BS EN IEC 62471-6:2023

BSI Standards Publication

Photobiological safety of lamps and lamp systems

Part 6: Ultraviolet lamp products

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This British Standard is the UK implementation of EN IEC 62471-6:2023. It is identical to IEC 62471-6:2022.

The UK participation in its preparation was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2023

ISBN 978 0 580 51083 0

ICS 29.140.01; 31.260

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2023.

Amendments/corrigenda issued since publication

Date	Text affected

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IEC 62471-6

Edition 1.0 2022-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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Photobiological safety of lamps and lamp systems – Part 6: Ultraviolet lamp products

Sécurité photobiologique des lampes et des appareils utilisant des lampes – Partie 6: Appareils à lampes ultraviolettes

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 29.140.01; 31.260

ISBN 978-2-8322-5828-6

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PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

Part 6: Ultraviolet lamp products

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The text of this International Standard is based on the following documents:

FDIS	Report on voting
76/714/FDIS	76/718/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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conformity statements: in italic type.

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INTRODUCTION

Most lamps and lamp products are safe and do not pose photobiological risks except under unusual exposure conditions; however, one group of products-ultraviolet lamp products-can under some conditions pose optical hazards during use and require risk assessment for direct and indirect exposure of the eyes and skin. Optical radiation hazards from all types of lamps or other broadband light sources are assessed by the application of IEC 62471:2006/CIE S009:2002. IEC 62471 covers light emitting diodes (LEDs), incandescent, low- and high- pressure gas-discharge, arc and other lamps. It also covers lamps which are designed primarily to emit ultraviolet radiant energy, such as ultraviolet sources intended to excite fluorescence of irradiated materials, for insect light traps, for scientific studies, mineral identification, for non-destructive testing, germicidal irradiation, and other purposes.

This document provides a risk group (RG) classification system for all ultraviolet lamp products, and the assessment distances and measurement conditions for different products (Annex A and Annex C). It includes manufacturing and user safety requirements that may be required as a result of an ultraviolet lamp product being assigned to a particular risk group. The scope is limited to products where the sole intent is to emit ultraviolet radiant energy. The advantage of applying this document, intended solely for ultraviolet lamp products, instead of the horizontal IEC 62471 standard, is that the risks from visible and infrared optical radiation need not be assessed using this document, as they are assumed to be insignificant for a lamp that emits mainly UV. The assigned risk group of an ultraviolet lamp product using this document may also be used to assist with any needed risk assessments, e.g. for occupational exposure in workplaces.

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PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

Part 6: Ultraviolet lamp products

1 Scope

This part of IEC 62471 provides the optical radiation safety requirements for ultraviolet lamp products, including UV LED lamp products.

This document provides requirements for:

- optical radiation safety assessment and ultraviolet-product risk groups;
- user information for safety measures;
- appropriate labelling of ultraviolet lamp products.

This document addresses those lamps and lamp products where the ultraviolet emission serves the primary purpose of the product and where more than half of the radiant power emitted between 180 nm and 3 000 nm is in the spectral region 180 nm to 400 nm. If more than half of the optical radiation emitted between 180 nm and 3 000 nm is outside of the spectral region 180 nm to 400 nm, then the base standard IEC 62471 should be used. This document covers medical diagnostic and cosmetic devices/products that emit primarily UV radiation.

Because photobiological effects from UV radiation are based on the total accumulated exposure (dose) received, this document relies on the concept of ‘time-weighted average’ exposures where the assessment distance for determining the RG is chosen based on realistic exposure distances and exposure durations. In other words, it is not expected that people will be exposed at very close distances, e.g. 20 cm to 30 cm, for extended periods of time. This document provides assessment distances and specific guidance that are application-specific and realistic rather than the more general values in IEC 62471 where the specific application is unknown and time-weighted average exposures are not application-specific.

This document does not provide requirements for:

- lamps which primarily emit visible (such as GLS – general lighting source) and/or infrared radiant energy;
- lamp products used for general lighting or infrared illumination or heating, which are treated in separate standards;
- fluorescent ultraviolet lamps for tanning (covered by IEC 60335-2-27 and IEC 61228);
- medical treatment devices/products (see IEC 60601-2-57), but covers UV medical diagnostic products;
- non-optical hazards, e.g. ozone, mercury, etc.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60335-2-27, *Household and similar electrical appliances – Safety – Part 2-27: Particular requirements for appliances for skin exposure to optical radiation*

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IEC 60417:2002, *Graphical symbols for use on equipment – 12-month subscription to regularly updated online database comprising all graphical symbols published in IEC 60417*

IEC 60601-2-57, *Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

IEC 61549, *Miscellaneous lamps*

IEC 62471:2006/CIE S009:2002, *Photobiological safety of lamps and lamp systems*

ISO 7010: *Graphical symbols – Safety colours and safety signs – Registered safety signs*

ISO 15004-2: *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

CIE 247:2021*, Guide for the Gonioradiometric Measurement of Upper Air Ultraviolet Germicidal Irradiation Luminaires, ISBN 978-3-902842-19-0, Vienna*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
actinic UV
UV radiation capable of producing a photochemical effect

Note 1 to entry: In the context of this document, the biological effects have a demonstrated action spectrum, S(λ), and refer most significantly to UV-B and UV-C effects, e.g, UV erythema (skin reddening), UV photokeratitis ('welder's flash' or 'snowblindness'), etc. See also Annex B.

3.2
assessment distance
distance used to determine the risk group classification of a lamp or lamp product

Note 1 to entry: The risk group assessment distance takes account of the TWA exposure (variable irradiance, exposure distances and durations).

Note 2 to entry: This is usually the distance from the closest point of human access to the emission, to the point of assessment or measurement.

3.3
blue light hazard
potential for a photochemically induced retinal injury resulting from radiation exposure at wavelengths primarily between 400 nm and 500 nm

Note 1 to entry: This damage mechanism normally dominates over thermal mechanisms for intense visible light for viewing times exceeding 10 s, but is rarely of concern from UV lamps (unless the basic lamp is an arc lamp).

[SOURCE: IEC 60050-845:2020,845-26-055]

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3.4
competent person
person who can demonstrate a combination of knowledge and skills to effectively, efficiently, and safely carry out specific activities

3.5
consumer
person who purchases or employs goods and services for personal use

Note 1 to entry: Consumers include not only users of the ultraviolet lamp product, but also all persons who may have access to the lamp product or who may be in the vicinity of the product.

Note 2 to entry: Also termed “ordinary person” in IEC 62368-1.

3.6
controlled access location
location where an engineering and/or administrative control measure is established to restrict access except to authorised personnel with appropriate safety training

3.7
dose-limited product
product where the emitted radiant exposure (dose) is limited by time or actual exposure monitoring at the assessment distance to a set level during any day

Note 1 to entry: The emission limit is expressed in J/m^2.

3.8
emission limit
limit defined for each risk group, based upon reasonably foreseeable conditions of time-weighted average (TWA) exposure

Note 1 to entry: The emission limit incorporates both the concept of exposure duration and variable exposure distance and is derived from exposure limits, however, the risk group assessment distance incorporates the TWA exposure.

3.9
general lighting source
GLS
general term for lamps, nominally of “white” colour, intended for lighting spaces that are typically occupied or viewed by people

Note 1 to entry: See IEC 62471 for requirements.

Note 2 to entry: This document does not cover GLS lamps or lamp products.

3.10
germicidal lamp product
any UV lamp product designed to disinfect by ultraviolet germicidal (UVG) irradiation to inactivate microorganisms so they are no longer capable of replicating and causing adverse health effects

3.11
instructed person
person who has been instructed and trained by a competent person, or who is supervised by a competent person, to identify ultraviolet sources that may cause pain or injury and to take precautions to avoid unintentional exposure to those sources

[SOURCE: IEC 62368-1:2018, 0.2.3, modified to use competent instead of skilled person]

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3.12
intended use
usage of a product, process or service in accordance with specifications, instructions and information provided by the manufacturer or supplier

3.13
UV lamp
electric lamp or light emitting diode (LED) lamp that radiates especially strongly in the ultraviolet, the visible radiation produced, if any, not being of direct interest

Note 1 to entry: There are several types of ultraviolet lamp used for photobiological, photochemical and biomedical purposes.

[SOURCE: IEC 60050-845:2020, 845-27-091, modified, with Note 2 to entry omitted and with LED lamp (845-27-054) addition]

3.14
UV lamp product
product incorporating a UV lamp or UV lamps, including fixtures, and possibly filters, where the ultraviolet emission is the primary purpose of the lamp product and where more than half of the optical radiation emitted between 180 nm and 3 000 nm is in the spectral region 180 nm to 400 nm

3.15
UV luminaire
apparatus which distributes, filters or transforms the ultraviolet radiant energy transmitted from at least one source of optical radiation and which includes, except the sources themselves, all the parts necessary for fixing and protecting the sources and, where necessary, circuit auxiliaries together with the means for connecting them to the power supply

[SOURCE: IEC 60050-845:2020,845-30-001, modified for UV]

3.16
photocuring lamp product
lamp product that usually employs UV-A to photopolymerize liquid polymers to a solid state

Note 1 to entry: Examples include photopolymerization of liquid inks in printing or rapid curing of plastic products.

3.17
time-weighted average exposure
TWA exposure
averaged cumulative exposure dose over a given period of time (normally any 30 000 s to approximately 8 h period) divided by the exposure duration to provide an effective irradiance for both variable distances and durations

Note 1 to entry: The TWA is essential in considering lengthy exposures to ultraviolet hazards, since variable exposure distances at different irradiances and durations determine the reasonably foreseeable worst-case exposures (for photochemical hazards) which correspond therefore to the measured/calculated irradiance at a specified distance for RG determination (analogous to the 500-lx assessment distance for GLS lamps). See Annex E.

3.18
ultraviolet radiation
optical radiation within the wavelength range from 100 nm to 400 nm

Note 1 to entry: The UV-C extends from 100 nm to 280 nm, UV-B from 280 nm to 315 nm, and UV-A from 315 nm to 400 nm.

Note 2 to entry: Ultraviolet radiation at wavelengths less than 180 nm is considered vacuum ultraviolet radiation for the purpose of this document and is not included in the scope.

[SOURCE: IEC 60050-845:2020, 845-21-008, modified: Notes 2 to 5 to entry omitted and new Note 2.]

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3.19
ultraviolet-fluorescence illuminator
any UV-A lamp designed to illuminate and excite fluorescence to permit increased visualization of the material

Note 1 to entry: Examples include “black-light” fluorescent illuminators, security-code reading UV-A lamps used for counterfeit money detection, medical applications, etc.

4 Risk groups applied for ultraviolet lamp-product safety assessments

4.1 Basis for optical radiation safety risk group determination

IEC 62471/CIE S009 provides the fundamental method to determine the risk group of any individual lamp and also the default measurement condition to determine the risk group of any lamp or any product incorporating a lamp, unless a vertical (application-specific) standard exists that includes measurement conditions for its specific application. The risk groups in IEC 62471 indicate the degree of risk from potential optical radiation hazards and minimize the need for further measurements. The risk groups were developed based upon decades of lamp use experience and the analysis of accidental injuries related to optical radiation emission (where injuries were, generally, quite rare except from ultraviolet-emitting lamps or arc lamps). The risk groups are also used in determining appropriate measures for risk management. There are four basic risk groups:

- Exempt group (RG-0) where no optical hazard is considered reasonably foreseeable, even for continuous, unrestricted use. Typical examples are small UV-A LED lamps and UV-A fluorescent lamps used in ultraviolet fluorescence illuminators or in domestic insect light traps;
- Risk group 1 (RG-1) products are safe for most use applications, except where prolonged direct ocular exposures may be expected. An example of a risk group 1 lamp products are some battery-operated UV-A torches (flashlights) or large, industrial insect light traps;
- Risk group 2 (RG-2) products generally do not pose a realistic optical hazard because of either discomfort glare from lens fluorescence or where lengthy exposures are unrealistic; examples include some UV-C germicidal fixtures;
- Risk group 3 (RG-3) products pose a potential hazard even for very brief exposures at close distance, and product safety requirements are generally essential; examples include sunlamp products (IEC 60335-2-27), Vitamin-D lamp products and unenclosed UV-C germicidal lamp products.

IEC 62471 does not provide guidance on manufacturing requirements and control measures. These issues are addressed in application-specific vertical standards such as this document. Labelling requirements and user information for each UV-lamp-product risk group are provided in this document (see 7.2 and 7.3).

4.2 Assessment criteria (background) for UV lamp products

The standard measurement conditions consider the emission spectrum and, for ultraviolet radiation, the irradiance to determine risk to the eye and/or the skin. The measurement conditions are intended to optimize the signal of trace amounts of UV-B and UV-C radiation that are emitted from lamp products intended to emit largely in the UV-A spectral region. The risk-group assessment distance is related to potentially hazardous exposure conditions and time-weighted-average (TWA) effective assessment distances based upon reasonably foreseeable worst-case exposure durations. This is built into the emission limits. The concept of a hazard distance normally does not apply to photochemical hazards, since UV hazardous doses accumulate, and the daily exposure determines the potential hazard. For time-varying sources, the accumulated exposure (dose) determining the TWA exposure will be the same as a continuous (CW) exposure for the same total duration. Optical sources are rarely at a fixed distance from the eyes, nor does an individual stare at a UV source for 30 000 s (approximately 8 h) a day, or more. The UV (actinic) S(λ) corneal/skin limit (see Annex D) applies to chronic exposure, where daily skin exposure will be higher than ocular exposure in almost all

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applications. The risk-group assessment distances, therefore, vary for each application and are listed in Table 2, Table 3 and Table 4 for various types of lamp products.

Assessment and measurement conditions necessarily differ for different special application lamp systems, such as insect light-traps, germicidal lamps, UV photocuring lamp products or UV-A fluorescence illuminators. Different application groups define a range of operational, maintenance and servicing conditions. Thus, the assessment applied to UV lamp products in this document justifies somewhat different measurement conditions than default measurement/assessment conditions in IEC 62471 for some products.

In general, the assessment of a single lamp/LED cannot be automatically transferred to the final lamp product. Under specific conditions, the assessment of a single lamp/LED is directly transferable to the lamp system. The risk group will remain the same, or may be reduced (e.g., by filters, etc.). However, as a general rule the UV luminaire will alter the spectrum or geometry of the irradiance field. The use of reflectors or appropriate focussing optics may increase the irradiance and increase the risk group, in which case the lamp assessment is not transferrable to the lamp system. Results may not be transferrable if multiple lamps are used in a lamp system.

The requirements in this application-specific (vertical) standard are for the risk group that can be used in some specific applications. Examples include unrestricted-use products which can be used in the home or uncontrolled environments. Performance features are based upon the risk group specifications and application-specific control measures. Basic guidance, based on the likelihood of direct source viewing, is provided in Clause 7. The hierarchy of applicable safety measures follow the internationally accepted priority ranking of manufacturer safety measures. That is, engineering controls (e.g., filters, shielding, interlocks, relevant proximity sensing, etc.) are the highest priority, followed by administrative measures (such as warnings and labels, see 7.3) and then personal protective equipment as the last resort.

An underlying assumption of this document is that it is not necessary to reduce optical radiation exposure to as low as reasonably achievable; however, as a general guideline, needless emissions that would produce unnecessary human exposure should be minimized.

5 Measurements to determine applicable risk group

5.1 General

This document addresses those lamps and lamp products for which more than half of the optical radiation (radiant power) emitted between 180 nm and 3 000 nm is in the spectral region 180 nm to 400 nm. Examples generally include low and medium pressure mercury lamps, UV LED lamps, excimer lamps and deuterium lamps.

For other lamp types, it is not intended that a spectral measurement be performed to verify this condition for emission. Prior knowledge of the spectral emission regions of the lamp or the spectral transmittance/ reflectance properties of optics used in the lamp product is sufficient to determine whether or not a product falls within the scope.

In case of doubt, a simple test to determine whether a particular lamp meets this criterion could be performed using a thermal detector and a long wavelength pass filter having a cut-on around 400 nm (UV blocking).

Measurements of irradiance in the UV are limited to a full cone angle of 80° (i.e. ± 40) field of view (FOV).

NOTE Due to the large reduction factor for skin, it is appropriate to apply the 80° FOV that applies for ocular risks (ICNIRP, 2004). Normally the 80° FOV will capture all of the significant radiation. However, if a detector with a wider FOV (e.g., a cosine-response detector) is used, the assessment will over-estimate the exposure.

- The specified output shall be determined for foreseeable variations in the environment (temperature, air pressure, humidity, outdoor-use, etc.).

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- The emitted radiant power of an installed system shall not increase nor change its direction as a result of any reasonably foreseeable events or single fault condition.

5.2 Time-weighted averaged irradiance

The applicable emission limits for risk groups for time-weighted averaged irradiance are specified in Table 1.

Although the full spectral range in consideration is 180 nm to 400 nm, measurement need not be performed over the full range as described below.

In the region between 180 nm and 200 nm, atmospheric oxygen strongly absorbs photons. As a result, few spectroradiometers are specified and it is difficult to obtain traceable spectral irradiance standards operating over this range. Measurement below 200 nm should therefore be reserved only for the special case of a low-pressure mercury lamp with vacuum UV transmitting quartz envelope.

In the region between 200 nm and 250 nm, low spectroradiometer sensitivity may cause measurement results with poor signal-to-noise ratio. While this may be remedied (see Clause C.6), prior knowledge of the spectral emission regions of the lamp or the spectral transmittance/ reflectance properties of optics used in the lamp product may be used to limit the spectral range of measurement to 250 nm to 400 nm.

Table 1 – Emission limits for risk groups for time-weighted averaged irradiance

Hazard	Wavelength range nm	Symbol for emission level	Emission[a] limits			Units
			Exempt group	Risk group 1	Risk group 2	
UV (actinic)[b]	180 to 400	E_s	0,001	0,003	0,03	$W \cdot m^{-2}$
UV-A[c]	315 to 400	E_{UVA}	10	33	100	$W \cdot m^{-2}$

[a] Emission limits are expressed as irradiance specified at a given application dependent assessment distance and not at the surface of the source. Actinic irradiance is spectrally weighted: the UV-A irradiance is not.

[b] For dose-limited products, the spectrally-weighted dose emission limit is 30 $J \cdot m^{-2}$. See 5.3.3.

[c] In the unusual case of a lamp source to be directly and intentionally viewed for more than 1 000 s in any 30 000 s (approximately 8 h) period (view-related risk), the dose emission limit for the exempt limit is reduced to 10 kJ/m^2 as determined by the intended stare time.

5.3 Risk group assessment conditions

5.3.1 Maximum output conditioning

The optical source shall be operated at maximum optical power to achieve the highest accessible radiant power emission.

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5.3.2 Measurement and assessment distances for UV lamp products

When measuring irradiance or spectral irradiance from UV lamp products, measurements of effective UV-B and UV-C irradiance and/or spectral irradiance shall be made at a distance that is sufficiently close in order to minimize the measurement errors from stray light where filtered, but biologically significant, emissions are very weak. However, in the case that the radiant output is so intense that the instrument detector might be saturated, then the measurement distance shall be greater. If the measurement distance differs from the risk group assessment distance in Table 2, Table 3 and Table 4, then it is necessary to transfer the measurements to the assessment distance. Normally the transfer of measurements made at a closer distance is obtained by determining the ratio of $S(\lambda)$-weighted UV to total irradiance or radiant power (i.e., µW-eff/mW-total) in the same manner as determining the µW/lm ratio when assessing GLS lamps. The actual measurement values and the extrapolated measurement values at the assessment distance shall be reported.

5.3.3 Risk-group assessment distances

Table 2, Table 3 and Table 4 provide the risk-group assessment distances for specific ultraviolet lamp products. Table 2 applies to products intended for use by consumers in uncontrolled environments that require no restrictions other than the provision of user information. Under normal or abnormal operating conditions, ordinary persons should not be exposed to ultraviolet sources capable of causing pain or injury. Under a single fault condition, ordinary persons should not be exposed to ultraviolet sources capable of causing injury. Those products used in applications that require special use training and generally only administrative controls are listed in Table 2; these are normally intended for professional use or use by instructed persons.

Under normal operating conditions, abnormal operating conditions or single fault conditions, instructed persons should not be exposed to parts comprising ultraviolet sources capable of causing injury. Lamps and lamp products intended for use by consumers/ordinary persons or instructed persons shall not emit accessible RG-3 emission levels. Those products requiring engineering controls and/or personal protective equipment as well as administrative controls and special training, and typically limited to professional use by competent persons are in Table 2. For UV lamp products listed in Table 2, if the $S(\lambda)$-weighted irradiance and the UV-A irradiance meets the exempt group limits at the assessment distance, no further testing is required. However, a calculation should be performed to ensure that the S(λ)-weighted irradiance and the UV-A irradiance cannot exceed the emission limit for RG-2 at 20 cm (unless a closer distance is indicated in Table 2). If the UV lamp product's $S(\lambda)$-weighted irradiance exceeds the emission limit for RG-2 at 20 cm, then the product should be labelled RG-3 and its use should be restricted, meaning that the UV lamp product should not be used by consumers/ordinary persons. For UV lamp products not listed in Table 2, Table 3 and Table 4, the assessment distance shall be 1 m, or the manufacturer's recommended use distance in the case that lengthy exposure times (i.e. greater than 100 s) at this distance are feasible.

Systems that emit radiation exceeding the emission limit for RG-2, but with access restricted due to installation by a competent person to restrict the likelihood of persons being exposed above the RG-2 limits remain RG-3 products unless engineering controls prevent access.

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