Certified translation from the German

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Expert medical report on the examination of the rough-cast ceiling above the GIF ventilation ceiling in the staff canteen of the Freiburg University Clinic.

1. The issue

According to the manufacturer of GIF ventilation ceilings (GIF GmbH, Freiburg), the individual coffers of this ventilation ceiling act as a fat and condensate separator: the directing of the air current over phase separating chambers leads to the depositing of dirt, fat and other suspended particles on the inner surface of the small coulisses, thus avoiding contamination of the ceiling cavity of the rough-cast ceiling.

As instructed by GIF (Managing Director Mr. Hammer) in their letter of 26 October 2000, the rough-cast ceiling above the GIF ventilation ceiling which was installed in the staff canteen of the Freiburg University Clinic about 15 years ago (in the area above the tilt-type frying pan, see Fig.1) was examined and appraised with regard to hygiene.

2. Methods

Within the course of routine cleaning of the removable element of the GIF ventilation ceiling, the area situated above this section (rough-cast ceiling) was thoroughly examined on 10 November 2000. In addition, a microbiological examination was carried out using sterile, commercial RODAC contact agar plates ("Replicate Organism Detection and Counting", Biotest Columbia blood contact agar, Heipha Diagnostika, Heidelberg; contact surface approx. 21 cm^2). These were opened taking aseptic precautions, put on the various accessible control points (plasterboard ceiling, ventilation duct, girder element, cut-off wall) applying moderate pressure for 10 seconds each, and then sealed immediately to avoid contamination. The plates were incubated in the laboratory for 48 hours at 37°C, followed by a germ count and, where necessary, by a microbiological analysis.

3. Results

The macroscopic inspection of the clearly designed and largely visible ceiling area above the GIF ceiling elements, which had been removed a few minutes before, did not show any conspicuities: the yellowish surface of the plasterboards was dry, smooth and did not show any specific sediments. The steel plate surface of the ventilation duct and the steel girder construction for the GIF elements were also in good condition commensurate with their age (refer to Fig. 3-5).

In total, 19 RODAC plates were used to take multiple samples from all accessible areas (refer to item 1). Using an additional plate, the rear of a dismantled GIF ceiling element was sampled.

In 16 cases, there was no germ growth on the RODAC plate after the incubation period. One colony-forming unit (CFU) of coagulase-negative staphylococci was isolated in three plates, with an additional CFU of micrococci found on one of these plates.

On the RODAC plate used to sample the rear of the ceiling element, the following germs were isolated: aerobic spore-forming organisms 5 CFU, coagulase-negative staphylococci 11 CFU, non-fermentors 2 CFU, micrococci 4 CFU.

4. Summary assessment

As mentioned above, the external (macroscopic) aspects did not give any cause for objection, the visible areas above the GIF ventilation ceiling showed findings commensurate with their age without any relevant sediments/contamination.

The results of the microbiological examination of selected surfaces by means of contact agar plates presented no conspicuous findings and/or a low degree of contamination (0 CFU - 2 CFU for each RODAC plate). The European Good Manufacturing Practices (EU GMP, 1997) were applied in the assessment; the germ concentration found corresponds to the second highest purity level (Grade B) as defined for the manufacture of medical products. The 22 CFU/RODAC plate isolated on the rear of a ceiling element are to be assigned to 'Grade C' (3rd level). The spectrum of the isolated germs corresponds to the usual colonization of surfaces (mainly by gram-positive bacteria).

We fully agree with the manufacturer's statement that ceiling cavity contamination on the rough-cast ceiling can be ruled out by the special GIF ventilation ceiling design. In summarizing, it may be stated that, even after many years of using the GIF ventilation ceiling in the staff canteen of the Freiburg University Clinic, the accessible areas of the rough-cast ceiling above the ventilation elements were in perfect condition in terms of hygiene.

Freiburg, 20 February 2001
Dr. med. M. Dettenkofer (signature illegible)

I hereby certify that the above text is a true and correct translation of the original German document/certified copy submitted:

Freiburg, dated: - 8 MAR 2001

(Sworn translator)

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