

FRENCH REPUBLIC

Ministry of Health, Families, Autonomy
and Persons with Disabilities

Order No. of
amending the Order of 19 August 2011 on the assessment of the risk of exposure to lead
NOR:

The Minister of Health, Families, Autonomy and Persons with Disabilities,

Having regard to the Public Health Code, in particular Articles L. 1334-5 to L. 1334-10 and R. 1334-10 to R. 1334-12;

Having regard to the Order of 19 August 2011 on the assessment of the risk of exposure to lead;

Having regard to the opinion of the Supreme Council for Public Health dated ...,

Hereby orders:

Article 1

The third paragraph of Article 2 of the aforementioned Order of 19 August 2011 is replaced by a paragraph worded as follows:

‘They shall be carried out with a portable X-ray fluorescence device meeting the performance criteria set out in Annex 3 to this Decree, verified by the transferor prior to their transfer and during their maintenance. ’

Article 2

Article 3 of the same decree is replaced by a new Article 3 worded as follows:

‘ *Art. 3.* - The distribution, possession and use of X-ray fluorescence devices fitted with a radioactive source or an X-ray tube are subject to the regulatory requirements laid down pursuant to Article L. 1333-4 of the Public Health Code.

‘For X-ray fluorescence devices fitted with a radioactive source, the person carrying out the inspection must have a certificate from the device manufacturer stating the maximum service life of the radioactive source. During this period, the device shall ensure that 95% of the results of measurements carried out on a standardised sample with a concentration close to 1

mg/cm² are included in an interval of: [target value – 0.1 mg/cm²; target value + 0.1 mg/cm²].’

Article 3

Article 9 of the same Order is supplemented by a subparagraph worded as follows:

‘The lead concentration measurements of the coatings referred to in Article 2 shall be carried out with a device meeting the criteria set out in Annex 3 to this Order by 1 April 2027 at the latest.’

Article 4

After Annex 2 to the same Order, an Annex 3 is added, worded as follows:

ANNEX 3: PERFORMANCE CRITERIA FOR PORTABLE X-FLUORESCENT DEVICES FOR LEAD MEASUREMENTS OF COATINGS TO BE CHECKED BEFORE RELEASE AND DURING MAINTENANCE

1. Preparation of test samples

Two categories of samples to support the measurements shall be used and kept until the next inspection.

a) First category of samples: certified reference materials for the determination of lead in paints:

NIST 2570-2576 (National Institute of Standards and Technology, Washington D.C., USA : Standard Reference Materials : Lead Paint films for portable X-ray Fluorescence Analysers NIST SRMs 2570-2576)

The NIST reference materials are polyester films covered with a homogeneous layer of lead paint and protected by a plastic film against abrasion. The addition of a different colour by reference makes it easy to recognise them visually. The thickness of the layer is approximately 0.04 mm.

The following table summarises the characteristics of the NIST references to be used:

Certified values				
SRM No.	Colour	Concentration mg/cm²	Uncertainty mg/cm²	Pigment of lead base
2570	Blank	0 (<0.001)	-----	-----
2572	Orange	1.527	0.091	Lead chromate
2573	Red	1.04	0.064	Lead chromate
2574	Gold	0.714	0.083	Lead chromate

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b) Second category of samples: synthetic samples

These samples are selected as follows:

- on three types of substrate: iron, wood and plaster;
- for each of these carrier materials, cover with lead-containing paint at the concentration of 1 mg/cm².

Furthermore, using these samples, create further samples by covering them with:

- thin coatings. Each of the following thin coatings shall be tested: modern titanium paint, 'mixed' paint with zinc-barium-titanium, wallpaper;
- thick coatings. Each of the following thick coatings shall be tested: 10 layers of titanium paint (0.73 mm), 10 layers of wallpaper (1.3 mm), glass fibre mesh (0.35 mm), thick plastic coating (TPC) (1.4 mm).

2. Calibration of the device before testing

The X-ray fluorescence device shall be calibrated in accordance with the procedures provided by the manufacturer of the device.

For performance evaluation, X-ray fluorescence devices shall be used according to the methodology recommended by their manufacturers and within the limits of their accuracy.

3. Evaluation of performance criteria

a) Criterion 1: accuracy of measurements on NIST samples in the vicinity of the threshold of 1 mg/cm²

The accuracy of the device's measurements is assessed on the basis of 20 consecutive measurements taken on the NIST gold (reference 2574, 0.714 mg/cm²), red (reference 2573, 1.04 mg/cm²) and orange (reference 2572, 1.527 mg/cm²) standards. The mean value is statistically compatible with the reference data presented in the NIST table above.

The accuracy of the measurements is tested by checking whether the mean falls within the confidence interval of the certified value, or by conducting a statistical test to compare the mean and its confidence interval with a reference value and its confidence interval.

b) Criterion 2: Measurement repeatability at the threshold of 1 mg/cm²

Repeatability measurements are obtained from a series of 100 measurements on the NIST red reference sample (reference 2573, 1.04 mg/cm²).

The standard deviation of the series of 100 consecutive measurements shall be less than or equal to 10% of the average, i.e. 0.10 mg/cm².

c) Criterion 3: Measurement repeatability for different substrate materials and interferences at a threshold of 1 mg/cm²

The influence of the substrate material and interferences is investigated using a series of 100 measurements on synthetic samples.

The standard deviation of the series of 100 consecutive measurements is less than or equal to 10% of the average, i.e. 0.10 mg/cm².

d) Criterion 4: reproducibility of measurements at different temperatures at the 1 mg/cm² threshold

Reproducibility measurements according to room temperature are obtained from series of 20 measurements on the red NIST reference sample (reference 2573, 1.04 mg/cm²), the film being placed on wood. The influence of temperature is studied by considering the two limit values: -5 °C to 40 °C (or the manufacturer's specified limits).

The standard deviation of a series of 20 consecutive measurements is less than or equal to 10% of the average, i.e. 0.10 mg/cm².

Article 5

This Order shall be published in the *Official Journal* of the French Republic.

The Minister of Health, Families,
Autonomy and Persons with Disabilities
Stéphanie RIST

The Minister of Housing and Urban
Renovation

Vincent JEANBRUN