

EN

From the IEC standard
IEC 61331:2014
to the German standard
DIN EN 61331:2016



MAVIG

Overview of Contents

The Current Standard Series **IEC 61331:2014** (international) / **DIN EN 61331:2016** (German)

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The Most Important Things in Brief

With these guidelines, MAVIG would like to advise you regarding the selection of your radiation protection apron. The most important criteria for making a decision are highlighted, especially taking into account the current state-of-the-art and the revised and now solely valid standard series.

Standard series **DIN EN 61331:2016**

based on:

Standard **IEC 61331:2014**

IEC 61331-1:1994, IEC 61331-3:1998, DIN EN 61331-1:2006, DIN EN 61331-3:2002 and DIN 6857-1:2009, the predecessor versions of the current standards/standard series, are **outdated** and have been **replaced**.



Pay explicit attention to the year following the standard. Without specification of the year, it is not possible to evaluate the validity of a standard!

Content of the standard series DIN EN 61331:2016

Part 1 of the standard series deals with the “**Determination of attenuation properties of materials**” and **part 3**, entitled “**Protective clothing, eyewear and protective patient shields**”, with the design of the protective clothing.

You will find more details on the following pages.

(Note: Part 2 of the standard series deals with the topic “Translucent protective plates” and is not relevant for the purpose of this flyer.)

How can you find out whether an apron corresponds to the latest state-of-the-art?

- The label includes the **CE mark**, followed by the **four-digit reference number** of the notified body
- The lead equivalent was determined according to **IEC 61331-1:2014 / DIN EN 61331-1:2016**
- The design corresponds to IEC 61331-3:2014 / DIN EN 61331-3:2016: On the largest girth, the apron covers **at least 60%** of the girth.
- The **surface weight** of the radiation protection material is indicated on the label.

IEC 61331-1:2014, DIN EN 61331-1:2016

▶ Methodology for determining the lead equivalent

For the first time at international levels, the current standard for the determination of the lead equivalent takes the occurrence of **fluorescent radiation*** into account by means of a prescribed **measuring method**.

(* low-energy radiation occurring mainly with lead-reduced and lead-free material)

This is important, as fluorescent radiation represents an additional **hazard** for the user, with a higher biological effect ^{*1}.

▶ Verify comprehensive protective effect

It is now mandatory for all manufacturers to demonstrate the **protective effect** of the apron across the **entire X-ray tube voltage range** of **50 kV to 110 kV** or **50 kV to 150 kV**.

This is important, as the **protective effect** at the lower and upper end of the X-ray tube voltage range can **decreases** significantly, especially in the case of lead-reduced or lead-free protective material.

Since 2009, MAVIG has had its radiation protective aprons tested according to the national standard DIN 6857-1:2009, which already took fluorescent radiation into consideration as well as specified a measurement across the entire X-ray tube voltage range.

In short, this means:

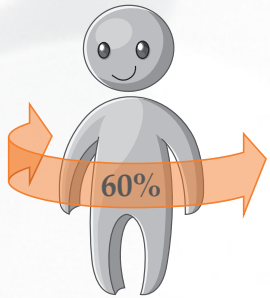
- Fluorescent radiation is taken into account.
- The protective effect of a material must be measured and demonstrated across the entire X-ray tube voltage range.

(^{*1}) Regulla DF et al: *Patient exposure in medical X-ray imaging in Europe. Radiat Prot Dosimetry 2005, Vol 114 (1-3), pp. 11-25*

IEC 61331-3:2014, DIN EN 61331-3:2016

► Design of personal protective equipment

Part 3 specifies that at least **60% of the girth of the user's chest, waist, or hip** (the largest value counts) is to be covered by protective material, in order to better protect the sides of the body.



Well-thought-out, weight-distributing designs are now even more important than before. Due to the new regulations any radiation protective apron is enforced to have a higher total weight.

► Specification of surface weight

Additionally, the new IEC and DIN EN demand more transparency regarding the **properties** of the radiation protective material. The real **surface area weight** now has to be indicated on the apron, in order to simplify a **comparison** of different models and different manufacturers of protective aprons.

Always take into account that a slightly heavier radiation protective apron can still offer higher wearing comfort through skilful design and weight distribution.

► Apron size to fit your body measurements

The size of a radiation protective aprons must now be **assigned to the corresponding body measurements**, making it easier to select the appropriate radiation protective apron without trying it on.

In summary, this means:

- The front protective area of the radiation protective apron must cover at least 60%.
- The surface area weight of the radiation protective material must be indicated on the label.
- The size of the radiation protective apron must be assigned to the body measurements.

The New Product Label

Based on these **four traits**, you can recognise whether your protective clothing corresponds to the latest state-of-the-art.

- 1** Indication of the X-ray tube voltage range 50 - 110 kV or 50 - 150 kV in which the protective effect of the protective clothing has been measured and demonstrated.

All around protective model
Balance, including 1x hanger

Costume, front: 0,35 mmPb, back: 0,25 mmPb,
Small (S), 70 cm, Curacao,
ComforTex HPMF, NovaLite 0,35, 50-110 kV



CE 0123

SN 5760140000001

REF RA631K32S702228

Fig. 1: Example of a product label

- 3** CE mark with four-digit reference number of the notified body.

- 2** *Statement of the standards with indication of the year!
Only the combination of part 1 and part 3 of the standard series in conjunction with the indication of the year 2014 (IEC) or 2016 (DIN EN) corresponds to the latest state-of-the-art (see also pages 4-5).*



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Cleaning & Disinfection



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according to: IEC 61331-1:**2014**,
IEC 61331-3:**2014**, DIN EN 61331-1:**2016**,
DIN EN 61331-3:**2016**, 89/686/EEC

4
Surface area weight front: 4,3 - 4,9 kg/m²
Surface area weight back: 3,0 - 3,6 kg/m²

MAVIG HC 0,35 mmPb / 50-110 kV IEC 61331-3:2014

- 4** *Indication of the surface area weight of the radiation protective material.*

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