U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
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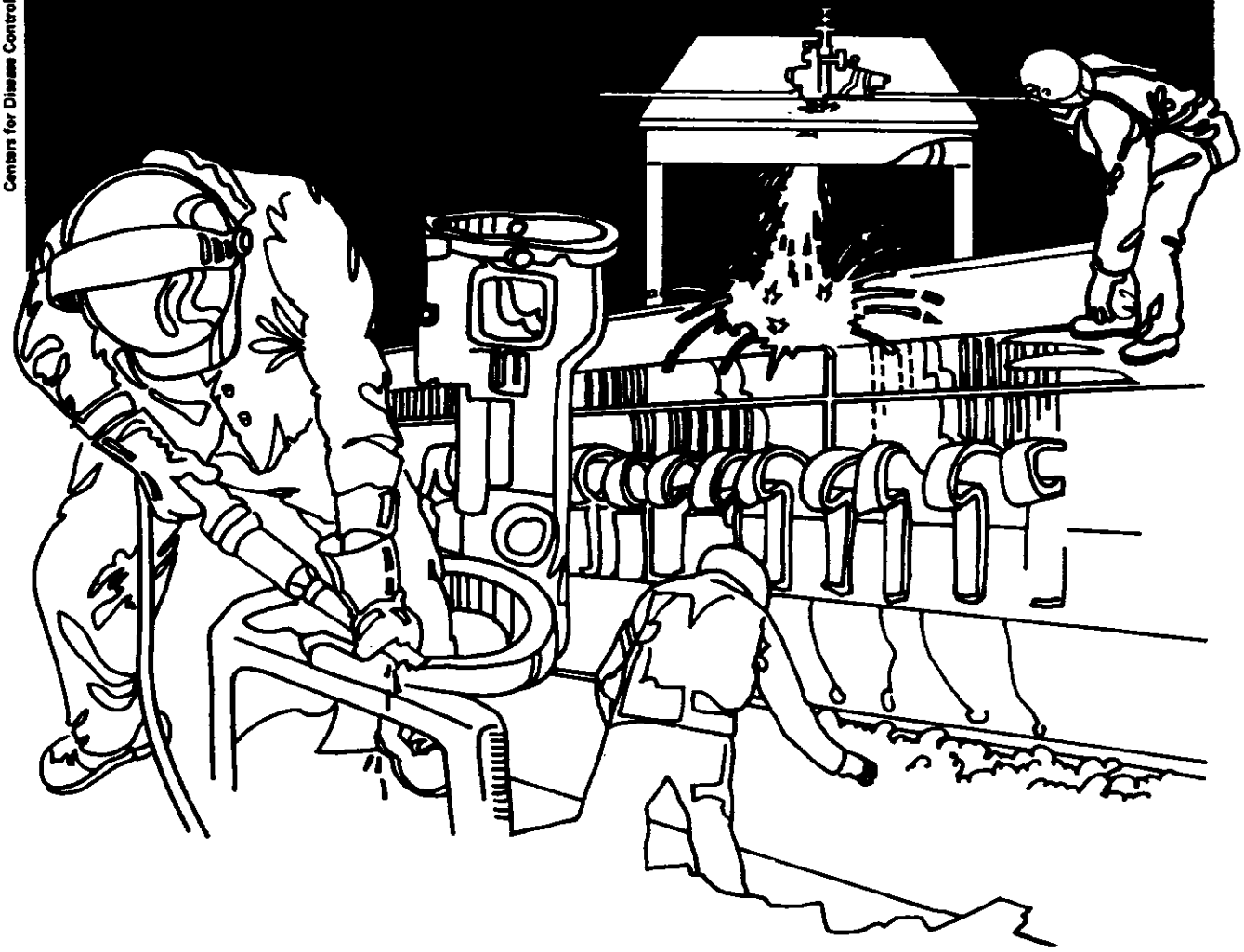

Health Hazard Evaluation Report

HETA 87-339-1863
ST. FRANCIS-ST. GEORGE HOSPITAL
CINCINNATI, OHIO

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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ST. FRANCIS-ST. GEORGE HOSPITAL
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I. SUMMARY

On August 19 and 20, 1987, a health hazard evaluation was conducted by the National Institute for Occupational Safety and Health (NIOSH) at St. Francis-St. George Hospital, Cincinnati, Ohio. The purpose of this evaluation was to assess potential lead exposure of health care workers in the Supply, Processing and Distribution (SPD) department who handle lead-containing steam sterilization indicators. Nineteen workers are assigned to the SPD department who are responsible for inspection, preparation, and sterilization of instruments, trays, and other items used in surgery and patient areas. The types of steam indicators used at this facility included Surgicot® indicator strips, Surgicot® indicator tape, and Tomac® test records.

Both environmental and medical monitoring were conducted to assess potential lead exposure. Three types of environmental samples were collected to assess lead exposure and/or contamination: personal breathing-zone and general area air samples, surface wipe samples, and passive filter samples positioned inside test packs. The latter samples were collected to determine whether lead volatilized from the test record during sterilization. Bulk samples of the indicator strips, tape, and test records were obtained for analysis of lead content. Medical monitoring included the collection of blood samples from several SPD workers. These samples were analyzed for lead and free erythrocyte protoporphrin (FEP).

Bulk sample analysis revealed that the lead content of the indicator strips and tape (18 cm. section) was approximately 2200 micrograms (ugs) lead each. The test records each contain approximately 135,000 ugs lead.

All ten personal and general area air samples had no detectable lead. The environmental limit of detection for these samples was calculated to be less than 1.6 ug/M^3, well below the OSHA Permissible Exposure Limit of 50 ug/M^3. These samples show that during routine handling of the indicators, lead exposure via inhalation is probably negligible.

A total of forty-three surface wipe samples were collected. Twenty-nine were collected from surfaces directly or indirectly contacted by the indicators, including the worker's fingers. Only one of these samples, from the autoclave rack track, contained a detectable amount of lead, 12 ug. The remaining 14 were surface wipes of the treated surface of the three types of indicators, both non-autoclaved

and autoclaved. Lead was detected only on two samples of autoclaved indicator tape, at levels no higher than 4.4 ug per sample. Overall, these samples show that the indicators do not cause contamination of surgical implements, work surfaces, or workers' hands via direct or incidental contact.

Analysis of the passive filter samples showed lead only on filter samples placed directly on top of the treated side of the test record; amounts ranged from 5.7 to 9.7 ug per sample. Lead was not detected at any of the other sites inside the test pack. The presence of lead on these filters probably resulted from direct contact of, rather than volatilization of lead from, the treated surface of the test record. These results indicate that the test records do not pose a lead contamination problem during normal usage applications.

All nine SPD processing technicians who had their blood drawn had blood lead and FEP levels at or below 8 and 26 ug/dl, respectively. These results indicate that the body burden of lead in these individuals was not elevated.

Based on the environmental and medical sampling results, lead exposure of SPD processing technicians is probably negligible during normal use of Surgicot® steam sterilization strips and tape, and Tomac® test records.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals), lead, steam sterilizer indicators, health care workers

II. INTRODUCTION

In April 1987, the Hazard Evaluations and Technical Assistance Branch of NIOSH received information which showed that a number of commercially available steam sterilization indicators contain appreciable amounts of lead, and that the lead could be released from the indicators by contact or by the sterilization procedure. Based on this information, there was a concern that health care workers were being exposed to lead while handling the lead-containing indicators and that surgical implements were being contaminated with lead, posing a potential health hazard to patients. Because of this concern, NIOSH initiated a health hazard evaluation of health care workers at the St. Francis-St. George hospital, a user of lead-containing steam sterilization indicators.

On July 13, 1987, an initial site visit was conducted by a NIOSH industrial hygienist, during which a walkthrough familiarization tour of the Supply, Processing and Distribution (SPD) department was made and pertinent information gathered for development of a sampling protocol. On August 18 and 19, 1987, NIOSH investigators returned to the hospital and collected environmental samples for lead determination. Blood was drawn from selected workers to assess lead exposure.

The results of the survey were summarized for hospital management and workers via letter dated October 6, 1987.

III. BACKGROUND

a. Workforce

Health care workers who routinely handle the steam sterilization indicators at St. Francis-St. George hospital are assigned to the SPD department. They consist of 19 full-and part-time processing technicians (three shifts) who are responsible for inspection, preparation, and sterilization of all instruments, trays, and other items used in surgery and patient areas.

b. Process

Steam sterilization indicators are used to provide the user with a quick and decisive method, via color change, of determining whether the steam sterilization process was complete. Three types of (lead-containing) indicators were used at this hospital. These included: Surgicot® steam indicator strip, Surgicot® indicator tape, and Tomac® Check-a-Clave autoclave test record. The

indicator strips are used inside every packet or tray that is prepared for sterilization; the tape is typically used on the outer surface of cloth-wrapped items to visually identify whether they have been sterilized. The test records are used exclusively for the Bowie and Dick technique, a quality control test of sterilizer performance. Although test packs are commercially available, St. Francis-St. George hospital prepares their own test packs. The packs are prepared by placing one test record between a number of folded towels to yield a specified thickness on each side of the test record (to test steam penetration). This assembly was wrapped with a Kimguard® disposable towel with a piece of indicator tape on the outer suface for identification purposes. One or more test packs are placed into the sterilizer during each batch run. Following sterilization, the test packs are disassembled and the test records are inspected for complete and uniform color change. The test records are stored in a binder for future reference.

IV. MATERIALS AND METHODS

a. Environmental Evaluation

Environmental monitoring was conducted on August 19 and 20, 1987 during routine operations on the first shift, when the majority of the sterilization work is performed. Monitoring consisted of the collection of three types of environmental samples to assess lead exposure and/or contamination: (1) personal and general area air samples, (2) surface wipe samples, and (3) test pack samples. In addition, bulk samples of the indicator strips, tape, and test records were obtained for analysis of lead content.

Four personal and six general area air samples were collected to measure air lead levels. The personal air samples were collected from the breathing-zones of processing technicians who handled the indicators during this survey. The general area air samples were collected from above the doors on both steam sterilizers, and from the work table located in the center of the main processing area. These samples were collected on 37 mm mixed cellulose ester (MCE) filters connected via flexible tubing to battery-operated sampling pumps calibrated at 1.5 liters per minute (Lpm). The filters were analyzed by atomic absorption spectrosopy (AAS) according to NIOSH Method 7082.[1] The limit of detection for the analysis was 1 microgram (ug) per sample.

Forty-three wipe samples were collected from various surfaces to determine whether the steam indicators contaminate these surfaces with lead via direct or incidental contact. Wipe samples were collected from selected surgical tools and their plastic sealable pouches, both before and after autoclaving; interior and exterior of both autoclaves; sterilization racks; work tables; processing

technicians' fingers following handling of the indicators; and the three types of steam indicators, before and after they were autoclaved. These samples were collected on 25 mm smear tab filters pre-soaked with deionized water. On irregular surfaces, such as surgical implements, the entire surface was wiped with the filter, whereas on flat surfaces, such as the work table, an area of 100 square centimeters was wiped. Upon collection, the filters were placed into metal-free containers. Samples were analyzed by atomic absorption spectroscopy (AAS) according to NIOSH Method 7082.[1] The limit of detection for the analysis was 2 ug per sample.

Of the three types of indicators in use, the test records represented the single greatest source of lead. Therefore, we collected samples from inside several test packs to determine whether lead was being volatilized during the sterilization process. Five 37 mm MCE filters were placed at selected sites inside each of six test packs, which were prepared by the processing technicians specifically for this study. Thus, a total of thirty samples were collected. Sample sites inside the test pack are illustrated in Figure 1. The test packs were autoclaved in the normal manner, cooled, and disassembled, and the filters were removed and placed into Petrislides for shipment to the laboratory. In two of the six test packs, to serve as controls, lead-free paper was used instead of the test record. The test pack samples were analyzed by AAS according to NIOSH Method 7082.[1] The limit of detection for the analysis was 0.9 ug per sample.

Bulk samples of indicator strips, indicator tape, and test records, both autoclaved and non-autoclaved, were obtained and analyzed for lead content. These samples were collected to determine whether the lead content decreased following autoclaving, possibly indicative of lead volatilization. These samples were analyzed by AAS according to NIOSH Method 7082.[1] The limit of detection was 2 ug per sample.

b. Medical Evaluation

The medical evaluation consisted of the collection of whole blood samples from nine processing technicians who routinely handle the indicators, for determination of blood lead (PbB) and free erythrocyte protoporphrin (FEP), both indicators of lead exposure. Blood samples were drawn directly into vacutainers containing sodium heparin anticoagulant, and subsequently mixed to prevent clotting. The samples were sent to ESA Laboratories, Bedford, Massachusetts for analysis.

V. EVALUATION CRITERIA AND TOXICOLOGY DISCUSSION

A. Environmental Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Recommended Exposure Limits (REL's),[2] (2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs)[3], and (3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH REL's and ACGIH TLVs are lower than the corresponding OSHA standards. Both NIOSH REL's and ACGIH TLV's usually are based on more recent information than are the OSHA standards.[4] The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH REL's, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure

limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

B. Inorganic Lead

Inhalation of lead dust and fumes is the major route of lead exposure in industry. A secondary source of exposure may be from ingestion of lead dust contamination on food, cigarettes, and other objects. Once absorbed, lead is excreted from the body very slowly. The absorbed lead, can damage the kidneys, peripheral and central nervous systems, and the blood-forming organs (bone marrow). Effects may include weakness, tiredness, irritability, digestive disturbances, high blood pressure, mental deficiency, or slowed reaction times. Chronic lead exposure is associated with infertility and with fetal damage in pregnant women.

The OSHA standard for PbB considers levels above 50 micrograms per deciliter (ug/dl) excessive; however, adverse health effects can be seen at levels as low as 30 ug/dl in adults.[4] FEP levels below 50 ug/dl are considered to be within the normal range in adults. The OSHA standard for airborne lead is 50 ug/M^3 for an 8-hour time-weighted average daily exposure. No lead standard exists for surface contamination.

VI. RESULTS AND DISCUSSION

a. Environmental

The air sampling results are presented in Table 1. Four personal breathing-zone and 6 general area air samples were collected to measure airborne lead levels. None of these samples had detectable lead. When adjusted for air volume, the environmental limit of detection for all samples was calculated to be less than 1.6 ug/M^3. By comparison, OSHA's Permissible Exposure Limit is 50 ug/M^3, as an 8-hour time-weighted average. This data shows that during routine handling of the steam sterilization indicators lead exposure via inhalation is negligible.

Table 2 presents the results of the surface wipe samples. Forty-three filter wipe samples were collected. Twenty-five were collected from various surgical implements, plastic sealable implement pouches, interior and exterior of the autoclave, sterilization racks, and table tops. Only one of these twenty-five samples contained detectable quantities of lead. This sample from the autoclave rack track had 12 ug lead. No detectable lead was measured on the four wipe samples obtained from fingers of two processing technicians following handling of the indicator

strips and the test records. Fourteen wipe samples were made of autoclaved and non-autoclaved indicator strips, tape, and the test records. Lead was detected only on the samples from autoclaved indicator tape, at 4.1 and 4.4 ug/sample. Overall, the wipe sampling results show that the steam sterilization indicators do not cause contamination of surgical implements, work surfaces, or workers' hands, via direct or incidental contact.

Table 3 presents the results from samples placed inside the test packs. In the four test packs where test records were placed inside, lead was detected only on the filter sample placed directly on top of the treated side of the test record. The amount of lead detected in these samples ranged from 5.7 to 9.7 ug/filter. These amounts are very small and probably resulted from direct contact with, rather than volatilization of lead from, the treated surface of the test record. Lead was not detected in any of the samples placed inside the two control test packs. These results indicate that the test records do not pose a lead contamination problem during normal use applications.

The lead content of autoclaved and non-autoclaved indicator strips, tape, and test records is presented in Table 4. The indicator strips contain approximately 2200 ug lead each. The indicator tape contains about 2200 ug of lead per 18 centimeter piece. The test records each contain approximately 135,000 ug of lead. Although testing was designed to determine whether the amount of lead decreased following sterilization (indicative of volatilization), this testing was inconclusive because of the inherent variability in lead content between samples of the same type of indicator. Nevertheless, it appears that volatilization is unlikely based on the test pack and wipe sampling results.

b. Medical Evaluation

All nine workers who had their blood drawn had PbB and FEP levels at or below 8 and 26 ug/dl, respectively. These results indicate the the body burden of lead in these individuals was not elevated.

VII. CONCLUSIONS

Based on the enviromental and medical sampling results, lead exposure of SPD processing technicians is negligible during routine use of Surgicot® steam sterilization strips and tape, and Tomac® test records.

It should be noted that there are other lead-containing steam sterilization indicators available which have not been tested. Additional testing is necessary before conclusions can be made related to these devices.

VIII. RECOMMENDATIONS

Provided that the same lead-containing indicators are used, no corrective action needed at this hospital since the sampling results show that workers are most likely not exposed to excessive lead levels.

Additional testing of other lead-containing steam sterilization indicators should be conducted to determine whether they pose a lead hazard to workers using them.

IX. REFERENCES

1. National Institute for Occupational Safety and Health. NIOSH manual of analytical methods. 3rd ed. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1984. (DHHS (NIOSH) publication no. 84-100).

2. NIOSH Recommendations for Occupational Safety and Health Standards. Morbidity and Mortality Weekly Report Supplement. Vol. 35, No.1S, September 26, 1986.

3. American Conference of Governmental Industrial Hygienists. Threshold limit values and biological exposure indices for 1987-88. Cincinnati, Ohio: ACGIH, 1987.

4. Occupational Safety and Health Administration. OSHA safety and health standards, 29CFR 1910.1025. Occupational Safety and Health Administration, revised March 1983.

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XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. St. Francis-St. George Hospital
2. U.S. Department of Labor/OSHA- Region V
3. NIOSH Cincinnati Region
4. Manufacturers

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

Figure 1
Schematic of Test Pack Showing Locations of Filter Samples
St. Francis - St. George Hospital
HETA 87-339

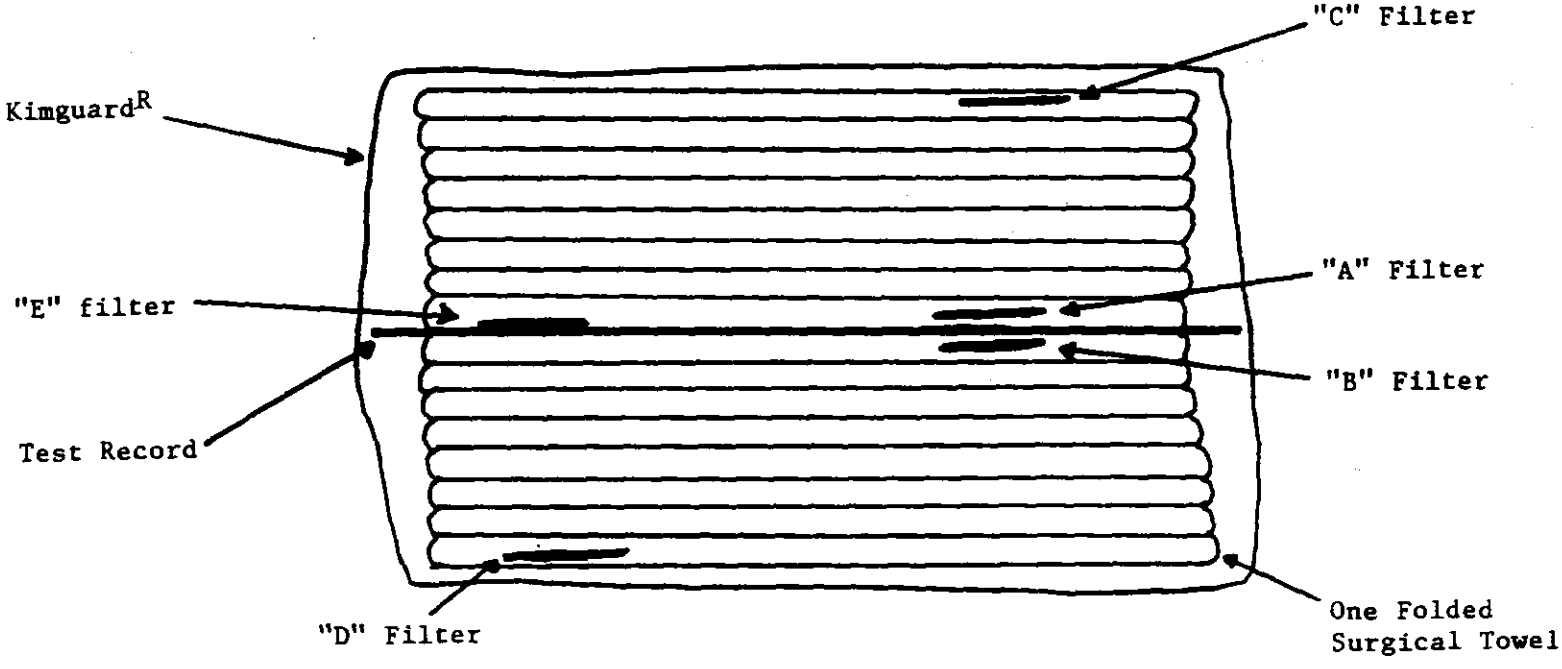

Table I

Personal and General Area Air Samples for Lead

St. Francis-St. Georges Hospital
HETA 87-339

August 19-20, 1987

Date	Sample Description	Sampling Time (min)	Sample Volume (liters)	Lead Concentration (ug/M^3)
8-19-87	Processing technician, PBZ	407	607	ND
8-19-87	"	470	705	ND
8-20-87	"	453	680	ND
8-20-87	"	453	680	ND
8-19-87	Above steam sterilizer #1 door, GA	468	702	ND
8-20-87	"	455	683	ND
8-19-87	Above steam sterilizer #2 door, GA	465	698	ND
8-20-87	"	455	683	ND
8-19-87	Table top, center room	465	698	ND
8-20-87	"	457	696	ND
Evaluation Criteria (OSHA):				50

ND - not detected; less than 1 ug/sample (no greater than 1.6 ug/M^3 for air volume sampled)
PBZ - personal breathing-zone air sample
GA - general area air sample

Table 2

Surface Wipe Sampling Results

St. Francis - St. George Hospital
HETA 87-339

August 19 and 20, 1987

Sample Description	Lead Content (ug/sample)
Kelley implement 1, before autoclaving	ND
Kelley implement 1, after autoclaving	ND
Kelley implement 2, before autoclaving	ND
Kelley implement 2, after autoclaving	ND
Gauge, before autoclaving	ND
Gauge, after autoclaving	ND
Osteotome, before autoclaving	ND
Osteotome, after autoclaving	ND
Inside surface of implement pouch, before autoclaving	ND
Inside surface of implement pouch, after autoclaving	ND
Door handle, autoclave #1	ND
Inside door, autoclave #1	ND
Inside autoclave #1, left wall	ND
Door handle, autoclave #2	ND
Inside door, autoclave #2	ND
Inside autoclave #2, left wall	ND
Inside autoclave #2, floor	ND
Rack track, autoclave #2	12
Door gasket, autoclave #2	ND
Table, directly across from autoclaves	ND
Table, directly across from autoclaves	ND
Table, adjacent to washers	ND
Sterilization rack, side bar	ND
Sterilization rack, horizontal bar	ND
Sterilization rack, main frame	ND
Processing technician 1, rt. hand digits following handling of test records and indicator strips	ND
Processing technician 1, lt. hand digits following handling of test records and indicator strips	ND
Processing technician 2, rt. hand digits following handling of indicator strips and test records	ND
Processing technician 2, lt. hand digits following handling of indicator strips and test records	ND

continued

Table 2 (continued)

Surface Wipe Sampling Results

St. Francis - St. George Hospital
HETA 87-339

August 19 and 20, 1987

Sample Description	Lead Content (ug/sample)
Surgicot® indicator strip, not autoclaved	ND
Surgicot® indicator strip, not autoclaved	ND
Surgicot® indicator strip, not autoclaved	ND
Surgicot® indicator strip, autoclaved	ND
Surgicot® indicator strip, autoclaved	ND
Surgicot® indicator strip, autoclaved	ND
Tomac® test record, treated surface, not autoclaved	ND
Tomac® test record, treated surface, not autoclaved	ND
Tomac® test record, treated surface, autoclaved	ND
Tomac® test record, treated surface, autoclaved	ND
Surgicot® indicator tape, not autoclaved	ND
Surgicot® indicator tape, not autoclaved	ND
Surgicot® indicator tape, autoclaved	4.4
Surgicot® indicator tape, autoclaved	4.1

ND = not detected, less than 2 micrograms (ug) per sample.

Table 3

Lead Content of Filters Placed
Inside Test Packs

St. Francis - St. George Hospital
HETA 87-339

August 19 - 20, 1987

Test Pack-Filter Sample Location	Lead Concentration (ug/filter)
1-A	ND
1-B	ND
1-C	ND
1-D	ND
1-E	7.9
2-A	ND
2-B	ND
2-C	ND
2-D	ND
2-E	9.7
3-A	ND
3-B	ND
3-C	ND
3-D	ND
3-E	6.4
4-A	ND
4-B	ND
4-C	ND
4-D	ND
4-E	5.7
5-A	ND
5-B	ND
5-C	ND
5-D	ND
5-E	ND

continued

Table 3 (continued)

Lead Content of Filters Placed
Inside Test Packs

St. Francis - St. George Hospital
HETA 87-339

August 19 - 20, 1987

Test Pack-Filter Sample Location	Lead Concentration (ug/filter)
6-A	ND
6-B	ND
6-C	ND
6-D	ND
6-E	ND

ND - not detected; less than 0.9 ug/filter.

Notes: Test packs 1-4 were assembled in usual manner using autoclave test records. Test packs 5 and 6 were assembled without the test records. Lead-free paper was used intead, to serve as controls

The letters A-E represent sites inside the test pack where sample filters were placed (See Figure 1).

- "A" filters were place one surgical towel thickness (1/16") away from treated side of test record
- "B" filters were placed one towel thickness away from back side of test record
- "C" filters were placed immediately inside outer Kimguard® cover, on treated side of test record
- "D" filters were placed immediately inside outer Kimguard® cover, on back side of test record
- "E" filters were placed directly on the treated side of the test record or lead-free paper.

Table 4

Lead Content of Indicator Strips, Tape, and Test Records

St. Francis - St. George Hospital
HETA 87-339

August 19-20, 1987

Sample Description	LEAD CONTENT ug/sample[A]	ug/device
Surgicot® indicator strip, not autoclaved	2200	2200
" "	2200	2200
" "	2300	2300
" "	2200	2200
" "	2000	2000
Surgicot® indicator strip, autoclaved	2400	2400
" "	2000	2000
" "	1800	1800
" "	2100	2100
" "	2400	2400
Surgicot® indicator tape, not autoclaved	2200	2200
" "	2200	2200
" "	2200	2200
Surgicot® indicator tape, autoclaved	2400	2400
" "	2200	2200
" "	2300	2300
Tomac® test record, not autoclaved	4800	235,200
" "	4300	210,700
Tomac® test record, autoclaved	5200	254,800
" "	4900	240,100

A. An indicator strip sample consisted of an entire test strip.

A test record sample consisted of a cut-out portion of the treated paper, which approximated about 1/49th of the entire treated surface of the test record.

An indicator tape sample consisted of an 18 cm long piece of tape, each with 10 treated markings.