American Hospital Association

AHA

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Facmgt

May 1984

TO: Institutional Members
Members of the American Society for Hospital Central Service Personnel
Members of the American Society for Hospital Engineering

SUBJECT: New Ethylene Oxide Regulation

Since our earlier letters to you on controlling potential hazards from ethylene oxide (EtO) a new regulation has been promulgated that calls for your immediate evaluation and action.

On April 18, 1984, a final regulation was published by the Environmental Protection Agency (EPA) concerning the continued safe use of Ethylene Oxide (EtO) in the sterilization of equipment and supplies. (See enclosed Federal Register, April 18, 1984, Vol. 49, No. 76.)

Since the first deadline for compliance begins as soon as manufacturers can start attaching the appropriate labels on EtO containers (EPA estimates about 6 months), it is important to evaluate your current situation and begin to develop procedures that will ensure that you comply with the requirements contained on the new lables.

Requirements that must be met as soon as the new label appears include:

- o Installation of gas line hand valves
- o Installation of "capture boxes" for floor drains
- o Ventilation during gas cylinder changing
- o Ventilation of sterilizer relief valve
- o Installation of dedicated exhaust/ventilation systems
- o Installation of ventilation system alarm system
- o Posting of workplace practices for the changing of supply line filters
- o Establishment of restricted areas
- o Sterilizer door opening procedures
- o Establishment of sterilizer chamber unloading procedures
- o Maintenance practices(i.e., required recordkeeping)
- o Bi-weekly leak detection testing

Additionally, the following requirements must be met no later than July 1, 1986:

- o Venting of existing aerators
- o New equipment installation (i.e., new aeration units where required)
- o Installation of a hood or canopy over the sterilizer door.

As stated in the Federal Register, the statutory basis for these requirements in found in Section 12 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. Sec. 136j). This section prohibits detachment, alteration, defacement or destruction of any pesticide (as EtO is classified under FIFRA) labeling. Moreover, under FIFRA it is unlawful for any person to use any "registered pesticide" in a manner inconsistent with its labeling. As defined in the statutes, this essentially means using the substance in any manner not permitted by its label. Civil penalties can be imposed for violation of FIFRA requirements knowingly. Hospital managers should note that under 7 U.S.C. Sec. 1361(b)(4), any unlawful act, omission, or failure of a hospital officer, agent, or employee will be deemed to be the act, omission or failure not only of that individual but also of the employing entity.

Considering the severe regulatory options currently under study, this new requirement appears reasonable, achievable and consistent with the ability to provide cost-effective patient care, while taking appropriate steps to ensure a safe working environment for your employees. If you agree, the AHA encourages you to communicate your support for these requirements in writing to Mr. Edwin L. Johnson, Director, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460.

If you have questions regarding the enclosed labeling requirement, or require assistance, please call AHA's toll-free number at 800-621-6712, or in Illinois, 800-527-6850. Your calls will be logged and referred for appropriate action. Or you may contact Clarence W. Daly directly at, 312/280-6160.

Sincerely

Herluf V. Olsen
Group Vice President
American Hospital Association

Information Services Section (TS–757C), Program Management and Support Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460

In person, bring comments to:

Information Services Section (TS–757C), Environmental Protection Agency, Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (TS–767C), Attn: (Product Manager (PM) named in each petition), Environmental Protection Agency, Office of Pesticide Programs, 401 M St., SW., Washington, D.C. 20460.

In person: Contact the PM named in each petition at the following office location/telephone number:

Product manager	Office location/ telephone No.	Address
PM–16, William Miller.	Rm. 211, CM#2 (703–557–2500).	EPA, 1921 Jefferson Davis Hwy, Arlington, VA 22202.
PM–21, Henry Jacoby.	Rm. 229, CM#2 (703–557–1900).	Do.
PM–23, Richard Mountfort.	Rm. 202, CM#2 (703–557–1830).	Do.
PM–12, Jay Ellenberger.	Rm. 202, CM#2 (703–557–2386).	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide (PP) and feed additive petitions (FAP) relating to the establishment of tolerances for residues of certain pesticide chemicals in or on certain commodities in accordance with the Federal Food, Drug, and Cosmetic Act. The analytical method for determining residues, where required, is given in each petition.

I. Initial Filings

1. *4F3051.* Chevron Chemical Co., 940 Hensley St., Richmond, CA 94804–0036. Proposes to amend 40 CFR 180.108 by establishing a tolerance for the combined residues of the insecticide acephate (*O,S*-dimethyl acetylphosphoramidothioate) and its cholinesterase-inhibiting metabolite *O,S*–dimethyl phosphoramidothioate in or on the raw agricultural commodity sunflower seed at 0.1 part per million (ppm). The proposed analytical method for determing residues in extraction with ethyl acetate, cleanup using either gel permeation chromatography or a silica gel column chromatography, and measurement by gas chromatography, using either a thermionic or flame photometric detector. (PM–16, William Miller).

2. *FAP 4H5429.* Chevron Chemical Co. Proposes amending 21 CFR 561.20 by establishing a regulation permitting the combined residues of the insecticide acephate and its metabolite in or on the feed commodity sunflower hulls at 0.2 ppm. (PM–16, William Miller).

3. *FAP 3H5401.* Ciba-Geigy Corp., PO Box 11422, Greensboro, NC 27409. Proposes to amend 21 CFR 561.273 by establishing a regulation permitting the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-[2-(hydroxymethyl)-6-methylphenyl]-*N*-(methoxyacetyl) alanine, each expressed as metalaxyl in or on the feed commodities apple pomace (dry) at 2.0 ppm and apple pomace (wet) at 0.4 ppm. (PM–21, Henry Jacoby).

4. *PP 4F3054.* Dow Chemical, PO Box 1706, Midland, MI 48640. Proposes amending 40 CFR Part 180 by establishing a tolerance for the herbicide 3,6-dichloro-2-pyridinecarboxylic acid in or on the raw agricultural commodity forage grasses at 100.0 ppm. The proposed analytical method for determining residues is gas chromatography. (PM–23, Richard Mountfort.)

5. *PP 4F3052.* FMC Corp., 2000 Market St., Philadelphia, PA 19103. Proposes amending 40 CFR Part 180 by establishing tolerances for the combined residues of the pesticide chemical carbosulfan (2,3-dihydro-2,2-dimethyl-7-benzofuranyl [(dibutyl-amino) thio] methylcarbamate) and 2,3,-dihydro-2,2-dimethyl-benzofuranyl-*N*-methylcarbamate (carbofuran), its carbamate metabolites 2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate, and 2,3-dihydro-2,2-dimethyl-3-keto-7-benzofuranyl-*N*-methylcarbamate; its phenolic metabolites, 2,3-dihydro-2,2-dimethyl-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-3-oxo-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-3-,7-benzofurandiol and its metabolite di-*N*-butylamine in or on the following raw agricultural commodities:

a. *Milk* at .12 ppm total, of which no more than .01 ppm is carbosulfan *per se*, .02 ppm is carbamate metabolites, .03 ppm is its phenolic metabolites, and .01 ppm is the dibutylamine metabolites.

b. *Eggs and poultry* at 1.1 ppm total, of which no more than .05 ppm is carbosulfan and its cholinesterase metabolites, and .05 ppm is the dibutylamine metabolite.

c. *Corn grain* at .2 ppm total, of which .05 ppm is carbosulfan *per se*, .05 ppm is carbamate metabolites, .05 ppm phenolic metabolites, and .05 ppm of the dibutylamine metabolite.

d. *Corn fodder and forage* at 7.25 ppm total, of which .05 ppm is carbosulfan *per se*, 2.0 ppm is carbamate metabolites, 5.0 ppm is phenolic metabolites, and .2 ppm of the dibutylamine metabolite.

e. *Fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep* at .07 ppm total, of which no more than .01 ppm is carbosulfan, .02, ppm is carbamate metabolites, .03 is phenolic metabolites, and .01 ppm is the dibutylamine metabolite. (PM–12, Jay Ellenberger.)

(Secs. 408(e) 68 Stat. 514 (21 U.S.C. 346a(e)) and 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: April 2, 1984.

Robert Brown,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 84-9904 Filed 4-17-84; 8:45 am]

BILLING CODE 6560-50-M

[OPP–30074; PH–FRL 2564–8]

Ethylene Oxide; Revised Labeling for Pesticide Products Containing Ethylene Oxide Which Are Registered for the Sterilization of Equipment and Supplies in Hospitals and Health Care Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Agency has recently requested that registrants of pesticide products containing ethylene oxide (EtO) which are registered for use in the sterilization of equipment and supplies used in hospitals and health care facilities make certain changes in the approved labeling for such products. These label changes will specifically affect workplace design and practice in hospitals and health care facilities performing sterilization necessary for routine patient care. Users will have to conform to most of the label changes when they appear on EtO product

labels. Certain label changes however, will not be effective until July 1, 1986. Those changes with later effective dates are described in this notice and will also appear on the amended product labeling. Registrants of small canisters, cylinders or containers which are registered solely for use with specific sterilization equipment also marketed by the registrant have not been requested to make lable changes at this time.

FOR FURTHER INFORMATION CONTACT:
By mail: Walter I. Waldrop, Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 711C, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–557–7400).

SUPPLEMENTARY INFORMATION:

I. Background

The Agency issued a "Notice of Rebuttable Presumption Against Registration (RPAR) and Continued Registration of Pesticide Products Containing Ethylene Oxide" which was published in the Federal Register of January 27, 1978 (43 FR 3301). This notice cited multitest evidence of mutagenicity and possible reproductive effects in experimental animals as the basis of presumptions against continued registration for pesticide products registered with EPA which contained EtO as an active ingredient. Since the publication of the notice, additional evidence concerning the possible adverse effects of EtO has been reported. This new evidence has persuaded the Agency to develope certain label changes directed at workplace design and practice in hospitals and health care facilities to reduce exposure to EtO of workers who are involved in equipment and supply sterilization procedures necessary for routine patient care. The changes contained in this notice are limited to hospital and health care facility use. The Agency decided to focus on this use first because hospital and health care facility workers are the single largest group of workers exposed to EtO and are believed to be occupationally exposed to the highest levels of EtO. However, registrants of small canisters, cylinders and containers used in hospitals or health care facilities and which are registered solely for use with specific sterilization equipment also marketed by the registrant have not been requested to make these label changes. The EtO product label changes affecting workplace design and practice for these specialized sterilization units differ slightly from the label changes for the generally larger cylinders used in most hospital sterilization procedures. Label amendments for these specialized types of EtO products will be developed in the near future.

Exposure reduction measures for other workers who use EtO for sterilization and fumigation, such as workers in manufacturing facilities, museums, libraries, etc., and in protecting certain food crops will be addressed at a later date. Exposure reduction measures for these uses will be implemented either through interim label changes similar to those required for the hospital and health care facility use of EtO or through informal channels, such as information bulletins, etc.

Two specific groups will be directly affected by the amended labeling requirements described in this notice. First, certain registrants of products containing EtO used for the sterilization of equipment and supplies in hospitals and health care facilities have been requested to make the label changes contained in this notice. All procedures and requirements for EtO registrants have been detailed in a certified letter sent to each registrant by EPA.

The second group to be affected by the amended labeling described in this notice will be hospital and health care facility staff who must modify their workplace design and practices to comply with the label requirements described in this notice. The Agency is issuing this notice in part to provide affected hospitals and health care facilities and personnel with advance notice of forthcoming label changes and an opportunity to begin to implement those changes that may require modifications of existing workplace design or practice. The Agency anticipates that EtO products bearing these new label requirements will begin to appear in the market place approximately six months from the date of this notice. Failure of affected hospitals and health care facilities to comply with these new label requirements will place them in violation of section 12 of FIFRA.

The Agency also intends to pursue the comprehensive evaluation of all EtO data and, upon completion of this evaluation, to issue a "Preliminary Notice of Determination Concluding the RPAR Process." This notice will cover all of the uses of EtO discussed in the January 27, 1978 PRAP Notice. Following public comment on the Agency's preliminary notice, the Agency will develop its final position on EtO. This final position may include additional label modifications.

The Agency has decided to seek interim label changes at this time because it will take additional time to develop the final position on all EtO uses and it is evident from available information that exposure reduction measures should be implemented as soon as practical.

The Department of Labor, Occupational Safety and Health Administration (OSHA), has established a current permissible exposure limit (PEL) for EtO in the workplace of 50 parts EtO per million parts of air; 8-hour time weighted average (TWA). In the Federal Register of April 21, 1983 (48 FR 17284), OSHA proposed to reduce the PEL for EtO to a TWA of 1 part per million (ppm). The basis for this action was new data that indicated that the 50 ppm level was inadequate for employee health protection. As of the publication of this notice, OSHA has not established a new PEL for EtO. EPA has consulted with OSHA on the product label changes contained in this notice and will continue to work cooperatively with OSHA on any future label changes for other EtO pesticide products and to assure that all regulatory actions are implemented in a complementary and consistent manner. EPA supports the proposed OSHA exposure limit of 1 ppm to the extent that monitoring equipment sensitive to that level is available and is using the 1 ppm as an exposure reduction goal.

II. New Evidence

The new evidence received by the Agency includes studies indicating that EtO may present an unacceptably high cancer risk at current levels of exposure. A two-year inhalation study conducted on rats demonstrated that EtO exposure levels of 33 and 100 parts per million resulted in a dose-related increase in primary brain neoplasms for both males and females. The study also showed an increased incidence of peritioneal mesothelioma in male rats at air levels of 50 and 100 ppm (Ref. 1). Preliminary results of a chronic rat inhalation study, conducted by NIOSH (Ref. 2), indicate an increased incidence of brain tumors (gliomas) in male rats and a dose-response relationship with borderline statistical significance for leukemia. In addition, EPA's Carcinogen Assessment Group has evaluated three epidemiologic studies of persons occupationally exposed to EtO, and has concluded that these studies provide evidence for an association between the

occurrence of cancer and EtO exposure (Ref. 3).

Evidence of the mutagenicity of EtO has also continued to accumulate and the Agency believes that EtO poses a mutagenic risk to exposed humans. The compound is a direct-acting alkylating agent of DNA and has been shown to produce mutagenic effects in many species throughout the animal and plant kingdoms, including cells of mammals. The chemical has been demonstrated to reach the genetic components of the gonads in animals and produce genetically transmissible conditions following peritoneal injection of liquid EtO into the abdomen of test animals (Ref. 4).

New evidence also augments the concern that EtO may produce adverse reproductive effects. Experimental animal studies show decreased fertility at a dose level of 100 ppm in a one-generation reproduction study in rats (Ref. 5). It has been reported that EtO-exposed hospital workers show an increased incidence of spontaneous abortions (Ref. 6). However, the author has subsequently reported that the EtO levels during the period of the study were not known. Further, the data were based on a 1973 survey of hospital workers who were employed between 1955 and 1975 (Ref. 7). The interpretation of these findings is difficult and will require further investigation to clarify them.

As noted earlier, the Agency has limited these label changes to EtO products used in hospitals and health care facilities for the sterilization of equipment and supplies because these workers are the single largest group of workers and are believed to be occupationally exposed to the highest levels of EtO. The following table presents a summary of all the pesticidal uses of EtO, the annual pounds used and estimated number of operators.

TABLE 1.—SUMMARY OF ESTIMATED ETHYLENE OXIDE FUMIGATION USE AND POTENTIAL OPERATOR EXPOSURE

Site	EtO pounds x 10^3/ year	Estimated number of operators
Manufacturing facilities production of sterile disposables (medical)	3.0–5.7	3,000–4,500
Hospitals (1976 figures)	862–1,000	11,000–26,000
Medical clinics	111	1,150
Dental clinics	65.5	400
Doctors (private)	37	750
Dentists (Private)	7.3	80
Veterinarians (private) and clinic (estimated)	0.1	NA[1]
Museums	0.7	15
Libraries/ archives	1.9	40
Research laboratories:		
Animal breeding	50	25–30
Drug/ medical device	550–900	NA[1]
Microbiological/ cancer	5–25	NA[1]
Redroad cars	2	5–10
Beehives (States, USDA)	1–2	20
USDA high containment research labs	4.3	10–15
USDA APHIS quarantine FCE	0.7	200–300
Spices	750	60
Black walnuts	3.2	10
Cosmetics	24	25
Dairy packaging	32	30
Total	5.8–8.7	

[1] NA = Not available.

Exposure to EtO during sterilization is quite variable within a given hospital and health care facility and also varies greatly from one hospital or health care facility to another. Some hospitals/ health care facilities may have several sterilization cycles per day involving a number of different sterilization units, whereas, in other hospitals/health care facilities, there may be only one sterilizer unit which is run infrequently. Other important variables affecting exposure include the nature of the sterilization equipment, its installation, design and layout of the room housing the sterilizer, nature and frequency of maintenance activities, sterilizer operator practices, and the type and functioning capacity of the ventilation systems. Thus, exposures to EtO of sterilizer personnel are highly variable; some sterilizer personnel are exposed every day, and others may be exposed intermittently, or infrequently.

Major emissions of EtO into the workroom air occur during discharge of EtO into floor drains, following opening of the door of the sterilization equipment after completion of a cycle, and during the change of gas cylinders. Additional exposure may result from off-gassing of EtO from sterilized articles during aeration, leaks in the sterilizer system, and releases during maintenance of equipment (Ref. 8).

All of these variables affect exposure of workers to EtO and make it extremely difficult to determine the precise worker exposure levels. However, exposures to EtO have been recorded at 250 ppm for several minutes following the opening of the sterilizer door at the termination of a sterilization cycle, and 8-hour time-weighted averages (TWA) of up to 160 ppm have been recorded (Ref. 9). These extremes include exposure levels that have produced adverse effects in experimental animals.

Some exposed workers have complained of clinical symptoms of the upper respiratory tract and central nervous system following reported exposures to EtO (Ref. 10). These symptoms are well recognized to be induced from exposures to EtO. Some hospital workers have shown increases in sister chromatid exchanges in peripheral blood lymphocytes following exposures to EtO (Ref. 11), which may indicate that EtO vapors are able to enter the human body and induce biological effects.

Although the risks of exposure to EtO are of concern, the benefits of the use of EtO as a sterilant of hospital and health care facility equipment and supplies are also significant. Heat and radiation can be used to sterilize some items, but there are many items that can only be sterilized with EtO. Some of these items include electronic equipment, prostheses, disposable syringes and tubing, scopes, etc. There are no chemical alternatives that are as efficacious as EtO. In addition, these alternative chemicals have also been demonstrated to pose health risks to humans.

The benefits to human health of continued use of EtO for hospital/health care facility sterilization are clearly recognized. However, the Agency also believes that the risks to human health from exposures to EtO are unreasonable at the levels which likely exist in many hospitals and health care facilities. Thus, as noted earlier, while the Agency continues its evaluation of all pesticidal uses of EtO, it has also decided to introduce interim product label changes that will require modification in workplace design and practice in hospitals and health care facilities as outlined in this notice.

These product label changes will require modifications in workplace design and practice have been developed by the Agency following the review of consultant reports on means and costs of reducing worker exposures (Refs. 8 and 12), a review of available scientific and technical data, site visits to several hospitals using EtO in sterilization chambers, and extensive discussions with individuals knowledgeable in current technology available to control the release of EtO in hospitals.

III. Product Label Changes That Will Require Modifications in Workplace Design and Practice in Hospitals and Health Care Facilities

A. Introduction

The following modifications are intended to reduce the exposure of hospital and health care facility workers to EtO to 1 ppm, or as close to that level as practicable. To achieve this, the

Agency has requested that registrants change EtO product labeling to require users to modify workplace design and workplace practice. The modifications in workplace design focus on the installation of certain equipment such as gas line hand valves, a "capture box" as part of the sterilizer drainage system, installation of aerators, and installation and/or upgrading of ventilation systems. Modifications in ventilation systems are directed toward those points where high concentrations of EtO are most likely to occur, e.g. during the change of gas cylinders, during removal of treated items from sterilizers, and at the floor drain which receives the discharge from the sterilizer. Workplace practice modifications focus on the adoption of systematic worker routines that will reduce both the time of worker exposure to EtO and the levels of exposure.

Users of EtO for the sterilization of equipment and supplies in hospitals and health care facilities must comply with the amended label language when it appears on a registered EtO product. The Agency expects new product labels to begin showing up in the market place approximately six months from the date of this notice. All modifications in workplace design and practice will be effective when they appear on product labeling, except for certain changes in workplace design that will not be required until July 1, 1986. Those changes that are not required until July 1, 1986 will be specifically noted on the product labeling.

EPA understands that many hospitals have already begun to make the changes in workplace design and practice outlined in this notice. EPA anticipates that hospitals and health care facilities affected by this notice will now begin to implement these changes in order to avoid any interruption of EtO usage when the amended product labels begin appearing in the market place.

Following in Units B.1. and B.2. of this notice is a description of the amended label wording. This description differs from the actual label language since the label language will not contain all the narrative explanation of Agency intent and rationale as provided in this notice.

Also, the suggestion in this notice that a written log be kept documenting the date of leak detection checks and any maintenance procedures undertaken (Unit B.2.e.) is not included in the amended label language.

As noted earlier in this notice, registrants of small canisters, cylinders or containers which are registered solely for use with specific sterilization equipment also marketed by the registrant have not been requested to make these label changes. It is likely that many hospitals and health care facilities use these small canisters, cylinders and containers and therefore would not have to make the changes outlined in this notice for those pieces of equipment. Label changes for these specialized products will be forthcoming in the near future. If hospital or health care facility staff have questions about which products are and are not subject to these label changes, they should call or write the contact person for this notice.

B. Label Modifications

1. Workplace Design

a. *Installation of gas line hand valves.* Hand valves must be installed on the gas supply line at the connection to the supply cylinders to minimize leakage during cylinder change.

b. *Installation of capture boxes.* Sterilizer operations result in a gas/water discharge at the completion of the process. This discharge is routinely piped to a floor drain which is generally located in an equipment or an adjacent room. When the floor drain is not in the same room as the sterilizer and workers are not normally present, all that is necessary for compliance is that the room be well ventilated.

The installation of a "capture box" will be required for those work place layouts where the floor drain is located in the same room as the sterilizer or in a room where workers are normally present. A "capture box" is a piece of equipment that totally encloses the floor drain where the discharge from the sterilizer is pumped. The "capture box" is to be vented directly to a non-recirculating or dedicated ventilation system. Sufficient air intake should be allowed at the bottom of the box to handle the volume of air that is ventilated from the top of the box. The "capture box" can be made of metal, plastic, wood or other equivalent material. The box is intended to reduce levels of EtO discharged into the workroom atmosphere. The use of a "capture box" is not required if: (1) The vacuum pump discharge floor drain is located in a well ventilated equipment or other room where workers are not normally present or (2) the water sealed vacuum pump discharges directly to a closed sealed sewer line (check local plumbing codes).

If it is impractical to install a vented "capture box" and a well ventilated equipment or other room is not feasible, a box that can be sealed over the floor drain may be used if: (1) The floor drain is located in a room where workers are not normally present and EtO cannot leak into an occupied area, and (2) the sterilizer in use is less than 12 cubic feet in capacity (check local plumbing codes).

c. *Ventilation of aeration units.* i. *Existing aeration units.* Existing units must be vented to a non-recirculating or dedicated system or vented to an equipment or other room where workers are not normally present and which is well ventilated. Aerator units must be positioned as close as possible to the sterilizer to minimize the exposure from the off-gassing of sterilized items.

ii. *Installation of new aerator units (where none exist).* New aerator units must be vented as described above for existing aerators. Aerators must be in place by July 1, 1986.

d. *Ventilation during cylinder change.* Workers are likely to be exposed to short but relatively high levels of EtO during the change of gas cylinders. To reduce exposure from this route, users must select one of three alternatives designed to draw off any gas that may be released when the line from the sterilizer to the cylinder is disconnected:

i. Location of cylinders in a well ventilated equipment or other room where workers are not normally present.

ii. Installation of a flexible hose (at least 4" in diameter) connected to a non-recirculating or dedicated ventilation system and located in the area of cylinder change in such a way that the hose can be positioned at the point where the sterilizer gas line is disconnected from the cylinder.

iii. Installation of a hood that is part of a non-recirculating or dedicated system and is positioned approximately one foot above or behind the point where the change of cylinders takes place.

e. *ventilation of sterilizer door area.* One of the major sources of exposure to EtO occurs when the sterilizer door is opened following the completion of the sterilization process. In order to reduce this avenue of exposure, a hood or metal canopy closed on each end must be installed over the sterilizer door. The hood or metal canopy must be connected to a non-recirculating or dedicated ventilation system or one that exhausts gases to a well ventilated equipment or other room where workers are not normally present. A hood or canopy over the sterilizer door is required for use even with those sterilizers that have a purge cycle and must be in place by July 1, 1986.

f. *Ventilation of sterilizer relief valve.* Sterilizers are typically equipped with a safety relief device to release gas in case of increased pressure in the sterilizer. Generally, such relief devices are used on pressure vessels. Although these pressure relief devices are rarely

opened for hospital and health care facility sterilizers, it will be required that they be designed to exhaust vapor from the sterilizer by one of the following methods:

i. Through a pipe connected to the outlet of the relief valve ventilated directly outdoors at a point high enough to be away from passers by, and not near any windows that open, or near any air conditioning or ventilation air intakes.

ii. Through a connection to an existing or new non-recirculating or dedicated ventilation system.

iii. Through a connection to a well ventilated equipment or other room where workers are not normally present.

g. *Ventilation systems.* Each hospital and health care facility affected by this notice that uses EtO for the sterilization of equipment and supplies must have a ventilation system which enables compliance with the requirements of sections (b) through (f) in the manner described in those sections and within the timeframes allowed. Thus, each affected hospital and health care facility must have or install a non-recirculating or dedicated ventilation system, or have available a well ventilated equipment or other room where workers are not normally present in which to vent EtO.

h. *Installation of alarm systems.* An audible and visual indicator alarm system must be installed to alert personnel of ventilation system failure, i.e. when the ventilation fan motor should be on but is not working.

2. Workplace Practices

All the workplace practices discussed in this unit must be permanently posted near the door of each sterilizer prior to use by any operator.

a. *Changing of supply line filters.* Filters in the sterilizer liquid line must be changed as necessary by the following procedure:

i. Close the cylinder valve and the hose valve.

ii. Disconnect the cylinder hose (piping) from the cylinder.

iii. Open the hose valve and bleed slowly into a proper ventilating system at or near the in-use supply cylinders.

iv. Vacate the area until the line is empty.

v. Change the filter.

vi. Reconnect the lines and reverse the valve position.

vii. Check hoses, filters, and valves for leaks with a fluorocarbon leak detector (for those sterilizers using the 88 percent chlorofluorocarbon, 12 percent ethylene oxide mixture (12/88)).

b. *Restricted access area.* i. Areas involving use of EtO must be designated as restricted access areas. They must be identified with signs or floor marks near the sterilizer door, aerator, vacuum pump floor drain discharge, and in-use cylinder storage.

ii. All personnel must be excluded from the restricted area when certain operations are in progress, such as discharging a vacuum pump, emptying a sterilizer liquid line, or venting a non-purge sterilizer with the door ajar, or during other operations where EtO might be released directly into the face of workers.

c. *Door opening procedures.* i. *Sterilizers with purge cycles.* A load treated in a sterilizer equipped with a purge cycle should be removed immediately upon completion of the cycle (provided no time is lost opening the door after cycle is completed). If this is not done, the purge cycle must be repeated before opening the door.

ii. *Sterilizers without purge cycles.* For a load treated in a sterilizer not equipped with a purge cycle, the sterilizer door must be ajar 6" for 15 minutes, and then fully opened for at least another 15 minutes before removing the treated load. The length of time of the second period should be established by peak monitoring for one hour after the two 15-minute periods suggested. If the level is above 10 ppm time weighted average for 8 hours, more time should be added to the second waiting period (door wide open). However, in no case may the second period be shortened to less than 15 minutes.

d. *Chamber unloading procedures.* i. Procedures for unloading the chamber must include the use of baskets or rolling carts, or baskets and rolling tables to transfer treated loads quickly, thus avoiding excessive contact with treated articles, and reducing the duration of exposures.

ii. If rolling carts are used, they should be pulled not pushed by the sterilizer operators to avoid off-gassing exposure.

e. *Maintenance.* A written log should be instituted and maintained documenting the date of each leak detection and any maintenance procedures undertaken. This is a suggested use practice and is not required.

i. *Leak detection.* Sterilizer door gaskets, cylinder and vacuum piping, hoses, filters, and valves must be checked for leak under full pressure with a fluorocarbon leak detector (for 12/88 systems only) every two weeks by maintenance personnel. Also, the cylinder piping connections must be checked after changing cylinders. Particular attention in leak detection should be given to the automatic solenoid valves that control the flow of EtO to the sterilizer. Specifically, a check should be made at the EtO gasline entrance port to the sterilizer, while the sterilizer door is open and the solenoid valves are in a closed position.

ii. *Maintenance procedures.* Sterilizer/aerator door gaskets, valves, and fittings must be replaced when necessary as determined by maintenance personnel in their bi-weekly checks; in addition, visual inspection of the door gaskets for cracks, debris, and other foreign substances should be conducted daily by the operator.

Note.—Fluorocarbon detectors cannot be used for testing the aerator because it is under negative pressure and EtO will not register on such a detection device.

IV. Estimated Incremental Costs Associated With Implementation of Required Modifications

The costs of implementing the exposure reduction measures contained in this notice are of concern to the Agency. Consequently, EPA has made cost estimates which are contained in Table 2. Because of the differences in equipment, facility design, use patterns, and work practices among the hospitals and health care facilities estimates of incremental costs can be developed only within a wide range. These estimates must consider the specific control measures which are applicable, their initial and recurring costs, and the incremental cost of treatment. The estimates presented are developed for typical facilities. Where individual hospitals and health care facilities already have in place some of the modifications, their incremental costs would be reduced commensurately.

These modifications generally apply to most units; however, their costs are a function of particular facility design and use patterns. The costs in Table 2 are estimates of those direct costs that would be incurred if modifications were done by internal staff. The cost incurred if modifications were made by an independent contractor would be significantly higher.

TABLE 2.—Estimated incremental direct costs associated with implementation of proposed modifications for ethylene oxide use in hospitals

[Estimated costs in dollars]

Proposed modification	Initial	Annual
1. Workplace design:		
a. Gas line hand valve	15 each	None
b. "Capture hood"	50	None
c. Material handling devices	200 to 600 Per chamber	100 to 200 Per chamber

TABLE 2.—Estimated incremental direct costs associated with implementation of proposed modifications for ethylene oxide use in hospitals—Continued

[Estimated costs in dollars]

Proposed modification	Initial	Annual
c. Vent system to existing aerator	500 to 2,000	50 to 200
e. Aerators	3,500 to 17,000	80 to 870
f. Local exhaust systems	4,500 to 5,500	1,400 to 4,300
g. Alarm systems		
2. Workplace practices.		
a. General improvements		500 to 2,000 Per location
b. Maintenance and EtO leak detection		500 to 2,000 Per chamber

Source: EPA Estimates.

V. Summary

The Agency has developed the label changes described in this notice in order to reduce the exposure of hospital and health care facility workers to EtO. While available data indicate that there is reason for concern about exposure to EtO at levels that may be occurring in many hospitals' and health care facilities' sterilization procedures, the benefits of EtO use make it essential that it remain available for use.

As noted earlier in this notice, users of EtO for hospital and health care facility sterilization procedures must comply with the changes in this notice when and as they appear on product labeling. Certain products, however, are not subject to these label changes at this time. These products are small canisters, cylinders and containers which are registered solely for use with specific sterilization equipment also marketed by the registrant. Users who do not comply with label changes when they appear on product labels will be in violation of section 12 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

VI. References

(1) Garman, R. H. and Snellings, W. M., Final Report, Ethylene Oxide Two-Year Inhalation Study on Rats, Bushy Run Research Center, June 7, 1983.

(2) Lynch, D. W., Lewis, J. R. and Moorman, W. J., Chronic Inhalation Toxicity of Ethylene Oxide and Propylene Oxide in Rats and Monkeys, A preliminary report, presented at the 21st Annual Society of Toxicology Meeting, Boston, Massachusetts, Feb. 22–26, 1982.

(3) Singh, D. V. Evaluation of the Carcinogenicity of Ethylene Oxide. Memo to Ann Barton, Jan. 27, 1983.

(4) Generoso, W. M., Cain, K. T., Krishna, M., Suen, C. W., and Gryden, R. M. Heritable Translocation and Dominant-Lethal Mutation Induction with Ethylene Oxide in Mice. Mutation Research 73:133–142.

(5) Snellings, W. M., Zelenak, J. A., Weil, C. S. Effects on Reproduction in Fischer 344 Rats Exposed to Ethylene Oxide by Inhalation for One Generation. Toxicology and Applied Pharmacology. 63, 382–388, 1982.

(6) Hemminki, K., Mutanen, P., Saloniemi, I., Niemi, M. L., Vaino, N. Spontaneous Abortions in Hospital Staff Engaged in Sterilizing Instruments with Chemical Agents. British Medical Journal, Vol. 285, p. 1461–1463, Nov. 20, 1982.

(7) Hemminki, K., British Medical Journal, Vol. 288, p. 1976–1977, June 18, 1983.

(8) Mitigation of Worker Exposure to Ethylene Oxide, Mitre Corp., March 1981. EPA Contract #68–01–5944.

(9) Draft Final Report, Hospital Worker Exposure to Ethylene Oxide, Versar, Inc., August, 1983. EPA Contract #68–01–6271, Task Nos. 57 and 58.

(10) Carry, V. F., Hozier, J., Jacobs, D., Wade, R. L., and Gray, D. G. 1979. Ethylene Oxide: Evidence of Human Chromosomal Effects, Environmental Mutagenesis, 1:375–382.

(11) Yager, J., Hines, C., Spear, R., 1983. Exposure to Ethylene Oxide at Work Increases Sister Chromatid Exchanges in Human Peripheral Lymphocytes. Science 219:1221–1223.

(12) The Costs of Measures to Mitigate Worker Exposure to Ethylene Oxide, Mitre Corp., August 1981. EPA Contract #68–01–5965.

The references cited in this notice are available for public inspection in: Rm. 238, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Dated: March 30, 1984.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

[FR Doc. 84-10039 Filed 4-17-84; 8:45 am]

BILLING CODE 6560-50-M

[PP 3G2790/T441; PH-FRL 2586-2]

Acephate; Establishment of Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established a temporary tolerance for the combined residues of the insecticide acephate and its metabolite in or on the raw agricultural commodity apples. This temporary tolerance was requested by Chevron Chemical Company.

DATE: This temporary tolerance expires March 13, 1986.

FOR FURTHER INFORMATION CONTACT:

By mail: William Miller, Product Manager (PM) 16, Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telphone number: Rm. 211 CM #2, 1921 Jefferson Davis Highway, Arlington, VA. (703–557–2600).

SUPPLEMENTARY INFORMATION: Chevron Chemical Company, 940 Hensley St., Richmond, CA 94804, has requested in pesticide petition PP 3G2790, the establishment of a temporary tolerance for the combined residues of the insecticide acephate and its cholinesterase-inhibiting metabolite methamidophos, in or the raw agricultural commodity apples at 2.0 parts per million (ppm).

This temporary tolerance will permit the marketing of the above raw agricultural commodity when treated in accordance with the provisions of experimental use permit 239–EUP–108 which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act) FIFRA) as amended, (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that establishment of the temporary tolerance will protect the public health. Therefore, the temporary tolerance has been established on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceeed the quantity authorized by the experimental use permit.

2. Chevron Chemical Co. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This tolerance expires March 13, 1986. Residues not in excess of this amount remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific cata on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

NAVAL HOSPITAL
CAMP LEJEUNE, NORTH CAROLINA 28542

5000
Code 104
2 Aug 1984

MEMORANDUM

From: Head, Facilities Management Department
To: Director of Administration

Subj: ETHYLENE OXIDE REGULATIONS AND PROBLEMS

Encl: (1) AHA Regulation dated May 1984

1. All air from the spaces concerned is exhausted to the outside. No air is recirculated.

2. The vent pipes from the Ethylene Oxide Sterilizer/Aerator run to the roof and no other vents are attached.

3. The present facility is already in compliance with three of the items listed on Encl (1).

4. The system was installed by Castle Steerlizers Co., but they did not do the design. The design work was done in 1979.

Ricky V. Richards

RICKY V. RICHARDS

American Hospital Association

840 North Lake Shore Drive
Chicago, Illinois 60611
Telephone 312.280.6000
Cable Address AMHOSP

Fac Mgt

May 1984

TO: Institutional Members
Members of the American Society for Hospital Central Service Personnel
Members of the American Society for Hospital Engineering

SUBJECT: New Ethylene Oxide Regulation

Since our earlier letters to you on controlling potential hazards from ethylene oxide (EtO) a new regulation has been promulgated that calls for your immediate evaluation and action.

On April 18, 1984, a final regulation was published by the Environmental Protection Agency (EPA) concerning the continued safe use of Ethylene Oxide (EtO) in the sterilization of equipment and supplies. (See enclosed Federal Register, April 18, 1984, Vol. 49, No. 76.)

Since the first deadline for compliance begins as soon as manufacturers can start attaching the appropriate labels on EtO containers (EPA estimates about 6 months), it is important to evaluate your current situation and begin to develop procedures that will ensure that you comply with the requirements contained on the new lables.

Requirements that must be met as soon as the new label appears include:

- o Installation of gas line hand valves
- o Installation of "capture boxes" for floor drains
- o Ventilation during gas cylinder changing
- o Ventilation of sterilizer relief valve
- o Installation of dedicated exhaust/ventilation systems
- o Installation of ventilation system alarm system
- o Posting of workplace practices for the changing of supply line filters
- o Establishment of restricted areas
- o Sterilizer door opening procedures
- o Establishment of sterilizer chamber unloading procedures
- o Maintenance practices(i.e., required recordkeeping)
- o Bi-weekly leak detection testing

Additionally, the following requirements must be met no later than July 1, 1986:

- o Venting of existing aerators
- o New equipment installation (i.e., new aeration units where required)
- o Installation of a hood or canopy over the sterilizer door.

DEPARTMENT OF THE NAVY
Naval Hospital
Camp Lejeune, NC 28542

6260.8
372
28 Sep 84

From: Head, Occupational and Preventive Medicine Department
To: Commanding Officer

Subj: REPORT OF ETHYLENE OXIDE (ETO) SURVEYS IN CENTRAL SUPPLY AND ADJACENT SPACES

1. The most recent ETO surveys in the subject spaces were conducted on 20-21 September 1984. Conditions on the former date had not changed from previous surveys, i.e., leakage occurred during the purge cycle but none of the gas was detected in the clean or sterile rooms. ETO levels in the equipment room were 250+ ppm, for a period of 5 to 8 minutes, during the early part of the cycle. The concentration rapidly fell below detectable levels, as it was removed by the overhead exhaust. Repair parts are on order. No new leak sources were discovered.

2. On 21 September 1984, the Industrial Hygiene Branch responded to notification of a sizeable ETO leak which affected not only CSR but adjoining spaces. Reportedly the ETO cylinder tanks were turned off and personnel had been evacuated from CSR and supply areas. At 1120 monitoring of the supply area showed 10 to 20 ppm of ETO just inside the door. Subsequent monitoring showed about 5-10 ppm above the ceiling of the supply rooms and housekeeping offices. No ETO concentrations were detected in surrounding passageways. Personnel were permitted to return to work at 1330 when monitoring prevailed that the ETO had dissipated to below detectable levels.

3. Comments and Recommendations. This experience and the past history of ETO leaks in the CSS suggests that the gas can suddenly escape the system in quantities too large for the present exhaust system to handle in timely fashion. In fact, there is no exhaust in the supply spaces. ETO levels in these rooms remained relatively high well after CSR concentrations fell below detectable levels. To facilitate removal of the gas from supply the adjoining doors to CSR were opened. The following recommendations are submitted.

a. CSR personnel on all shifts should be acquainted with the basic use of ETO monitoring instruments. Installation of the photo (ionization) meter with an audible alarm should be expedited.

b. The origin of many leaks have been inside the cylinder room. A method for quick removal of the gas close to the leak sources is advisable. Canopy exhausts over the sterilizer, the sterilizer doors, and cylinders are recommended. A system such as this should be dedicated to ETO removal. Sufficient make up air to insure optimal operation of the system should be provided.

M. P. GENTRY

Direct Facilities Management Head, & Fiscal Officer, & Supply Officer to meet & CCDR Gentry and immediately develop plan for complete corrective action.

DEPARTMENT OF THE NAVY
Naval Hospital
Camp Lejeune, North Carolina 28542-5008

6260.8
371
1 Nov 85

From: Head, Occupational and Preventive Medicine Department
To: Commanding Officer

Subj: ETHYLENE OXIDE (EtO) MONITORING IN CENTRAL STERILE SUPPLY (CSS)

Ref: (a) OPNAVINST 5100.23B
(b) Workplace Monitoring Plan dtd 22 Oct 84
(c) OSHA CFR 1910 Occupational Exposure to Ethylene Oxide; Final Standards

Encl: (1) Results of Sampling

1. Reference (a) requires annual industrial hygiene surveys of all workspaces with more frequent evaluations in high hazard areas. Reference (b) identified sampling protocol for ethylene oxide (EtO) which specified quarterly sampling due to historical problems of personnel exposures to EtO in excess of the 1.0 parts per million (ppm) as an eight (8) hour time-weighted average (TWA). Reference (c) now requires:

(a) Quarterly monitoring for areas where personnel exposures exceed the 1.0 ppm TWA.

(b) Written notification of exposure levels to employees.

(c) Implementation of engineering controls and workpractices to reduce exposure levels below the 1.0 ppm TWA.

2. Enclosure (1) represents results of personnel exposure to EtO on 18 and 25 June 1985 which were recently received. On 18 June, the gas autoclave was operated through a full cycle. It should be noted that most personnel exposures exceed the 1.0 ppm TWA. Furthermore, personnel in the MDB area were exposed to EtO. On 25 June, the gas autoclave developed operating problems and could not complete a full sterilizing cycle. Again, results indicate two (2) personnel overexposed with five (5) of seven (7) other personnel exposed to levels requiring medical surveillance (0.5 ppm TWA).

3. It is believed that all possible work practices, including respiratory protection, have been instituted to reduce personnel exposure to EtO. Personnel exposure data and ventilation checks with velometers and smoke tubes indicate that the attempt to reduce the levels of EtO, by the installation of a canopy hood, has not provided a permanent solution to the EtO leak problem on the sterilizer. Exposure to personnel in adjacent spaces, particularly MDB and the Sterile Side, remains a serious problem.

4. Exposure data will be entered in personnel health records and all personnel will receive written notification as to their exposure levels, as required by reference (c). Should the Naval Hospital desire to continue the use of the gas autoclave, an engineering effort through the use of NAVOSH abatement funds will be required as a highest priority. As a NAVOSH Program Element, the continued high levels of exposure to personnel in CSS and adjacent areas would result in an unsatisfactory evaluation of the Ethlyene Oxide Program.

Subj: ETHYLENE OXIDE (EtO) MONITORING IN CENTRAL STERILE SUPPLY (CSS)

5. The Industrial Hygiene Branch will continue quarterly monitoring. Point of contact is Mr. G. L. Winters, Supervisory Industrial Hygienist, extensions 2707/2767.

M. P. CENTRY

Results of EtO Sampling

Name	SSN	Rank	Area	Day 1 TWA/ppm	Day 2 TWA/ppm
LOSITO, Carl	044-30-9703	WG-5	MDB	1.17	0.62
PICKETT, J.	239-56-3867	GS-5	Clean Room	1.22	0.53
CASTRO, J.	570-69-2487	HN	Clean Room	0.26	0.78
PEQUES, E.	240-54-4123	GS-5	Clean Room	1.82	1.62
MASSEY, J.	237-64-2299	GS-5	Sterile Room	1.40	0.45
SMITH, E.	444-66-5950	HA	DECON	2.00	0.34
PEARSON, B.	263-54-7025	GS-5	DECON	1.95	1.34
STRINGER, B.	569-31-1706	HM3	Clean Room	1.27	--
			Sterile Side	--	0.73
MARTELL, A.	147-24-2824	GS-9	Clean Room	1.66	0.67
VINCENT, G.	095-62-0257	HN	Sterile Side	3.22	
Vent Hood				--	0.78

DEPARTMENT OF THE NAVY
NAVAL MEDICAL COMMAND
NATIONAL CAPITAL REGION
BETHESDA, MARYLAND 20814 -5000

432 LAM
A [illegible]

IN REPLY REFER TO
11019
Ser 22E/3042
05 NOV 1984

From: Commander
To: Commander, Naval Medical Command (MEDCOM ~~432A~~ 02F), Department of the Navy, Washington, D.C. 20372

Subj: SPECIAL PROJECT C2-84, ALTERATIONS TO THE ETHYLENE OXIDE STERILIZERS, BUILDING 9

Ref: (a) COMNAVMEDCOM Ltr 11019 Ser 432A/40718018 dtd 18 Jul 84

Encl: (1) NAVOSH Deficiency Abatement Program Occupational Safety and Health Report (OCR) for Special Project C2-84.

1. In accordance with reference (a), enclosure (1) is forwarded to support NAVOSH funding for the subject project.

2. If you have further questions, please contact LT Percival at 295-0519.

R.A. Taylor
R. A. TAYLOR
By direction

CDR Brown 2-4-85
Attached is a copy of a project worked up by Bethesda under Def. Abatement Program for ETO! Just for info.
VR
Please Return Terry

LTJG Richards
Please review & determine if our repair meet or exceed those proposed in Bethesda's plans
BT

OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

Ref: NAVFACINST 5100.14

UIC: N00168
SERIAL NO.

PROJ. NAME: ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

PROGRAM: HEALTH
FUNDING COMMAND: NAVFAC

DATE PREPARED: 02 AUG 84
DATE INPUT:
DATE REVISED:
PROJ. NO. C002-84

AGENCY: DEPARTMENT OF THE NAVY

1. ACTIVITY: NMCNCR
ADDRESS: BETHESDA, MD.

NAVFAC CONTACT:

NARRATIVE
(LIMIT OF 65 POSITIONS PER LINE INCLUDING SPACES AND PUNCTUATION)

2. PROBLEM DESCRIPTION:

ETHYLENE OXIDE (ETO) IS SUSPECTED TO BE A STRONG CARCINOGEN. OSHA HAS PROPOSED RULEMAKING WHICH WILL REDUCE EMPLOYEE EXPOSURE LEVELS FROM 50 PPM EIGHT HOUR TIME WEIGHTED AVERAGE (TWA) TO 1 PPM 8 HR TWA. THE PROPOSED RULEMAKING IS EXPECTED TO BECOME EFFECTIVE BEFORE THE END OF CY 1984. THE PRIMARY PROBLEM IS REDUCING ETO EXPOSURE TO 1 PPM 8 HR TWA FOR ALL HOSPITAL EMPLOYEES THAT WORK IN AREAS UTILIZING ETO.

3. SPECIFIC HAZARD AND LOCATION:

NAVAL HOSPITAL BETHESDA, CENTRAL PROCESSING AND DISTRIBUTION, BUILDING 9, GROUND FLOOR. OPERATES STERILIZATION EQUIPMENT THAT UTILIZES ETO IN ITS OPERATION. INFILTRATION OF ETO INTO THE WORK SPACES IS OCCURRING WHEN THE STERILIZER LOADS ARE MOVED FROM THE STERILIZERS TO THE AREATORS. ETO DISSIPATES INTO THE ENVIRONMENT DURING THIS MOVE. PERSONNEL EMPLOYED IN THE SPACES WHERE STERILIZER LOADS ARE TRANSFERRED THROUGH ARE AT RISK OF BEING EXPOSED TO ETO WELL ABOVE 1 PPM 8 HR TWA.

OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

UIC: N00168
SERIAL NO.

PROJ. NAME: ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

4. INTERIM CONTROL MEASURES:

MONITORING DATA SUGGESTS THAT RESPIRATORY PROTECTION IS INDICATED FOR PROTECTION OF PERSONNEL DURING THE FOLLOWING ACTIVITIES:

1) OPENING OF STERLIZER DOOR AND TRANSFERRING TO
2) CYLINDER CHANGE-OUT DUE TO UNFORSEEN AND UNDETECTABLE LEAKS
3) BOILERROOM MAINTENANCE ACTIVITIES DUE TO UNPREDICATABLE LEAKS.

ALTHOUGH 8 HOURS OF TWA EXPOSURES ARE GENERALLY UNDER 1 PPM, PEAK EXCURSIONS EXCEED ACCEPTABLE LIMITS

5. EFFECTIVENESS OF INTERIM CONTROL MEASURES:

RESPIRATORS SHOULD BE AN EFFECTIVE INTERIM MEASURE BUT ARE TRAUGHT WITH PROBLEMS REGARDING ENFORCEMENT OF THEIR PROPER USE. DEFINITIVE ENGINEERING CONTROLS ARE MANDATED IN THE STANDARD WITH AN IMPLEMENTATION DEADLINE OF 8/85

6. PROPOSED CORRECTIVE ACTION AND EFFECTIVENESS:
(NON RECIRCULATING)

1. INSTALLATION OF A DEDICATED EXHAUST SYSTEM OR INSTALLATION OF EMERGENCY SHUT OFF DAMPERS IN THE EXISTING VENTING SYSTEM.

2. INSTALLATION OF EXHAUST HOODS OUTSIDE THE STERILIZERS DOORS OR CONVERSION OF THE EQUIPMENT ROOM INTO AN EXHAUST PLENUM.

3. INSTALLATION OF LOCALIZED EXHAUSTS IN THE LOAD TRANSFER AREAS, TANK STORAGE AREAS AND ISCHARGE AREAS.

4. INSTALLATION OF AIRFLOW ALARMS.

5. INSTALLATION OF EXPOSURE MONITORS

CONSTRUCTION AND USE OF THE ABOVE ACTION SHOULD REDUCE AND INSURE THAT PERSONNEL EXPOSED REMAINS BELOW 1 PPM.

7. OTHER RELEVANT INFORMATION:

LOCAL CONTACT:

LCDR JONES, HEAD, CENTRAL PROCESSING & DISTRIBUTION, 295-4542.

LT W. PERCIVAL, CEC, FACILITIES MANAGEMENT DEPARTMENT, 295-0519.

Ms. B. MONSALVE, INDUSTRIAL HYGENIST, NAVAL HOSPITAL, BETHESDA, MD., 295-5722.

NAVOSH DEFICIENCY ABATEMENT PROGRAM
OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

UIC: N00168
SERIAL NO.

PROJ. NAME: ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

8. APPLICABLE STANDARDS:

29 CFR 1910.1047 OCCUPATIONAL EXPOSURE TO ETHYLENE OXIDE

9. COST OF SAFETY AND HEALTH MEASURES: (IN THOUSANDS OF DOLLARS)

	CONSTRUCTION				REPAIR			
F Y	DESIGN	FND	CONSTR	FND	DESIGN	FND	REPAIR	FND
UP	10	NO	100	NO				
	TOTAL				TOTAL			

10. PROJECT SCHEDULE:

	ACTIVITY (MMM/YY)	REGULATION (MMM/YY)
DESIGN (START)		
DESIGN (COMPLETION)		
CONSTR (START)		
CONSTR (COMPLETION)		
OPERATION (START)		
FINAL COMPLIANCE		

NAVOSH DEFICIENCY ABATEMENT PROGRAM
OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

UIC: N00168
SERIAL NO.

PROJ. NAME: ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

11. MISCELLANEOUS DATA:

APPROPRIATION: O & MN

MAJOR CLAIMANT: NAVMEDCOM

SUB-CLAIMANT: N/A

HEALTH CATEGORY:

HAZARD SUB-CATEGORY:

HAZARD CATEGORY:

VARIOUS LOCATIONS:

REMARKS:

STATUS:

12. BUILDINGS AFFECTED:

PROPERTY RECORD CARD NO(S): 2-000930

NAVY CATEGORY CODE(S): 510-10

BUILDING NO(S): 9

13. HAZARD CONTROL ASSESSMENT:

SAFETY	OR	HEALTH
1) SPECIFIC HAZARD		1) SPECIFIC HAZARD ETHYLENE OXIDE
2) HAZARD VIOLATION (REGULATIONS)		2) HAZARD VIOLATION (REGULATIONS 29 CFR 1910.1047
3) PROBABILITY (CIRCLE ONE) A) LIKELY B) PROBABLE C) POSSIBLE D) UNLIKELY		3) CONCENTRATION OF HAZARD: 15-1/ UNITS: ppm(PEA IS CONCENTRATION ABOVE CEILIN [A) YES] B) NO
4) SEVERITY OF MOST LIKELY INJURY		4) CURRENT STANDARDS: 1PPM 8H TV 0.5PPM ACTI THE UNITS MUST BE THE SAME AS LEVEL ITEM 3.
5) DAYS LOST PER INCIDENT (CIRCLE ONE) A) 4200 B) 2500-4199 C) 1200-2499 D) 400-1199 E) 100-399 F) 30-99 G) < 30		5) TIME BETWEEN EXPOSURE AND HARMFUL IMPACTS (CIRCLE ONE): A) IMMEDIATE B) IN MONTHS [C) IN YEARS]

NAVOSH DEFICIENCY ABATEMENT PROGRAM
OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

UIC: N00168
SERIAL NO.

PROJ. NAME: ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

13. HAZARD CONTROL ASSESSMENT: (Cont'd):

6) NORMAL WORKING POPULATION EXPOSED TO HAZARD (EMPLOYEES) (CIRCLE ONE):

A) 1-4 B) 5-9 [C) 10-50] D) > 50

7) RATE OF EXPOSURE TO HAZARD (HOURS/YEAR PER PERSON EXPOSED) (CIRCLE ONE):

A) < 40 B) 40-150 [C) 151-959] D) 960-2000 E) > 2000

8) INSTALLED COST OF CORRECTIVE ACTION ($X10^3) (CIRCLE ONE):

A) ≤ 40 B) 41-60 C) 61-80 D) 81-100 [E) > 100]

9) CHANGE IN ANNUAL O&M COST ($X10^3) (CIRCLE ONE):

A) < (-5) B) (-5)-0 [C) 1-5] D) 6-10 E) > 10

10) TIME TO ACCOMPLISH THE CONSTRUCTION OF CORRECTIVE ACTION (MONTHS) (CIRCLE ONE):

A) 1-3 [B) 4-6] C) 7-9 D) 10-12 E) 13-24 F) > 24

SAFETY -OR- HEALTH

11) UPON COMPLETION, WILL THE SAFETY PROJECT BE IN FULL LEGAL COMPLIANCE? (CIRCLE ONE):

A) YES B) NO

11) UPON COMPLETION, WHAT WILL THE ESTIMATED CONCENTRATION OF THE DESIGNATED HEALTH HAZARD BE?

CONCENTRATION < 1 PPM
THE UNITS MUST BE THE SAME AS ITEM 3.

12) CHANGE IN ENERGY CONSUMPTION CAUSED BY CORRECTIVE ACTION (10^6BTU/YEAR) (CIRCLE ONE):

A) < (-500) B) [(-500)-0] C) 1-500 D) 501-1000 E) > 1000

13) EFFECTIVE LIFE OF CORRECTIVE ACTION (YEARS):

[A) ≥ 10] B) 5-9 C) 3-4 D) 1-2 E) < 1

NAVOSH DEFICIENCY ABATEMENT PROGRAM
OCCUPATIONAL SAFETY AND HEALTH CONTROL REPORT (OCR)

UIC: N00168
SERIAL NO.

PROJ. NAME ALTERATIONS TO ETO STERILIZERS, BUILDING 9 (C2-84)

13. HAZARD CONTROL ASSESSMENT: (Cont'd)

14) POTENTIAL FOR RELOCATING THE PROCESS OR FUNCTION TO AVOID THE HAZARD (CIRCLE ONE):

A) HIGH B) MEDIUM [C) LOW]

15) EXPECTED LIFE OF HAZARDOUS OPERATION (YEARS) (CIRCLE ONE):

[A) > 10] B) 6-10 C) 3-5 D) 1-2 E) < 1

WORK AUTHORIZATION/ESTIMATE (MAINTENANCE MANAGEMENT)

NAVFAC 11014/22 (10-74) S/N 0105-LF-002-7110
Supersedes NAVDOCKS 2353 and 2356

Instructions for completing form are contained in NAVFAC MO-321

3. JOB ORDER NO.
25024

1. ACTIVITY	2. ACTIVITY CODE	4. ESTIMATE NO.
FACILITIES MANAGEMENT DEPARTMENT, NHCLNC	068093	

5. REQUESTED STARTING DATE	6. PRIORITY	7. INSPECTION GENERATED	8. FACILITY NO.	9. EQUIPMENT NO.
		[X] YES [ ] NO	NH-100	

10. RPI CAT CODE	11. COST ACCOUNT CODE	12.	13.	14.

15. NAVY ACCOUNTING DATA

a. APPROPRIATION SYMBOL AND SUBHEAD	b. OBJECT CLASS	c. BUREAU CONTROL NUMBER	d. AUTH. ACCOUNTING ACTIVITY	e. TRANS CODE	f. PROPERTY ACCTG. ACTIVITY	g. COST CODE
1751804.1880		680930			68093	

16. FOR FURTHER INFORMATION CALL *(Name and telephone)*	17. SKETCH/PLAN ATTACHED IF "YES" INDICATE NUMBER	18. LABOR CLASS CODE *(Except for overhead)*
	[X] YES 2 [ ] NO	07

19. JOB TITLE

PROVIDE ALTERATIONS FOR ETO IN CSS

20. GENERAL JOB DESCRIPTION

Perform work shown on attached sketch

21. ESTIMATE

a. BREAKDOWN OF WORK				b. SUMMARY OF ESTIMATE				
JOB PHASE NO. (1)	WORK CENTER (2)	DESCRIPTION (3)	EST. HOURS (4)	WORK CENTER (5)	LABOR HOURS (6)	LABOR (7)	MATERIAL (8)	TOTAL ESTIMATE (9)
	32	Perform all work as shown on attached sketch	118	32	118	1670	520	2190
	33	Perform work as shown on attached sketch	8	33	8	120	10	130
	34	Perform work as shown on attached sketch	12	34	12	200	130	330
	35	Perform work as shown on attached sketch	32	35	32	596	195	791
		CONTRACT FOR FABRICATION OF SS HOODS (3 ea)					1125	1125
				TOTAL	170	2586	1980	4566

22. DISTRIBUTION

MCD							
ADP							
MAINT							

c. CONTINGENCY	
d. OVERHEAD AND/OR SURCHARGE	
e. GRAND TOTAL	4566

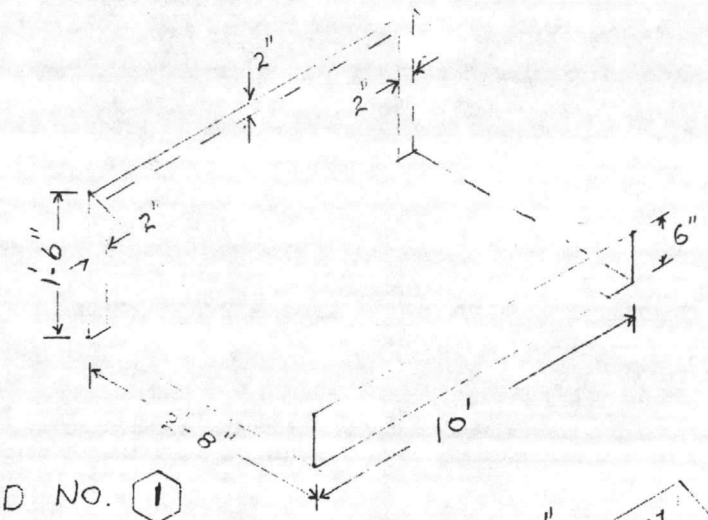
23. AUTHORIZED WORK TO BE PERFORMED *(Signature)*

R.W. RICHARDS LTJG CEC USN

TITLE: Head, Fac Mgt Dept

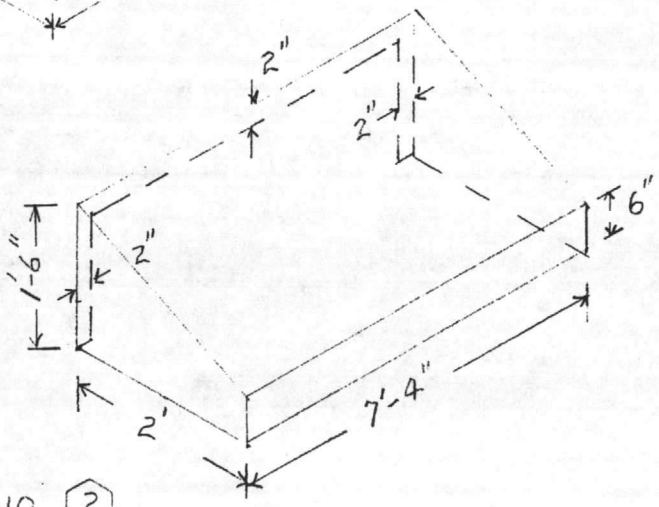
DATE: 25 Jan 85

B-9379

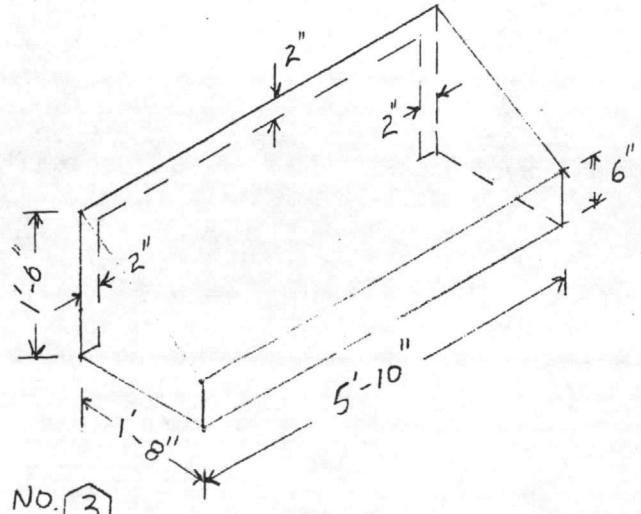


NOTE: HOODS TO BE CONSTRUCTED OF 20 GAGE STAINLESS STEEL
PROVIDE 2" FLANGE AROUND BACK SIDE
ALL JOINTS TO BE WELDED

HOOD NO. (1)



HOOD NO (2)



HOOD NO. (3)

SKETCH
FOR
HOODS
N. T. S.

DEPARTMENT OF THE NAVY SELF-DUPLICATING NOTE

Use only for an informal, preferably hand-written note. Make duplicate only when required for follow-up or working file. See correspondence manual for formal, official memoranda.

TO:

MR RICHARDS

☐ ACTION	☐ COORDINATE	☐ PREPARE FOR SIGNATURE
☐ AS DISCUSSED	☐ CORRECTION	☐ REPORT BACK
☐ CALL/SEE ME	☑ INFORMATION	☐ RETURN
☐ COMMENT/CLEAR	☐ PREPARE DRAFT	☐

SUBJECT E.O. SYSTEM IN CSS

COST ESTIMATE TO ACCOMPLISH OS P&L

Attached from SUNHEALTH

ESTIMATED COST $4850

FROM:

DATE 12 Dec 84

EXT.

OPNAV 5216/142 (Rev. 5-74) S/N 0107-LF-778-7110

520618

COST ESTIMATE
CSS E.O. JOB.

1. Remove DUCT on each side of Sterilizer
CAP DUCT. 33 SHOP - 8 hrs + $10 MAT
8 hrs @ 16.18 = 129 = 139

2. PATCH Holes in ceiling 4 ea.
32 SHOP - 4 hrs 57

3. EXTEND ~~wall~~ PARTITIONS to ceiling above. Taped JOINT
52 LF 6' high 312 SF
104 hrs @ 14.15 LABOR 1471 MAT ~~250~~ 450 = ~~1721~~ 1921

4. INSTALL 3 each 6"x18" through wall registers in wall.
32 SHOP LAB 6 hrs = 85 MAT 18 = 103

5. RUN EXISTING Gravity VENT over to EXHAUST ~~DUCT~~ DUCT. CAP OFF VENT above
34 SHOP - 4 hrs 62 MAT 10 72

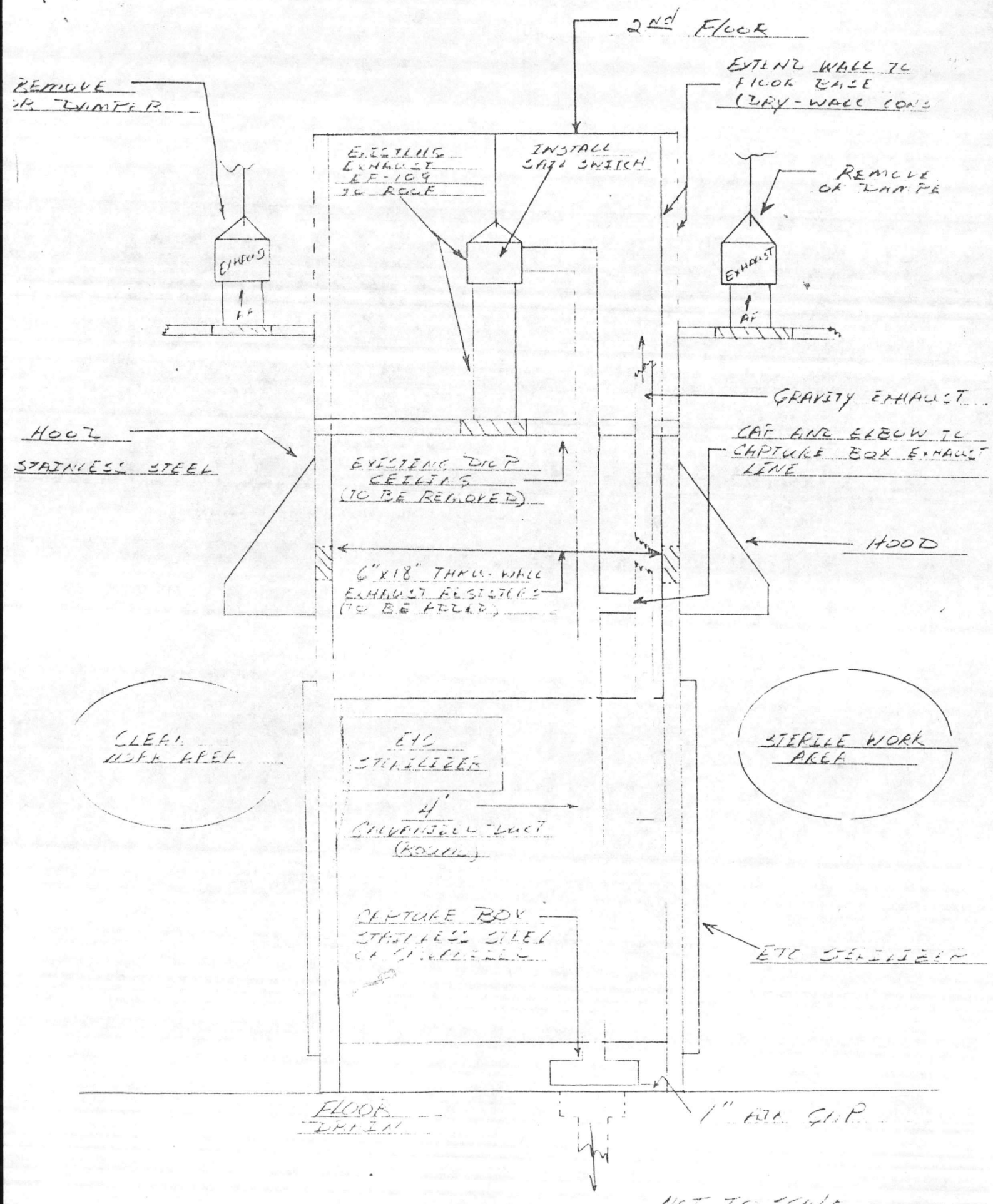
6. RUN 4" ROUND DUCT FROM EXHAUST DUCT ABOVE TO FLOOR DRAIN. CONSTRUCT ROUND CAPTURE BOX.
8 hrs LABOR 34 SHOP 124 · 120 244

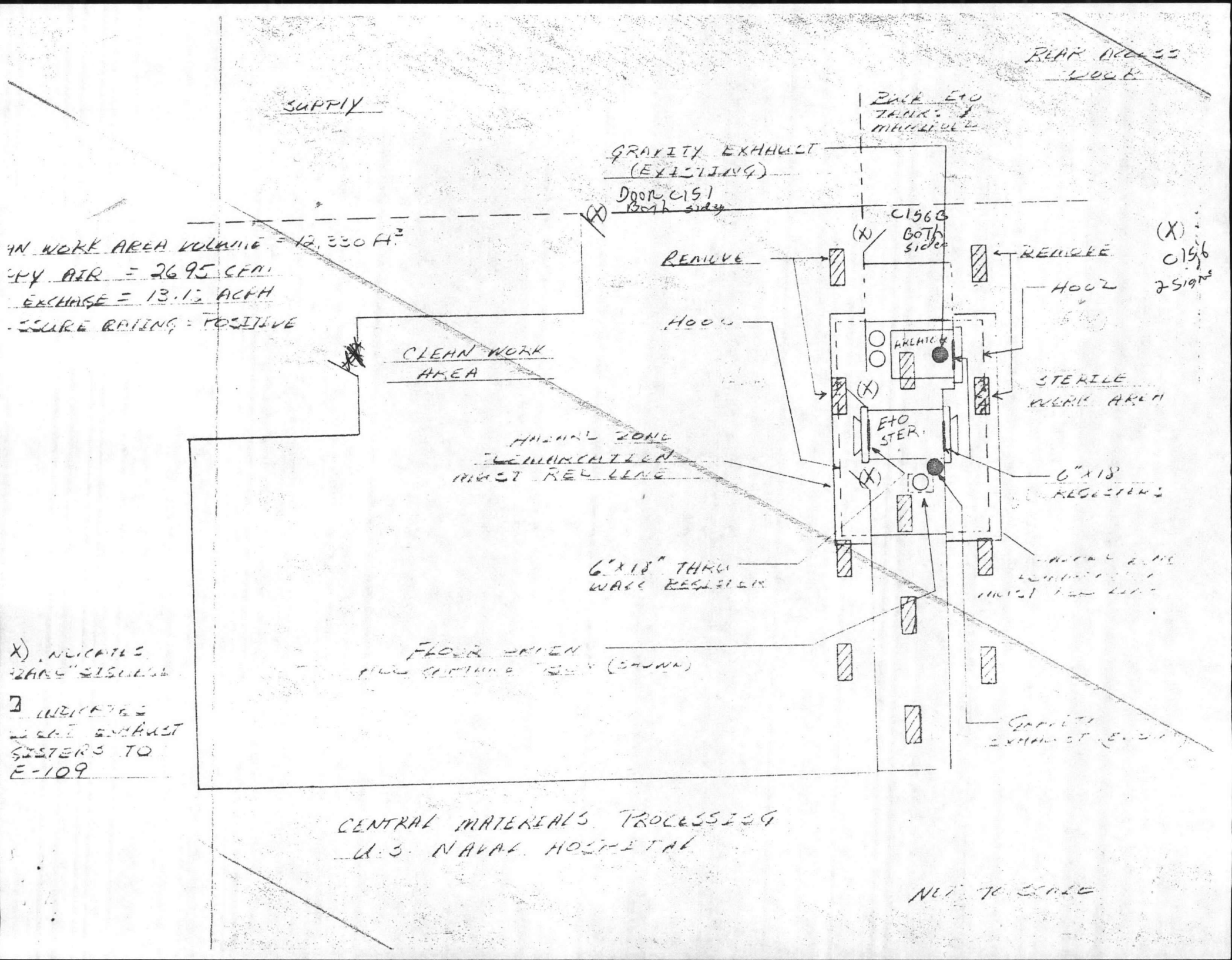
7. INSTALL SAID ~~SWITCH~~ SWITCH IN DUCT WITH A AUDIO AND VISUAL ALARM IN ROOM C151 + C153
35 SHOP. 32 hrs $575 MAT $195 = 770

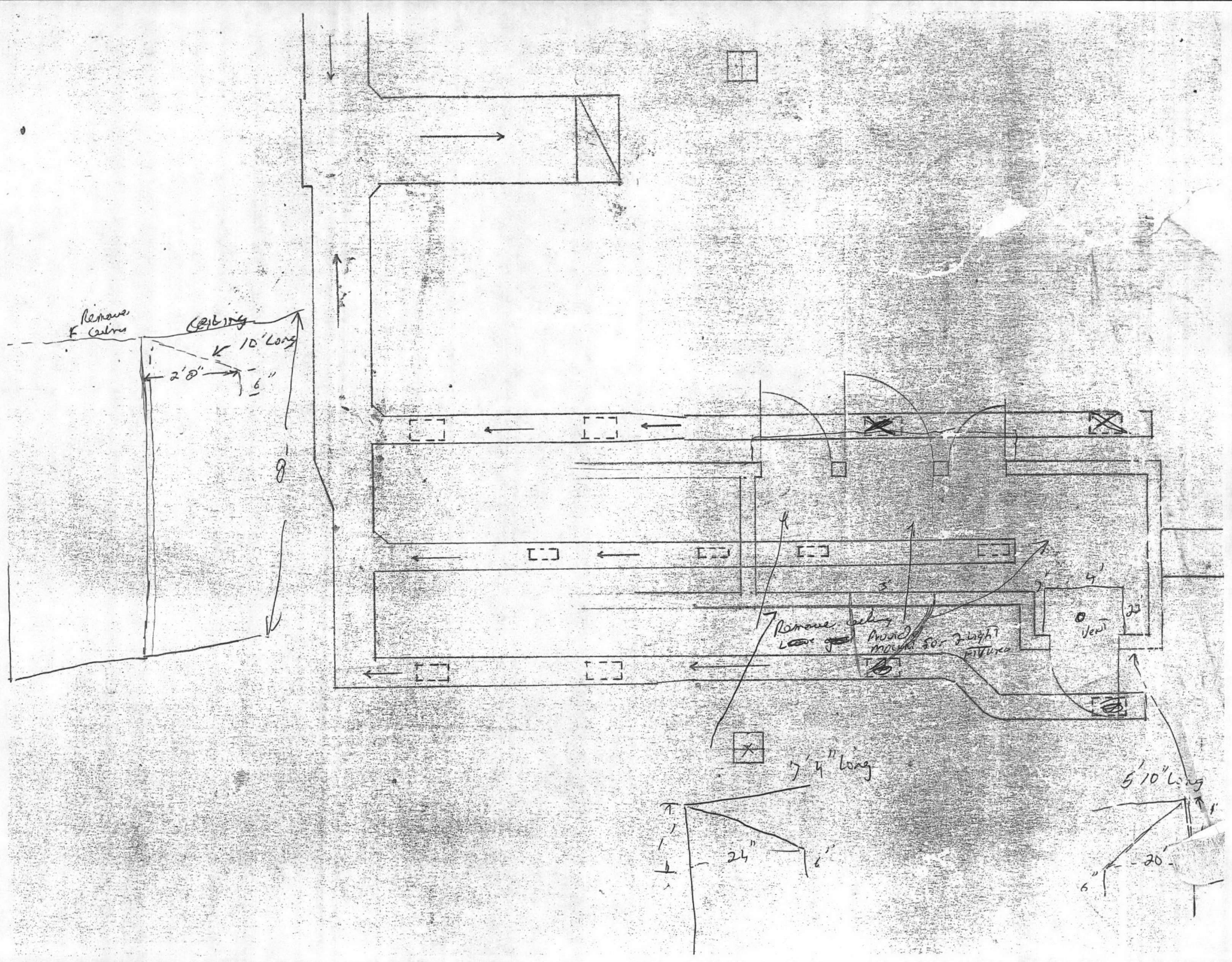
8. PAINT 2" WIDE RED HAZARD ZONE MARKING ON FLOOR.
32 SHOP 4 hrs. 57 MAT $10 67

9. PROCURE 20 GA. SS WELDED HOODS AND INSTALL ~~OVER~~ ON WALL.
16 hr LAB 249 MAT $1,025 1,274

SPECIFICATION




SUPPLY
GRAVITY EXHAUST (EXISTING)
DOOR C151 Both sides
C156 BOTH SIDES
(X)
REMOVE
REMOVE
HOOD
HOOD
CLEAN WORK AREA
STERILE WORK AREA
E+O STER.
6"x18" THRU WALL REGISTER
6"x18" THRU WALL REGISTER
FLOOR GRILL
GRAVITY EXHAUST E-109
REAR ACCESS DOOR
(X) C156 2 SIDES
N WORK AREA VOLUME = 12,330 FT³
Y AIR = 2695 CFM
EXCHANGE = 13.1 ACPH
SURE RATING = POSITIVE
X) INDICATES
WALL REGISTER
INDICATES
WALL EXHAUST
REGISTERS TO
E-109
CENTRAL MATERIALS PROCESSING
U.S. NAVAL HOSPITAL
NOT TO SCALE



Remove F Ceiling
Ceiling
10' Long
2'8"
6"
8
Remove Ceiling
Provide mounting for 2 light fixture
4'
Vent
7'4" Long
24"
6"
5'10" Long
20"
6"