parameters should be established to provide the details necessary for a specific approval of a treatment facility. Calibration and quality control procedures should be documented by the treatment provider. The documented procedures should include the following:

- [128]commodity handling procedures before, during and after irradiation;
- [129]orientation and configuration of the commodity during irradiation;
- [130]critical process parameters and the means for measuring and recording them;
- [131]dosimetry and calibration of dosimetry system;
- [132]contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- [133]procedures for handling rejected lots;
- [134]labelling, record keeping and documentation requirements;
- [135]training of personnel.

[136]6.2 Record keeping

[137]The treatment provider should keep appropriate records for each treatment application. These records should be made available to the NPPO of the country in which the treatment facility is located for auditing and verification purposes or when a trace-back is necessary.

[138]Appropriate treatment records for irradiation as a phytosanitary measure should be retained by the treatment provider for at least one year to enable the trace-back of treated lots. Information that may be required to be recorded includes:

- [139]identification of facility and responsible parties;
- [140]commodity treated;
- [141]target regulated pest;
- [142]owner, packer, grower and place of production of the commodity;
- [143]lot size and volume, including number of articles or packages;
- [144]identifying markings or characteristics;
- [145]absorbed doses (required doses and measured doses), dosimetry calibration records;
- [146]date of treatment;
- [147]any observed deviation from treatment schedule and, where appropriate, subsequent actions taken;
- [148]orientation and configuration of the commodity during irradiation (including dose mapping).

[149]6.3 Documentation by the NPPO

[150]All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and phytosanitary certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available upon request as described in ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*).

[151]7. Inspection

[152]Inspection should be carried out by the NPPO of the exporting country and inspection at import may be carried out by the NPPO of the importing country to determine compliance with phytosanitary import requirements.

[153]Live target pests may be found after treatment, but this should not result in the refusal to issue a phytosanitary certificate. Where mortality is the required response, live target-pests may be found during the period immediately following the irradiation; in such cases, phytosanitary certification should be based on confirmation from audit checks that mortality is attained for the specific commodity and treatment conditions concerned. Where mortality is not the required response, it is more likely that live target pests may persist in the treated consignment; in such cases, phytosanitary certification should be based on confirmation from the normal validation programme that the required response is achieved for the specific commodity and treatment conditions concerned.

[154]8. Responsibilities

[155]The NPPO of the country in which the irradiation treatment is conducted is responsible for the evaluation, approval and auditing of the application of irradiation as a phytosanitary measure.

[156]To the extent necessary, the NPPO should cooperate with other national regulatory agencies concerned with the development, approval and safety of irradiation treatments, including the training and certification of personnel conducting the treatment and the approval of treatment facilities. The respective responsibilities of the NPPO and the other regulatory agencies should be identified to avoid requirements that are overlapping, conflicting, inconsistent or unjustified.

[157]Potential implementation issues

[158]This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

[159]

[160]This annex is a prescriptive part of the standard.

[161]ANNEX 1: Checklist for facility approval

[162]The following checklist is intended to assist persons inspecting or monitoring facilities for which the treatment provider is seeking to establish or maintain facility approval and phytosanitary certification of irradiated commodities for international trade.

[163]Criteria	[164]Yes	[165]No
[166]1. Premises	[167]	[168]
[169]The treatment facility meets the approval of the national plant protection organization (NPPO) as regards phytosanitary requirements, and the NPPO has reasonable access to the facility and appropriate records as necessary to validate phytosanitary treatments	[170]	[171]
[172]Facility buildings are designed and built to be suitable in size, materials and placement of equipment to facilitate proper maintenance and operations for the lots to be treated	[173]	[174]
[175]Appropriate means, integral to the facility design, are available to maintain non-irradiated lots separate from irradiated lots	[176]	[177]
[178]Buildings, equipment and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent contamination of the lots being treated	[179]	[180]
[181]Effective measures are in place to protect against the infestation or contamination of consignments or lots being stored or processed	[182]	[183]
[184]Adequate measures are in place to handle breakages, spills or other damage to lots	[185]	[186]
[187]Adequate systems are in place to dispose of lots that are improperly treated or unsuitable for treatment	[188]	[189]
[190]Adequate systems are in place to control non-compliant lots and when necessary to suspend facility approval	[191]	[192]
[193]2. Personnel	[194]	[195]
[196]The facility is adequately staffed with trained personnel	[197]	[198]
[199]Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes	[200]	[201]
[202]3. Commodity handling, storage and segregation	[203]	[204]
[205]Commodities are inspected upon receipt to ensure that they are suitable for irradiation	[206]	[207]
[208]Commodities are handled in an environment that does not increase the risk of dangerous physical, chemical or biological contaminants	[209]	[210]
[211]Commodities are appropriately stored and adequately identified	[212]	[213]
[214]Procedures and facilities are in place to ensure the segregation of treated and untreated lots, including physical separation between incoming and outgoing holding areas	[215]	[216]
[217]4. Irradiation treatment	[218]	[219]
[220]The facility is suitably designed and equipped to allow required treatments to be conducted in conformity with a treatment schedule	[221]	[222]
[223]A process control system is in place providing criteria to assess irradiation effectiveness	[224]	[225]
[226]Proper process parameters are established for each type of commodity to be treated	[227]	[228]

[163]Criteria	[164]Yes	[165]No
[229]Written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel	[230]	[231]
[232]The absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry, and dosimetry records are kept and made available to the NPPO as needed	[233]	[234]
[235]5. Packaging and labelling	[236]	[237]
[238]Each commodity is packaged using materials suitable for the commodity and process	[239]	[240]
[241]Treated lots are adequately identified or labelled and adequately documented	[242]	[243]
[244]Each lot carries identification to distinguish it from all other lots	[245]	[246]
[247]6. Documentation	[248]	[249]
[250]All records about each lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed	[251]	[252]

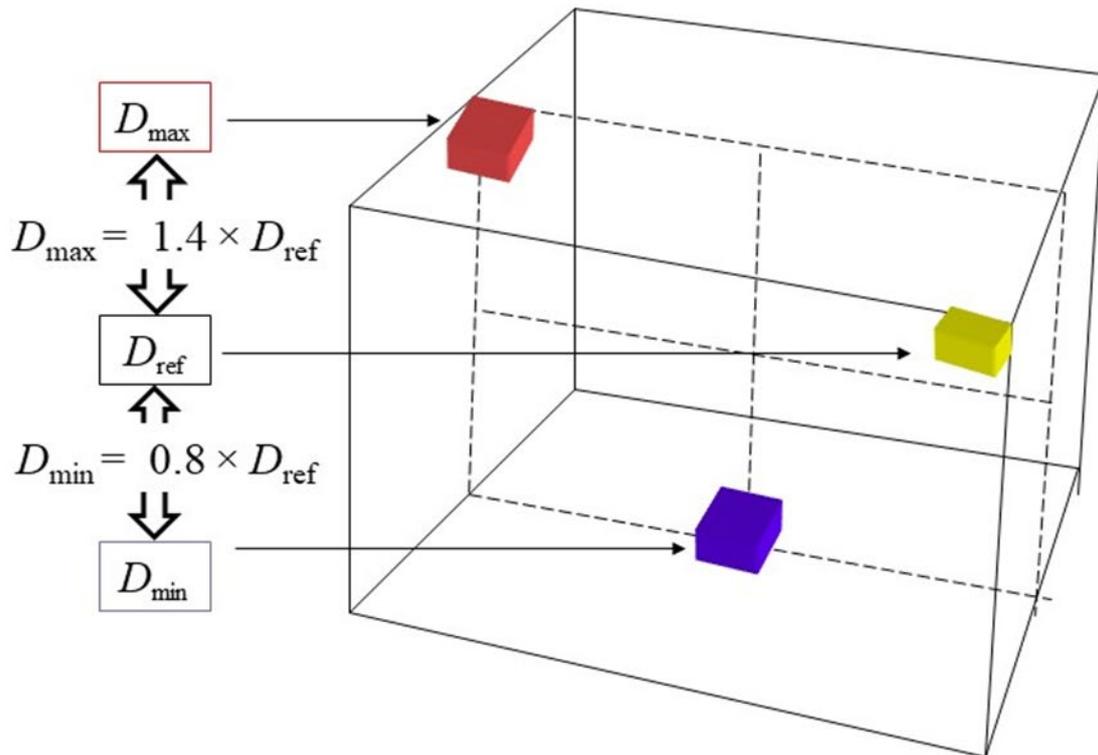
[263]

[256] This appendix is for reference purposes only and is not a prescriptive part of the standard.

[257] APPENDIX 1: Example of a dosimeter in a reference location

[258] The relationship between minimum (D_{\min}) and maximum (D_{\max}) absorbed doses and the dose in the reference location (D_{ref}) in Figure 1 has been calculated as 0.8 and 1.4, respectively. For further examples, please refer to IAEA (2015).

[259]



[260] **Figure 1.** Example of relationship between minimum and maximum doses and the dose in the reference position. Blue box, position of minimum absorbed dose (D_{\min}); red box, position of maximum absorbed dose (D_{\max}); yellow box, position of dosimeter in the reference location (dose measured is D_{ref}).

[261] Source: IAEA, 2015.