FRENCH REPUBLIC

Ministry of Health, Families, Autonomy
and Persons with Disabilities

Order No.

amending the Order of 19 August 2011 on the diagnosis of the risk of lead poisoning from paints

NOR:

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

Having regard to the Public Health Code, with particular reference to Articles L. 1334-1 and R. 1334-4;

Having regard to the Order of 19 August 2011 on the diagnosis of the risk of lead poisoning from paints;

Having regard to the opinion of the High Council for Public Health dated

Hereby orders:

Article 1

In the title of the aforementioned order of 19 August 2011, the word: “paints” is replaced by the word “coatings.”

Article 2.

In the first paragraph of Article 1 of the same order, the words: “of paints” are deleted.

Article 3

Articles 3 and 4 of the same order are replaced by two new Articles 3 and 4, worded as follows:

“Article 3 –The measurements of lead concentration of all the coatings referred to in Article 1(3) shall be carried out with a portable X-ray fluorescence device meeting the performance criteria set out in Annex 2 to this order, verified by the transferor before their transfer and during their maintenance.

“Article 4. – The distribution, possession and use of X-ray fluorescence devices fitted with a radioactive source or an X-ray generating 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 diagnostic operator must have a certificate from the device manufacturer stating the maximum lifespan 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 4

In the first paragraph of Article 7 of the same order, after the words: “of the Annex”, the following number is inserted: “1”.

Article 5

Article 8 of the same order is supplemented by a subparagraph worded as follows:

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

Article 6

The annex to that order is referred to as “Annex 1: “PROTOCOL FOR CONDUCTING A LEAD POISONING DIAGNOSIS”

Article 7

A new Section 2 is inserted after Annex 1, worded as follows:

Annex 2: PERFORMANCE CRITERIA FOR PORTABLE X-RAY FLUORESCENCE DEVICES FOR MEASURING LEAD IN COATINGS, TO BE VERIFIED BEFORE THEIR TRANSFER AND DURING MAINTENANCE

1. Preparation of test samples

Two categories of samples to support the measurements shall be used and retained 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 uniform layer of lead paint and protected by a plastic film against abrasion. The addition of a different dye for each reference allows them to be easily identified visually. The thickness of the coating 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**	**Lead-based pigment**
2570	**White**	**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**

b) Second category of samples: synthetic samples

These samples are constituted as follows:

- using three types of substrate: iron, wood and plaster;

- for each of these substrates, apply a coating of lead-containing paint at a concentration of 1 mg/cm².

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

- thin coatings. Each of the following thin coatings shall be tested: modern titanium paint, ‘mixed’ zinc-barium-titanium paint, wallpaper;

- thick coatings. Each of the following thick coatings shall be tested: 10 layers of titanium-based paint (0.73 mm), 10 layers of wallpaper (1.3 mm), glass fibre mesh (0.35 mm), thick plastic coating (RPE) (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 samples: gold (reference 2574, 0.714 mg/cm²), red (reference 2573, 1.04 mg/cm²) and orange (reference 2572, 1.527 mg/cm²). The mean value is statistically compatible with the reference data presented in the NIST table above.

Measurement accuracy performance 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 1 mg/cm² threshold

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 interfering factors at the 1 mg/cm² threshold

The influence of the substrate material and interfering factors is investigated using a series of 100 measurements on the 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: Measurement reproducibility at different temperatures at the 1 mg/cm² threshold

Measurement reproducibility with respect to room temperature is obtained from series of 20 measurements on the red NIST reference sample (reference 2573, 1.04 mg/cm²), the film 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 8

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 for the Urban Affairs and Housing,

Vincent JEANBRUN