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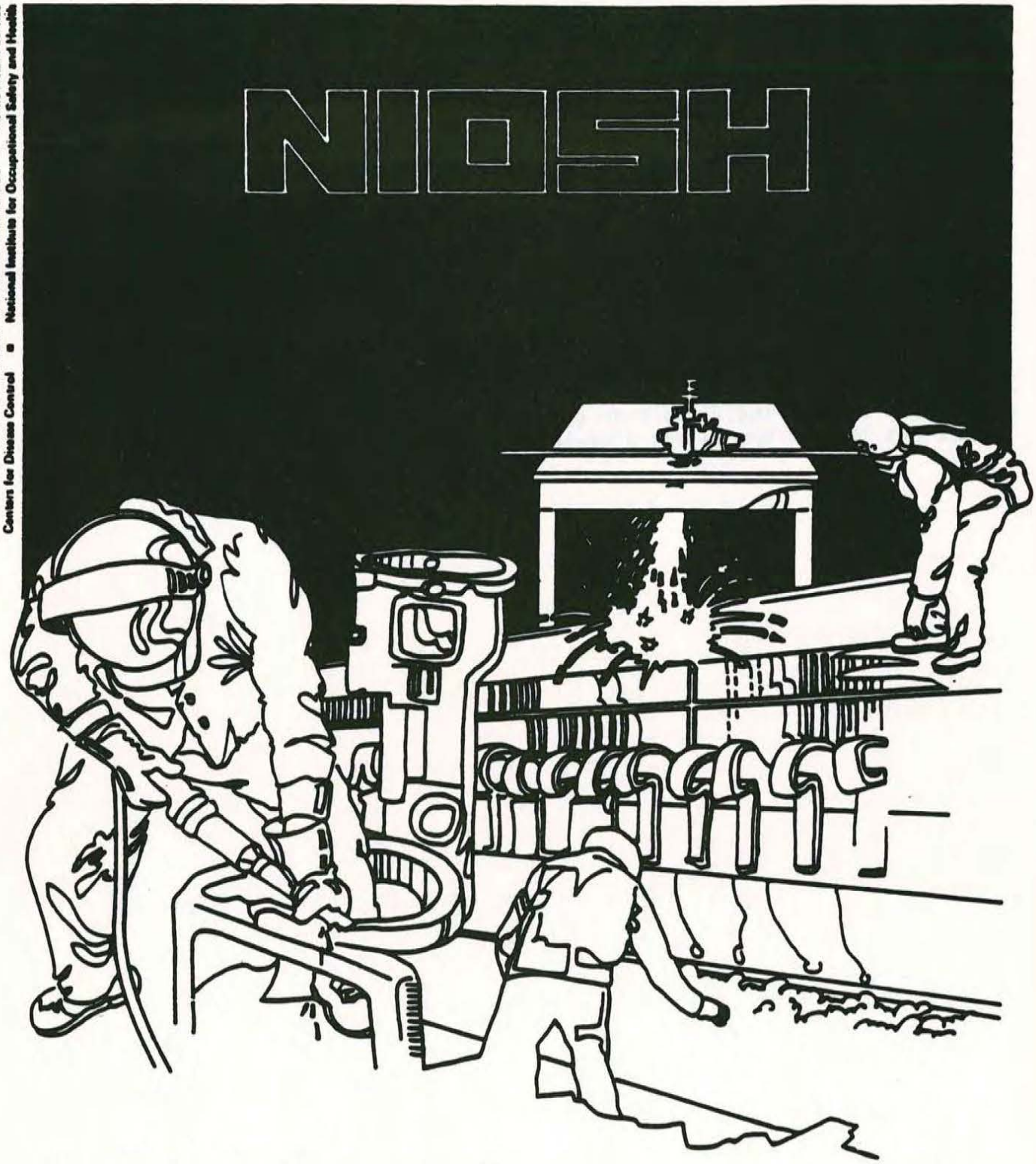

Health Hazard Evaluation Report

HETA 85-491-1660
COBE LABORATORIES, INC.
DENVER, COLORADO

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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COBE LABORATORIES INC.
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I. SUMMARY

In October, 1985, The National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate exposures of workers using radiofrequency (RF) sealers at Cobe Laboratories Inc., Lakewood and Arvada, Colorado. The company used five heat sealers, three for the manufacture of vinyl and plastic containers and two for research.

NIOSH conducted environmental surveys on November 19, and December 19, 1985. Measurements of the electric (E) and magnetic (H) fields were taken at the face, chest, waist, hip, and feet. These anatomical locations varied depending on whether the worker was standing or sitting while operating the (RF) sealers. Exposures, when corrected for work (duty) cycles of the machines, ranged up to 3.5×10^4 V^2/M^2 for the E-Field and up to 0.05 A^2/M^2 for the H-field. By comparison, ACGIH currently recommends TLVs of 3.77×10^3 V^2/M^2 (E-Field) and 0.027 A^2/M^2 (H-Field). The E and H field strength equivalents of the OSHA standard are 4.0×10^4 V^2/M^2 and 0.25 A^2/M^2, respectively. Measurements from three of the heat sealers, Callanan 2-cycle sealer, and the two research sealers, exceeded the ACGIH TLVs. The OSHA standard was not exceeded for any of the five sealers. The highest exposure to the Callanan 2-cycle sealer was 3.5×10^4 V^2/M^2 and 0.050 A^2/M^2. The two research sealers (1) (Thermatron) had a high exposure of 8×10^3 V^2/M^2 with no excessive exposure in the (H) field, (2) Faratron had a high of 0.035 V^2/M^2 in the (H) field but no overexposure in the (E) field. A previous NIOSH Health Hazard Evaluation at another location had recommended improved shielding on RF sealers that were very similar to these and the results following the installation of the shielding showed exposures well within the ACGIH TLVs.

On the basis of the data collected during this evaluation, it was determined that workers were overexposed to RF radiation while using three of the heat sealers. Recommendations are provided in this report that may help eliminate this health hazard.

Keywords: SIC 2299 (miscellaneous, textile goods, not elsewhere classified), heat sealers, radiofrequency radiation, shielding.

II. INTRODUCTION

In October, 1985, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Industrial Hygienist at Cobe Laboratories, Inc., Lakewood, Colorado, to evaluate radiofrequency (RF) radiation from heat sealers at their Lakewood and Arvada, Colorado locations. No specific health and safety complaints were reported.

On November 19 and December 19, 1985, an Industrial Hygienist from NIOSH conducted a survey of the plant and found exposures that exceeded the ACGIH TLVs but not the OSHA standards. Findings from this survey were summarized in tables and discussed with the requester on December 19, 1985. A copy of the results was also given to the requester.

III. BACKGROUND

The (RF) heat sealers are currently used at Cobe Laboratories, Inc., in the manufacture of plastic parts for kidney dialysis and other disposable medical equipment. Some of the products made include plastic bags, blood flow monitors, and plastic tubing. Four of the heat sealers are usually "manned" by one worker. The 5th sealer, which is a 2-cycle sealer is "manned" by two workers. All operators are located about 2-feet from the (RF) source.

Two of the sealers were made by Sealomatic Electric Corporation, one was made by Callanan, one by Thermatron and one by Faratron. All five of the sealers operated at a frequency of 27.12 (MHZ). The two Sealomatic and the Callanan sealers are used in production. The Thermatron and Faratron are used in research and only used occasionally.

IV. MATERIALS AND METHODS

During this survey the heat sealers were operated so that we could measure exposures typical of a normal work day. RF measurements were made with a calibrated Holaday Model HI 3002 broadband field strength meter equipped with an electric (E) probe and magnetic (H) probe. The E field probe was used to measure the electric field strength in volts squared per meter squared (V^2/M^2). The H field probe was used to measure the magnetic field strength in amperes squared per meter squared (A^2/M^2). The minimum detectable field strength for the E and H probes was 0.5×10^3 V^2/M^2 and 0.005 A^2/M^2, respectively.

E and H field strength measurements were taken at the site of the operator of each of the five heat sealers. Measurements were taken at the face, chest, waist, hip, and feet positions. Since the RF output of all heat sealers was not continuous, the measurements made with the Holaday monitor were corrected for the work cycle of the heat sealer before comparisons could be made with occupational exposure standards. The work cycle of the heat sealer was considered to be the RF on-time divided by the total process time. Observations of processing times for the heat sealers revealed a work cycle of 0.40 for the Rotary Sealomatic, 0.20 for the Indexer Sealomatic and 0.50 for the Callanan Rotary. The other two machines are not used in production and duty cycles were only estimates. The product of the meter reading and the work cycle correction factor was judged to be equivalent to the workers exposure.

V. EVALUATION CRITERIA

A. Environmental

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 Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH)

Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. 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-recommended standards, 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.

For radiation in the radiofrequency and microwave range of 30 MHZ to 100 MHZ, ACGIH recommends TLVs of 3.77×10^3 V^2/M^2 for the E field and 0.027 A^2/M^2 for the H field.[1] OSHA specified, in 29 CFR 1910.97, a power density exposure limit of 10 milliwatts per centimeter squared (mW/cm^2) averaged over any 6 minute period.[2] In the far field this power density level corresponds to 4×10^4 V^2/M^2 (E field) and 0.25 A^2/M^2 (H field). The ACGIH TLVs for the E and H fields, as can be seen, are about 10 times lower than the corresponding levels in the OSHA standard.

B. Biological effects of radiofrequency radiation.

Radiofrequency (RF) radiation is that portion of the nonionizing electromagnetic spectrum from approximately 0.01 - 300,000 MHZ. The principal biological effect of RF radiation is heating of tissues.[3] The extent of heating is primarily dependent on the water content of the tissue and the intensity and duration of the RF energy. Most parts of the body have sufficient blood supply to dissipate heat resulting from absorption of RF radiation. However, the eye (especially the lens) is particularly vulnerable to heating since it lacks an efficient blood supply to dissipate heat. Consequently, damage may occur to the transparent cells around the lens resulting in the formation of cataracts.[4] Other tissues which display high sensitivity to heat include the testes and brain (specifically the reticular formation of the brain stem and hypothalamus).[5]

In addition to thermal effects, absorption of RF radiation may result in nonthermal effects which may occur without a measurable increase in tissue or body temperature, and at RF field strengths lower than those necessary to cause thermal effects.[6] Nonthermal effects have been widely reported in the Soviet and Eastern European literature. Effects which have been described but poorly substantiated include those on the nervous system (headache, fatigue, irritability, altered memory function, altered EEG recordings, and sleep disturbances), and effects

on the blood (leukocytosis, thrombocytopenia). Also reported are sweating, hypotension, dyspnea, chest pain, cardiac arrhythmias, and changes in blood levels of enzymes, hormones, and immunity factors. These studies, however, have been severely criticized for problems with subjective measurements and for lack of appropriate experimental design and statistical analysis of data.

Experimental and observational data from animal and human studies indicate no carcinogenic or mutagenic effects resulting from exposure to RF radiation.[6] Human studies indicate that no teratogenic effects occur, but are inconclusive as to whether reproductive effects occur. Animal studies have shown some reproductive and teratogenic effects, but the evidence is often contradictory. It appears that the reproductive effects in animals correlate well with RF-induced heat production. NIOSH will soon complete a criteria document which will review in detail the potential health hazards of RF radiation.

VI. RESULTS AND DISCUSSION

Tables 1, 2, and 3 summarizes RF exposures of operators to the five (RF) sealers included in this survey. The only overexposures were to the Callanan Rotary 2-cycle sealer and the research Thermatron and Faratron sealers.

The highest exposure to the Callanan 2-cycle sealer was 3.5×10^4 V^2/M^2 and 0.050 A^2/M^2. This compares to a TLV of 3.77×10^3 V^2/M^2 and 0.027 A^2/M^2 and a corresponding OSHA standard of 4.0×10^4 V^2/M^2 and 0.25 A^2/M^2. The two research sealers (1) (thermatron) had a high exposures of 8×10^3 V^2/M^2 with no excessive exposure in the (H) field, (2) Faratron had a high of 0.035 A^2/M^2 in the (H) field but no overexposure in the (E) field. These research machines had no shielding and would overexpose workers if they were on the production line with longer duty cycles. The OSHA standard was not exceeded for any of the five sealers.

A previous NIOSH Health Hazard Evaluation had recommended improved shielding on RF sealers that were very similar to these and the results following the installation of the shielding showed exposures well within the ACGIH TLVs. The shielding used to control RF emmissions from the heat sealers was constructed with perforated aluminum sheet stock and flexible phosphor bronze contacts. The aluminum sheet stock was used to construct a box-like enclosure around the press die and was connected to the dielectric insulation supporting the top plate of the heat sealer. The phosphor bronze contacts were attached around the bottom of the enclosure and were used to ensure good electrical contact between the bottom fixed (ground) plate of the sealer and the open bottom of the aluminum enclosure.

VII. CONCLUSION

On the basis of data collected during this evaluation it was concluded that additional shielding is necessary in order to lower exposures to levels less than the ACGIH TLVs. All machines comply with the OSHA standards.

VIII. RECOMMENDATIONS

1) Additional shielding and grounding as described in this report should help eliminate exposure.

IX. REFERENCES

1. American Conference of Governmental Industrial Hygienists. Threshold limit values for chemical substances and physical agents in the workroom environment with intended changes for 1984-85. Cincinnati, Ohio ACGIH, 1984.

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X. AUTHORSHIP AND ACKNOWLEDGEMENTS

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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 will be available through the National Technical Information Service (NTIS), 5285 Port Royal Road, 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. Cobe Laboratories, Inc.
2. U.S. Department of Labor/OSHA - Region VIII.
3. NIOSH - Region VIII.
4. Colorado Department of Health.
5. State Designated Agency.

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.

Table 1

Measurements Corrected for Duty Cycle of
Electric (E) and Magnetic (H)
Fields on Radiofrequency (RF) sealers at
Cobe Laboratories, Inc.
Arvada, Colorado
November 19, 1985

Job/Anatomical Location

Rotary Sealomatic

4 KW at 27.12 MHZ
Normal Operating Mode (NOM)
Right Side Worker

Sitting Pstn	E Field V^2/M^2 Meter Rdng	V^2/M^2 Exposure	H Field Meter Rdng	A^2/M^2 Exposure
FACE	2×10^3	8.4×10^2	0.5 x 0.01	0.002
CHEST	1.5×10^3	6.3×10^2	0.5 x 0.01	0.002
WAIST	1×10^4	4.2×10^2	1.0 x 0.1	0.004
HIP	1×10^4	4.2×10^2	1.0 x 0.1	0.004
FEET	1×10^4	4.2×10^2	0.5 x 0.01	0.002

Left Side Worker

FACE	2×10^3	8.4×10^2	1 x 0.01	0.004
CHEST	5×10^3	2.1×10^3	2 x 0.01	0.008
STOMACH	5.5×10^3	2.3×10^3	6 x 0.01	0.025
KNEES	5.5×10^3	2.3×10^3	6 x 0.01	0.025
FEET	1.5×10^3	6.3×10^2	6 x 0.01	0.025

Indexer Sealomatic
4 KW at 27.12 MHZ (NOM)

Standing Pstn	E Field Meter Rdng	V^2/M^2 Exposure	H Field Meter Rdng	A^2/M^2 Exposure
FACE	1×10^3	2.7×10^2	0.5 x 0.01	0.001
CHEST	0.25×10^3	0.7×10^2	0.5 x 0.01	0.001
STOMACH	0.5×10^3	1.4×10^2	0.5 x 0.01	0.001
GROIN	1×10^3	2.7×10^2	0.5 x 0.01	0.001
KNEE	0.5×10^3	1.4×10^2	0.5 x 0.01	0.001
FEET	0.25×10^3	0.7×10^2	0.25 x 0.01	0.001
HANDS	2×10^3	5.4×10^2	0.25 x 0.01	0.001

Evaluation Criteria
ACGIH (TLV) = 3.77×10^3
OSHA (Std) = 4.0×10^4

Evaluation Criteria
ACGIH (TLV) = 0.027
OSHA (Std) = 0.025

Table 2

Measurements Corrected for Duty Cycle of
Electric (E) and Magnetic (H)
Fields on Radiofrequency (RF) sealers at
Cobe Laboratories, Inc.
Arvada, Colorado
November 19, 1985

Job/Anatomical Location

Rotary Two Cycle Sealer

Right Side Operator
8 KW at 27.12 MHZ (NOM)
First Cycle

Standing Pstn	E Field Meter Rdng	V^2/M^2 Exposure	H Field Meter Rdng	A^2/M^2 Exposure
FACE	0.5×10^4	2.5×10^3	1×0.01	0.005
CHEST	1.0×10^4	5×10^3	1×0.01	0.005
STOMACH	1.5×10^4	7.5×10^3	1×0.01	0.005
KNEES	0.5×10^3	2.5×10^2	1×0.01	0.005
GROIN	2.0×10^3	1×10^3	1×0.01	0.005
FEET	2.0×10^3	1×10^3	1×0.01	0.005
Second Cycle				
FACE	3.0×10^4	1.5×10^4	9×0.01	0.045
CHEST	7×10^4	3.5×10^4	9.5×0.01	0.048
STOMACH	1.5×10^4	0.75×10^4	10×0.01	0.050
KNEES	3.5×10^3	1.75×10^3	7×0.01	0.035
GROIN	8×10^3	4.0×10^3	8.5×0.01	0.043
FEET	9×10^3	4.5×10^3	8.5×0.01	0.043
Left Operator				
First Cycle				
FACE	0.5×10^4	2.5×10^3	1×0.01	0.005
CHEST	1.0×10^4	5×10^3	2×0.01	0.010
STOMACH	1.0×10^4	5×10^3	2.5×0.01	0.013
KNEES	0.5×10^3	2.5×10^2	1.5×0.01	0.008
GROIN	1.0×10^4	5×10^3	2.5×0.01	0.013
FEET	1.5×10^3	7.5×10^2	2.5×0.01	0.013
Second Cycle				
FACE	4.5×10^4	2.3×10^4	8.5×0.01	0.043
CHEST	7.0×10^4	3.5×10^4	10×0.01	0.050
STOMACH	7.0×10^4	3.5×10^4	9×0.01	0.045
KNEES	6.5×10^3	3.3×10^3	9.5×0.01	0.048
GROIN	3.0×10^4	1.5×10^3	9.0×0.01	0.045
FEET	6.5×10^3	3.3×10^3	9.0×0.01	0.045

Evaluation Criteria
ACGIH (TLV) = 3.77×10^3
OSHA (Std) = 4.0×10^4

Evaluation Criteria
ACGIH (TLV) = 0.027
OSHA (Std) = 0.025

Table 3

Measurements Corrected for Duty Cycle of
Electric (E) and Magnetic (H)
Fields on Radiofrequency (RF) sealers at
Cobe Laboratories, Inc.
Arvada, Colorado
November 19, 1985

Job/Anatomical Location

Thermatron

7.0 KW at 27.12 MHZ
Normal Operating Mode (NOM)

Standing Pstn	E Field Meter Rdng	V^2/M^2 Exposure	H Field Meter Rdng	A^2/M^2 Exposure
FACE	3×10^4	8×10^3	0.5×0.01	0.001
CHEST	1.5×10^4	4×10^3	0.5×0.01	0.001
GROIN	0.5×10^4	1.3×10^3	0.5×0.01	0.001
FEET	1.0×10^3	2.6×10^2	0.5×0.01	0.001

Faratron

7.0 KW at 27.12 MHZ (NOM)

FACE	1×10^4	5×10^2	1×10^4	.035
CHEST	0.5×10^4	2.5×10^2	0.5×10^4	.020
GROIN	2.5×10^3	1.2×10^2	2.5×10^3	.005
FEET	2.0×10^3	1×10^2	2.0×10^3	.005

Evaluation Criteria
ACGIH (TLV) = 3.77×10^3 (E) Field
OSHA (Std) = 4.0×10^4

Evaluation Criteria
ACGIH (TLV) = 0.027 (H) Field
OSHA (Std) = 0.25

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