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# federal register

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| Monday | Tuesday | Wednesday | Thursday | Friday |
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Documents normally scheduled on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this trial program are invited. Comments should be submitted to the Director of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

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(For Details, See 41 FR 22997, June 8, 1976)

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- Gramicidin and tyrothricin potency assay; comments by 7–12–76. 19348; 5–12–76
- Peptide antibiotic drugs; comments by 7–12–76 19349; 5–12–76
- Vancomycin hydrochloride; revision of standard; comments by 7–12–76 19347; 5–12–76

### INTERSTATE COMMERCE COMMISSION

- Accounts, reports and records of railroad companies; branch line accounting system; comments by 7–15–76. 23172; 6–8–76

### JUSTICE DEPARTMENT

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- Coral Bay, St. John, V.I.; closing of port of entry; comments by 7–12–76 23718; 6–11–76

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- Parole of prisoners, youth offenders and juvenile delinquents; comments by 7–14–76 19341; 5–12–76

### LABOR DEPARTMENT

Occupational Safety and Health Administration—
- Safety standards; Maryland plan supplement; comments by 7–15–76. 24154; 6–15–76
- Safety standards; North Carolina plan supplement; comments by 7–15–76 24154; 6–15–76

### LEGAL SERVICES CORPORATION

- Attorney hiring; comments by 7–12–76. 23730; 6–11–76
- Criminal convictions; actions challenging; restrictions; comments by 7–12–76 23730; 6–11–76
- Criminal proceedings; assistance; restrictions; comments by 7–12–76. 23729; 6–11–76
- Juveniles; assistance; restrictions; comments by 7–12–76 23729; 6–11–76
- Legal support for financially unable; eligibility; comments by 7–12–76. 23728; 6–11–76

### MANAGEMENT AND BUDGET OFFICE

- Public information; implementation of procedures; comments by 7–16–76. 24610; 6–17–76

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- Tolls for use of the Panama Canal; comments by 7–16–76 19981; 5–14–76

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- Airworthiness directives; Dowty Rotol propellers; comments by 7–12–76. 23420; 6–10–76
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- Exemption from loading standards for tires; comments by 7–17–76. 24608; 6–17–76

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## Next Week's Meetings

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New Jersey Advisory Committee, New Brunswick, N.J. (open), 7–14–76. 24212; 6–15–76

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**GENERAL SERVICES ADMINISTRATION**

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Economic Conditions Task Group, Committee on Enhanced Recovery Techniques, Denver, Colo. (open), 7–15 and 7–16–76 ..... 26236; 6–25–76

**JUSTICE DEPARTMENT**

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Guards and Investigators Committee of LEAA's Private Security Advisory Council, Boston, Mass. (open), 7–15 and 7–16–76..... 26589; 6–28–76

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Occupational Safety and Health Administration—

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Advisory Panel for Genetic Biology, Washington, D.C. (closed), 7–12 through 7–14–76.... 26280; 6–25–76

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**TRANSPORTATION DEPARTMENT**

Coast Guard—

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National Highway Traffic Safety Administration—

National Motor Vehicle Safety Advisory Counsel, Washington, D.C. (open), 7–15–76..... 24623; 6–17–76

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Station Committee on Educational Allowances; White River Junction, Vt. (open), 7–15–76.... 24469; 6–16–76

## List of Public Laws

This is a continuing numerical listing of public bills which have become law, together with the law number, the title, the date of approval, and the U.S. Statutes citation. The list is kept current in the FEDERAL REGISTER and copies of the laws may be obtained from the U.S. Government Printing Office.

H.R. 10051..... Pub. Law 94–331
To amend section 815 of the Internal Revenue Code to allow a life insurance company to disregard (for purposes of that section) a distribution during the last month of its taxable year, determined to have been made out of the policyholders surplus account, if such distribution is returned to the company not later than the due date for filing its income tax return (including extensions thereof) for that year, and for other purposes.
(Jun. 30, 1976; 90 Stat. 781)

H.R. 12203..... Pub. Law 94–330
Foreign Assistance and Related Programs Appropriations Act, 1976, and the period ending September 30, 1976".
(Jun. 30, 1976; 90 Stat. 770)

H.R. 13680..... Pub. Law 94–329
International Security Assistance and Arms Export Control Act of 1976
(Jun. 30, 1976; 90 Stat. 729)

H.J. Res. 726..... Pub. Law 94–322
Joint resolution to authorize and request the President to establish a "National Bicentennial Highway Safety Year"
(Jun. 30, 1976; 90 Stat. 715)

S. 2529..... Pub. Law 94–324
Veterans Housing Amendments of 1976.
(Jun. 30, 1976; 90 Stat. 720)

S. 3122..... Pub. Law 94–325
An act to extend the authorization for appropriations to carry out the Endangered Species Act of 1973
(Jun. 30, 1976; 90 Stat. 724)

S. 3147..... Pub. Law 94–326
An act to extend the Marine Protection, Research, and Sanctuaries Act for two years
(Jun. 30, 1976; 90 Stat. 725)

S. 3475..... Pub. Law 94–327
An act relating to the display of certain historical documents within the United States Capitol Building during the calendar year 1976
(Jun. 30, 1976; 90 Stat. 726)

S. 98..... Pub. Law 94–323
An act to authorize the Secretary of the Interior to establish the Klondike Gold Rush National Historical Park in the States of Alaska and Washington, and for other purposes
(Jun. 30, 1976; 90 Stat. 717)

S.J. Res. 203..... Pub. Law 94–328
Emergency Technical Provisions Act of 1976
(Jun. 30, 1976; 90 Stat. 727)

# rules and regulations

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

## Title 7—Agriculture

### SUBTITLE A—OFFICE OF THE SECRETARY OF AGRICULTURE

### PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

#### Department Counselor

Part 2, Subtitle A of Title 7, Code of Federal Regulations is amended to repeal the designation of the General Counsel as the Department Counselor in view of the designation of the Assistant General Counsel, Legislation, Litigation, Research and Operations as Department Counselor which appears in 7 CFR 0.735–3 (41 FR 24107).

§ 2.31 [Amended]

Section 2.31 is amended by revoking paragraph (p).

Dated: June 30, 1976.

EARL L. BUTZ,
*Secretary of Agriculture.*

[FR Doc.76–19510 Filed 7–6–76;8:45 am]

### CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Docket No. AO–214–A5]

### PART 981—ALMONDS GROWN IN CALIFORNIA

#### Order Amending Order; Findings and Determinations

*Correction*

In FR Doc. 76–18917, appearing at page 26852 in the issue for Wednesday, June 30, 1976, the following corrections should be made:

1. On page 26853 in the third column, in the table in § 981.62(a), in the column under the heading "Varieties", the eighth entry which now reads "Bureka" should read "Eureka".

2. On page 26854 in the first column, in the table in § 981.62(a), in the column under the heading "Varieties", the second entry which now reads "Suitana" should read "Sultana".

## Title 14—Aeronautics and Space

### CHAPTER II—CIVIL AERONAUTICS BOARD

[Regulation ER–948; Amendment No. 20]

### PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR CERTIFICATED AIR CARRIERS

#### Updating the Accounting Provisions; Correction

The adopted date of this Regulation should appear as March 19, 1976 rather than March 9, 1976 as it appeared in the FEDERAL REGISTER at page 12286 on March 25, 1976.

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
*Acting Secretary.*

[FR Doc.76–19537 Filed 7–6–76;8:45 am]

## Title 16—Commercial Practices

### CHAPTER I—FEDERAL TRADE COMMISSION

[Docket 9036]

### PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

#### Boverman Fabrics, Inc., et al.

Subpart—Corrective actions and/or requirements: § 13.533 Corrective actions and/or requirements; 13.533–20 Disclosures. Subpart—Invoicing products falsely: § 13.1108 Invoicing products falsely; 13.1108–90 Wool Products Labeling Act. Subpart—Misbranding or mislabeling: § 13.1185 Composition; 13.1185–90 Wool Products Labeling Act; § 13.1200 Content; § 13.1212 Formal regulatory and statutory requirements; 13.1212–90 Wool Products Labeling Act. Subpart—Misrepresenting oneself and goods—Goods: § 13.1590 Composition; 13.1590–90 Wool Products Labeling Act; § 13.1605 Content; § 13.1623 Formal regulatory and statutory requirements; 13.1623–90 Wool Products Labeling Act. Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1845 Composition; 13.1845–80 Wool Products Labeling Act; § 13.1850 Content; § 13.1852 Formal regulatory and statutory requirements; 13.1852–80 Wool Products Labeling Act.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; Secs. 2–5, 54 Stat. 1128–1130; 15 U.S.C. 45, 68.)

*In the matter of Boverman Fabrics, Inc., a corporation, and Milton Boverman, individually and as an officer of said corporation*

Consent order requiring a New York City importer and distributor of fabrics, among other things to cease misrepresenting the wool content of wool blend fabrics; and to notify its customers that the fabrics they have purchased were misbranded.

The Order to cease and desist, including further order requiring report of compliance therewith, is as follows:[1]

ORDER

*It is ordered,* That respondents Boverman Fabrics, Inc., a corporation, its successors and assigns, and it officers, and Milton Boverman, individually and as an officer of said corporation, and respondents' representatives, agents, and employees, directly or through any corporation, subsidiary, division, or any other device, in connection with the introduction, or importing for introduction, into commerce, or the offering for sale, sale, transportation, distribution, delivery for shipment or shipment, in commerce, of wool products, as "commerce" and "wool product" are defined in the Wool Products Labeling Act of 1939, do forthwith cease and desist from misbranding such products by:

1. Falsely and deceptively stamping, tagging, labeling, or otherwise identifying such products.

2. Failing to securely affix to or place on, each such product a stamp, tag, label, or other means of identification showing in a clear and conspicuous manner each element of information required to be disclosed by section 4(a)(2) of the Wool Products Labeling Act of 1939.

*It is further ordered,* That respondents Boverman Fabrics, Inc., a corporation, its successors and assigns, and its officers and Milton Boverman, individually and as an officer of said corporation, and respondents' representatives, agents, and employees, directly or through any corporate or other device, in connection with the importing, advertising, offering for sale, sale or distribution of fabrics in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended, do forthwith cease and desist from misrepresenting such products on invoices or shipping memoranda applicable thereto, or in any other manner.

*It is further ordered,* That respondents mail a copy of this order by registered mail to each of their customers that purchased the wool products which gave rise to this complaint.

*It is further ordered,* That the individual respondent named herein promptly notify the Commission of each change in business or employment status, which includes discontinuance of his present business or employment and each affiliation with a new business or employment, for ten (10) years following the effective date of this order. Such notice shall include respondent's current business address and a description of the business or employment in which he is engaged as well as a description of his duties and responsibilities. The expiration of the notice provision of this paragraph shall not affect any other obligations arising under this order.

*It is further ordered,* That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

[1] Copies of the Complaint, Decision and Order filed with the original document.

*It is further ordered*, That the respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

*It is further ordered*, That the respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist contained herein.

The decision and order was issued by the Commission May 17, 1976.

CHARLES A. TOBIN,
*Secretary.*

[FR Doc.76-19445 Filed 7-6-76;8:45 am]

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## SUBCHAPTER C—RULES, REGULATIONS, STATEMENTS, AND INTERPRETATIONS UNDER MAGNUSON-MOSS WARRANTY ACT

## PART 703—INFORMAL DISPUTE SETTLEMENT PROCEDURES

### Postponement of Effective Date for Sale of New Homes

By letter of April 28, 1976, the National Association of Home Builders (NAHB) and the Home Owners Warranty Corporation (HOW) requested a postponement until January 4, 1977 of the effective date of the rule on Informal Dispute Settlement Procedures, 16 CFR Part 703, 40 FR 60215, as it applies to written warranties on consumer products offered by sellers of new homes. The Commission considered the logistical problems set forth by NAHB and HOW and determined that granting the postponement requested would be in the public interest.

The Commission's Rule on Informal Dispute Settlement Procedures became generally effective on July 4, 1976. However, for written warranties on consumer products offered with the sale of new homes for which a contract of sale is signed after July 4, 1976, but before January 4, 1977, that Rule is not applicable. Compliance with the requirements of the Rule will be required for warranties on consumer products offered by sellers of new homes, contracts for the sale of which are entered into after January 4, 1977.

Issued by direction of the Commission dated June 28, 1976.

JAMES A. TOBIN,
*Acting Secretary.*

[FR Doc.76-19628 Filed 7-6-76;8:45 am]

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## Title 18—Conservation of Power, Water Resources

## CHAPTER I—FEDERAL POWER COMMISSION

[Docket No. R-458; Order No. 551]

## PART 2—GENERAL POLICY AND INTERPRETATIONS

### Policy With Respect to Sales Where Reduced Pressures, Need for Reconditioning or Deeper Drilling, or Other Factors Make Further Production Uneconomical at Existing Prices

JUNE 29, 1976.

Since the issuance of Order No. 481 on April 12, 1973, as amended in an order issued June 8, 1973, adopting Section 2.76 of the Commission's General Policy and Interpretations[1], the data needed to process petitions submitted under this section has become generally standardized. Codification of the data for petitions filed under Section 2.76 would be of great assistance to the producers in the preparation of their filings and would expedite the processing of these applications by the Staff and Commission. Therefore, pursuant to this policy statement, we are amending Section 2.76 in order to facilitate the handling of such filings by specifying hereinafter the data requisite for processing.

At the present time, Section 2.76 merely provides the "[A]pplicants shall establish the economic justification for their request, including information on additional costs, the unit price which if applied to the sale of additional reserves would justify the additional expenditure, and the amount of gas to be recovered and sold in the interstate market."

As of April 30, 1976, 109 petitions for special relief have been submitted under Section 2.76. Of these, 71 have been approved, 27 withdrawn or dismissed and 11 are pending. Most of these petitions have contained incomplete information necessary to determine properly the reasonableness of the proposal and one or more Staff deficiency letters and telephone calls have usually been required before all data necessary to evaluate the petition has been received. In many instances, the Staff has also made field checks to verify the submitted data. Accordingly, the time required to process these petitions has been lengthened by the time required to obtain the necessary data.

We recognize two exceptions to the proposed policy that all filings respond to each of the data items requested:

(1) Where specific data is either unavailable to the petitioner or inapplicable to the circumstances of the petition, the Petitioner may seek a waiver of that data item by providing specific justification for so requesting. In addition, waiver of a particular item will be considered upon a showing by Petitioner that its conclusions can be supported through substantial substitute evidence. Failure of Petitioner to provide any requested additional information within a reasonable time would be cause for dismissal of the petition by the Commission.

(2) Where the petitions relate to minor projects involving work on older wells, involving such items as additional compression, cleaning out wells, replacing defective equipment and correcting salt water problems, we believe it may not be necessary in each case to examine detailed, specific project data in order to determine the justness and reasonableness of this class of special relief application. Therefore, where Petitioner requests a rate less than 50¢/Mcf, exclusive of production or severance taxes, at 14.73 psia which will obtain additional revenues of less than $50,000, we shall require a more limited evidentiary presentation, as hereinafter set forth, to be filed with applicant's petition. Staff, however, may request additional data if necessary.

The Commission further finds: (1) Prior notice and opportunity for public participation in this proceeding promulgating this Statement of Policy is not required either pursuant to the provisions of the Natural Gas Act, 15 U.S.C. 717(a) et seq., or the provisions of the Administrative Procedure Act, 5 U.S.C. Subchapter II, 553. Moreover, compliance with the effective date requirements of 5 U.S.C. 553(d), is not required since this Statement of Policy does not prescribe an added duty or restriction.

(2) It is necessary and appropriate for purposes of the administration of the Natural Gas Act, 15 U.S.C. 717(a) et seq., to amend Part 2, General Policy and Interpretations, Subchapter A, Chapter I, Title 18 of the Code of Federal Regulations, by the inclusion of subsection (d) of Section 2.76.

The Commission, acting pursuant to Section 16 of the Natural Gas Act (52 Stat. 830; 15 U.S.C. § 717o) orders:

(A) Part 2, General Policy and Interpretations, Subchapter A, Chapter I, Title 18, Code of Federal Regulations, is hereby amended by adding a new subsection to Section 2.76 to read as follows:

**§ 2.76 Policy with respect to rates where reduced pressures need for reconditioning, deeper drilling, or other factors make further production uneconomical at existing prices.**

* * * * *

(d) The petition consisting of an original and three copies filed under oath by

[1] 18 CFR 2.76.

signatory operators and signatory owners as provided in § 154.91 of this chapter shall include the information and supporting documents set forth in Exhibit A with the following exceptions:

(1) Where the proposed additional work will return Petitioner less than $50,000, in additional revenues, the proposed investment in the project is in excess of 25% of the estimated additional revenues, and the total rate to be received for the sale of gas is less than 50¢/Mcf, exclusive of production or severance taxes, at 14.73, Petitioner need initially file only the information shown in items (1) through (9) of Exhibit A with its petitions.

(2) Where Petitioner is granted waiver of particular information either because it is unavailable or is inapplicable to the circumstances of the petition or upon a showing that conclusions can be supported through substantial substitute evidence.

(B) The amendment provided for herein shall be effective as of the date of issuance of this order.

(C) The Secretary shall cause prompt publication of this Policy Statement to be made in the FEDERAL REGISTER.

By direction of the Commission.

[SEAL] KENNETH F. PLUMB,
*Secretary.*

PETITION FOR SPECIAL RELIEF FROM ESTABLISHED PRODUCER CEILING RATES PURSUANT TO § 2.76 OF THE COMMISSION'S RULES

(1) Name of Petitioner.

(2) Location of principal place of business.

(3) Person responsible for petition: (a) Name and title, (b) Mailing address, (c) Telephone number.

(4) Description and estimated cost of the work being proposed and the necessity therefor, in the petition. Give an estimate of the remaining gas and liquid reserves expected to be recovered along with a schedule of projected annual production for each. State if the additional gas is to be obtained from previously non-productive formations.

(5) Indicate the Certificate Docket No. and FPC Gas Rate Schedule No., where applicable, under which the sale is being made. State the contract date and expiration date of the gas sales contract.

(6) Name and address of purchaser.

(7) Location of the facilities to be used in the project. Include state, county or parish and field and well designations.

(8) Attach three (3) copies of "Notice of Independent Producer Rate Change Filing" as provided in § 154.94(f) and (g) of this chapter and three (3) executed copies of the document(s) entered into with the purchaser providing for the payment of the proposed rate where the term of the contract has not expired.

(9) List working interest owners (and their respective percentages in the project who are covered by the petition. Identify any interest owners not covered by the petition. Give full details where working interest varies for investment, operating expenses, revenues, etc.

(10) Furnish royalty, overriding royalty or other nonoperating interest percentages in the properties associated with the project.

(11) List the current net remaining (gross less depreciation reserve) book investment for the most recent 12 month period prior to date of application related to the working interest owners who are covered by the petition and broken down by major capital items making up the investment.

(12) Show dollar amounts and describe the method or methods used in computing depletion or depreciation expenses for the most recent 12 month period. State how and when the properties were acquired.

(13) State the amount of proposed investment in the project, as described in (4) above, and timing thereof, applicable to each working interest owner in the project.

(14) Attach copies of engineering and economic studies, equipment and service bids, and any other related documents necessary to substantiate the proposed investment.

(15) Provide an estimate of salvage value for the equipment in Item Nos. 12 and 13 above at the end of its useful life.

(16) Provide operating expenses detailed by cost item, for the two most recent 12 month period prior to date of application for 100 percent of the working interest. Also provide an estimate of future operating expenses by years for the 100 percent working interest for the estimated life of the properties. Report as separate items any production (include rate) and ad valorem taxes claimed.

(17) Report the revenues, production volumes and average unit Btu content for liquids sold and produced at the lease level. Report and describe miscellaneous revenues received. Report these on a net working interest basis for the most recent 12 month period.

(18) Submit average unit Btu content of gas for sales at point of price determination. Give location(s) of point of delivery to purchaser for gas sales.

(19) Federal Income Taxes—If you include Federal Income Taxes as an item of cost in your special relief application, provide a detailed computation of such taxes and data including (a) the eligibility or ineligibility of such gas for percentage depletion and (b) the applicable tax rates used in such calculations.

(20) The following is a listing of data required relative to the determinations of reserve and deliverability of the gas subject to the petition.

A. Map delineating the exact acreage in the project area and also showing the location of each completed, abandoned or proposed well and other facilities associated with the project.

B. Copies of all electrical, acoustical, radioactive or other logs run on any well on the project acreage.

C. Core analyses, conventional or sidewall, from any cores taken from any well on the project acreage.

D. Copies of all tests, including open hole drill stem tests, wire line formation tests, initial production tests, single or multiple point back-pressure tests, build-up or drawdown tests and subsurface pressure surveys run on any well drilled on the project acreage.

E. Tabulated production by year and month, separately by products including oil, gas, condensate and water, for all well completions on the project acreage.

F. Copies of all well completion reports filed with the oil and gas regulatory authority having jurisdiction for all wells drilled on the project acreage.

G. Copies of analyses made on separator or well stream gas or separator liquids from the project acreage.

H. Tabulation by month and year of any plant liquids credited back to the leases in the project acreage from any processing plant.

I. Tabulated reservoir parameters by reservoir for all reservoirs that are actually producing or that have been proved productive by actual formation test on the project acreage or that can be reasonably demonstrated to underlie the project acreage.

J. Top of structure maps and isopach maps for all reservoirs that are actually productive or that have been proved productive by actual formation tests on the project acreage or that can be reasonably demonstrated to underlie the project acreage.

(21) If any of the data requested in (20) above was filed in the application for the certificate authority to make the subject sale or is included in the applicable FPC Gas Rate schedule, Petitioner may make reference to the files of the Commission by delineating where such data may be found.

(22) Any additional information or data which the applicant believes necessary to evaluate particular circumstances related to a proposed project may also be filed.

[FR Doc.76-19466 Filed 7-6-76;8:45 am]

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[Docket No. RM74-15; Order No. 541-A]

## PART 35—FILING OF RATE SCHEDULES

### Fixed Rate Contract Provisions in Initial and Superseding Electric Rate Schedules; Order Modifying Rulemaking and Denying Rehearing

JUNE 29, 1976.

On November 21, 1975, the Commission issued its Order No. 541 which amended § 35.1 of its Regulations under the Federal Power Act, 18 CFR 35.1, by redesignating the existing subsection (d) as subsection (e) and by adding a new subsection (d). This new subsection required that, effective March 1, 1976, certain rate schedules filed with the Commission [1] must expressly indicate whether or not service was to be rendered under a "fixed rate contract" by including one of two provisions in the tendered rate schedule.

Applications for rehearing were filed on December 22, 1975, by the American Public Power Association (APPA) and by a group of municipalities and municipal electric companies (Cities).[2] In our order of January 20, 1976, we granted rehearing to provide the opportunity for further consideration of the issues raised in the respective applications. In the same order of January 20, we granted intervention to APPA, to Cities and to all persons who had filed comments in this proceeding. Upon consideration of the arguments contained in the two applications for rehearing, we have concluded that the proposed amendments to Section 35.1 of the

[1] The requirements of subsection (d) applied to rate schedules covering "the transmission or sale or firm power for resale to an all-requirements customer, whether filed as an initial rate schedule in accordance with § 35.12 or whether filed as a change in accordance with § 35.13 where such change is to an existing rate schedule whose term has expired, or where the term is to be extended * * *". Rate schedules tendered for filing prior to March 1, 1976 and contracts executed prior to March 1, 1976, were expressly excluded from the requirements of subsection (d).

[2] This latter group is composed of (1) the Massachusetts Municipal Wholesale Electric Company, a utility regulated by the Commonwealth of Massachusetts and wholly controlled by the municipal electric departments and plants of twenty-five Massachusetts cities and towns; (2) the ElectriCities of North Carolina, an unincorporated association whose members are representatives of all municipalities in North Carolina and certain municipalities in Virginia; (3) two cities in California; and (4) twelve cities in Florida.

Commission's Rules and Regulations, 18 CFR 35.1, previously adopted in Order No. 541 should be modified and that as so modified these amendments should be adopted.

Before discussing the arguments raised by APPA and Cities and our response thereto, a prefatory comment is in order. Both APPA (pp. 2–3, 5) and Cities (pp. 3, 8, 12–13) have alleged that the Commission's purpose in issuing Order No. 541 was to attempt an "end run" around the so-called Sierra-Mobile doctrine. While such an allegation may be fashionable, it is inaccurate. As stated in our notice issued in this docket on April 22, 1974, the Commission's purpose in instituting this rulemaking proceeding was, in part, "to avoid the uncertainty and controversy caused by ambiguous contractual provisions as to whether certain contracts are in fact fixed rate contracts * * *." (Mimeo, p. 1). While Cities have at one point in their application for rehearing (pp. 11–13) attempted to deny that this "uncertainty and controversy" exists, we note that at another point (p. 3, note "* *") they cite no fewer than six appellate decisions to date, three by the Supreme Court, which involved the question of whether particular contracts were fixed rate contracts.[8] It was in an attempt to eliminate the very confusion and controversy which leads to such cases that we instituted the proceedings in this docket.

The attack by APPA and Cities on Order No. 541 is two pronged. We are told that the order is both illegal and unwise. It is allegedly illegal because it would impair the freedom of wholesale customers to contract for the service they receive. In making their freedom of contract argument APPA and Cities cite language from *United Gas Pipe Line Co.* v. *Mobile Gas Corp.*, 350 U.S. 332, 338–339, 343 (1956); and *City of Richmond* v. *FPC*, 481 F. 2d 490, 493, 496–497 (D.C. Cir. 1973) to the effect that under both the Natural Gas Act and the Federal Power Act relations between parties are established initially by contract. By requiring rate schedules filed with the Commission to contain one of the two boilerplate provisions prescribed by Order No. 541, the Commission has allegedly impaired the ability to contract freely for jurisdictional service.

The *Mobile* and *City of Richmond* cases cited by APPA and Cities do indeed state that the relations between wholesale customers and their suppliers are initially set by contract. However, the language in those opinions clearly does not preclude the Commission from requiring utilities to include in the rate schedules they file with the Commission, a statement that the terms and conditions under which service is rendered are, or are not, subject to unilateral change by the supplier. Section 205(c) of the Federal Power Act, 16 U.S.C. 824 d (c) expressly recognizes the Commission's authority to prescribe the form in which rate schedules may be filed with the Commission:

> (c) *Under such rules and regulations as the Commission may prescribe*, every public utility shall file with the Commission, within such time *and in such form as the Commission may designate* * * * schedules showing all rates and charges for any transmission or sale subject to the jurisdiction of the Commission, and the classification, practices, and regulations affecting such rates and charges * * * [emphasis added].

The Commission's authority to require the filing of rate schedules in a particular form is also based upon Section 309, 16 U.S.C. 825 h, which reads in pertinent part as follows:

> The Commission shall have power to perform any and all acts, and to prescribe, issue, make, amend, and rescind such orders, rules, and regulations as it may find necessary or appropriate to carry out the provisions of this Act.

In short, requiring rate schedules filed with the Commission to be in a particular form does not place an impermissible restraint on the parties' freedom to contract.

However, APPA and Cities have argued that the boilerplate provisions prescribed in Order No. 541 go beyond merely prescribing a rate schedule form which clearly indicates whether the rate schedule can be changed unilaterally. Their argument is based upon the fact that under the express terms of these two provisions the party furnishing service under the subject rate schedule would either have the right under Section 205 of the Act to file unilateral changes in all of the terms and conditions of service, including the rate at which service is rendered, or would have no right to file unilateral changes in any of the terms or conditions of service. Inclusion of such "all or nothing" language in a filed rate schedule would, we are told, severely restrict the bargaining power of the wholesale customers. Thus, for example, a customer, who would otherwise have been able to bargain for various fixed terms and conditions of service in exchange for the supplier's right to file for unilateral rate increases under Section 205, will as a practical matter, be required to enter into contracts in which not only the rate, but all of the other terms and conditions of service as well, will be subject to unilateral changes at the pleasure of the supplier.

Moreover, APPA and Cities state that the boilerplate language would also impair their right to contract by failing to provide for contractual agreements which specified the circumstances in which, and the extent to which, rates could be unilaterally changed. Such restraints on the contracting parties' right to bargain would allegedly prevent the tailoring of contracts to meet the needs of special circumstances, and is therefore allegedly contrary to the intent of Congress as expressed in both the Natural Gas Act and the Federal Power Act.

APPA and Cities allege further that by eliminating the practical ability of the wholesale customer to bargain for fixed terms or conditions of service the Commission will encourage suppliers to offer their customers unconscionable adhesion contracts and contracts that may be in restraint of trade. APPA states (p. 9) that the Commission would thereby fail to provide "the protection of competition that the Supreme Court has required. See *Otter Tail Power Co.* v. *United States*, 410 U.S. 366 (1973); *Gulf States Utilities Co.* v. *FPC*, 411 U.S. 747 (1973)".

These arguments admittedly raise difficult questions regarding our authority to require that rate schedules filed with the Commission contain either of the boilerplate provisions. These arguments admittedly raise difficult questions regarding our authority to require that rate schedules filed with the Commission contain either of the boilerplate provisions. However, we do not reach these issues, since for the reasons set forth hereinafter we have decided to modify Order No. 541. We will provide that the scope of the boilerplate provisions may be limited to some proration of the provisions of the rate schedule, and that other provisions, or the entire rate schedule, may be subject to neither boilerplate provision.

APPA and Cities have argued that the amendments to § 35.1 adopted in Order No. 541 are, in addition to their purported illegality, unwise. As noted, supra, contracting parties will allegedly be precluded from tailoring their contractual obligations to meet the necessities of special circumstances. Thus, in the absence of Order No. 541, both the supplier and the customer would have been able to agree that certain contractual provisions would be subject to unilateral change by the supplier, while other provisions would not be subject to unilateral change. By including both fixed and changeable provisions in the same contract the parties could strike a balance between stability and flexibility that is peculiarly suited to their particular circumstances. If, however, the contract must provide that all or none of the terms and conditions of service are subject to unilateral change, the result, we are told, will be that suppliers will be in a much stronger position to bargain for the right to make unilateral changes in all the terms and conditions of service. APPA and Cities state further that unless wholesale customers are able to bargain effectively for contractual provisions that cannot be changed unilaterally, it may not be possible for such wholesale customers to obtain the financing necessary to construct and operate the costly facilities necessary to provide service. The result would allegedly be the erosion of the financial health of such wholesale customers, resulting ultimately in their inability to render service and/or in the takeover of their operations by their suppliers.

[8] In addition to the cases cited by Cities, we note that the following cases also involved the issue of whether service was being rendered under a fixed rate contract: *Gulf States Utilities Co.* v. *FPC*, 518 F. 2d 450 (1975); *East Mississippi Electric Power Assn.* v. *FPC* (unreported decision issued December 23, 1975); *Appalachian Power Co.* v. *FPC*, —— F. 2d —— (decided January 8, 1976); *Kentucky Utilities Co.* v. *FPC*, —— F. 2d —— (decided January 8, 1976); and *Minnesota Power & Light Co.* v. *FPC* (unreported decision issued January 16, 1976).

APPA's and Cities' point appears to be well taken. Accordingly, we will modify the two boilerplate provisions by limiting their scope to changes in rate levels.

APPA and Cities state that the boilerplate provisions present a further difficulty by failing to provide for contractual agreements which specify when, or to what extent, unilateral changes can be made. For example, Cities point out (pp. 4–5) that in certain situations wholesale suppliers and their wholesale customers are in direct competition for industrial retail markets. While Cities acknowledge that wholesale customers may be unable to bargain for fixed rate provisions, they may be able to protect their competitive position by bargaining for contractual provisions which permit unilateral rate increases only in certain clearly defined situations, such as when the supplier seeks retail rate increases for service to the same industrial markets, and then only to the same level as the rates to the retail industrial customers. See Richmond Power & Light v. FPC, supra. Cities has offered several additional examples of existing contractual provisions which permit unilateral rate increases subject to certain expressly enumerated limitations. For example, parties may contract to:

(1) Leave the rate terms to be set following a Section 206, non-Sierra proceeding, with the just and reasonable rates to be effective prospectively, as is the case in many state procedures;

(2) Allow for Section 205 filings by the supplier up to a constraint imposed by some extrinsic factor such as state retail rates;

(3) Fix rate design for a time certain with the overall revenue level subject to Section 205 procedures.

Cities complain that it is not at all clear that the two boilerplate provisions prescribed in Order No. 541 accommodate such contractual arrangements. In short, Cities conclude that if contracting parties are by virtue of the boilerplate provisions precluded from entering into these types of arrangements, wholesale customers will be unable to engage in the kind of planning and coordination necessary to provide adequate and reliable service.

As we stated earlier, our purpose in issuing Order No. 541 was to eliminate the uncertainty and controversy that has followed in the wake of the Mobile, Sierra and Memphis cases by requiring that all filed rate schedules include standard language which clearly sets forth whether the parties intend that a wholesale rate can, or cannot, be changed unilaterally. We continue to believe that the inclusion of such boilerplate language would achieve this result. However, upon careful consideration of the arguments advanced by APPA and Cities, we have concluded that the boilerplate provisions set forth in Order No. 541, as previously modified herein (supra, pp. 6–7), may not adequately cover all contractual agreements that might be executed and filed with the Commission as rate schedules. Accordingly, we have concluded that subsection (d) of Section 35.1 should be amended to provide (1) that all rate schedules filed on or after August 1, 1976, shall contain the first boilerplate provision with respect to such portions of the schedule where it is the intent of the parties to give the supplier the unrestricted right to file unilateral rate changes; (2) that all rate schedules filed on or after August 1, 1976, shall contain the first bolierplate provisions with respect to such portions of the schedule where it is the intent of the parties to withhold from the supplier the right to file any unilateral rate changes; and (3) the parties are free to file rate schedules which contain neither boilerplate provisions, or which have certain provisions subject to neither boilerplate provision

The Commission further finds: Good cause exists for amending the new subsection (d) of § 35.1 of the Commission's Regulations under the Federal Power Act previously adopted by the Commission in Order No. 541. These amendments are necessary to aid the Commission in carrying out its regulatory responsibility under the Federal Power Act to insure just and reasonable rates and the maintenance of adequate and reliable service to customers.

The Commission orders: (A) Pursuant to Section 553 of Title 5 of the United States Code and to Section 309 of the Federal Power Act, the Commission hereby amends paragraph (d) of § 35.1 of the Commission's Regulations under the Federal Power Act, "Application; obligation to file rate schedules," to read as follows:

**§ 35.1 Application; obligation to file rate schedules.**

* * * * *

(d) (1) The provisions of this paragraph (d) shall apply to rate schedules tendered for filing on or after August 1, 1976, which are applicable to the transmission or sale of firm power for resale to an all-requirements customer, whether tendered pursuant to § 35.12 as an initial rate schedule or tendered pursuant to § 35.13 as a change in an existing rate schedule whose term has expired or whose term is to be extended.

(2) Rate schedules covered by the terms of paragraph (d) (1) of this section shall contain the following provision when it is the intent of the contracting parties to give the party furnishing service the unrestricted right to file unilateral rate changes under section 205 of the Federal Power Act:

Nothing contained herein shall be construed as affecting in any way the right of the party furnishing service under this rate schedule to unilaterally make application to the Federal Power Commission for a change in rates under section 205 of the Federal Power Act and pursuant to the Commission's Rules and Regulations promulgated thereunder.

(3) Rate schedules covered by the terms of paragraph (d) (1) shall contain the following provision when it is the intent of the contracting parties to withhold from the party furnishing service the right to file any unilateral rate changes under section 205 of the Federal Power Act:

The rates for service specified herein shall remain in effect for the term of _____ or until _____, and shall not be subject to change through application to the Federal Power Commission pursuant to the provisions of Section 205 of the Federal Power Act absent the agreement of all parties thereto.

(4) Rate schedules covered by the terms of paragraph (d) (1) of this section, but which are not covered by paragraphs (d) (2) or (d) (3) of this section, are not required to contain either of the boilerplate provisions set forth in paragraph (d) (2) or (d) (3) of this section.

* * * * *

(B) This rule shall become effective on August 1, 1976.

(C) Except to the extent granted herein, the applications for rehearing filed by APPA and Cities are in all other respects hereby denied.

(D) The Secretary shall cause prompt publication of this order to be made in the FEDERAL REGISTER.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

[FR Doc.76-19467 Filed 7-6-76;8:45 am]

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## Title 24—Housing and Urban Development

## CHAPTER VII—LOW INCOME HOUSING, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. R-76-399]

## PART 845—PHA ACQUISITION WITH OR WITHOUT REHABILITATION

### PHA Acquisition of HUD-Owned Properties and Properties With HUD-Insured and HUD-Held Mortgages; Interim Rule

*Correction*

In FR Doc. 76-16490, appearing on page 23292, in the issue of Wednesday, June 9, 1976, on page 23295, in the third column, the last line of paragraph (d) should read "a written notice of displacement as described in this paragraph (d)".

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## Title 31—Money and Finance: Treasury

## CHAPTER I—MONETARY OFFICES, DEPARTMENT OF THE TREASURY

## PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

### Change of Definition of Monetary Instruments

In order to clarify the recordkeeping and reporting requirements imposed pursuant to Titles I and II of Pub. L. 91-508 (84 Stat. 1114 et seq.) the Department of the Treasury finds that it is advisable to revise the definition of Monetary instruments contained in 31 CFR Part 103. The amendment would specifically include within the definition bank checks, travelers' checks, and money orders which are signed but on which the name

of the payee has been omitted. It would specifically exclude restrictively endorsed travelers' checks and money orders. Since the term "monetary instruments" appears in § 103.23, Reports of transportation of currency or monetary instruments, the definition makes the reporting requirements of that section more readily understood by members of the public.

The Department also finds that, since this amendment is either liberalizing or clarifying in nature, the notice and public rulemaking procedures of 5 U.S.C. 553 with respect to said amendment are unnecessary, and that good cause exists not to delay the effective date of this amendment.

Effective date: This amendment takes effect on June 30, 1976.

HENRY C. STOCKELL, Jr.,
*Acting General Counsel.*

DAVID R. MACDONALD,
*Assistant Secretary, Enforcement, Operations and Tariff Affairs.*

Section 103.11 of Title 31 of the Code of Federal Regulations is amended as follows:

**§ 103.11 Meaning of terms.**

* * * * *

*Monetary instruments.* Coin or currency of the United States or of any other country, travelers' checks, money orders, investment securities in bearer form or otherwise in such form that title thereto passes upon delivery, and negotiable instruments (except warehouse receipts or bills of lading) in bearer form or other in such form that title thereto passes upon delivery. The term includes bank checks, travelers' checks and money orders which are signed but on which the name of the payee has been omitted, but does not include bank checks, travelers' checks or money orders made payable to the order of a named person which have not been endorsed or which bear restrictive endorsements.

* * * * *

(Sec. 203(1), Pub. L. 91-508, 84 Stat. 1114 (31 U.S.C. 1052).)

[FR Doc.76-19492 Filed 7-6-76;8:45 am]

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## Title 37—Patents, Trademarks and Copyrights

## CHAPTER I—PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE

## PART 1—RULES OF PRACTICE IN PATENT CASES

### Revision of Rules in Interference Practice

On February 19, 1976, notice of proposed rulemaking regarding the revision of §§ 1.228, 1.243, 1.244, 1.254, and 1.256 of Title 37, Code of Federal Regulations, was published in the FEDERAL REGISTER (41 FR 7513). Interested persons were asked to comment and a period extending from the date of publication of the proposed rule changes to March 26, 1976 was allocated for such purpose. Five comments were received. The comments and a summary of the comments are available for public inspection in Room 11E10 of Crystal Plaza Building 3, at 2021 Jefferson Davis Highway, Arlington, Virginia. All but one of the comments were favorable to the proposed changes. In view of the one adverse comment received, the proposal to amend § 1.254 is not being adopted. Section 1.228 was amended as proposed to provide a time for oral arguments at the hearing set under the provisions of said section and §§ 1.243 and 1.244 were rearranged without changing the wording therein. Finally, § 1.256 was amended to amplify the procedure therein.

In consideration of the comments received and pursuant to the authority contained in section 6 of the Act of July 19, 1952, as amended (85 Stat. 364; 35 U.S.C. 6), Part 1 of Title 37, Code of Federal Regulations is hereby amended as follows:

**§ 1.228 Summary Judgment.**

When an interference is declared on the basis of a showing under § 1.204(c), such showing will be examined by an Examiner of Interferences. If the Examiner considers that the facts set out in the showing provide sufficient basis for the interference to proceed, the interference will proceed in the normal manner as provided by the regulations in this part; otherwise an order shall be entered concurrently with the notice of interference pointing out wherein the showing is insufficient and notifying the applicant making such showing that summary judgment will be rendered against him because of such insufficiency at the expiration of a period specified in the notice, not less than 30 days, unless cause be shown why such action should not be taken. In the absence of a showing of good and sufficient cause, judgment shall be so rendered. Any response made during the specified period will be considered by a Board of Patent Interferences without an oral hearing unless such hearing is requested by the applicant, but additional affidavits, declarations or exhibits will not be considered unless accompanied by a showing in excuse of their omission from the original showing. If the applicant files a response to the order to show cause, the patentee will be furnished with one copy of the showing under § 1.204(c) and will be allowed not less than 30 days from its mailing date within which to present his views with respect thereto. He shall also be entitled to be represented at any oral hearing on the matter. Unless it shall be otherwise ordered before the hearing begins, oral arguments will be limited to not more than 30 minutes for each party. The Board will determine, on the basis of the original showing and the response made, whether the interference should be allowed to proceed or summary judgment should be entered against the junior applicant.

**§ 1.243 Motions before the Board of Patent Interferences.**

(a) Motions relating to matters other than those specified in § 1.231 will be determined by a patent interference examiner or the Board of Patent Interferences, as may be deemed appropriate. Such motions shall be made in writing and shall contain a full statement of the action sought and the grounds therefor, and satisfactory proof of any facts required must accompany the motion. Oral hearings will not be held except on order of a patent interference examiner or Board of Patent Interferences. Briefs or memoranda in support of such motions shall accompany the motion. Any opposition to the motion, together with any brief or memorandum in support thereof, shall be filed within 20 days from the date of service of the motion unless some other date is set by the patent interference examiner.

(b) Typewritten briefs may be used in connection with all motions. By stipulation of the parties subject to approval or by order of the tribunal before whom the motion is pending, briefs may be received if filed otherwise than as prescribed.

(c) In oral hearings on motions, the moving parties shall have the right to make the opening and closing arguments. Unless otherwise ordered before the hearing begins, oral arguments will be limited to 30 minutes for each party.

(d) Any request for reconsideration or modification of a decision or other action by the Board of Patent Interferences or patent interference examiner must be filed within 20 days after the date of the decision or other action and any reply thereto must be filed within 20 days from the date of service of the request. With regard to requests for reconsideration of a decision after final hearing, see § 1.256 (b).

**§ 1.244 Petition to the Commissioner from decisions on motions.**

There is no appeal from decisions rendered on motions, but the Commissioner may consider on petition any matter involving abuse of discretion or the exercise of his supervisory authority, or such other matters as he may deem proper to consider. Any such petition must comply with § 1.181 and, if not filed within 20 days from the decision complained of, may be dismissed as untimely. Any opposition thereto must be filed within 20 days from the date of service of the petition.

**§ 1.254 Briefs at final hearing.**

Briefs at final hearing before the Board of Patent Interferences shall be submitted in printed form, except that when not in excess of 50 legal-size double-spaced typewritten pages, or the equivalent thereof, and in any other case where satisfactory reason therefor is shown they may be submitted in type written form. If submitted in printed form, they shall be the same in size and the same as to page and print as is specified for printed copies of testimony. Typewritten briefs shall conform to the requirements for typewritten copies of testimony, except that legal-size paper may be used and the binding and covers specified are not required. Every brief of more than 15 pages shall contain a subject index with page references, supplemented by a list of all authorities referred to, together with references to

pages thereof. Three copies of each brief must be filed. The times for filing briefs will be set at an appropriate stage in the proceeding prior to final hearing. The brief for the junior party shall present a full, fair statement of the questions involved, including his position with respect to priority evidence presented on behalf of other parties, and a clear statement of the points of law or fact on which he relies. The main brief for each party shall contain a copy of the counts in interference.

§ 1.256 Final hearing.

(a) Final hearings will be held by the Board of Patent Interferences on the day appointed at the designated time. If either party appears at the proper time, he will be heard. After the day of hearing, the case will not be taken up for oral argument except by consent of all parties. If the Board of Patent Interferences be prevented from hearing the case at the time specified, a new assignment will be made, or the case will be continued from day to day until heard. Unless it shall be otherwise ordered before the hearing begins, oral arguments will be limited to not more than one hour for each party. A junior party may reserve a portion of his time for rebuttal purposes, but a full, fair opening of his case must be made, including his position with respect to the case presented on behalf of other parties. After a contested case has been argued nothing further relating thereto will be heard unless upon request of the Board of Patent Interferences.

(b) Any request for rehearing or reconsideration, or modification of the decision after final hearing, must be filed within 30 days from the date of the original decision, unless that decision is so modified as to become, in effect, a new decision, and the Board of Patent Interferences so states. Any reply thereto must be filed within 15 days from the filing of the request. The times specified herein may be extended by the Board of Patent Interferences upon a showing of sufficient cause. (See § 1.304).

Effective date: These amendments shall become effective on August 31, 1976.

Dated: June 23, 1976.

C. MARSHALL DANN,
*Commissioner of Patents and Trademarks.*

Approved:

BETSY ANCKER-JOHNSON,
*Assistant Secretary for Science and Technology.*

[FR Doc.76-19526 Filed 7-6-76;8:45 am]

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## Title 40—Protection of Environment

### CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

### SUBCHAPTER C—AIR PROGRAMS

[FRL 569-6]

### PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

### Revision to the New Jersey State Implementation Plan

On January 8, 1976, the State of New Jersey submitted to the EPA Region II Office a proposed revision to the New Jersey State Implementation Plan. This revision request was submitted in accordance with all applicable EPA requirements as contained in 40 CFR Part 51. The proposed revision consists of a newly adopted State regulation, N.J.A.C. 7:27-16.1 et seq., entitled, "Control and Prohibition of Air Pollution By Volatile Organic Substances" (Subchapter 16). In addition, a technical justification supporting the regulation was submitted on March 3, 1976. The regulation provides for the control of hydrocarbon emissions from the following operations:

(1) The storage of volatile organic substances; and,

(2) The transfer of organic liquids including gasoline.

This regulation is intended by the State to replace the Federal regulations which appear in 40 CFR 52.1594, "Storage of Volatile Organic Liquids," § 52.1595, "Organic Liquid Loading," and § 52.1598, "Gasoline Transfer Vapor Control."

The technical justification submitted by the State and an analysis performed by EPA conclude:

(1) The reduction of hydrocarbon emissions attainable from section 16.2, "Storage of Volatile Organic Substances," of Subchapter 16 is greater than the reduction attainable if the provisions of 40 CFR 52.1594 were met by all affected sources.

(2) For transfer of non-gasoline organics from bulk terminals to delivery vessels, section 16.3, Transfer Operations, is equally as stringent or possibly more stringent than 40 CFR 52.1595.

(3) For transfer of gasoline from bulk terminals to delivery vessels, 40 CFR 52.1595 is more stringent than section 16.3.

(4) For transfer of gasoline from delivery vessels to receiving vessels, 40 CFR 52.1598 is more stringent than section 16.3. It should be noted that section 16.3 requires control on the transfer of other organics as well as gasoline, whereas 40 CFR 52.1598 only controls the transfer of gasoline.

Based on these findings, the Administrator is requiring that: (1) The portion of 40 CFR 52.1595, Organic Liquid Loading, controlling gasoline transfer remain in effect and enforceable; (2) the portion of § 52.1595 treating non-gasoline organics be revoked; (3) § 52.1598, Gasoline Transfer Vapor Control, remain in effect and enforceable in its entirety; and, (4) § 52.1594, Storage of Volatile Organic Liquids, be revoked.

On April 23, 1976 (41 FR 16972), the Environmental Protection Agency published a notice of proposed revision to the New Jersey State Implementation Plan. The notice solicited public comments on the approvability of the proposed revision request. The public comment period ended on May 23, 1976 and no comments were received.

After review of all relevant material, the Administrator has determined that the proposed revision is consistent with current EPA policies and goals set forth in the requirements of section 110(a)(2)(A)-(H) of the Clean Air Act and EPA regulations in 40 CFR Part 51 in that there will be no violations of any applicable ambient air quality standard. Therefore, the Administrator is approving the proposed New Jersey revision and making the appropriate amendments to existing EPA regulations as discussed in this notice.

Effective date: In view of the fact that EPA regulations currently exist similar to these being adopted for the control of organic substances and it will serve no useful purpose to defer the effectiveness of this approval for 30 days, the Administrator hereby finds good cause for making this rulemaking effective immediately.

(42 U.S.C. 1857c-5 and 9.)

Dated: July 1, 1976.

RUSSELL E. TRAIN,
*Administrator,*
*Environmental Protection Agency.*

Part 52 of Chapter I, Title 40 Code of Federal Regulations is amended as follows:

### Subpart FF—New Jersey

1. In § 52.1570 paragraph (c) is revised by adding new paragraphs (10) and (11) as follows:

§ 52.1570 Identification of plan.

* * * * *

(c) * * *

(10) Regulation entitled: "Control and Prohibition of Air Pollution by Volatile Organic Substances," New Jersey Administrative Code (N.J.A.C.) 7:27-16.1 et seq., submitted on January 8, 1976 by the New Jersey Department of Environmental Protection.

(11) Technical justification supporting N.J.A.C. 7:27-16 et seq. submitted on March 3, 1976.

§ 52.1594 [Reserved]

2. Section 52.1594 is revoked and reserved.

3. Section 52.1595 is revised to read as follows:

§ 52.1595 Gasoline loading.

(a) Definitions:

(1) "Vapor recovery system" means a vapor gathering system capable of collecting the hydrocarbon vapors and gases discharged, and a vapor disposal system capable of processing such hydrocarbon vapors and gases so as to reduce their emissions to the atmosphere.

(b) This section is applicable in the New Jersey portions of the New Jersey-New York-Connecticut and Metropolitan Philadelphia Air Quality Control Regions. Compliance with paragraph (c) of this section shall be in accordance with the provisions of § 52.1597.

(c) A person shall not load gasoline into any truck, trailer, or railroad tank car from any loading facility unless the loading facility is equipped with a vapor recovery system, as defined in subparagraph (a)(1) of this section or its equivalent approved by the Administrator.

(d) Loading of gasoline shall be accomplished in such a manner that all displaced vapors and air will be vented only to the vapor collection system.

Measures shall be taken to prevent liquid drainage before the loading device is disconnected. The vapor disposal portion of the vapor recovery system shall consist of the following:

(1) An absorber system or condensation system that processes all vapors and recovers at least 90 percent by weight of the gasoline vapors and gases from the equipment being controlled.

(2) A vapor handling system that directs all vapors to a fuel gas system.

(3) Other equipment of an efficiency equal to or greater than subparagraphs (1) or (2) of this paragraph, if approved by the Administrator.

(e) This section shall apply only to the loading of gasoline, as defined in paragraph (a) of § 52.1598, having a Reid vapor pressure of 4.0 psia or greater under actual loading conditions.

[FR Doc.76-19768 Filed 7-6-76;8:45 am]

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## Title 41—Public Contracts and Property Management

## CHAPTER 3—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## PART 3-4—SPECIAL TYPES AND METHODS OF PROCUREMENT

### Architect-Engineer Services

On October 24, 1975, a notice of proposed rulemaking was published in the FEDERAL REGISTER (40 FR 49792-49794) stating that the Department of Health, Education, and Welfare is considering an amendment to 41 CFR, Chapter 3, by adding a Subpart 3-4.10, Architect/Engineer Services to Part 3-4, Special Types and Methods of Procurement.

Interested persons were invited to submit written data, views, and comments within 30 days after publication. Comments were received from two organizations.

One coment was addressed to having announcements published in local newspapers in addition to the Commerce Business Daily. The publishing of announcements in the Commerce Business Daily is required by the Federal Procurement Regulations and the Department has found the publication of such announcements an adequate method of publicizing proposed procurements. Therefore, as a matter of policy, publication of such announcements in local newspapers will not be mandatory. The second comment received involved the rewording of a phrase in § 3-4.1003(c). The phrase "Construction Supervision" was changed to "Administration and Inspection."

Additional changes have been made for the purpose of clarifying various parts of the regulation. These changes came about as a result of internal reviews of the proposed rule.

Accordingly, the amendment is hereby adopted, subject to the following changes:

1. In 3-4.1001, *General policy*, the following changes are made:

a. The FPMR citations in the second sentence reading "§ 101-17.402(c)" and "§ 101-17.502" are changed to read "§ 101-19.402(c)" and "§ 101.19.502."

b. That part of the last sentence reading " * * * Federal Property and Administrative Services Act of 1949 * * *" is changed to read "* * * Federal Property and Administrative Services Act of 1949 as amended * * *"

2. That part of the second sentence of paragraph (a) of § 3-4.1003, *Public announcements*, reading "* * * requirement should contain wording * * *" is changed to read "* * * requirement shall contain wording * * *"

3. The phrase "Whenever possible" is deleted from the beginning of the second sentence of paragraph (B) of § 3-4.-1003, *Public announcements*.

4. That part of the third sentence of paragraph (c) of § 3-4.1003, *Public announcements*, reading "* * * Construction Supervision * * *" is changed to read "* * * Administration and Inspection * * *".

5. That part of paragraph (d) of § 3-4.1003, Public announcements reading "* * * head of the procuring activity * * *" is changed to read "* * * contracting officer * * *."

6. That subparagraph (2) of paragraph (a) of § 3-4.1004-1, Establishment of A/E evaluation boards, reading "* * * under paragraph (a)(3) of this section" is changed to read "* * * under subparagraph (a)(3) of this subsection."

7. Paragraph (a)(5) of § 3-4.1004-1, Establishment of A/E evaluation boards, is deleted and the following is substituted therefor:

(5) When the Government estimate for the total proposed A/E requirement is more than $10,000 each evaluation board shall consist of five licensed professional architects or engineers (with the Regional Engineer or his representative serving as chairman on a ROFEC board), one program or administrative representative, and one nonvoting recording secretary. A minimum number of three licensed architects or engineers shall be present at all evaluation board meetings and shall constitute a quorum.

(ii) When the independent government estimate is $10,000 or less, each evaluation board shall consist of at least one licensed professional architect or engineer (with the Regional Engineer or his representative serving as Chairman on a ROFEC board), one program or administrative representative, and one nonvoting recording secretary.

8. The following reference, in parenthesis, is added at the conclusion of paragraph (a)(6) of § 3-4.1004-1, Establishment of A/E evaluation boards: "(§ 3-4.1004)".

9. The following is added to paragraph (a)(7) of § 43-4.1004-1, Establishment of A/E evaluation boards: "Any member so approved will be a nonvoting member."

10. That part of paragraph (c) of § 3-4.1004-2, Functions of evaluation boards, reading "* * * comply with paragraph (a) of this section * * *" is changed to read "* * * comply with § 1-4.1004-2(c) of this title * * *"

11. Subparagraph (2) of paragraph (c) of § 3-4.1004-2, Functions of the evaluation boards is deleted and the following substituted therefor:

(2) SF-254's and 255's plus any essential brochures for each A/E firm; and

12. That part of paragraph (e) of § 3-4.1004-3, Evaluation criteria, reading "* * * to be qualified and capable of handling" is changed to read "* * * to be qualified and to be capable of handling."

13. The following changes are made in paragraph (1) of § 3-4.1004-4 Action by agency head or authorized representative:

(1) The word "or" is added at the conclusion of subparagraph (i).

(2) Subparagraph (ii) is deleted.

(3) Subparagraph (iii) is redesignated subparagraph (ii).

14. That part of subparagraph (2) of paragraph (a) of § 3-4.1004-4, Action by agency head or his authorized representative, reading "* * * paragraph (a)(3) of this section * * *" is changed to read "* * * subparagraph (a)(3) of this subsection."

15. That part of paragraph (b) of § 3-4.1004-4, Action by agency head or his authorized representative, reading "* * * his decision and authorization shall be likewise addressed * * *" is changed to read "* * * the decision, justification, and authorization shall be addressed * * *".

16. The first paragraph of § 3-4.1004-5, Procedure for procurements estimated not to exceed $10,000, is deleted and the following is substituted therefor:

Either one of the procedures set forth in paragraphs (a) and (b) of § 1-4.1004-5 of this title may be used instead of the procedures prescribed in §§ 1-4.1004-2 (b) and (c) of this title, 3-4.1004-2(c) and 3-4.1004-4 for procurements estimated not to exceed $10,000. That part of the paragraph beginning with "Upon receipt of the approving official * * *" is designated subparagraph (4).

17. That part of subparagraph (4) of paragraph (b) of § 3-4.1005-4, Procedures for procurements estimated not to exceed $10,000, reading "* * * § 1-4.004-5(a) of this chapter." is changed to read "* * * § 1-4.1004-5(a) of this title."

18. Subparagraph (3) of paragraph (d) of § 3-4.1005-1, General, is deleted and the following is substituted therefor: (3) The total contract design cost obtained by subparagraph (2) of this paragraph will be divided by the total construction cost obtained by subparagraph (1) of this paragraph.

19. Paragraph redesignations are made as follows:

a. Paragraph (a) of § 3-4.1002, Definitions, is redesignated (d).

b. Paragraph (a) of § 3-4.1004-2, Functions of the evaluation boards, is redesignated (c).

c. Paragraph (a) of § 3-4.1004-3, Evaluation criteria, is redesignated (e).

d. That part of 3-4.1004-2, Procedures for procurements estimated not to exceed $10,000, which begins, "Upon receipt of the approving official's decision * * * is designated subparagraph (4).

e. Subparagraphs (1) and (2) of paragraph (a) of § 3-4.1005-1, General, are redesignated (4) and (5).

20. The word "Director" is changed as follows:

a. In § 3–4.1003(d), it is changed to Deputy Assistant Secretary for Facilities Engineering and Property Management (DASFEPM)."

b. In § 3–4.1004–1(a)(4), § 3–4.1004–1(a)(6), § 3–4.1004–1(a)(7), § 3–4.1004–2(c), § 3–4.1004–4(a)(1) and § 3–4.1005–1(a) it is changed to DASFEPM.

21. The phrase "OFEPM" is inserted after the word "staff" in the introductory language of § 3–4.1004–2.

(5 U.S.C. 301; 40 U.S.C. 486.)

Effective date: These regulations become effective August 23, 1976.

Dated: June 30, 1976.

JOHN OTTINA,
*Assistant Secretary for Administration and Management.*

Subpart 3–4.10, Architect-Engineer Services will read as follows:

**Subpart 3–4.10—Architect-Engineer Services**

Sec.


3–4.1001 General policy.
3–4.1002 Definitions.
3–4.1003 Public announcements.
3–4.1004 Selection.
3–4.1004–1 Establishment of A/E evaluation boards.
3–4.1004–2 Function of the evaluation boards.
3–4.1004–4 Action by agency head or his authorized representative.
3–4.1004–5 Procedure for procurements estimated not to exceed $10,000.
3–4.1005 Negotiation procedures.
3–4.1005–1 General.
3–4.1005–6 Record of negotiation.


AUTHORITY: 5 U.S.C. 301; 40 U.S.C. 486.

## Subpart 3–4.10—Architect-Engineer Services

### § 3–4.1001 General policy.

Pursuant to Pub. L. 92–582 dated Oc-471, et seq.), it is the policy of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 471, et seq.), it is the policy of the Federal Government to publicly announce all requirements for Architect/Engineer (A/E) services, and to negotiate contracts for A/E services on the basis of demonstrated competence and qualification for the type of professional services required and at fair and reasonable prices. The acquisition of such services in connection with a "public building" as that term is defined in section 13 of the Public Building Act of 1959 (40 U.S.C. 612), may be exercised only under the conditions prescribed in § 101–19.402(c) of this title and subject to standards prescribed by the Administrator of General Services pursuant to § 101–19.502 of this title. The procurement of such services in connection with special purpose space such as schools, hospitals, laboratories, and research centers is subject to the requirements and conditions prescribed by section 302(c)(4) of the Federal Property and Administrative Services Act of 1949, as amended (41 U.S.C. 252(c)(4)) and § 1–3.204 of this title.

### § 3–4.1002 Definitions.

(a)–(c) [Reserved].

(d) "Fee" means the total amount payable to the A/E for the work and services to be performed.

### § 3–4.1003 Public announcements.

(a) One of the first steps in beginning the A/E selection process is to assure the availability of funds so that the succeeding A/E selection steps will be accomplished in a proper manner and that the Government and interested A/E firms will not be expending resources on projects that are tentative or stand little chance of being approved. In the event a certification of available funding has not been received but is reasonably anticipated in the near future, and it is imperative that the Government's requirement be publicized without further delay, the notice(s) publicizing the requirement shall contain wording to the effect that the Department expects to receive the design funds in the near future and discussions will not be held with the proposed A/E firm until receipt of such funds.

(b) *Program of requirements.* The program of requirements or design criteria is normally prepared by the appropriate program element, and is the basis for the subsequent preparation of the statement of work. The Office of Facilities Engineering and Property Management (OFEPM), including its Regional Offices (ROFEC), should provide assistance in the preparation of the program of requirements. The program requirements as well as the A/E statement of work (scope of services, see § 3–4.50–3, and the Independent Government estimate, see § 1–4.1005–3, should be prepared and completed prior to the public announcement of the proposed procurement to ensure that the announcement complies with the requirements of FPR 1–1.1003–3 and 1–1.1003–7.

(c) *Preparation of A/E Statement of Work (Scope of Services).* The statement of work shall be prepared by that office responsible for the evaluation and selection action. A statement of work should facilitate price negotiations, eliminate ambiguities, and assure that the design will satisfy program needs. Each A/E statement of work should reflect the specific design requirements. Such items as scheduling, cost control, and value management including life cycle costs are important factors for consideration. Typical areas covered by an A/E statement of work are: Predesign; Concepts & Schematics; Design Development; Contract Document Development; Administration and Inspection; and other pertinent requirements such as time and payment scheduling, and phased options.

(d) To insure the broadest publicity concerning the Government's interest in obtaining A/E services, the contracting officer shall have developed notices in accordance with § 1–1.1003–7(b)(9) with respect to individual projects. The following should be included in notices which publicize procurement of A/E services:

Firms desiring to be considered for architect/engineer contracts in a given area must file the Standard Form 254 and Standard Form 255, when applicable, with either the Principal Operating Component or the ROFEC whichever may be appropriate, or with the Deputy Assistant Secretary for Facilities Engineering and Property Management (DASFEPM), Office of Architectural and Engineering Service, OFEPM, Office of the Secretary, DHEW, 330 Independence Avenue, SW., Washington, D.C. 20201, depending on the geographical area of interest.

### § 3–4.1004 Selection.

### § 3–4.1004–1 Establishment of A/E evaluation boards.

(a) The following shall apply to the establishment of A/E evaluation boards:

(1) When the independent Government estimate of the total A/E proposed contract exceeds $10,000 or regardless of the dollar amount involved whenever A/E services are to be procured under an open-end (requirements) contract, all evaluation and selection actions shall be performed by evaluation boards of the Office of Facilities Engineering and Property Management (OFEPM) which includes ROFEC's.

(2) When the independent Government estimate of the total A/E proposed contract is $10,000 or less and the project is not within the scope of an open-end contract, such action for the evaluation and selection may be performed by ROFEC boards with the concurrence of the Regional Engineer when such functions cannot be performed by the principal operating component under paragraph (a)(3) of this section.

(3) When the independent Government estimate of the total A/E proposed contract is $10,000 or less and not within the scope of an open-end contract, the evaluation and selection actions may be conducted by the principal operating component's personnel who meet the qualifications as set forth herein and consistent with the requirements of Subpart 1–4.10.

(4) In the event of special circumstances involving a proposed A/E contract estimated to exceed $10,000 which would not fall within the scope of an open-end contract, and which a principal operating component (POC) believes would warrant its exercising evaluation and selection functions in lieu of OFEPM, the POC must submit its request and justification to the DASFEPM, OFEPM, for approval.

(5) (i) When the Government estimate for the total proposed A/E requirement is more than $10,000 each evaluation board shall consist of five licensed professional architects or engineers (with the Regional Engineer or his representative serving as chairman on a ROFEC board), one program or administrative representative, and one nonvoting recording secretary. A minimum number of three licensed architects or engineers shall be present at all evaluation board meetings and shall constitute a quorum.

(ii) When the independent government estimate is $10,000 or less, each evaluation board shall consist of at least one licensed professional architect or engineer (with the Regional Engineer or his representative serving as Chairman on a ROFEC board), one program or administrative representative, and one nonvoting recording secretary.

(6) The makeup of evaluation boards in the Office of the DASFEPM, OFEPM, is determined by the DASFEPM, OFEPM, so as to meet varying requirements. The Regional Engineers shall determine the makeup of the evaluation boards in the ROFEC's. Each principal operating component shall determine the makeup of the evaluation boards, consistent with this Section (3-4.1004).

(7) No member of an outside firm or organization shall participate as a member of an evaluation board without the prior written approval of the DASFEPM, OFEPM. Any member so approved will be a nonvoting member.

**§ 3-4.1004-2 Functions of the evaluation boards.**

Under the general authority of the Secretary's technical staff, OFEPM, the Departmental A/E evaluation boards shall perform the following functions:

(a)-(b) [Reserved].

(c) Prepare the report for submission to the DASFEPM, OFEPM, or his authorized representative, whichever may be appropriate under 3-4.1004-4, listing in the order of preference not less than three firms with addresses considered to be the most highly qualified to perform the required services. The report shall comply with § 1-4.1004-2(c) of this title and include the following:

(1) Summary sheet and rating factors tabulating the individual member scores, ranking, and rating factors;

(2) SF-254's and 255's plus any essential brochures for each A/E firm, and

(3) Government estimate of total A/E fee.

**§ 3-4.1004-3 Evaluation criteria.**

(a)-(d) [Reserved].

(e) Whenever possible, small business firms will be selected for projects for which they are considered to be qualified and to be capable of handling.

**§ 3-4.1004-4 Action by agency head or his authorized representative.**

(a) The responsible official to whom the authority has been delegated shall review the report of the A/E evaluation board, and in concert with appropriate technical and staff representatives, shall either concur or otherwise advise the Board of his decision in writing.

(1) The approval of the DASFEPM, OFEPM, or his designee is required, whenever:

(i) The Government's estimate of the total proposed A/E contract exceeds $100,000; or

(ii) Any modification to an existing contract would increase the total contract amount by more than 35 percent.

(2) The approval of the cognizant Regional Engineer is required whenever the Government's estimate is less than $100,000, except for paragraph (a)(3) of this section. (In the Baltimore-Washington metropolitan area, such approval should be requested of the Director, Office of Architectural and Engineering Services (OFEPM).)

(3) The approval of the head of a principal operating component or his designee shall be provided when:

(i) The Government's estimate of the total proposed A/E contract is $10,000 or less and selection is made pursuant to § 1-4.1004-5; or

(ii) Under the circumstances referenced in § 3-4.1004-1(a), (3), and (4), the principal operating component will perform the evaluation and selection functions in lieu of OFEPM.

(b) The approving official shall inform the board in writing of his decision which will serve as an authorization for the contracting officer to commence negotiations. If the approving official changes the order of preference listing, his decision justification and authorization shall be likewise addressed to the board. A copy of the board's recommendation and evaluation data shall be submitted by it with the authorization to the contracting officer.

**§ 3-4.1004-5 Procedure for procurements estimated not to exceed $10,000.**

Either one of the procedures set forth in paragraphs (a) and (b) of § 1-4.1004-5 of this title may be used instead of the procedures prescribed in §§ 1-4.1004-2 (b) and (c), 3-4.1004-2(c), and 3-4.1004-4 for procurements estimated not to exceed $10,000.

(4) Upon receipt of the approving official's decision the chairman of the board shall furnish the contracting officer a copy of the report which will comply with § 1-4.1004-5(a) of this title.

**§ 3-4.1005 Negotiation procedures.**

**§ 3-4.1005-1 General.**

(a) The negotiation and award of A/E contracts shall be performed by ROFEC's who have been delegated contracting officer authority whenever the applicable evaluation and selection actions are accomplished by their offices under § 3-4.1004-1(a) (1) and (2). Negotiation and award of A/E contracts are performed for OFEPM in Washington, D.C., by the Supply Operations Branch, OA/OAM, unless the DASFEPM, OFEPM, provides written authorization for another POC to do so. When evaluation and selection actions are performed by a principal operating component consistent with the provisions of § 3-4.1004-1(a) (3) and (4) the responsible contracting officer of the POC may likewise negotiate and award the related A/E engineer contracts. Qualified contracting officers shall use the services of technical, legal, audit-pricing, and other specialists in the component to the extent deemed appropriate (see §§ 1-3.801-2 and 1-3.803-3). Negotiations should be directed toward:

(4) Reaching mutual agreement on the provisions of the contract; and

(5) Arriving at a fair and reasonable price. See § 1-3.807-2, Requirements for Cost and Price Analysis; and § 1-3.807-1, Overhead Rate Considerations. See § 3-3.50.301(j) regarding the documentation requirements for cost breakdown and analysis.

(c) The principles set forth relative to preparation for negotiation (see § 3-4.1005) shall apply to the negotiation of modifications to contracts.

(d) Where the modification involves work not initially included in the contract the statutory limitation is applicable, consistent with the following provisions, to the revised total estimated construction costs. Where redesign is required and the contract is modified, the following methods shall be used in determining the amount of the basic fee to be paid the architect:

(1) The estimated construction cost of the redesigned features will be added to the original estimated construction cost;

(2) The contract cost for the original design will be added to the contract for redesign; and

(3) The total contract design cost obtained by subparagraph (2) of this paragraph will be divided by the total construction cost obtained by subparagraph (1) of this paragraph.

**§ 3-4.1005-6 Record of negotiation.**

Promptly at the conclusion of each negotiation, a memorandum setting forth the principal elements of the negotiations shall be prepared by the contracting officer in accordance with the requirements of § 1-3.811, for use by the reviewing authorities and for inclusion in the contract file. The memorandum shall contain sufficient detail to reflect the significant consideration controlling the establishment of the price and other terms of the contract. Negotiation memorandums must be prepared in accordance with § 3-50.3 and meet the requirements of that subpart.

[FR Doc.76-19557 Filed 7-6-76;8:45 am]

## Title 43—Public Lands: Interior

## CHAPTER II—BUREAU OF LAND MANAGEMENT, DEPARTMENT OF THE INTERIOR

### Appendix—Public Land Orders

[Public Land Order 5590; (OR-7127)]

### OREGON

### Partial Revocation of Executive Order of August 23, 1895

By virtue of the authority vested in the President, and pursuant to Executive Order No. 10355 of May 26, 1952 (17 F.R. 4831), it is ordered as follows:

1. The Executive Order of August 23, 1895, reserving lands for lighthouse purposes near the mouth of the Umpqua River is hereby revoked so far as it affects the following described land:

WILLAMETTE MERIDIAN

T. 22 S., R. 13 W.,
Sec. 13, lot 1, W½SW¼NW¼ and W½E½SW¼NW¼.

The area described contains 70 acres in Douglas County.

2. At 10 a.m. on August 4, 1976, the land shall be open to operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable laws.

JOHN KYL,
*Assistant Secretary of the Interior.*

[FR Doc.76-19503 Filed 7-6-76;8:45 am]

## Appendix—Public Land Orders

[Public Land Order 5591; (OR-13503)]

### OREGON

### Partial Revocation of Reclamation Project Withdrawal

By virtue of the authority contained in section 3 of the Act of June 17, 1902, as amended and supplemented, 43 U.S.C. 416 (1970), it is ordered as follows:

1. The departmental order of August 25, 1909, withdrawing lands for the Umatilla Project, is hereby revoked so far as it affects the following described land:

WILLAMETTE MERIDIAN

T. 4 N., R. 28 E.,
Sec. 26, NW¼.

The area described contains 160 acres in Umatilla County.

2. The above described land has been classified for public sale, and will not be subject to entry or disposition under other public land laws unless the lands are reclassified. A notice of public sale will be published in accordance with the requirements of 43 CFR 2711.

Inquiries concerning the land should be addressed to the Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, P.O. Box 2965, Portland, Oregon 97208.

JOHN KYL,
*Assistant Secretary of the Interior.*

JUNE 29, 1976.

[FR Doc.76-19504 Filed 7-6-76;8:45 am]

## Title 45—Public Welfare

### CHAPTER XVI—LEGAL SERVICES CORPORATION

### PART 1602—PROCEDURES FOR DISCLOSURE OR PRODUCTION OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

### Regional Records Rooms; Correction

In FR Doc. 75-30638 appearing at page 52847 in the FEDERAL REGISTER of November 13, 1975, paragraph (b) of § 1602.6 appearing on page 52849 is corrected to read as follows:

§ 1602.6 Regional records rooms.

* * * * *

(b) The regional records rooms are located at the following addresses:

Boston Regional Office, 11 Beacon Street, Room 800, Boston, Massachusetts 08108. Phone: 617-223-4093.

New York Regional Office, 10 E. 40th Street, Room 2010, New York, New York 10016. Phone: 212-264-1940.

Philadelphia Regional Office, 101 North 33rd Street, Suite 115, Philadelphia, Pennsylvania 19104. Phone: 215-596-6104.

Atlanta Regional Office, 615 Peachtree Street, N.W., Room 919, Atlanta, Georgia 30308. Phone: 404-285-3049.

Chicago Regional Office, 310 South Michigan Avenue, 24th Floor, Chicago, Illinois 60604. Phone: 312-663-5740.

Dallas Regional Office, Davis Building, 1309 Main Street, Room 1310, Dallas, Texas 75202. Phone: 214-749-1357.

Kansas City Regional Office, 911 Walnut Street, Kansas City, Missouri 64106. Phone: 816-758-5821.

Denver Regional Office, Majestic Building, Suite 730, 209 16th Street, Denver, Colorado 80202. Phone: 303-327-3306.

San Francisco Regional Office, American Savings Building, 690 Market Street, Suite 700, San Francisco, California 94104. Phone: 415-556-6952.

Seattle Regional Office, 1321 Second Avenue, Seattle, Washington 98101. Phone: 206-442-0593.

Dated: June 29, 1976.

THOMAS EHRLICH,
*President,*
*Legal Services Corporation.*

[FR Doc.76-19336 Filed 7-6-76;8:45 am]

## Title 47—Telecommunication

### CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 20626; FCC 76-584]

### PART 0—COMMISSION ORGANIZATION

### PART 1—PRACTICE AND PROCEDURE

### Adjudicatory-Re-Regulation Proposals; Correction

*Order.* In the matter of amendments of Parts 0 and 1 of the Commission's rules with respect to adjudicatory re-regulation proposals, Docket No. 20626.

1. It has come to our attention that the effective date provisions for the rules adopted in this proceeding (Report and Order, FCC 76-237, April 2, 1976; 41 FR 14865, April 8, 1976) are not entirely clear. We are therefore revising paragraph 47 of Report and Order to restate those provisions. The revised paragraph is set out below.

2. Accordingly, it is ordered that the revised effective date provisions for rules adopted in this proceeding, set out below, are adopted.

Adopted: June 24, 1976.

Released: June 30, 1976.

FEDERAL COMMUNICATIONS COMMISSION,[1]
VINCENT J. MULLINS,
*Secretary.*

Paragraph 47 of the Report and Order in this proceeding (FCC 76-237, April 2, 1976), is revised to read as follows:

41. *Accordingly, it is ordered,* Effective July 1, 1976, that Parts 0 and 1 of the rules and regulations are amended as set out in Appendix B hereto. The consent procedures shall apply to any case pending on July 1 in which an initial decision has not been issued. Application processing and predesignation pleading procedures shall apply to applications filed on or after July 1, except that applications filed on or after July 1 which are mutually exclusive with an application filed prior to July 1 shall be subject to preexisting procedures. Procedures relating to post-designation pleadings (e.g., motions to modify the issues, interlocutory appeals, briefs and exceptions, and applications for review) shall apply if the initial pleading is filed on or after July 1, except that applications for review of a motion filed prior to July 1 shall be subject to the preexisting rules. Procedures for submission of evidence in writing shall apply to cases designated for hearing on or after July 1. Procedures for the decision of rate making cases shall apply to cases designated for hearing on or after July 1.

[1] Commissioner Lee absent.

[FR Doc.76-19525 Filed 7-6-76;8:45 am]

## Title 49—Transportation

### CHAPTER X—INTERSTATE COMMERCE COMMISSION

### SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[Ex Parte No. MC-29 (Sub-No. 3)]

### PART 1041—INTERPRETATION—CERTIFICATES AND PERMITS

### PART 1054—SPECIAL OR CHARTERED PARTIES BY COMMON CARRIERS

### SPECIAL OR CHARTERED PARTY SERVICE

• *Purpose:* The purpose of this document is to amend the Commission's regulations governing special or chartered party service so as to deem the movement of one group of non-identical passengers the "return" movement of another group of passengers, under certain conditions. •

At a general session of the Interstate Commerce Commission, held at its office in Washington, D.C., on the 15th day of June 1976.

It appearing, That investigation of the matters and things involved in this proceeding has been made and that the Commission has made and filed its report herein containing its findings of facts and conclusions thereon, which report is hereby referred to and made a part hereof:

*It is ordered,* That the attached notice be, and it is hereby, adopted and incorporated by reference into this order.

*It is further ordered,* That Parts 1041 and 1054 of Chapter X of Title 49 of the Code of Federal Regulations be, and they are hereby, modified in the manner set forth following the notice attached hereto and incorporated by reference herein.

*It is further ordered,* That the modifications herein prescribed be, and they are hereby, prescribed to become effective September 7, 1976.

*It is further ordered,* That notice of the modified regulations shall be given to the general public by depositing a copy of this order and the attached notice in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., for public inspection, and by delivering a copy of the notice to the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER.

*And it is further ordered,* That this proceeding be, and it is hereby discontinued.

By the Commission.

ROBERT L. OSWALD,
*Secretary.*

By order published in the FEDERAL REGISTER on December 3, 1974, the Interstate Commerce Commission instituted the above-entitled proceeding in order to develop information concerning (1) The interpretation of Commission regulations pertaining to special or chartered party service rendered in *Greyhound Corp.* v. *Edwards,* 100 M.C.C. 453, 465 (1966), (2) The effects of such interpretation upon the operations of motor common carriers of passengers and upon the public, (3) The possible modification of relevant regulations, and (4) The formulation of any legislation which the public interest might require. All regulated motor carriers of passengers were made parties to the proceeding, and all interested parties were invited to file written initial and reply statements of their views and suggestions within prescribed time limits.

Based upon analysis of the petition filed by the United States Department of Defense (DOD), which led to the institution of this proceeding, and upon the representations received from DOD and a number of passenger carriers and passenger carrier associations, the Commission has modified its rules and regulations as set forth at the end of this notice. These rules add two new definitional concepts to the present special or chartered party regulations—"third party" and "round trip." Application of these terms will permit special or chartered parties to be transported from the destination territory, as defined in the regulations, to the defined origin territory either on return movement of the same special or charter party, or pursuant to a "round trip contract" with a "third party" as defined. Similar relief will be afforded to those carriers which hold specific certificated authority to conduct charter operations. The Commission's report in this proceeding summarizes the representations received, discusses the issues, and arrives at these conclusions. Generally, it has been found that the regulations will serve the public interest by leading to a decrease in deadhead mileage, fuel savings, decreases in air and noise pollution, and increased efficiency in the operations of passenger carriers. The report explains why the regulations do not improperly authorize any "new" service and states that the benefit to be gained by these modifications outweighs any possible detriment to existing carriers. While it is asserted that the modifications will be beneficial to the environment, it is believed that the decision herein is not a major Federal action significantly affecting the environment within the meaning of the National Environmental Policy Act of 1969 so as to necessitate the preparation of an environmental impact statement.

This modification of regulations is issued under the authority of sections 552, 553, and 559 of the Administrative Procedure Act (5 U.S.C. 552, 553, and 559) and sections 204 and 208 of the Interstate Commerce Act (49 U.S.C. 304 and 308).

ROBERT L. OSWALD,
*Secretary.*

Accordingly, 49 CFR, Parts 1041 and 1054 are hereby modified in the following manner. The following new section is added to 49 CFR 1041:

**§ 1041.24 Special or chartered party service.**

A certificate issued by the Commission to any motor carrier of passengers pursuant to the provisions of part II of the Interstate Commerce Act (49 U.S.C. 301 et seq.) authorizing the transportation of passengers and their baggage, in charter operations, (a) from a described point, points, or territory to another described point, points, or territory, and return, or (b) beginning and ending at a described point, points, or territory, and extending to another described point, points, or territory, shall be construed as authorizing the transportation of charter groups pursuant to round trip contracts with third parties, as defined in § 1054.2, without regard to the identity of the individuals transported for each segment of trip.

The following paragraph (c) is added to 49 CFR 1054.2:

**§ 1054.2 Definitions.**

* * * * *

(c) (1) The term "third party," as used in the regulations in this part, means a government agency or person (as defined in § 203(a)(1)), engaged in a business or activity other than the transportation of passengers or other than as a broker of passenger transportation, who enters into a contract with a carrier for the exclusive use of a passenger-carrying motor vehicle covering either (i) A one-way movement of passengers for whom the contracting party is responsible from a specified origin to a specified destination, or (ii) A round trip movement of passengers, as defined in paragraph (c)(2) of this section, for whom the contracting party is responsible, without regard to the identity of the individuals transported for any segment of the trip.

(2) The term "round trip," as used in the regulations in this part, means a movement of passengers from a specified origin to a specified destination followed by a movement of passengers from that destination back to the origin point, provided that, where the identity of the group of passengers for each segment of the trip is not the same, the time between completion of the origin-to-destination segment of the trip and the commencement of the destination-back-to-origin segment does not exceed 24 hours.

The last sentence of 49 CFR 1054.4 is revised as follows:

**§ 1054.4 Destination territory.**

* * * Special or chartered parties may not be transported from the destination territory described in this rule to the origin territory described in § 1054.3 except on return movement of the same special or charter party as provided therein, or pursuant to a round trip contract with a third party as described in § 1054.2(c).

[FR Doc.76-19562 Filed 7-6-76;8:45 am]

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## SUBCHAPTER B—PRACTICE AND PROCEDURE

[Ex Parte No. 55 (Sub-No. 4)]

## PART 1100—GENERAL RULES OF PRACTICE

## PART 1108—REVISED GUIDELINES FOR IMPLEMENTATION OF THE NATIONAL ENVIRONMENTAL POLICY ACT OF 1969

### Revised Guidelines for the Implementation of the National Environmental Policy Act of 1969

At a general session of the Interstate Commerce Commission, held at its office in Washington, D.C., on the 9th day of June 1976.

It appearing, That the Commission on the date hereof, has made and filed its report in this proceeding setting forth its conclusions and findings and its reason therefor, which report is hereby referred to and made a part hereof;

*It is ordered,* That Subchapter B of Chapter X of Title 49 of the Code of Federal Regulations be, and it is hereby, amended as follows:

(1) Part 1100.250 be eliminated in its entirety, and

(2) A new Part 1108 be added to read as set forth in the attached notice.

*It is further ordered,* That this order shall become effective on July 7, 1976.

*And it is further ordered,* That notice of environmental rules adopted in this report shall be given to the general public by depositing a copy of this order and the attached notice in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., for public inspection, and by delivering a copy of the notice to the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER as notice to interested persons.

By the Commission.

ROBERT L. OSWALD,
*Secretary.*

NOTICE OF REVISED ENVIRONMENTAL RULES

Under the National Environmental Policy Act of 1969, all agencies of the Federal Government are required to identify and develop methods and procedures, in consultation with the Council on Environmental Quality which will insure that environmental amenities and values are given appropriate consideration in the decisionmaking process.

In February 1972, the Interstate Commerce Commission adopted environmental rules which were applicable to all proceedings before the Commission (49 CFR 1100.250). Since that time, the

Council on Environmental Quality has revised its guidelines and there have been a number of court decisions interpreting the Commission's environmental procedures. Based on these NEPA-related developments, the Commission by Notice and Order served August 15, 1975, instituted the above-entitled proceeding for the purpose of proposing substantial and detailed revisions to the Commission's existing rules. Implementation—Natl. Environmental Policy Act, 1969, 350 I.C.C. 492 (1975).

Based on the comments received, the Commission has adopted revised environmental rules which are set forth at the end of this Notice. The most significant provisions of the adopted rules are as follows:

The adopted rules distinguish among the various classes of actions which come before the Commission, and identify (1) actions which have the potential for significant environmental impact and normally require an environmental impact statement, (2) actions which may have environmental issues present, but normally do not require an environmental impact statement, and (3) actions which normally have no environmental issues present.

Detailed environmental information is required to be filed along with an application. The information required varies significantly according to which of the three above-described categories is applicable to a particular proceeding.

Draft environmental impact statements will be prepared and circulated for comment by the Environmental Affairs Staff of the Commission. Final statements will likewise be prepared by the staff.

Both draft and final statements will normally be prepared and made available prior to the holding of evidentiary hearings, whether oral or written.

The Commission will make all necessary findings and conclusions with respect to environmental issues in both initial and final decisions.

The revised environmental rules are effective on July 7, 1976.

Issued at Washington, D.C., on June 9, 1976.

ROBERT L. OSWALD,
*Secretary.*

Accordingly, this action eliminates 49 CFR Part 1100.250 and adds a new Part 1108 to read as follows:

**§ 1100.250 [Revoked]**

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**Subpart A—General Provisions**

Sec.
1108.1 Purpose and scope.
1108.2 Authority.
1108.3 Policy.
1108.4 Interpretations.
1108.5 Waivers or exemptions.

**Subpart B—Definitions**

1108.6 Definitions.

**Subpart C—Designation of Responsibility**

1108.7 Designation of responsible staff.

**Subpart D—Identification of Major Federal Actions Significantly Affecting the Quality of the Human Environment**

1108.8 Actions significantly affecting the quality of the human environment.
Sec.
1108.9 Actions with a potential effect on the environment.
1108.10 Actions where no environmental issues are present.
1108.11 Review of environmental determination.

**Subpart E—Environmental Procedures**

1108.12 Reporting requirements.
1108.13 Preparation of environmental threshold assessment surveys.
1108.14 Preparation of environmental impact statements.
1108.15 Public meetings in preparation of environmental impact statements.
1108.16 Minimum periods for review.

**Subpart F—Final Determinations**

1108.17 Hearing procedure.
1108.18 Initial and final decisions.

**Subpart G—Miscellaneous Provisions**

1108.19 Official notice.
1108.20 Cost of materials distributed to the public.

AUTHORITY: Secs. 17(3), 204(a)(6), 304(a), 403(a) of the Interstate Commerce Act, the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et. seq. (NEPA), and Executive Order 11514, and pursuant to secs. 553 and 559 of the Administrative Procedures Act.

## Subpart A—General Provisions

### § 1108.1 Purpose and scope.

(a) The National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq., hereinafter referred to as NEPA) authorizes and directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies for the protection and enhancement of the environment as set forth in NEPA, thus establishing national policies, goals, and procedures for protecting and enhancing the environment.

(b) The purpose of these regulations is to amend and supplant the regulations established by order of the Interstate Commerce Commission dated January 14, 1972 (49 CFR 1100.250), and to establish procedures for facilitating the Commission's discharge of its duties under the National Environmental Policy Act of 1969.

(c) These guidelines apply to all proceedings before the Commission.

### § 1108.2 Authority.

(a) NEPA establishes a broad national policy to promote efforts to improve the relationship between man and his environment NEPA sets out certain policies and goals concerning the environment and requires that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted in accordance with those policies and goals. Section 102(2)(C) of NEPA requires that, for each recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, the involved agencies of the Federal Government prepare a detailed statement of the environmental impact of the proposed action, and that such statement accompany the proposed action through each important stage of the agency decisionmaking process.

(b) Guidelines from the Council on Environmental Quality (CEQ), dated August 1, 1973 (38 FR 20550), set forth recommended procedures which should be followed by Federal agencies in implementing NEPA.

(c) Sections 17(3), 204(a)(6), 304(a) and 403(a) of the Interstate Commerce Act authorize the Commission, consistent with the purpose of the act, to establish such rules, regulations, and procedures as are necessary to the exercise of its functions.

### § 1108.3 Policy.

(a) *General.*—It is the policy of the Commission to implement NEPA to the fullest extent possible and as fully as statutory authority permits and to orient the Commission's administrative policies under the Interstate Commerce Act toward the broad national goal of preserving and enhancing the environment. Environmental factors are to be considered in the decisionmaking process. In accordance with section 101 of NEPA, adverse environmental effects should be minimized to the fullest extent practicable consistent with the national transportation policy and other national policies affecting Commisison action.

(b) *Implementation.*—The implementation of this policy shall consist of an environmental review process as specified in these regulations for all Federal actions under the jurisdiction of this Commission. The policies and goals set forth in NEPA are supplemental to those set forth in the existing authorization of the Interstate Commerce Commission. The Commission will interpret the provisions of NEPA as supplemental to its existing authority and as a mandate to view traditional policies and misisons in the light of national environmental objectives.

(c) *Other statutes.*—Whenever possible, statements required by other statutes concerning environmental impacts, such as the National Historic Preservation Act of 1966 (16 U.S.C. 470 et seq.), will be incorporated into environmental impact statements or threshold assessments.

(d) *Public notice and availability.*—(1) The Commission will insure timely notice and opportunity for public comment on impact statements and threshold assessments in an appropriate manner.

(2) A list of proposed actions for which an environmental impact statement is being prepared will be maintained by the Commission in its Press Release Room. The list will be available for public inspection and will be submitted to CEQ every 3 months for publication.

(e) *Proceedings in progress.*—(1) Proceedings in progress on the effective date of these regulations shall be governed to the fullest extent practicable by the procedures set forth herein, recognizing, however, that full compliance in all such proceedings may not be possible.

(2) Nothing in paragraph (e)(1) of this section shall be deemed to relieve any person or party from complying with a Commission directive to supply

environmental data for any proceeding in progress.

**§ 1108.4 Interpretations.**

Interpretations, either written or oral, with respect to the meaning of these regulations may be rendered by the Director of the Office of Proceedings or designee. Any such interpretation shall be advisory only, and, as such, not binding upon the Commission unless specifically endorsed by the Commission.

**§ 1108.5 Waivers or exemptions.**

(a) The Commission may, upon its own motion or application of any interested person for good cause shown, tions by order such waivers or exemptions from applicant reporting reqcirements as it determines is authorized by law or otherwise in the public interest. The Commission may waive the requirement that an environmental report accompany an application if it finds that the proposed Federal action is not "major" within the meaning of NEPA, or that the submission of a written environmental report is impractical because of time limitations and would lead to delay having the effect of denying the relief requested.

(b) Every request for a waiver or exemption must be timely filed, in writing, either with the application or not less than 10 days before the due date of the required information.

(c) The granting of a waiver or exemption under these regulations will not be in disregard of any requirement of NEPA nor shall it preclude the Commission from considering environmental values as part of its decision on the merits.

## Subpart B—Definitions

**§ 1108.6 Definitions.**

As defined in this part:

(a) "Act" means the Interstate Commerce Act, as amended.

(b) "Application" includes a request by an applicant, complainant, or proponent for the granting of any right, privilege, authority, or relief under or from any provision of the act, any regulation or requirement made pursuant to a power granted by such act, or any other statute conferring jurisdiction upon the Commission.

(c) "Commission" means the Interstate Commerce Commission.

(d) "Detailed environmental impact report" (DEIR) is a report to be filed by each applicant along with the application containing the information as set forth in § 1108.12(a) in those instances when an environmental impact statement is normally prepared.

(e) "Environmental impact" is any alteration of environmental conditions or creation of a new set of environmental conditions, adverse or beneficial, caused or induced by the action or set of actions under consideration.

(f) "Environmental impact statement" (EIS) is a complete and fully comprehensive environmental analysis including such formal review as may be provided by other Federal, State, and local agencies and the public pursuant to section 102(2)(C) of NEPA. The EIS is developed in two stages, draft and final.

(g) "Supplemental environmental evaluation" (SEE) is a statement containing the information required by § 1108.12 (b) or (c), as appropriate. A supplemental environmental evaluation shall be filed by each applicant, proponent, or complainant seeking authorization or relief in actions listed in § 1108.9 (a).

(h) "Environmental threshold assessment survey" (TAS) is a written Environmental Affairs Staff study concluding that an EIS is not necessary. The study includes a review of the proposed action, the supplemental environmental evaluation, and other available data. The TAS identifies areas of relevant environmental concern and assesses alternatives to the proposed action.

(i) "Federal action" includes the entire range of activities undertaken by the Commission.

(j) "Major Federal action" is any Federal action which requires the substantial commitment of resources or triggers such a substantial commitment by others.

(k) "NEPA" means the National Environmental Policy Act of 1969.

(l) "Summary environmental negative declaration" (SEND) is a statement in an initial procedural order indicating that the proposal is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

## Subpart C—Designation of Responsibility

**§ 1108.7 Designation of responsible staff.**

(a) The Environmental Affairs Staff is assigned the responsibility of preparing environmental impact statements and related documents.

(b) The Assistant to the Director for Environmental Affairs shall maintain liaison for the Commission with the Council on Environmental Quality, the Environmental Protection Agency (EPA), and the other departments and agencies with interest or expertise in environmental matters. Duties of the Assistant to the Director for Environmental Affairs, or designees, shall include, among other things:

(1) Coordination of environmental policies with Commission practices and procedures;

(2) Supervision of the Environmental Affairs Staff in carrying out the functions and responsibilities duly assigned;

(3) Preparation of a quarterly list of all environmental impact statements and threshold assessment surveys prepared under the circumstances set forth in § 1108.13(b); and

(4) Provision of advisory assistance to Commission decisionmakers (groups and individuals) in any proceeding or action wherein there arises environmental issues requiring the special competence and expertise of the multidisciplinary Environmental Affairs Staff.

## Subpart D—Identification of Major Federal Actions Significantly Affecting the Quality of the Human Environment

**§ 1108.8 Actions significantly affecting the quality of the human environment.**

(a) In determining whether a proposed action will significantly affect the quality of the human environment consideration will be given to:

(1) The extent to which the action will cause environmental effects in excess of those created by existing uses in the area affected by it;

(2) The absolute quantitative environmental effects of the action itself, including the cumulative harm that results from its contribution to existing adverse conditions or uses in the affected area; and

(3) The extent to which the proposed action is consistent with local land use plans.

(b) In determining whether an action is a major Federal action, consideration will also be given to the following:

(1) Whether the action is environmentally controversial;

(2) Whether proposed actions, though individually limited, may cumulatively have a significant environmental impact; and

(3) Whether the proposed action involves secondary or indirect effects upon patterns of social and economic activity.

(c) If it is determined that the Federal action contemplated is "major" and will have a significant impact on the quality of the human environment, the Environmental Affairs Staff will prepare an EIS in accordance with § 1108.14 Such actions include, but are not limited to, actions which would have a significant impact or effect on:

(1) Air, noise, or water pollution;

(2) Consumption of energy or natural resources;

(3) Diversion of traffic from one mode of transportation to another;

(4) Land use plans, policies, or controls;

(5) Recreation sites or wildlife areas;

(6) Publicly owned lands or parks;

(7) Areas of cultural, historical, or archaeological significance; or

(8) The safety of the community.

(d) The following classes of actions have the potential for significant environmental impact and normally require an EIS:

(1) Rail line constructions;

(2) Commuter fare increases;

(3) Discontinuance of passenger trains; and

(4) Merger, control, or consolidation involving two or more class I railroads.

(e) If for some reason an EIS is not required for an action included in one of the classes listed in paragraph (d) of this section, the following procedure will apply:

(1) The Environmental Affairs Staff will normally prepare a TAS in accordance with § 1108.13; and

(2) The Commission will notify all parties, CEQ, and the public that an EIS will not be prepared.

**§ 1108.9 Actions with a potential effect on the environment.**

(a) The following classes of actions may have environmental issues present, but normally do not require an EIS:

(1) Abandonment, acquisition, or operation of a line of railroad;

(2) Common use of rail terminals;

(3) Railroad merger, purchase, control, or trackage rights proceedings, except as provided in § 1108.8(d)(4);

(4) Water carrier certification;

(5) Investigation and suspension, rate complaint, or formal docket cases involving recyclable commodities;

(6) Rulemaking and legislative proposals affecting carrier operations; and

(7) General rate increases.

(b) Actions listed in paragraph (a) of this section will be examined on a case-by-case basis, with the supporting data, in order to determine whether a SEND is appropriate, or whether further environmental analysis, in the form of an EIS or TAS, may be required.

**§ 1108.10 Actions where no environmental issues are present.**

(a) If it is determined that the Federal action contemplated is not "major" in character within the meaning of NEPA, or that the environmental impacts are inconsequential or not cognizable under NEPA, or that the allegations of impacts are frivolous, an initial procedural order shall include a SEND stating that the proposal is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

(b) For proceedings not listed in §§ 1108.8(d) and 1108.9(a) the initial procedural order will normally contain a SEND. If any interested person, or the Commission on its own initiative, identifies environmental issues of consequence, an action falling within the scope of this section will be subject to further environmental evaluation.

(c) If environmental issues of consequence arise after a SEND has been served, the Commission shall assess such issues and, in appropriate instances, prepare a TAS or EIS.

**§ 1108.11 Review of environmental determination.**

Any determination with respect to environmental issues will be subject to Commission review in the same manner as other issues in the proceeding.

**Subpart E—Environmental Procedures**

**§ 1108.12 Reporting requirements.**

(a) *Detailed environmental impact report (DEIR).*—Every application within § 1108.8(d) shall include a DEIR, similar in scope to an EIS under section 102(2)(C) of NEPA.

(1) A DEIR will include, but not be limited to, a discussion of the following, as appropriate:

(i) A description of the proposed action;

(ii) The relationship of the proposed action to land use plans, policies, and controls for the affected area;

(iii) The probable impacts of the proposed action on the environment, including secondary or indirect, as well as primary or direct, impacts;

(iv) Alternatives to the proposed action;

(v) Any adverse environmental effects which cannot be avoided;

(vi) The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and

(vii) Irreversible and irretrievable commitments of resources which will be involved in the proposed action should it be implemented.

(2) The DEIR should also address the considerations set forth in §§ 1108.8 (b) and (c), as appropriate.

(3) For actions described in § 1108.8 (d), applicants may contact the Assistant to the Director for Environmental Affairs for assistance and advice on how to prepare the DEIR. Early and continuing consultation with the Assistant to the Director for Environmental Affairs, even prior to the filing of the application, is encouraged. This consultation should regard, among other things: (i) The need for consultants and experts for special studies (such as archaeological surveys, diversion modeling, et cetera), (ii) Specification of additional environmental information required, and (iii) Early awareness of related Federal actions proposed by applicant or others.

(b) *Supplemental environmental evaluation (SEE).*—(1) Every applicant, complainant, or proponent instituting an action described in § 1108.9(a) shall submit an SEE which, except as provided in paragraph (2)(b) of this section, shall be included with the application.

(2) A SEE for an investigation and suspension or a formal docket case involving recyclable commodities must be submitted within thirty (30) days after service of the order of investigation.

(3) The SEE shall include a discussion of the following, as appropriate:

(i) A description, in narrative form, of the contemplated action;

(ii) An indication of related applications or proposals before the Commission or not yet filed but contemplated;

(iii) The involvement of any other Federal, State, or local governmental agency (including the need for additional permits or licenses or the expectation of funding or financing);

(iv) The anticipated environmental impacts;

(v) Anticipated increases in energy requirements or natural resource consumption;

(vi) Probable and potential changes in transportation patterns;

(vii) The anticipated amount of traffic diversion to alternate modes of transportation, and, if no diversion is anticipated, the reasons why; and

(viii) The alternatives to the proposed action which applicant, proponent, or complainant has considered.

(c) *Additional environmental information for rail abandonment applications.*—In addition to the information listed in paragraph (b) of this section applications to abandon a line of railroad, or operations over such line, shall include the following, as appropriate:

(1) A description, in narrative form, of the contemplated action, including the involvement of other railroads and related abandonment, construction, or trackage rights applications;

(2) A detailed map showing the exact location of the line to be abandoned and its relationship to other railroad lines;

(3) The most recently available traffic figures for the line in question, including type of commodities transported, the amount of carloads and tons handled, and a breakdown of traffic received and forwarded at each station on the line;

(4) The number of acres in the right-of-way proposed for abandonment and, stated separately, in the railroad property appurtenant thereto;

(5) Other contemplated abandonment applications which will have a direct effect on the geographic region involved in the pending application, and an analysis of the manner in which the line to be abandoned fits in with the applicant's overall operations and with available transportation service in or through the affected area;

(6) The number, type, and location, including a description, of all bridges, culverts, and grade crossings, or any other structures on the line;

(7) The anticipated plans for salvage operations, including the removal or sale of rail and ties, and the plans for removal of bridges and all structures, and steps to be taken to avoid the creation of public safety hazards as a result of salvage operations;

(8) Federal, State, or local laws or ordinances relating to salvage operations;

(9) The general nature of ownership of the underlying right-of-way, and specific plans for the property made available for disposition by the abandonment;

(10) A description of current land use in the area directly adjacent to the line and in the tributary territory; and

(11) The kind and amount of property taxes paid by the railroad to the local communities in the last 2 calendar years.

(d) *Applicant's environmental declaration.*—Applications described in § 1108.10 shall include a statement indicating the presence or absence of any environmental impact of the proposed action. If environmental impacts, either adverse or beneficial, are alleged, they must be identified and quantified to the maximum extent practicable.

(e) *Representations of other parties.*—Persons filing a protest or other representation in a proceeding before the Commission may include a statement indicating the presence or absence of environmental impacts. A statement alleging a significant environmental impact shall indicate with specific data the exact nature and degree of the anticipated impact.

(f) *Additional information.*—The supplemental information required by the previous paragraphs shall not preclude the Commission from requiring additional information from a party needed

to make a determination as to the environmental significance of the contemplated action. The Commission may require a party to perform additional contract or other studies deemed necessary to enable full and complete evaluation of pertinent environmental issues.

**§ 1108.13 Preparation of environmental threshold assessment surveys.**

(a) Upon a determination that a proposed action will not have a significant effect on the environment, but the potential environmental impacts are such that a SEND is not appropriate, a TAS will be prepared.

(b) In addition, if it is determined that an EIS is not necessary for a proposed action (1) Identified in § 1108.8(d) as normally requiring an EIS, (2) Similar to prior actions for which an EIS has generally been prepared, (3) Which the Commission previously announced would be the subject of an EIS, or (4) For which the Commission has received a request from CEQ to prepare an EIS, a TAS will normally be prepared setting forth the reasons why an EIS is not being prepared.

(c) The TAS shall include, but not be limited to, the following:

(1) A statement of the facts, describing the proposed action;

(2) Identification of all areas of relevant environmental concern and reasons why impacts are insignificant; and

(3) Discussion of the alternatives to the action and the anticipated environmental consequences of such alternatives.

(d) Notice of the conclusions in the TAS will be served on all parties and will be made available to the public by publication in the FEDERAL REGISTER and/or publication in local newspapers.

(e) Substantive comments of an environmental nature received in response to the notice specified in paragraph (d) of this section shall be filed in writing within 30 days of the date of service of said notice. Comments received will be considered and a determination made to (1) Affirm the prior finding of no significant impact without modification, (2) Modify or amend the TAS, or (3) Prepare an EIS for the proposed action.

**§ 1108.14 Preparation of environmental impact statements.**

(a) *General.*—Upon a determination that a proposed action may have a significant effect uopn the quality of the human environment, the Environmental Affairs Staff will prepare an EIS. The EIS is normally comprised of two stages, draft and final. The draft statement must satisfy to the fullest extent possible, at the time of its preparation, the requirements established for final statements by section 102(2)(C) of NEPA. An EIS shall be prepared early enough to be part of the decisionmaking process on the proposed action to which it relates.

(b) *Draft environmental impact statements.*—In preparing draft EIS the Environmental Affairs Staff will take into account the guidelines set forth in 40 CFR 1500.7–1500.8 (28 FR 20552–3). Draft statements will set forth in detail:

(1) The environmental impact of the proposed or contemplated action;

(2) Adverse environmental effects which cannot be avoided should the proposed or contemplated action be implemented;

(3) Alternatives to the proposed or contemplated action;

(4) The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and

(5) Irreversible and irretrievable commitments of resources which would be involved in the proposed or contemplated action should it be implemented.

In some cases environmental impact statements may be prepared by private consultants. In all cases the Commission will make its own evaluation of the environmental issues and take responsibility for the scope and content of draft and final environmental impact statements.

(c) *Filing and distribution of draft environmental impact statements.*—Draft EIS will be filed in the docket and distributed to CEQ, EPA, the parties, and Federal agencies having special expertise or jurisdiction with respect to related environmental impacts and authorized to develop and enforce relevant environmental standards (See appendixes II and III to 40 CFR 1500 (38 F.R. 20557–62)). Draft EIS will also be made available to State and local governments, as appropriate, and to other interested persons.

(d) *Request for comments on draft environmental impact statements.*—The draft statement shall be accompanied by a notice requesting comments on the draft. Normally the comments will be due within forty-five (45) days from the date the draft EIS is made available to CEQ and the public. An original, and to the extent practicable, six (6) copies of any such comments should be submitted to the Secretary, Interstate Commerce Commission, Washington, D.C. 20423.

(e) *Final environmental impact statements.*—After receipt of comments on the draft statement, the Environmental Affairs Staff will prepare a final EIS in accordance with the requirements for draft statements. To the extent opposing professional views and responsible opinion on the environmental effects of the proposed or contemplated action have not been discussed in the draft statement, but are brought out by the comments, the environmental effect of the action will be reviewed in the light of those comments. The final EIS will contain responsive reference to such views and opinion. All substantive comments on the draft EIS (or summaries thereof where the response is voluminous) will be attached to the final EIS, whether or not each such comment is thought to merit individual discussion in the text of the statement. The final EIS will be filed and distributed to those who submitted substantive comments on the draft statement. In all instances the final EIS will be distributed to CEQ, EPA, all parties to the proceeding, and any person requesting a copy. The final EIS and substantive comments received on the draft statement will accompany the proposal through the Commission's review process.

**§ 1108.15 Public meetings in preparation of environmental impact statements.**

During the preparation of an EIS where issues are unusually complex or there is substantial public controversy, the Commission may call public meetings for further input. Such public meetings may be scheduled independently of or in conjunction with formal public hearings which may be held for a particular proceeding. Formal transcripts of such meeting normally will be made.

**§ 1108.16 Minimum periods for review.**

(a) To the maximum extent practicable, no final administrative action subject to section 102(2)(C) of NEPA will be taken sooner than ninety (90) days after the date the draft statement is made available to CEQ and the public. Neither shall such final administrative action be taken sooner than thirty (30) days after the date the final EIS has been available to CEQ and the public. The ninety (90)-day and thirty (30)-day periods described above may run concurrently to the extent they overlap.

(b) When oral hearings are contemplated for a particular proceeding in which an EIS has been prepared, the final EIS will be available to the public at least fifteen (15) days prior to that portion of the oral hearing relating to the impact statement, except as provided in subsection (d).

(c) Where emergency circumstances make it necessary to take an action with significant environmental impact without observing the provisions of these guidelines concerning minimum periods for agency review and advance availability of environmental statements, the Commission will consult with CEQ about alternative arrangements.

(d) In light of the statutory obligations of this Commission to decide certain cases within a limited time period, the commenting period for the draft statement may be limited to thirty (30) days with no extensions of time granted. In addition, the thirty (30)-day waiting period after the issuance of the final EIS shall be shortened as necessary. In the event that statutory time limitations in a particular proceeding make it impractical to comply with the procedures as specified in these rules, the final EIS may be issued after the conclusion of the evidentiary hearings. In the event that any decision rests upon matters contained in a final impact statement issued after the conclusion of evidentiary hearings, any party may request an opportunity to show the contrary.

## Subpart F—Final Determinations

**§ 1108.17 Hearing procedure.**

(a) Subject to procedural requirements imposed by the Commission consistent with this part, in appropriate oral hearing cases the final EIS will be submitted for the record.

(b) Any party may take a position, offer probative evidence, and cross-examine witnesses of both the Environmental Affairs Staff (with respect to the preparation of the statement) and the applicant or others (with respect to the environmental information supplied by them), in light of the final EIS and on environmental issues within the scope of the proceeding. The Commission may designate counsel for Environmental Affairs Staff members called as witnesses on environmental matters.

**§ 1108.18 Initial and final decisions.**

(a) Where environmental matters are in issue in a proceeding, the initial decision will include all necessary findings and conclusions on such issues. It may also include findings and conclusions which affirm or modify the content of an EIS or TAS. To the extent such findings and conclusions differ from those in the EIS or TAS, the EIS or TAS will be deemed modified to that extent.

(b) If the Commission in a final decision reaches conclusions different from those contained in an initial decision with respect to environmental issues, the EIS or TAS will be deemed modified to that extent.

**Subpart G—Miscellaneous Provisions**

**§ 1108.19 Official notice.**

The Commission may take official notice of any facts relating to the environmental situation before it. This shall include facts set forth in documents such as scientific studies, environmental impact statements, governmental reports, and maps, which have not been presented in evidence by any party of record. In the event any decision rests upon official notice of any such fact, any party may, within a period allowed for the filing of exceptions or petitions for reconsideration, request an opportunity to show the contrary.

**§ 1108.20 Cost of materials distributed to the public.**

Copies of draft and final environmental impact statements and threshold assessment surveys will be made available to the public upon request without charge, to the extent practicable, or at a fee not exceeding actual reproduction costs.

[FR Doc.76-19563 Filed 7-6-76;8:45 am]

## Title 50—Wildlife and Fisheries

### CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

### SUBCHAPTER F—AID TO FISHERIES

### PART 258—FISHERMEN'S PROTECTIVE ACT PROCEDURES

**Provision of Fees**

*Correction*

In FR Doc. 76-18846, appearing at page 26693, in the issue for Tuesday, June 29, 1976, change the effective date in the fourth paragraph from "July 29, 1976" to "June 29, 1976".

## Title 19—Customs Duties

### CHAPTER 1—UNITED STATES CUSTOMS SERVICE

[T.D. 76-190]

### PART 153—ANTIDUMPING

**Water Circulating Pumps, Wet Motor Type, From the United Kingdom**

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the Secretary of the Treasury responsibility for determination of sales at less than fair value. Pursuant to this authority the Secretary of the Treasury has determined that water circulating pumps, wet motor type, from the United Kingdom are being or are likely to be, sold at less than fair value within the meaning of section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). (Published in the FEDERAL REGISTER of March 3, 1976 (41 FR 9245)).

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the United States International Trade Commission responsibility for determination of injury or likelihood of injury. The United States International Trade Commission has determined, and on May 27, 1976, it notified the Secretary of the Treasury, that an industry in the United States is being injured by reason of the importation of water circulating pumps, wet motor type, from the United Kingdom that are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. (Published in the FEDERAL REGISTER of June 4, 1976 (41 FR 22635)).

On behalf of the Secretary of the Treasury, I hereby make public these determinations, which constitute a finding of dumping with respect to water circulating pumps, wet motor type, suitable for use in residential and commercial hydronic heating systems, from the United Kingdom.

**§ 153.43 [Amended]**

Section 153.43 of the Customs Regulations is amended by adding the following to the list of findings of dumping currently in effect:

| Merchandise | Country | Treasury Decision |
|---|---|---|
| Water circulating pumps, wet motor type. | United Kingdom.. | 76-190 |

(Secs. 201, 407, 42 Stat. 11, as amended, 18; 19 U.S.C. 160, 173.)

DAVID R. MACDONALD,
*Assistant Secretary of the Treasury.*

JUNE 30, 1976.

[FR Doc.76-19491 Filed 7-6-76;8:45 am]

# proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### [ 50 CFR Part 32 ]

### HUNTING

### Proposed Opening of Ouray National Wildlife Refuge, Utah to Hunting of Migratory Game Birds

Notice is hereby given that it is proposed that 50 CFR Part 32 be amended by the addition of the Ouray National Wildlife Refuge, Utah, to the list of refuge areas open for the hunting of migratory game birds, which is published at 50 CFR 32.11.

Pursuant to the authority of 16 U.S.C. 668dd(d), as redelegated to the Director of the United States Fish and Wildlife Service at DM 242.1.1, the Director may open refuge areas to public hunting upon a determination that it would be in accordance with provisions of all laws applicable to the area, would be compatible with the principles of sound wildlife management, would otherwise be in the public interest and that such use is compatible with the major purposes for which such areas were estabilshed. As a general rule, most areas within the National Wildlife Refuge System are closed to hunting until officially opened by regulation. It is the purpose of this proposed rulemaking to allow the hunting of migratory game birds, on the Ouray National Wildlife Refuge, which is presently prohibited.

Furthermore, pursuant to the reqiurements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)), an environmental assessment has been prepared on this proposal which will help determine whether this rulemaking constitutes a major federal action significantly affecting the human environment. A copy of this assessment is available at the address below.

The policy of the Department of the Interior is, whenever practical, to afford the public an opportunity to participate in the rulemaking process. Therefore, interested persons may submit written comments, suggestions, or objections regarding the proposed amendment to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225 by July 31, 1976.

Accordingly, it is proposed to amend § 32.11, in Title 50 of the Code of Federal Regulations by the addition of:

UTAH

OURAY NATIONAL WILDLIFE REFUGE

Dated: June 29, 1976.

F. EUGENE HESTER,
*Acting Director,*
*U.S. Fish and Wildlife Service.*

[FR Doc.76-19446 Filed 7-6-76;8:45 am]

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### [ 7 CFR Part 916 ]

### HANDLING OF NECTARINES GROWN IN CALIFORNIA

### Approval of Expenses and Fixing of Rate of Assessment for the 1976–77 Fiscal Period

This notice invites written comment relative to the proposed expenses of $765,380 and rate of assessment of $0.065 per No. 22D standard lug box of nectarines to support the activities of the Nectarine Administrative Committee for the 1976–77 fiscal period under Marketing Order No. 916.

Consideration is being given to the following proposals submitted by the Nectarine Administrative Committee, established under the marketing agreement, as amended, and Order No. 916, as amended (7 CFR Part 916), regulating the handling of nectarines grown in California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), as the agency to administer the terms and provisions thereof:

(1) That expenses that are reasonable and likely to be incurred by the Nectarine Administrative Committee, during the period March 1, 1976, through February 28, 1977, will amount to $765,380; and

(2) The rate of assessment for such period, payable by each handler in accordance with § 916.41 to be fixed at $0.065 per No. 22D standard lug box, or equivalent quantity of nectarines in other containers or in bulk.

Terms used in the marketing agreement, as amended, and order, as amended, shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order, and "No. 22D standard lug box" shall have the same meaning as set forth in Section 1387.11 of the "Regulations of the California Department of Food and Agriculture."

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposals should file the same, in quadruplicate, with the Hearing Clerk, United States Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than July 23, 1976. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: July 1, 1976.

CHARLES R. BRADER,
*Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc.76-19556 Filed 7-6-76;8:45 am]

### [ 7 CFR Part 1124 ]

[Docket No. AO 368-A9]

### MILK IN THE OREGON-WASHINGTON MARKETING AREA

### Notice of Recommended Decision and Opportunity To File Written Exceptions on Proposed Amendments to Tentative Marketing Agreement and to Order

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to proposed amendments to the tentative marketing agreement and order regulating the handling of milk in the Oregon-Washington marketing area.

Interested parties may file written exceptions to this decision with the Hearing Clerk, United States Department of Agriculture, Washington, D.C., 20250, on or before July 22, 1976. The exceptions should be filed in quadruplicate. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The above notice of filing of the decision and of opportunity to file exceptions thereto is issued pursuant to the provisions of the Agricultural Marketing

Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

PRELIMINARY STATEMENT

The hearing on the record of which the proposed amendments, as hereinafter set forth, to the tentative marketing agreement and to the order as amended, were formulated, was conducted at Beaverton, Oregon, on March 10–11, 1976, pursuant to notice thereof which was issued on February 24, 1976 (41 FR 8189).

The material issues on the record of the hearing relate to:

1. Diversion of producer milk.
2. Location adjustments.
3. Partial payments to producers.
4. Charges on overdue obligations.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. *Diversion of producer milk.* The diversion provisions of the order should be revised to provide that milk of a dairy farmer shall be eligible for diverson as producer milk only after such dairy farmer's status as a producer has been established on the basis of physical receipt of milk at a pool plant. In addition, during the months of September, October, or November, at least one delivery must be received at a pool plant during the month to qualify such producer's milk for diversion privileges during the month.

A producer who meets the one day delivery requirement in all three months, September-November, is eligible to have his milk diverted as producer milk in any subsequent months through August, without further qualifying deliveries to a pool plant. A producer whose milk was not received at a pool plant at least one day during each of the months of September–November also must make one delivery of his milk to a pool plant during any month to qualify his milk for diversion during such month. When this delivery requirement has been met for three consecutive months, such producer's milk is elgible for diversion as producer milk in subsequent months through August without further deliveries to a pool plant.

A producer's milk now may be diverted only after a previous receipt of such producer's milk at a pool plant, and in any month at least three deliveries of his milk must be made to a pool plant. The order limits diversions of producer milk in the aggregate, by either a cooperative or a proprietary handler, to a quantity no greater than that delivered to a pool plant(s) in the same month. This quantity limitation was not at issue in this proceeding.

The diversion provisions are intended to facilitate the efficient handling of the market's reserve milk supply. Milk not needed at a pool plant may be handled most efficiently by movement directly from the farms (diverted) to nonpool manufacturing plants rather than by receipt at a pool plant and subsequent transfer.

The Farmers Cooperative Creamery Association, Portland Independent Milk Producers Association and the Corvallis Milk Producers Association, representing their member producers on the market, jointly requested a modification of the diversion qualification provisions applicable to a cooperative association as the diverting handler. They proposed a one delivery requirement during each month of September, October, and November as a condition for diversion of any producer's milk in such months and in the succeeding months through August each year.

Their proposal as noticed would apply to milk of "member producers" only whereas the diversion provisions of the order currently are not so limited. At the hearing, proponents modified their proposal to apply to any producer. In their post hearing brief they indicated that it was neither relevant nor their intent to make a substantive change in the diversion rule which would limit diversions to milk of cooperative members.

A corollary proposal by Safeway Stores, Inc., included in the hearing notice, would modify the diversion rules applicable to proprietary handlers essentially in the same manner as that proposed by the three cooperatives. At the hearing, all parties testifying on the diversion issue recognized the need for a similar application of diversion provisions to both cooperative associations and proprietary handlers.

Supporting the diversion rule changes applicable to both cooperatives and proprietary handlers were two additional cooperative associations, four non-cooperative producer groups and associations, and a proprietary handler.

The chief reasons given in support of the proposed relaxation of the receipt requirements were that such revision would save substantial uneconomic hauling and handling expenses now being necessarily incurred to preserve producer status for a large quantity of reserve milk associated with the market and would provide maximum flexibility for the handling of market fluid milk reserves.

Recent institutional changes in the market were cited on the record as support of the proposed revision of the diversion qualification provisions.

The three proponent cooperatives federated in the fall of 1974. This facilitated a more efficient means of supplying milk to plant operations in the Portland, Corvallis, McMinnville and Tillamook areas. The spokesman for the federation stressed the need for a coordinated marketing system so that plants are supplied with that milk closest to the area where produced with resulting substantial transportation savings.

Prior to the formation of this federation, the Farmers Cooperative Creamery Association of McMinnville (the only one of the three with processing facilities) and the two bargaining cooperatives, Portland Independent Milk Producers Association and Corvallis Milk Producers Association, were experiencing an overlap in supplying fluid milk to pool plants in the heavy populated Upper Willamette Valley portion of the marketing area and in the disposition of their reserve supplies. Under the OWMI federation, the two non-operating cooperatives assume primary responsibility for supplying milk for bottling use in the Portland and Corvallis area, and the operating cooperative assumes the function of handling the reserves and providing supplemental Grade A milk supplies for the fluid market, as needed.

As a result, the McMinnville plant changed status from a pool plant to a nonpool plant in January 1975. However, its member milk has been attached to other pool plants for purposes of pooling. Since that time, during the months of heavy production (beginning in April and extending through August), the Farmers Cooperative Creamery has experienced considerable difficulty in finding pool plant outlets for meeting the three delivery requirements necessary to qualify the milk of its member producers for diversion. In some cases this has necessitated the hauling of members' milk to a pool plant to be unloaded and reloaded for return to the McMinnville plant for manufacturing solely to maintain producer status for such milk.

Mayflower Farms, a cooperative association operating three pool plants under the order, supported the proponents' proposal to relax the present qualification standards. The spokesman for this cooperative association testified to having problems in qualifying some of its producers for diversion during the spring and summer months of relatively higher milk production.

It is the position of this association that the diversion provisions must continue to provide a basis for producer identification with the market. It is also the contention of the association that proponents' proposal provides a maximum flexibility for producers to find the best alternative for handling reserve milk supplies and will allow them to divert milk to nonpool plants at a savings in hauling costs.

A representative of fifteen Grade A milk producers all of whom are located in the Myrtle Point area stated that the cost of hauling their milk to a Clackamas pool plant (near Portland, about 212 miles) to meet the three delivery requirements ranges from 81.5 to 91.5 cents per hundredweight compared to about 32 cents per hundredweight hauling cost when such milk is diverted to a nearby manufacturing plant at Myrtle Point.

The volume of bulk milk diverted to nonpool plants has increased significantly in the past few years. In 1975, 138.6 million pounds of producer milk was diverted to nonpool plants compared to only 61.9 million pounds in 1974. This increase in the volume of reserve producer milk that must be moved to manufacturing outlets has intensified marketing problems which cannot be satisfactorily resolved under the existing diversion provisions.

The problems encountered in handling reserve producer milk supplies necessitated suspension of the three delivery requirements for producer milk for the months of April, May, June, and July 1976 (41 FR 15398). These four months in which milk production is seasonally heaviest in relation to demand in the market fall within the nine-month period (December-August) for which qualifying deliveries will not be required for diversions under the provisions adopted herein.

Considerable savings in hauling costs can be effected for those producers located in areas more remote from pool plant facilities by reducing the number of deliveries necessary for milk of individual producers in establishing diversion eligibility rights.

In this connection, the milk of producers whose farms are located nearest to pool plants may be moved to such plants on a more regular basis while milk of more distant producers may be moved to nearby nonpool manufacturing plants, unless otherwise needed for fluid use in the market.

Having concluded that the present deliveries which a producer is required to meet to establish diversion eligibility rights is a deterrent in the efficient handling of the market's reserve milk supplies, it is now necessary to determine the extent of relaxation which can be permitted and still retain adequate assurance against abuse of the diversion privileges. With no delivery requirement, the milk of an individual producer could be diverted to a manufacturing plant continuously for an indefinite period of time. Under such circumstance, there would be no assurance that such diverted milk continues to be qualified for fluid use and accordingly has a bona fide claim of association with the fluid market.

Appropriately, for the milk of a producer to be diverted as producer milk during the period of December through August, it should be required that such producer establish diversion eligibility by a single delivery for each of the three months of the preceding September–November period. Such eligibility performance established by the producer over a 3-month period will provide adequate evidence of such producer's association with the Oregon–Washington fluid market and that his milk is of acceptable quality for the fluid market.

A producer whose milk has not been received at a pool plant for at least one day during each of the months of September–November should be required to have at least one delivery of his milk received at a pool plant in any month to qualify his milk for diversion during such month. Once such producer has met this delivery requirement for any three consecutive months, beginning during or after the September–November period, his milk should have diversion privileges for any subsequent months through August in the identical manner as a producer who met the delivery requirement in the September–November period. This is appropriate since such producer would have met substantially the identical requirement as a prerequisite for diversion.

An additional eligibilty requirement currently provided in the order, and retained herein, that, notwithstanding the specific performance requirements discussed above, any producer must have had his milk physically received at a pool plant before his milk may be diverted. This requirement, in connection with the other eligibility requirements herein adopted, will serve the common purpose of demonstrating that those producers whose milk is diverted do in fact have a bona fide association with the fluid milk market.

2. *Location Adjustments.* The location adjustments provisions of the order should be modified to provide a 10 cent location adjustment for any plant located in the Oregon counties of Jackson and Josephine.

The present location adjustment rate under the order is 15 cents for a plant located between 100 and 110 miles from the nearer of Eugene or Portland, Oregon. An additional 1.5 cents adjustment is applicable for each 10 miles or fraction thereof with respect to any plant located in excess of 110 miles from the nearer of such basing points. The amount of the location adjustment applicable at a plant located 100 miles or more from the nearer of such basing points but within the Oregon counties of Clatsop, Coos, Douglas, Lane, Lincoln, and Tillamook (all within t he marketing area), however, is limited to a maximum of 10 cents. Elsewhere in the marketing area or in Grant County, Wash., the rate is limited to a maximum of 20 cents.

The testimony adduced at the hearing centered primarily on the question of whether or not the present location adjustments applicable to plants located in the Oregon portion of the marketing area should be eliminated. Most of such testimony was confined to location pricing at plants in the southern Oregon segment (Grants Pass, Klamath Falls, and Medford area) of the marketing area. Producers and handlers took diverse positions regarding this matter.

The principal cooperative in the market (Mayflower Farms), operating three regulated plants under the order (two of which are subject to the 20 cent location adjustment), proposed that Medford, Oregon be added as a basing point from which distances are measured in determining location adjustments. If adopted, their proposal would eliminate location adjustments at seven pool plants (including their Medford plant) located in the Oregon counties of Jackson, Josephine, and Klamath. Their proposal was supported by several organizations of producers.

Proposals of another cooperative association and a proprietary handler (both based at Roseburg, Oregon), which would eliminate all location adjustments under the order, were included in the hearing notice. However, proponents abandoned such proposals at the hearing. They joined with certain producers in the southern Oregon area who supported adding Medford as a basing point and proposed expanding the radius to 150 miles from the basing points of Medford and Eugene as the area within which no location adjustments would apply. Under this proposal, all location adjustments would be eliminated for plants located within the Oregon portion of the marketing area.

The OWMI, one producer, and a Caldwell, Idaho handler (a cooperative association operating a pool supply plant) proposed that the "base" pricing zone be extended to cover all territory within 150 miles of Portland, Eugene, and Medford. No substantial evidence was offered in support of the proposal, however.

A group of handlers operating plants in the southern and east central Oregon portions of the marketing area opposed any change in location adjustments. The spokesman for this group held that there has been no significant changes in marketing conditions within the Oregon portion of the marketing area since the present location adjustments in the order became effective.

Location adjustments, an essential tool in establishing milk prices under Federal milk orders, generally reflect the cost of moving milk from distant points to the central market. They implement continuing intermarket and intra market price alignment and promote equity among handlers in the cost of milk under the terms of the order. In the absence of appropriate location adjustments, plants distant from the central market could not compete for sales in the central market. It is within this context that the present location adjustment provisions in the Oregon-Washington order were developed.

The existing location pricing structure under the order was established by the decision of the Assistant Secretary issued November 11, 1971 (36 FR 21819 official notice of which is taken). In this decision, the Assistant Secretary concluded that location adjustments recognize the greater value of producer milk f.o.b. plants in or near the principal population centers (principally in the Willamette Valley between Portland and Eugene and the population centers located therein) as compared to its value at other locations including the Washington portion of the marketing area and the coastal, eastern and southern Oregon portions, thereof. He further concluded that location adjustments were necessary at certain locations in the marketing area to maintain a proper price alignment with nearby markets.

As previously indicated, there were essentially three proposals presented and discussed at the hearing that, if adopted, would change in varying degrees the present location pricing structure under the order. Most of the testimony that was presented in support of the proposals, however, was directed to the elimination of location adjustments in the southern Oregon (Jackson, Josephine, and Klamath Counties) portion of the marketing area. Proponents testimony was focused on establishing that circumstances have

changed in southern Oregon since the 1971 decision providing location adjustments for the first time at plants located in that area.

In support of the proposal, the witness for Mayflower Farms contended that present location adjustment rates applicable at plants in southern Oregon are no longer appropriate in light of current marketing conditions in the area. He held that increased population in southern Oregon had changed supply-demand conditions and that the closing of several plants had resulted in significant changes in the areas of supply. The spokesman for the cooperative testified that as a result, the Medford fluid operation has experienced a tight supply situation during the past year. This he stated occurred because part of the sales volume formerly handled in the cooperative's Coos Bay plant, which ceased fluid operations in 1974, was transferred to the Medford plant and because of an overall increase in sales. However, the witness was able to cite only one instance (October 1975) when it was necessary to obtain a load of milk from a plant in the base zone (the McMinnville cooperative plant), to meet the needs of its Medford operation.

The witness further testified that the tight supply situation has been ameliorated by Arden Farms discontinuation of operations at its Grants Pass distributing plant. Milk which the cooperative supplied to that plant is now being channeled through Mayflower's Medford operation. The Grants Pass packaged business of Arden Farms is now being served from its Portland operation.

Several other proponent producer spokesmen testified to a tightening supply situation in southern Oregon. They held this resulted from a decline in the number of producers in the area.

The record evidence does not support proponents contention that milk supplies are tight. Southern Oregon continues to be a surplus milk production area. It is basically rural and production greatly exceeds Class I needs. In 1975, only about 48 percent of the Grade A milk locally produced in the region (Coos, Jackson, Josephine and Klamath Counties) was utilized as Class I by local plants. This compares to about 51 percent in 1974.

Milk in excess of local distributing plants' needs in southern Oregon must be disposed of by movement to other plants. Limited quantities of milk are processed at the two local manufacturing plants, at Grants Pass and Klamath Falls. The bulk of the milk in the area not needed for fluid use, however, must be moved to more distant plants located at Eugene and Myrtle Point, Oregon for processing. While the excess milk of the area is used principally for manufacturing at these plants, it is available for use in fluid milk processing as needed.

The fact that milk does move from the base zone (Portland-Eugene area) to southern Oregon (a location adjustment zone) under certain circumstances is not a sufficient basis for elimination of location adjustments as proponent cooperative argued. It is not unusual for handlers to distribute milk in lower-priced zones within the same market, or even into other markets with somewhat lower Class I prices. Such movements reflect management decisions which are unrelated to the terms of regulation. The purpose of location adjustment is to appropriately reflect the value of milk at the plant of initial receipt rather than its value at the location disposition is made. If a producer delivers his milk to a plant located in the base zone, he assumes the cost of hauling the milk from the farm to the market center(s) and under such circumstances he should be compensated for such cost at the base zone price. Conversely, if the producer delivers his milk to an outlying plant located nearer his farm, the price to such producer appropriately may not reflect the value of milk at the market center(s), since in such circumstances it is the purchasing handler who thus would bear the cost of transporting the milk from the initial point of receipt to the market center.

Various proponents urging elimination of location adjustments in southern Oregon or throughout the Oregon portion of the marketing area suggested that the supply-management program operated by the Oregon Department of Agriculture eliminates any need for location adjustments in the Oregon portion of the marketing area. At the hearing, an official of the Milk Audit and Stabilization Division of the Oregon Department of Agriculture appeared as a witness to explain the Oregon supply-management program. He testified that the program is operated in conjunction with the Oregon "quota" plan.

Under the supply-management program, the State is authorized to direct as needed the receipts of quota milk in excess of the Class I and Class II needs of any handler to other handlers to supplement their total Class I and Class II requirements. The responsible State official stated that while the program recognizes the normal supply arrangements betweeen a producer and handler, it does implement the movement of excess quota milk as needed for Class I and II uses. According to the witness, both the producer and handler benefit by the program since it adjusts the seasonal and holiday supply patterns to implement the highest practical utilization of the quota milk supply.

Participation in the State quota plan by any producer is voluntary. The principal cooperative spokesman testified that about 90 percent of the cooperative's members participate in the plan. In 1975 about 83 percent of the total production in the three southern Oregon counties was under the quota plan. In view of this and considering that the State has call on only that portion of quota milk that is in excess of a handler's total Class I and Class II requirements, the amount of quota milk that can be moved under the supply-management program for Class I use can reasonably be expected to be quite limited.

The argument that the State supply management nullifies the need for location adjustments are not valid. As indicated above, the State supply system moves quota milk not only for fluid use but also for manufacturing of certain products (Class II). Further, the program does not involve all producers or handlers in the market.

Several proponent witnesses advocating discontinuation of location adjustments for Oregon based plants suggested that a recent innovation by the State of repooling total producer returns under the quota plan nullifies location pricing in the Oregon portion of the order's marketing area. Since its inception in 1970, the order has provided that producers, who so desire, may assign to the State of Oregon the returns otherwise due them for their milk in order that the State may redistribute such returns in accordance with the terms of the Oregon quota plan. Until last fall, the price paid to producers for quota milk under the plan was subject to the same location adjustments that apply to base milk under the order. Since that time, according to the testimony of certain witnesses, producer returns are repooled by the State to the end that the same quota price applies to a participating producer irrespective of the location of the plant to which his milk is delivered.

The four handlers opposing any change in location adjustments expressed concern in their post-hearing brief that the repooling of producer returns under the Oregon quota plan might be illegal pursuant to the Act which requires uniform prices to all producers subject to location adjustments. Consideration of this argument, however, is not relevant to the issue at hand since it involves matters beyond the scope of this rulemaking proceeding.

Since location adjustments are specifically authorized by the Act and are intended to adjust the basic price to reflect the value of milk at the location at which delivery is made, it would not be appropriate to consider a change in location pricing solely on the ground that producer payments under the Oregon quota plan (which does not involve all producers in the market) differs from the manner in which producer payments are paid under the Federal order.

An important feature of this regulation is that handlers regulated under the order and similarly located are uniformly subject to the same minimum class prices on all their milk. The uniformity of pricing among handlers is specifically prescribed in the Act. Location adjustments assist in carrying out the statutory requirement of uniformity in prices to all handlers.

The proposals to add Medford as an additional basing point for computing location adjustments at plants beyond 100 or 150 miles from such basing point would result in higher Class I and uniform base prices at outlying plants located in California that could become associated with the market. Proponents pointed out that there presently are no California plants pooled under the order and that this was not the case in 1971 when the present location adjustments were adopted for southern Oregon. Thus, proponents maintained that there is no

longer need to consider the relationship of order prices in southern Oregon to plants located outside the marketing area in northern California.

In his 1971 decision, the Assistant Secretary concluded that the Class I and uniform prices for base milk which would be applicable at plant locations outside the marketing area must appropriately reflect the value of milk at such locations relative to its value f.o.b. the marketing area. These findings are equally pertinent to the current marketing situation. To provide location adjustments which would increase the price structure at outlying northern California plants would distort the existing price alignment among competing regulated and non-regulated plants which is essential for continuing orderly marketing in the region. Thus, to increase Class I prices at plants located in northern California, as advocated by proponents, could only have the effect of limiting outside handlers access to the regulated market.

In view of the foregoing considerations, it is concluded that the general pattern of location pricing in the Oregon-Washington order must be maintained both at the handler and producer level. Accordingly, the proposals to add Medford as a basing point and to extend the base zone to 150 miles from either Portland, Eugene, or Medford, which in effect would eliminate all location pricing in the marketing area except at certain plants in southeastern Washington, are denied.

Notwithstanding, some modification of the location adjustments applicable in the southern Oregon counties of Jackson and Josephine is appropriate. It is concluded that in this area the present maximum 20 cent adjustment should be revised to a maximum 10 cent adjustment.

At the time of the hearing, there were five pool plants located in the two county area, four in the Medford area and one at Grants Pass. Presently, a 20 cent per hundredweight location adjustment applies at Medford and a 19.5 cent rate at Grants Pass.

The five handlers located in the two-county area compete with a handler located at Roseburg for both milk supplies and sales. No location adjustment applies at the latter handler's plant since it is in the base zone. The Roseburg plant is located about 71 miles south of the Eugene basing point and 68 and 96 miles from Grants Pass and Medford, respectively.

A substantial part of the milk supply for the Roseburg handler is obtained from dairy farmers located in the Grants Pass area. Also, this production area is a major source of milk supplies for the nearby Grants Pass–Medford handlers. The relationship of the price structure at plants located in or near this supply area with the Roseburg plant price is thus an important consideration.

Using the 1.5-cent per 10 mile transportation rate as a measure of price alignment which is generally used as an indicator of the cost of bulk movements of milk, the present price in the Roseburg area relative to the price in either Grants Pass or Medford appears to provide producers in the Grants Pass supply area with a more remunerative market than is the case if such producers deliver to nearby plants. In this connection if producers delivering to the Grants Pass-Medford plants in the location adjustment areas shipped their milk instead to the Roseburg area at which no location adjustments apply, they would incur additional increased hauling costs of about 10 cents per hundredweight. The present order, however, provides a unform price for base milk 20 cents higher for delivery to a plant in the Roseburg area than in the Grants Pass-Medford area. For producers who have a choice of outlets, there thus is an economic incentive to ship to the Roseburg area plant rather than to Grants Pass-Medford area plants. There is little doubt that this has occurred without regard to need for fluid milk supplies at the Roseburg location since considerable volume of this milk also is moving to manufacturing outlets. If this situation is allowed to continue, it could, over time jeopardize an adequate supply of milk for handlers in the two county area.

Accordingly, limiting the location adjustment applicable to plants in the Grants Pass-Medford area to ten cents, as herein provided, appears reasonable under existing circumstances and will more appropriately reflect the value of milk at such location in relation to the nearby plant where no location adjustment applies.

Testimony suggests that certain other areas of the Oregon portion of the marketing area also might warrant a reconsideration of location adjustments, particularly in the Bend-Redmond area. The record evidence in this regard was not compelling.

3. *Partial payments to producers.* The order should provide that all handlers be required to make partial payments to producers, or to cooperative associations that collect for their members, for producer milk delivered during the first 15 days of the month. Such payments to individual producers should be made on or before the last day of the month. Payments to cooperative associations should be made two days earlier. The rate of payment should be not less than the Class III price for the preceding month.

The order does not now provide for partial payments to producers. Most handlers in the market, however, make some form of partial payments to individual producers. The rates, time of payment and other aspects of such payments vary among handlers.

The three cooperative associations of the OWMI federation proposed partial payments to producers, or to a cooperative association(s) authorized to collect payments for milk of their member producer deliveries. They proposed that the rate of payment be the Class III price for the preceding month.

This proposal was supported by Mayflower Farms, a producer organization (a non-cooperative association) and a proprietary handler. There was no opposition to the proposal.

In support of the proposal, various spokesmen stated that most of the handlers in the market presently make partial payments in varying degrees to individual producers and cooperative associations. They stated, however, that there are a few handlers who do not make such payments for producer milk which cooperatives cause to be delivered to their respective pool plants as a bulk tank handler. The witnesses pointed out that even though the cooperatives do not receive partial payments on such milk they nevertheless pay a partial payment to all their member producers. This, it was contended, places an additional financial burden on cooperative associations and in effect provides a subsidy to those handlers who purchase part or all of their producer milk in this manner. In further support of their proposal, proponents argued that a uniform partial payment plan to producers and cooperative associations under the order will eliminate certain handler inequities that now exist under the present voluntary partial payment practices in the market.

Provisions requiring handlers to make partial payments to producers each month are customarily included in Federal milk orders. Such provisions assure producers supplying the market a uniform and more orderly system of partial payments, and reduce the period they must wait to be reimbursed in part for their milk sales.

With the diversity of partial payment practices existing in the Oregon-Washington market, producers supplying the market can not be assured of a regular partial payment schedule for milk delivered during the first part of the month. Under current milk production practices, producers require substantial operating capital. They must make substantial cash outlays during the month and have the ready cash available to meet such obligations. Requiring handlers to make regular and uniform partial payments for milk delivered during the first part of the month will improve the ability of producers to meet their financial obligations during the month.

Partial payment provisions, as herein adopted, also provide handlers with a uniform payment procedure. As indicated, many of these handlers in the market presently are making some form of partial payments to producers. Such payment practices among handlers, however, vary considerably because of their voluntary nature. Such variation in payment practices, can result in certain handlers who make partial payments being financially disadvantaged over others who take a longer period in accumulating the necessary funds for the purchase of their milk. This contributes to market disorder by affecting the competitive position of handlers in the market.

Requiring a handler to make partial payments to producers for milk he receives during the first half of the month, is not unreasonable. When only a final settlement for producer milk is required, payable by the 16th of the next

month, any handler not making partial payments has had the use of the money resulting from its sale for up to 45 days.

In view of these considerations, greater equity among producers and handlers can be achieved by requiring mandatory partial payments for producer milk.

The rate of partial payment should be not less than the Class III price for the preceding month. No adjustment should be made for butterfat content or plant location. Use of the Class III price for the previous month in making the partial payment will minimize the possibility of any overpayments on the part of a handler. The proposal of Mayflower Farms to use a partial payment rate of 120 percent of the Class III price for the preceding month is denied since its use could result in incidence of overpayments by handlers.

Proponents suggested that handlers be required to make partial payments directly to producers. Presently, handlers under the order are required to make a single payment to the market administrator reflecting the total value of their milk according to its use classification. The market administrator then pays individual producers or their cooperatives. For those producers who are under the Oregon State Quota Plan, the payments due such participating quota producers are paid to the State for redistribution to individual producers in accordance with the Plan.

No substantial purpose would be served in requiring that monies for partial payments to producers be channeled through the market administrator. Such a procedure likely would only delay a producer's receipt of the partial payment. Accordingly, it should be provided that partial payments be paid by such handlers directly to producers and/or cooperative associations.

A handler should be required to make partial payment only to producers who have not discontinued delivery of milk to the handler as of the 15th day of the month. This will essentially remove any possibility of over payments.

The order should provide that partial payments to a cooperative association, either in its capacity as the marketing agent of the producer or in its capacity as a bulk tank handler, be made at least two days prior to the last day of the month. This procedure is necessary in order that a cooperative will have the monies in hand to pay its members on the same dates that other producers are paid.

4. *Charges on overdue obligations.* The current charge on overdue payment obligations should be increased to three-fourths of 1 percent. Such charge should be applied on the first day that a payment is overdue and shall be increased by three-fourths of 1 percent on the 1st day of each succeeding month until the obligation is paid.

The order now applies a charge of one-half of 1 percent per month on handler obligations to the market administrator that are overdue. Such obligations include those due the producer-settlement fund, the administrative expense fund, and the marketing service fund, all of which are maintained by the market administrator. Currently, the late payment charge does not apply until the beginning of the first month following the date that the payment was due. Unpaid obligations, including late payment charges are further increased by one-half of 1 percent on the first day of each succeeding month until the obligations are paid.

The three cooperative associations of the OWMI federation proposed that the charge on overdue obligations be increased to at least three-fourths of 1 percent, to be applied on the fourth day following the due date of such obligation and at a similar rate on the first day of each month thereafter until the entire obligation is paid. At the hearing, proponents modified their proposal as it appeared in the hearing notice to require that a handler's unpaid obligation be increased at least three-fourths of one percent on the fourth day after the due date and on the same day of each month thereafter.

Another cooperative association supported an increase in the late payment charge to three fourths of 1 percent per month. This association proposed, however, that the late payment charge be applied on the 3rd day after the due date of such obligation.

In support of a late payment charge of three-fourths of 1 percent per month and advancing the date in which such charge should apply, witnesses for the four cooperative associations indicated that such changes are necessary to encourage prompt payment of obligations to the market administrator by regulated handlers. Witnesses stressed that late payments by handlers are a serious problem in the market and have impeded the ability of the market administrator to make required payments from the producer settlement fund on time, thus necessitating a delay in payments to certain producers in the market.

Proponents argued that the present charge on overdue obligations as provided by the order is not encouraging prompt payment of handler obligations but rather is providing a situation wherein some handlers are finding it to their financial advantage to delay payment obligations to the market administrator as a means of obtaining additional operating capital. This, they pointed out, creates an inequitable situation among handlers in the market since those handlers who are delinquent in their payments can have a substantial financial advantage over handlers who make timely payments to the market administrator.

The position of proponent cooperatives regarding charges on overdue obligations was supported by one other cooperative associated with the market, a proprietary handler and two producer groups (non-cooperative associations).

It is essential that payments to the funds maintained by the market administrator be made promptly so that the order may be administered in an efficient and timely manner. The successful operations of a Federal milk order depends, in large measure, upon prompt compliance by all regulated parties. The order provides for a sequence of dates that must be met by a handler that enables the market administrator to execute producer payments on schedule. Failure on the part of a handler to meet such due dates, including the payment due dates, is unfair to producers and other handlers and undermines the confidence which handlers and producers have in the program.

Prompt payment of amounts due the administrative expense and marketing funds, also, is essential to the performance by the market administrator of the various administrative functions prescribed by the order in a timely and efficient manner.

The charge on overdue accounts and the date that charges on overdue obligations apply are designed to encourage prompt settlement of accounts. The rate of charge, however, must be such that it does not provide an incentive for handlers to use producer money as a source of credit. Moreover, it is not reasonable to provide a grace period which can only encourage a delay in payments due the market administrator beyond the due date.

In this market, all handlers are required to make payments to the market administrator for the total value of all their milk according to its classification. The market administrator then pays individual producers or cooperative associations who do not participate in the Oregon Quota Plan.[1] With respect to producers participating in the Oregon quota plan (thus authorizing the State to collect for them) the market administrator pays the State the total amount otherwise due each participating quota producer. The State, in turn, settles with such producers and cooperative associations in accordance with the terms of the Oregon plan.

The market administrator usually mails handlers' billings on the 14th day of the month, following the month the transactions were made. This is the date he is required under the terms of the order to announce the uniform prices. If the 14th falls on a Saturday or Sunday the billings are mailed either the prior Friday or the following Monday, depending upon the extent that handler reports are available to the market administrator at the time. It should be noted, however, that since each handler's obligation to the market administrator reflects the full use value of his milk the uniform price announcement is not a necessary condition to the mailing by the market administrator of handler's billings. Hence, such billing reasonably can be issued promptly following receipt of a handler's report.

The due date for payment of handlers' obligations to the market administrator is the 16th and the market administrator in turn is required to make payments to individual producers by the 20th and two

[1] The Oregon quota plan is discussed in more detail elsewhere in these findings.

days earlier (18th) for such payments that are made to cooperative associations and to the State. Under the current provisions of the order, a handler has at least 14 days after the due date to make payment to the market administrator, from the 16th to the 30th or 31st of the month before he incurs a late payment charge. Since the current provisions do not specify what is considered as the date of payment—i.e., the postmark date of mailing, or the date payment actually is received in the market administrator's office, the postmark has been accepted as the "date of receipt."

Any handler, therefore, who posts his payment in the mail just prior to the first of the month following the due date incurs no additional charge. In such circumstances, he has the continued use of producer monies and is indemnified by the prolonged grace period presently allowed.

It is quite evident that the incidence of late payments by handlers is a serious problem and that the present order provisions as they relate to charges on overdue obligations are not achieving their desired purpose. Data submitted in evidence by the market administrator detailed the payment practices of 43 handlers required to make payments to the producer settlement and administrative funds during each of the six months, July through December 1975. During the six month period there were 258 payments made by the 43 handlers to the market administrator. For this period, only 63 percent of handler payments were received by the market administrator from the 16th through the 20th during such period ranged from 54 to 70 percent. During the next five day period (21st through the 25th payments were received during the 6-month period from 26 percent of the handlers. During the two periods of the 26th through the 30th, and the 31st (when applicable), and the 1st of the following month through the 3rd, payments from an average of 3 handlers in each period were received by the market administrator.

In terms of money owed, the payment delinquency experience for this period was a little better. For the same six month period, 73 percent of the total value of handler payments were received by the market administrator between the 16th and 20th of the month. The market administrator cannot be expected to make full payments to producers, cooperatives, and/or the State, whichever the case may be, if all payments from handlers are not available to him on the dates such payments are required to be made—i.e., the 18th to cooperatives and the State, and the 20th to individual producers. To accommodate to such payment delinquencies, the market administrator withholds funds from the particular producer(s) who supply a delinquent handler until such handler submits payment for his order obligations.

The current provisions for late payment charge, therefore, have had little impact in encouraging prompt handler payments. Since payments apparently are made in time to avoid a late charge in the majority of circumstances, the increase in the rate on overdue obligations as adopted herein reasonably can be expected to increase the flow of money to the market administrator and thus to implement final payment to producers on the prescribed payment dates.

Because of the extent of the late payment problem that has persisted in the market, it is appropriate that charges on overdue obligations apply on the first day that such obligation is overdue. Further, any such overdue obligation should be increased by three-fourths of 1 percent on the first day of each succeeding month until the obligation is paid.

A late payment charge of this amount should apply irrespective of whether the obligation is paid three or four days late or nearly a month late. If the late payment charge were treated as interest and computed on a daily basis, the order would merely represent a banking service for handlers who desire to use producer funds as an alternative source of money at the going interest rate. This is not the intended purpose of the late payment charge. Rather, it is a charge that will induce handlers to pay their obligations to the market administrator on time.

Proponents' proposal to provide either a 3 or 4 day grace period for payment to reach the market administrator could not achieve the objective sought.

The application of the late payment charge on the day following the date when payment is due may require some adjustment in the billing procedures of the market administrator to handlers. In this connection, the market administrator may need to reduce the period customarily taken to notify a handler of his monthly obligations so that the handler in turn will have sufficient time to mail the payment by the due date. This adjustment can be accomplished within the framework of the existing order and thus requires no amendatory action.

### Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

### General Findings

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) The tentative marketing agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreement and the order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, a marketing agreement upon which a hearing has been held.

### Recommended Marketing Agreement and Order Amending the Order

The recommended marketing agreement is not included in this decision because the regulatory provisions thereof would be the same as those contained in the order, as hereby proposed to be amended. The following order amending the order, as amended, regulating the handling of milk in the Oregon-Washington marketing area is recommended as the detailed and appropriate means by which the foregoing conclusions may be carried out:

1. In § 1124.11, paragraphs (a) and (b) are revised as follows:

**§ 1124.11 Producer.**

* * * * *

(a) A cooperative association may divert for its account to a nonpool plant the milk of any producer whose milk has been received previously at a pool plant and from whom at least one delivery per month during each of the months of September, October and November is received at a pool plant, except that in the case of any producer whose milk has not been received at a pool plant for at least one day during each of the preceding months of September–November such producer shall be required to have at least one delivery of his milk received at a pool plant in any month to qualify his milk for diversion during such month. This delivery requirement for diversion purposes shall continue until such producer's milk has been received at a pool plant for three consecutive months beginning during or after the September–November period. The aggregate quantity diverted may not exceed the aggregate quantity received during the month from all such producers at pool plants. Two or more cooperative associations may have their allowable diversions computed on

the basis of the combined deliveries of milk by their member producers if each association has filed such a request in writing with the market administrator on or before the first day of the month such agreement is effective. This request shall specify the basis for assigning any over-diverted milk to the producer members of each cooperative association according to a method approved by the market administrator.

(b) A handler in his capacity as the operator of a pool plant may divert for his account to a nonpool plant the milk of any producer whose milk has been received previously at a pool plant and from whom at least one delivery per month during each of the months of September, October, and November is received at his pool plant(s) and who is not a member of a cooperative association which is diverting milk pursuant to paragraph (a) of this section during the month, except that in the case of any producer whose milk has not been received at a pool plant for at least one day during each of the preceding months of September–November such producer shall be required to have at least one delivery of his milk received at a pool plant in any month to qualify his milk for diversion during such month. This delivery requirement for diversion purposes shall continue until such producer's milk has been received at a pool plant for three consecutive months beginning during or after the September–November period. The aggregate quantity diverted may not exceed the aggregate quantity received during the month from all producers at his pool plant(s);

* * * * *

2. In § 1124.52, paragraph (a) is revised as follows:

**§ 1124.52 Location adjustment to handlers.**

(a) The Class I price for producer milk and other source milk (for which a location adjustment is applicable) at a plant 100 miles or more from the nearer of the Multnomah County Court House in Portland, Oreg., or the city hall in Eugene, Oreg., by the shortest hard-surfaced highway distance as determined by the market administrator, shall be reduced 15 cents and an additional 1.5 cents for each 10 miles or fraction thereof that such distance exceeds 110 miles: *Provided,* That the location adjustment applicable at a plant located 100 miles or more from the nearer of such basing points but within the Oregon counties of Clatsop, Coos, Douglas, Jackson, Josephine, Lane, Lincoln, and Tillamook shall be not more than 10 cents and the location adjustment applicable at a plant located elsewhere in the marketing area or in Grant County, Wash., shall not be more than 20 cents; and

* * * * *

**§ 1124.62 [Amended]**

3. In § 1124.62 *Obligations of handler operating a partially regulated distributing plant,* the reference "1124.81(b)" in paragraph (a)(1)(i) is changed to "§ 1124.81(c)".

4. Section 1124.81 is revised as follows:

**§ 1124.81 Payments to the producer-settlement fund.**

On or before the 16th day after the end of each month, each handler shall pay to the market administrator his net pool obligation computed pursuant to § 1124.70, less:

(a) Payments made pursuant to § 1124.82a;

(b) The amount of the deductions and payments authorized by individual producers or cooperative association which are itemized on the handler's producer payroll; and

(c)(1) The value at the weighted average price computed pursuant to § 1124.71 (a) applicable at the location of the plant(s) from which received (not to be less than the Class III price) with respect to other source milk for which values are computed pursuant to § 1124.70(e); and

(2) In the calculation of the total amount of the deductions and charges to be subtracted, the deductions and charges to be considered with respect to each individual producer shall not be greater than the total value of the milk received from such producer.

**§ 1124.82 [Amended]**

5. In § 1124.82 *Payments from the producer-settlement fund,* the reference to "§ 1124.81(a)" in paragraph (a) is changed to "§ 1124.81 (a) and (b)".

6. A new § 1124.82a is added as follows:

**§ 1124.82a Partial payments to producers and to cooperative associations.**

(a) On or before the last day of each month, each handler shall make payment, subject to paragraph (b) of this section, to each producer, who had not discontinued shipping milk to such handler before the 15th day of the month, for milk received from such producer during the first 15 days of the month, at not less than the Class III price per hundredweight for the preceding month;

(b) In making payments to producers pursuant to paragraph (a) of this section, each handler, on or before the second day prior to the date specified in such paragraph, shall pay to each cooperative association that so requests for those producers for whom it markets milk and who are certified to the market administrator by the cooperative association as having authorized the cooperative association to receive such payment an amount equal to the sum of the individual payments otherwise due such producers pursuant to paragraph (a) of this section; and

(c) On or before the second day prior to the last day of the month, each handler shall make payment to a cooperative association for milk received from such association in its capacity as a handler described in § 1124.7 (c) and (d) for milk received during the first 15 days of the month at not less than the Class III price for the preceding month.

**§ 1124.83 [Amended]**

7. In § 1124.83 *Location differentials to producers and on nonpool milk,* the reference "§ 1124.81(b)" in paragraph (b) is changed to "§ 1124.81(c)".

8. In § 1124.85, paragraph (b) is revised as follows:

**§ 1124.85 Adjustment of accounts.**

* * * * *

(b) Any unpaid obligation of a handler pursuant to §§ 1124.81, 1124.86, and 1124.87, or paragraph (a) of this section, including any obligation incurred under this paragraph, shall be increased three-fourths of 1 percent on the next day following the due date of such obligation and at a similar rate on the first day of each month thereafter until paid.

Signed at Washington, D.C., on July 1, 1976.

WILLIAM T. MANLEY,
*Deputy Administrator,*
*Program Operations.*

[FR Doc.76-19509 Filed 7-6-76;8:45 am]

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## Farmers Home Administration

## [7 CFR Part 1861]

[FmHA Instruction 451.5]

## SERVICING OF COMMUNITY PROGRAM LOANS AND GRANTS

### Proposed Miscellaneous Amendments

Notice is hereby given that the Farmers Home Administration has under consideration the proposed amendments of § 1861.81 and various paragraphs of §§ 1861.82, 1861.85 and 1861.93 of Subpart F of Part 1861, Title 7, Code of Federal Regulations (37 FR 15502). The proposed amendments are as follows: § 1861.81 will be amended to include Community Facility loans and industrial development grants. Section 1861.82, paragraph (e)(1)(v) is amended to update the cross-reference to Part 1823 of this Chapter pertaining to proposed development work; § 1861.85, paragraph (b)(2) is amended to permit loans to be transferred to public bodies at the same interest rate as the original loan; § 1861.93(a) is amended to require the State Director to determine the value of security when facilities are to be merged.

Interested persons are invited to submit written comments, suggestions or objections to the Chief, Directives Management Branch, Farmers Home Administration, U.S. Department of Agriculture, Room 6316, South Building, Washington, D.C. 20250, on or before August 6, 1976.

All written submissions made pursuant to this notice will be made available for public inspection at the office of the Chief, Directives Management Branch during regular business hours. (8:15 a.m.–4:45 p.m.)

As proposed, the amendments to § 1861.81, § 1861.82 paragraph (e)(1)(v), § 1861.85 paragraph (b)(2) and § 1861.93 (a) read as follows:

1. Section 1861.81 is revised as follows:

**§ 1861.81 Purpose.**

This Subpart prescribes the policies, authorizations, and procedures for servicing the following: Community water and waste disposal system loans and

grants, community facility loans, comprehensive water and sewer planning grants, industrial development grants, loans for grazing and other shift-in-land use projects, association recreation loans, community irrigation and drainage loans, watershed loans and advances, resource conservation and development loans, economic opportunity cooperative loans, loans to Indian tribes and tribal corporations, and loans to timber development organizations. Servicing will be directed toward assisting the borrower to meet the objectives of the loan, repaying loans on schedule, complying with agreements, and protecting the Farmers Home Administration's (FmHA) financial interest.

2. Section 1861.82(e)(1)(v) is revised as follows.

**§ 1861.82 Loan servicing.**

* * * * *

(e) * * *

(1) * * *

(v) Any proposed development work will be planned and performed in accordance with §§ 1823.21 through 1823.33 of this Chapter or in a manner which reasonably attains the objectives of Subpart A, Part 1823 of this Chapter.

* * * * *

3. Section 1861.85(b)(2) is revised as follows:

**§ 1861.85 Transfer of security and assumption of loans.**

* * * * *

(b) * * *

* * * * *

(2) If the interest rate or terms of the loan are changed, Form FmHA 460–5, "Assumption Agreement (New Terms)," will be executed by the transferee. The new repayment period may not exceed the repayment period for a new loan of the type involved. If the current interest rate for such loans is higher than the rate specified in the note(s) being assumed, the current rate will apply, except in cases of transfers to public bodies and mergers.

* * * * *

4. Paragraph (a) of § 1861.93 is revised to read as follows:

**§ 1861.93 Determining present market value.**

(a) The value of security to be subordinated, sold, merged, transferred, voluntarily conveyed, or foreclosed under this Subpart will be determined by the State Director as follows:

* * * * *

(7 U.S.C. 1989, 42 U.S.C. 2942, delegation of authority by the Secretary of Agriculture, 7 CFR 2.23, delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70, delegations of authority by Director, OEO 29 FR 14764, 33 FR 9850)

Dated: June 29, 1976.

FRANK B. ELLIOTT,
*Administrator,*
*Farmers Home Administration.*

[FR Doc.76-19508 Filed 7-6-76;8:45 am]

## CONSUMER PRODUCT SAFETY COMMISSION

[ 16 CFR Part 1201 ]

### ARCHITECTURAL GLAZING MATERIALS

**Extension of Time for Issuance of Safety Standard or Withdrawal of Notice of Proceeding**

The purpose of this notice is to extend from June 11, 1976, until December 1, 1976 the period in which the Consumer Product Safety Commission must publish in the FEDERAL REGISTER a final consumer product safety standard for architectural glazing materials or a notice withdrawing the notice of proceeding for the development of a standard.

On June 20, 1973 the Consumer Safety Glazing Committee (CSGC) petitioned the Commission under section 10 of the Consumer Product Safety Act (15 U.S.C. 2059) to commence a proceeding for the development of a consumer product safety standard to address the hazards associated with architectural glass.

On November 1, 1973, the Commission, on the basis of information submitted by CSGC, consideration of reported injury data, and review of data and information gathered by the National Commission on Product Safety, granted CSGC's petition. Thereafter, a standard development proceeding applicable to architectural glass was commenced under section 7 of the Consumer Product Safety Act by notice in the FEDERAL REGISTER of May 28, 1974 (39 FR 18502), soliciting offers to develop a recommended consumer product safety standard or submission of previously existing standards for consideration as a proposed standard. The Commission subsequently accepted the offer of CSGC which submitted a recommended standard to the Commission on January 24, 1975. After some modification to the recommended standard, the Commission published for comment in the FEDERAL REGISTER of February 11, 1976 (41 FR 6178) a proposed standard for materials whose name, commencing with the February 11, 1976 proposal, had been changed from architectural glass to architectural glazing materials. A more detailed discussion of the history of the development of this proposed standard appears in the FEDERAL REGISTER of February 11, 1976.

The Commission has of this date received 50 written comments on the proposed standard, and 8 oral presentations concerning the proposal were made. The Commission staff has been reviewing and analyzing all the comments. However, in order for the Commission to adequately examine the comments and the responses thereto and to consider a number of complex issues that have been raised in the comments, the Commission in the FEDERAL REGISTER of April 15, 1976 announced the extension of the period in which it must either issue a final consumer product safety standard for architectural glazing materials, or withdraw the notice of proceeding by 60 days or until June 11, 1976.

In the course of the ongoing process of review and analysis of the entire public record by the Commission staff and in view of the complexity and variety of the technical issues which have been raised, the Commission has determined that it is necessary to additionally extend the period in which it must either issue a final standard, or withdraw the notice of proceeding until December 1, 1976. This period may be further extended by a notice published in the FEDERAL REGISTER showing good cause.

Dated: July 1, 1976.

SADYE E. DUNN,
*Secretary, Consumer Product Safety Commission.*

[FR Doc.76-19541 Filed 7-6-76;8:45 am]

## FEDERAL HOME LOAN BANK BOARD

[ 12 CFR Parts 563 and 570 ]

[No. 76-474]

### PENSION PLANS AND SERVICE CORPORATIONS

**Proposed Rulemaking**

JUNE 30, 1976.

The Federal Home Loan Bank Board, by Resolution No. 75-440, dated May 19, 1975, proposed to revoke its ruling set forth in § 570.2 of the Rules and Regulations for Insurance of Accounts (12 CFR 570.2) and restate it, with proposed amendments, as a regulation to be designated § 563.40 of said Rules and Regulations. These proposed amendments were published in the FEDERAL REGISTER on August 18, 1975 (40 FR 34614–15), for public comment until September 19, 1975. On the basis of public comments received on the proposal, and consideration of other relevant material available, the Board considers it desirable to issue a substantially revised proposal in this area.

The Board's May 19th proposal essentially restated Board Ruling 570.2 (effective since November 24, 1959), but would have permitted the board of directors of an insured institution to grant cost-of-living increases to retired employees. Enactment of the Employee Retirement Income Security Act of 1974 (ERISA) and amendments thereby made to the Internal Revenue Code of 1954 (IRC), however, required major changes in insured institutions' pension plans which appear to require revision of the Board's proposed regulations to provide greater flexibility to plan administrators in conforming to these statutory changes.

This new proposal would change the heading "Pension, retirement, and deferred compensation plans and contracts" to "Pension plans" and make the following substantive changes: (1) Service corporations would be included under the regulatory requirements; (2) plan funding methods authorized under ERISA and IRC provisions would be allowed; (3) plan termination, although permitted, would not be required to be without obligation, and would require prior notice to the Corporation; (4) contingent liability coverage, upon avail-

ability thereof, would be required in form acceptable to the Corporation; (5) provision for termination in the event of default of the institution would be deleted; and (6) a recordkeeping requirement would be added for plans not covered by ERISA and IRC recordkeeping and reporting requirements. These proposed revisions are discussed in greater detail below.

Paragraph (a) of this proposal would continue to permit all plans which are consistent with safe and sound practices. The Board's decision to extend coverage of the proposal to include service corporations reflects its view that soundness in establishing and maintaining such plans by service corporations is important to the safety of their insured institution parents.

Proposed paragraph (b), amount and funding of obligation, would substantially depart from Board Ruling 570.2 and the previous proposal, which severely limited methods available for funding actuarial liability, because they required that plans be funded either at the outset or over the course of a participant's normal period of employment. To provide greater flexibility in plan administration, the Board proposes to allow use of any actuarial cost method permitted under ERISA and the IRC. However, with the exception of insurance contract plans, all plans which incur past service liability, whether upon plan adoption or amendment, would be required to amortize such liability over a period of 10 plan years.

Paragraph (c), regarding plan amendments granting annual cost-of-living increases to retired plan participants, has been clarified to reflect the Board's intent that any such increase not exceed the annual increase in the Consumer Price Index as published by the Bureau of Labor Statistics.

Paragraph (d) would permit the board of directors of an insured institution or service corporation to terminate a plan or contract, but differs from Board Ruling 570.2 and the prior proposal in deleting the requirement that all obligations not previously fully funded also be terminated, since this provision is inconsistent with ERISA. This paragraph would also require that notice of plan termination be given to the Corporation 60 days before the proposed termination date, since under certain conditions an insured institution or service corporation terminating an underfunded ERISA-qualified plan could incur liability in an amount up to 30% of its net worth to the Pension Benefit Guarantee Corporation (PBGC). To protect against such liabiilty, proposed paragraph (e) would require maintenance of contingent liability coverage, once such coverage becomes available, either through the PBGC or a private insurer, in a form acceptable to the Corporation.

The provision regarding institutional default, set forth in paragraph (d) of the prior proposal and in Board Ruling 570.2, would be deleted as inconsistent with ERISA requirements.

Paragraph (f), as proposed, would add a recordkeeping requirement only for plans of institutions and service corporations not subject to ERISA and IRC recordkeeping and reporting requirements.

Interested persons are invited to submit written data, views and arguments to the Office of the Secretary, Federal Home Loan Bank Board, 320 First Street NW., Washington, D.C. 20552, by August 9, 1976, as to whether the proposal should be adopted, rejected, or modified. Written material submitted will be available for public inspection at the above address.

Accordingly, the Board hereby proposes to revoke § 570.2 and adopt a new § 563.40 to read as set forth below.

1. Add new § 563.40 to read as follows:

**§ 563.40 Pension plans.**

(a) *General.* No insured institution or service corporation thereof shall sponsor a pension plan which, because of unreasonable costs or any other reason, could lead to material financial loss or damage to the insured institution or service corporation. The prospective obligation or liability of the insured institution or service corporation to each participant shall be stated in or determinable from the plan.

(b) *Funding.* Actuarial cost methods permitted under the Employee Retirement Security Act of 1974 and the Internal Revenue Code of 1954, as amended, shall be used to determine plan funding: *Provided, however,* That any past service liability incurred must be amortized within 10 plan years, unless such plan is an insurance contract plan.

(c) *Plan amendment.* A plan may be amended to provide reasonable annual cost-of-living increases to retired participants: *Provided, however,* That:

(1) Any such increase shall be for such period and amount as determined by the institution's or service corporation's board of directors, but in no event shall an annual increase be greater than the annual increase in the Consumer Price Index as published by the Bureau of Labor Statistics; and

(2) No increase shall be granted unless (i) charges to net income for prior periods have first been found to be reasonable by the insured institution's or service corporation's board of directors as documented by appropriate resolution and supporting analysis; and (ii) such increase will not reduce the institution's net worth below the level required by § 563.13(b).

(d) *Termination.* The plan shall permit the institution's or service corporation's board of directors and its successors to terminate such plan: *Provided, however,* That notice of intent to terminate shall be filed with the Corporation at least 60 days prior to the proposed termination date.

(e) *Contingent, liability coverage.* Upon availability thereof, contingent liability coverage for losses arising from plan termination shall be maintained by each insured institution and its service corporations in a form acceptable to the Corporation.

(f) *Records.* Each insured institution and service corporation thereof maintaining a plan not subject to recordkeeping and reporting requirements of the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code of 1954, as amended, shall establish and maintain records containing the following:

(1) Plan description;

(2) Schedule of participants and beneficiaries;

(3) Schedule of participants' and beneficiaries' rights and obligations;

(4) Plan's financial statements; and

(5) An opinion signed by the institution's or sevice corporation's actuary affirming that actuarial assumptions in the aggregate are reasonable, take into account the plan's experience and expectations, and represent the best estimate of such actuary as to the plan's projected experiences.

**§ 570.2 [Revoked]**

2. Revoke § 570.2 effective (date new § 563.40 becomes effective).

(Secs. 402, 403, 407, 48 Stat. 1256, 1257, 1260, as amended (12 U.S.C. 1725, 1726, 1730, Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR 1943–48 Comp. p. 1071))

By the Federal Home Loan Bank Board.

—J. J. FINN,
*Secretary.*

[FR Doc.76-19515 Filed 7-6-76;8:45 am]

# notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF THE TREASURY

### Comptroller of the Currency

### MERCHANTILE NATIONAL BANK

### Suspension of Trading

It appearing that an extension of the Order, issued June 21, 1976, suspending trading in the securities of Mercantile National Bank, Atlanta, Georgia, on the over-the-counter market is required in the public interest and for the protection of investors;

Therefore, pursuant to Sections 12(i) and 12(k) of the Securities Exchange Act of 1934, the suspension of trading in the securities of Mercantile National Bank, Atlanta, Georgia, on the over-the-counter market is hereby extended for the ten-day period commencing at midnight (EDT) on July 1, 1976, and terminating at midnight (EDT) on July 11, 1976.

Dated: July 1, 1976.

JAMES E. SMITH,
*Comptroller of the Currency.*

[FR Doc.76-19523 Filed 7-6-76;8:45 am]

## DEPARTMENT OF DEFENSE

### Department of the Army

### AD HOC STUDY TEAM ON INFLUENZA OF THE ARMED FORCES EPIDEMIOLOGICAL BOARD

### Meeting

1. In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463) announcement is made of the following Advisory Committee meeting:

*Name of committee.* Ad hoc Study Team on Influenza of the Armed Forces Epidemiological Board.

*Date of meeting.* July 13, 1976.

*Place.* Conference Room 3092, Walter Reed Army Institute of Research, Walter Reed Army Medical Center, Washington, D.C.

*Time.* 0900-1630.

*Purpose.* This notice is being published giving less than 15 days notice of the meeting. An emergency situation has been created by the vaccine field trials which indicated that some of the vaccines do not produce an adequate antibody response in persons under 25 years of age. The ad hoc Study Team is meeting to review its recommendations for immunization of military personnel in light of the new data now available from the DoD/DHEW sponsored field trials, so that DoD can begin procurement of necessary vaccine for its immunization program by September 1. The proposed agenda includes the presentation and discussion of data on epidemiological and clincal studies on the proposed A Swine vaccine in order to formulate recommedations for the military immunization program. This meeting is open to the public, but limited by space accommodations. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, DASG-AFEB, Room 1B472 Pentagon, Washington, D.C. 20310.

DUANE G. ERICKSON,
*LTC, MSC, USA,*
*Executive Secretary.*

JULY 2, 1976.

[FR Doc.76-19634 Filed 7-6-76;8:45 am]

## DEPARTMENT OF JUSTICE

### Law Enforcement Assistance Administration

### NATIONAL INSTITUTE OF LAW ENFORCEMENT AND CRIMINAL JUSTICE

### Meeting

Notice is hereby given that the Advisory Committee of the National Institute of Law Enforcement and Criminal Justice, Law Enforcement Assistance Administration, will meet on July 22, 1976 from 9:30 a.m.-5:00 p.m. at the Key Bridge Marriott Hotel, Rosslyn, Virginia.

Topics of discussion will include a briefing on Institute activities and proposed research topics for FY 77.

The meeting will be open to the public.

For further information, please contact Gerald M. Caplan, National Institute of Law Enforcement and Criminal Justice, Law Enforcement Assistance Administration, U.S. Department of Justice, 633 Indiana Avenue, N.W., Washington, D.C. 20531. (202) 376-3606.

GERALD YAMADA,
*Attorney-Advisor,*
*Office of General Counsel.*

[FR Doc.76-19668 Filed 7-6-76;8:45 am]

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

### GULF INTERSTATE ENGINEERING CO.

### Notice of Application

JUNE 29, 1976.

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185) the Gulf Interstate Engineering Company on behalf of Nikiski Alaska Pipeline Company filed an application for a right-of-way (AA-11377) to construct a 10.750-inch diameter pipeline for the purpose of transporting natural gas or any other gases, liquids or substances which can be transported through a pipeline across the following described national resource and Federal lands.

SEWARD MERIDIAN, ALASKA

T. 13 N., R. 3 W.,
Sec. 7.

The pipeline will transport petroleum products from the Nikiski Alaska Pipeline Company delivery terminal located in Block 10, Port of Anchorage subdivision to the Military Anchorage Metering Station, Fort Richardson, Municipality of Anchorage, a distance of 1,760 feet more or less.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views on this matter should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 4700 East 72nd Street, Anchorage, Alaska 99502.

ROBERT E. SORENSON,
*Authorized Officer.*

[FR Doc.76-19505 Filed 7-6-76;8:45 am]

### Bureau of Reclamation

### COLORADO RIVER BASIN SALINITY CONTROL ADVISORY COUNCIL

### Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463) announcement is made of a meeting of the Colorado River Basin Salinity Control Advisory Council at 9:00 a.m. on July 22, 1976, at the Showboat Hotel, Las Vegas, Nevada.

*Purpose of Meeting:* Council members will be briefed on the status of salinity control activities and they will finalize their recommendations for Fiscal Year 1978 activities to the involved Federal agencies.

*Proposed Agenda:* Council report and recommendations on the Salinity Control activities being conducted under Title II of the Colorado River Salinity Control Act (Public Law 93-320); status report and discussions of Paradox Valley, Grand Valley, and Las Vegas Wash Units; and discussion of Soil Conservation Service report on Colorado River basin salinity control investigations.

The meeting of the Advisory Council is open to the public.

Any member of the public may file a written statement with the Council before, during, or after the meeting. To the extent that time permits, the Council Chairman may allow public presentation of oral statements at the meeting.

All communications regarding this Advisory Council should be addressed to Mr. Robert I. Strand, Acting Chief, Water Quality Office, Bureau of Reclamation, Engineering and Research Center, P.O. Box 25007, Denver, Colorado 80225.

Dated: July 1, 1976.

G. G. STAMM,
*Commissioner of Reclamation.*

[FR Doc.76-19624 Filed 7-6-76;8:45 am]

## DEPARTMENT OF AGRICULTURE

### Forest Service

### EVANS NOTCH UNIT PLAN, WHITE MOUNTAIN NATIONAL FOREST

#### Notice of Availability of Draft Environmental Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, has prepared a draft environmental statement on the Evans Notch Unit Plan for the White Mountain National Forest, USDA-FS-R9-DES-(ADM)-76-05.

The environmental statement concerns a proposed land use plan for 51,000 acres of Forest Service land located on the White Mountain National Forest in Oxford County in the State of Maine and Carroll and Coos Counties in the State of New Hampshire.

This draft environmental statement was transmitted to CEQ on June 23, 1976.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, South Agriculture Bldg., Room 3231, 12th St. & Independence Ave., SW., Washington, D.C. 20250.

USDA, Forest Service, Eastern Region, 633 West Wisconsin Avenue, Milwaukee, Wisconsin, 53203.

USDA, Forest Service, White Mountain National Forest, Federal Building, 719 Main St., P.O. Box 638, Laconia, New Hampshire 03246.

A limited number of single copies are available upon request to Forest Supervisor, White Mountain National Forest, Federal Building, 719 Main Street, P.O. Box 638, Laconia, New Hampshire 03246.

Copies of the environmental statement have been sent to various Federal, State, and local agencies as outlined in the CEQ Guidelines.

Written comments are invited from the public, and from State and local agencies which are authorized to develop and enforce environmental standards, and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental impact involved for which comments have not been requested specifically.

Written comments concerning the proposed action and requests for additional information should be addressed to Forest Supervisor, White Mountain National Forest, Federal Building, 719 Main Street, P.O. Box 638, Laconia, New Hampshire 03246. Written comments must be received by August 23, 1976, in order to be considered in the preparation of the final environmental statement.

CURTIS L. SMITH,
*Acting Regional Forester.*

JUNE 23, 1976.

[FR Doc.76-19501 Filed 7-6-76;8:45 am]

### Office of the Secretary

### CITIZENS ADVISORY COMMITTEE ON CIVIL RIGHTS

#### Notice of Public Meeting

Pursuant to the provisions of the Federal Advisory Committee Act of October 6, 1972, (Public Law 92-463, 86 STAT. 770-776), notice is hereby given that a public meeting of the USDA Citizens Advisory Committee on Civil Rights will be held on July 27-28, 1976, Room 2-W, Administration Building, U.S. Department of Agriculture, 14th & Independence Avenue SW., Washington, D.C. 20250. The meeting will convene at 9:00 a.m. on each day and adjourn at 12:00 noon on July 28, 1976. The meeting is open to the public.

The purpose of the meeting is to discuss certain Equal Opportunity matters with USDA officials.

Further information concerning this meeting may be obtained by contacting the Director, Office of Equal Opportunity, USDA, Washington, D.C. 20250. Interested persons may file written statements with the committee before or after the meeting.

Done at Washington, D.C. this 21st day of June 1976.

MILES S. WASHINGTON, Jr.,
*Acting Director,*
*Office of Equal Opportunity.*

[FR Doc.76-19507 Filed 7-6-76;8:45 am]

### Packers and Stockyards Administration

### OVERLAND STOCKYARDS, ET AL.

#### Deposting of Stockyards

It has been ascertained, and notice is hereby given, that the livestock markets named herein, originally posted on the respective dates specified below as being subject to the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 et seq.), no longer come within the definition of a stockyard under said Act and are, therefore, no longer subject to the provisions of the Act.

| *Facility No., name and location of stockyard* | *Date of posting* |
|---|---|
| CA-130 Overland Stockyards, Hanford, Calif. | Nov. 3, 1959. |
| IA-183 Marshalltown Livestock Auction, Inc., Marshalltown, Iowa. | May 22, 1959. |
| OR-117 Ontario Livestock Commission, Inc., Ontario, Oreg. | Jan. 27, 1938. |
| SD-119 Volmer Livestock Auction, Fort Pierre, S. Dak. | Sept. 30, 1967. |
| UT-102 J-B Land Company, North Salt Lake, Utah. | Aug. 6, 1968. |

Notice or other public procedure has not preceded promulgation of the foregoing rule. There is no legal justification for not promptly deposting a stockyard which is no longer within the definition of that term contained in the Act.

The foregoing is in the nature of a rule relieving a restriction and may be made effective in less than 30 days after publication in the FEDERAL REGISTER. This notice shall become effective upon publication in the FEDERAL REGISTER.

(42 Stat. 159, as amended and supplemented; 7 U.S.C. 181 et seq.)

Done at Washington, D.C., this 30th of June 1976.

EDWARD L. THOMPSON,
*Chief, Registrations, Bonds, and Reports Branch, Livestock Marketing Division.*

[FR Doc.76-19555 Filed 7-6-76;8:45 am]

## DEPARTMENT OF COMMERCE

### Economic Development Administration

### NATIONAL PUBLIC ADVISORY COMMITTEE ON REGIONAL ECONOMIC DEVELOPMENT

#### Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463) and section 8b(1) of OMB Circular No. A-63, announcement is made of the following Committee Meeting:

Name: National Public Advisory Committee on Regional Economic Development.

Date: August 3, 1976.

Place: The Fairmont Hotel, San Francisco, California.

Time: 9:00 a.m.

Purpose of Meeting: The Committee will review draft recommendations submitted by the Subcommittees on: (1) Financial Tools for Economic Development; (2) Policy and Program Conflicts between Public Development Programs; (3) Manpower.

The meeting of the Advisory Committee is open to the public. Any member of the public is permitted to file a written statement with the Committee, before or after the meeting. To the extent that time permits, the Committee Chairman or the Committee may permit oral statements by members of the public to be presented at the meeting.

All communications in regard to this meeting of the Advisory Committee should be addresed to Miss Marina Gentilini, Office of the Deputy Assistant Secretary for Economic Development, Economic Development Administration, Department of Commerce, Room 7814, 14th Street and Constitution Avenue, Washington, D.C. 20230, telephone 202-377-5059 or 377-3241.

J. W. EDEN,
*Acting Assistant Secretary for Economic Development.*

JUNE 30, 1976.

[FR Doc.76-19517 Filed 7-6-76;8:45 am]

### National Bureau of Standards

## FEDERAL INFORMATION PROCESSING STANDARDS COORDINATING AND ADVISORY COMMITTEE

### Meeting

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. IV, 1974), notice is hereby given that the Federal Information Processing Standards Coordinating and Advisory Committee (FIPSCAC) will hold a meeting from 9:00 a.m. to 1:00 p.m. on Thursday, August 26, 1976, in Dining Room C, Administration Building, of the National Bureau of Standards, in Gaithersburg, Maryland.

The purpose of the meeting is to review the actions of the Federal Information Processing Standards (FIPS) Task Groups and to consider other matters relating to Federal Information Processing Standards.

The public will be permitted to attend, to file written statements, and, to the extent time permits, to present oral statements. Persons planning to attend should notify Robert E. Rountree, Jr., Institute for Computer Sciences and Technology, National Bureau of Standards, Washington, D.C. 20234 (phone 301–921–3157).

Dated: June 30, 1976.

JOHN D. HOFFMAN,
*Acting Director.*

[FR Doc.76–19474 Filed 7–6–76;8:45 am]

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# DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

[Docket No. 76N–0208]

## PERMITTED USES OF CHLORINE IN FOOD PROCESSING

### Invitation To Submit Data, Information, and Views

The Food and Drug Administration (FDA) is requesting the submission of data, information, and views on the safety and use of chlorine in food processing. These data and information will be used to determine which conditions of use of chlorine are generally recognized as safe (GRAS) and functional in the processing of fruits and vegetables, meats, poultry, and fish and shellfish. Available data, information, and views may be submitted until October 5, 1976.

In recent months numerous petitions requesting affirmation of GRAS status, for uses of chlorine and chemically available sources of chlorine have been filed with FDA. These petitions, each referred to hereafter as GRASP, seek affirmation of GRAS status for general and specific uses of chlorine, hypochlorous acid, sodium and calcium hypochlorite, sodium chlorite, and chlorine dioxide as processing aids for red meats, fish and shellfish, fruits and vegetables, and potable water. Several notices of filing of these petitions were published in the FEDERAL REGISTER in accordance with the regulations for affirmation of GRAS status, § 121.40 (21 CFR 121.40), and include the following:

Olin Chemicals, 120 Long Ridge Rd., Stamford, CT 06904, submitted several petitions: GRASP 2G0004 proposing affirmation that 0.5 part per million (ppm) calcium hypochlorite used in live oyster-conditioning water is GRAS; GRASP 3G0013 proposing affirmation that 250 ppm sodium chlorite used as a slimicide in the manufacture of paper and paperboard for food-contact use is GRAS; GRASP 3G0017 proposing affirmation that calcium hypochlorite for use in potable water is GRAS; GRASP 3G0018 proposing affirmation that calcium hypochlorite for use in cannery-cooling water is GRAS; GRASP 3G0019 proposing affirmation that calcium hypochlorite for use in sanitizing barley is GRAS; GRASP 3G0020 proposing affirmation that chlorine dioxide for use in potable water for washing fruits and vegetables is GRAS; GRASP 3G0024 proposing affirmation that calcium hypochlorite solutions for use in the treating or washing of fish is GRAS; and GRASP 3G0027 proposing affirmation that calcium hypochlorite for use in potable water for washing fruits and vegetables is GRAS.

Swift and Co., 1919 Swift Dr., Oak Brook, IL 60521, submitted a petition, GRASP 3G0029, proposing affirmation that chlorine gas in an aqueous solution for use as a spray on hog, beef, and lamb carcasses during the cooler-chilling process is GRAS; Morton Salt Co., 110 North Wacker Dr., Chicago, IL 60606, submitted a petition GRASP 4G0037, proposing affirmation that hypochlorous acid for use as a spray on hog, beef, and lamb carcasses during the cooler-chilling process is GRAS; Quad Corp., 1852 Dale Ave., Highland Park, IL 60035, submitted a petition, GRASP 5G0053, proposing affirmation that chlorinated solutions for treatment of beef, pork, and lamb carcasses is GRAS; and Market Basket, 6014 South Eastern, Los Angeles, CA 90022, submitted a petition, GRASP 6G0058, proposing affirmation that chlorinated solutions applied as a spray for treatment of beef carcasses is GRAS.

Chlorine compounds have been used effectively as antimicrobial agents for well over 100 years. Various compounds have been used as sources of chlorine for wound irrigation, for disinfecting drinking water, as agents for bacterial treatment of milk-processing equipment, and for general sanitation. Many uses of available sources of chlorine in food processing have long been recognized as GRAS. However, exposure of foods to chlorine during processing is increasingly subject to wide variations. Further, the current proliferation of uses of chlorine makes it advisable that close scrutiny be given to these uses and that additional safety data to justify such uses be submitted to and reviewed by FDA. This review will enable the Commissioner of Food and Drugs to identify those uses of chlorine in food processing that are GRAS and those uses that require further data to establish that the use is safe.

The promulgation of general GRAS guidelines for use of chlorine in food processing will be a more efficient and comprehensive method for consideration of the safety of chlorine use than separate consideration of the individual petitions for affirmation of GRAS status. General GRAS guidelines identifying the conditions of safe use of chlorine in food processing and uses for which additional safety data is required will be published in the FEDERAL REGISTER at the conclusion of FDA review of the data, information, and views submitted in response to this notice and other data and information already made available to FDA on chlorine use in food processing.

An evaluation of the use of chlorine in food processing would eventually have been undertaken in the course of the general review of GRAS substances being conducted by FDA. However, this review is being undertaken now because of the new and widespread uses of chlorine, the apparent paucity of data to support some uses, and because of the need to accelerate the review of chlorine to assure a safe food supply.

The Commissioner anticipates that a large amount of data, information, and views will be submitted in response to this notice. To facilitate consideration of the material submitted, it is requested that the submissions follow, where feasible, the format required for petitions under § 121.40. The Commissioner specifically requests that data, information, and views be submitted on the following:

1. Food-grade specifications of individual chlorine sources, limits of impurities, test methods, and data resulting from the use of the methods.

2. Composition of chlorine solutions as prepared for application to food.

a. Identification af available chlorine reactants in water solutions when applied to food.

b. Qualitative and quantitative composition of the unreacted starting materials and any impurities from the manufacture of chlorine solutions.

c. Evaluation for the presence of chloro-organic compounds.

3. Uses of chlorine on specific plant and animal tissues.

a. Length, methods, and concentrations (initial and final where applicable) of exposure.

b. Variables such as temperature, pH, and pressure.

4. Evaluation of surface and subsurface exposure.

5. Date when use began, including documentation.

6. Functionality data under conditions of use including known mechanisms of action.

7. All available safety data on chlorine and chlorine-generating chemicals, including new residues of any reactant products formed when applied to foods.

8. Feeding studies on various types of representative treated foods.

9. Specifications of chlorine-generating equipment, including composition of tanks and transfer pipes and stability of electrodes and filters.

The Commissioner also solicits notice of and supporting documentation for any prior-sanctioned uses by actions of FDA or the U.S. Department of Agriculture.

Interested persons may, on or before October 5, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 29, 1976.

SAM D. FINE,
*Associate Commissioner for Compliance.*

[FR Doc.76-19475 Filed 7-6-76;8:45 am]

## TOXICOLOGY ADVISORY COMMITTEE

### Meeting Cancellation

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of June 18, 1976 (41 FR 24745), public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a)(1) and (2) of the act.

Notice is hereby given that the meeting of the Toxicology Advisory Committee scheduled for July 12 and 13, 1976 has been cancelled.

The meeting is cancelled because the necessary information to hold the meeting is not yet available.

Dated: June 30, 1976.

SAM D. FINE,
*Associate Commissioner for Compliance.*

[FR Doc.76-19618 Filed 7-6-76;8:45 am]

## Health Services Administration

## REGIONAL HEALTH ADMINISTRATORS

### Delegation of Authority

Notice is hereby given that the following delegations have been made under Section 1110 of the Social Security Act to approve grants and contracts, with the concurrence of the Medical Services Administration, Social and Rehabilitation Service, for projects of national significance to carry out the rural research and demonstration program mandated by the Labor-HEW Appropriations Report No. 93-1146:

1. Delegation from the Assistant Secretary for Health to the Regional Health Administrators, with authority to redelegate, of authority under Section 1110 of the Social Security Act to approve grants.

2. Delegation from the Assistant Secretary for Health to the Administrator, Health Services Administration, with authority to redelegate, of all authorities under Section 1110 of the Social Security Act except those specifically delegated to the Regional Administrators.

3. Redelegation from the Administrator, Health Services Administration, to the Director, Bureau of Community Health Services, with authority to redelegate, the authority delegated to the Administrator, Health Services Administration.

The above delegations were effective on June 28, 1976.

Dated: June 28, 1976.

R. MOURE,
*Executive Officer, Public Health Service.*

[FR Doc.76-19502 Filed 7-6-76;8:45 am]

## National Institutes of Health

## BOARD OF SCIENTIFIC COUNSELORS, NINCDS

### Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, September 2 and 3, 1976, in Conference Room 1B-07, Bldg. 36, at the National Institutes of Health, Bethesda, Maryland 20014. This meeting will be open to the public from 10:30 a.m. to 5:00 p.m. on September 2 to discuss program planning and program accomplishments. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Section 552(b)6, Title 5, U.S. Code and Section 10(d) of P.L. 92-463, the meeting will be closed to the public on September 3, from 9:00 a.m. until the conclusion of the meeting for the review, discussion and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Chief, Office of Scientific and Health Reports, Mrs. Ruth Dudley, Bldg. 31, Room 8A03, NIH, NINCDS, Bethesda, Maryland 20014, telephone 301/496-5751, will furnish summaries of the meeting and rosters of committee members.

The Executive Secretary from whom substantive program information may be obtained is: Dr. Thomas N. Chase, Director of Intramural Research, NINCDS, Building 36, Room 5A05, NIH, Bethesda, Maryland 20014, telephone 301/496-4297.

RONALD W. LAMONT-HAVERS,
*Deputy Director, NIH.*

(Catalog of Federal Domestic Assistance Program No. 13.852, National Institutes of Health.)

JUNE 29, 1976.

[FR Doc.76-19489 Filed 7-6-76;8:45 am]

## CANCER CONTROL COMMUNITY ACTIVITIES REVIEW COMMITTEE

### Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Cancer Control Community Activities Review Committee, National Cancer Institute, Building 31, Conference Room 8, National Institutes of Health, Bethesda, Maryland 20014 on August 23-24, 1976.

This meeting will be open to the public from 8:30 a.m. to 9:00 a.m. on August 23, 1976, for the discussion of administrative details. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92-463, the meeting will be closed on August 23, 1976, from 9:00 a.m. to 5:00 p.m. and on August 24, 1976, from 8:30 a.m. to adjournment for the review, discussion, and evaluation of individual contract proposals in response to request for proposals. The contract proposals contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data; such as salaries, and personal information about individuals associated with the contract proposals.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496-5708) will furnish summaries of the meeting and rosters of committee members.

Dr. Robert F. Browning, Executive Secretary, Blair Building, Room 7A07, National Institutes of Health, Bethesda, Maryland 20014 (201/427-7945) will furnish substantive program information.

JUNE 29, 1976.

RONALD W. LAMONT-HAVERS,
*Deputy Director, National Institutes of Health.*

(Catalog of Federal Domestic Assistance Program Number 13.399, National Institutes of Health)

[FR Doc.76-19488 Filed 7-6-76;8:45 am]

## CANCER CONTROL INTERVENTION PROGRAMS REVIEW COMMITTEE

### Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Cancer Control Intervention Programs Review Committee, National Cancer Institute, Building 31, Conference Room 8, National Institutes of Health, Bethesda, Maryland 20014 on August 5-6, 1976.

This meeting will be open to the public from 8:30 a.m. to 10:15 a.m. on August 5, 1976, for the review of contract projects supported by the National Institutes of Health. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4) and 552(b)

(6), Title 5, U.S. Code and Section 10(d) of Public Law 92–463, the meeting will be closed on August 5, 1976, from 10:15 a.m. to 5:00 p.m. and on August 6, 1976, from 8:30 a.m. to adjournment for the review, discussion, and evaluation of individual contract proposals in response to requests for proposals. The contract proposals contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data; such as salaries, and personal information about individuals associated with the contract proposals.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496–5708) will furnish summaries of the meeting and rosters of committee members.

Dr. Carlos E. Caban, Executive Secretary, Blair Building, Room 7A07, National Institutes of Health, Bethesda, Maryland 20014 (301/427–7945) will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Number 13,399, National Institutes of Health)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 29, 1976.

[FR Doc.76–19479 Filed 7–6–76;8:45 am]

## CLINICAL TRIALS REVIEW COMMITTEE

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Clinical Trials Review Committee, National Heart and Lung Institute, August 9, 1976, National Institutes of Health, Building 31, Conference Room 7. This meeting will be open to the public from 8:30 a.m. to 9:00 a.m. on August 9, 1976, to discuss administrative details and to hear a report concerning the current status of the National Heart and Lung Institute.

In accordance with the provisions set forth in Sections 552(b)(4), 552(b)(5) and 552(b)(6), Title 5, U.S. Code and Section 10(d) of P.L. 92–463, the meeting will be closed to the public on August 9, 1976 from 9:00 a.m. to adjournment, for the review, discussion and evaluation of individual initial pending, supplemental, and renewal grant applications and individual contract proposals. The closed portion of the meeting involves solely the internal expression of views and judgments of committee members on individual grant applications and individual contract proposals containing detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications and proposals.

Mr. York Onnen, Chief, Public Inquiries and Reports Branch, NHLI, National Institutes of Health, Building 31, Room 5A03, phone (301) 496–4236, will provide summaries of the meeting and rosters of the committee members. Dr. Earl W. Gardner, Review Branch, Division of Extramural Affairs, NHLI, Westwood Building, Room 653, phone (301), 496–7351, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13,837, National Institutes of Health)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 18, 1976.

[FR Doc.76–19480 Filed 7–6–76;8:45 am]

## COMMITTEE ON CANCER IMMUNOTHERAPY

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Committee on Cancer Immunotherapy, National Cancer Institute, Building 10, Room 4B–14, National Institutes of Health, Bethesda, Maryland 20014, on August 12, 1976.

This meeting will be open to the public from 1:00 p.m. to 1:30 p.m. on August 12, 1976 to review administrative details. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92–463, the meeting will be closed on August 12, 1976 from 1:30 p.m. to adjournment for the review, discussion, and evaluation of individual contract proposals. The proposals contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data; such as salaries, and personal information about individuals associated with the contract proposals.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496–5708) will furnish summaries of the meeting and rosters of committee members.

Dr. Harriet Gordon, Executive Secretary, Building 10, Room 4B17, National Institutes of Health, Bethesda, Maryland 20014 (301/496–1791) will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Number 13.395, National Institutes of Health)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 24, 1976.

[FR Doc.76–19483 Filed 7–6–76;8:45 am]

## ENZYME LINKED IMMUNO SPECIFIC ASSAY (ELISA) FOR INFECTIOUS AGENTS

### Meeting

Notice is hereby given of the meeting on Enzyme Linked Immuno Specific Assay (ELISA) for Infectious Agents, National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health, on September 9 and 10, 1976, in Building 31, Conference Room 8, NIH, Bethesda, Maryland 20014.

The entire meeting will be open to the public from 9:00 a.m. on September 9th, and until adjournment on September 10th, to discuss the development of the new ELISA technique for virus serology. Attendance by the public will be limited to space available.

Mrs. Ruth Dudley, Chief, Office of Scientific and Health Reports, Bulding 31, Room 8A03, NIH, NINCDS, Bethesda, Maryland 20014, telephone 301/496–5751, will furnish summaries of the meeting.

Dr. John L. Sever, Chief, Infectious Diseases Branch, Intramural Research Program, NINCDS, Building 36, Room 5D–04, Bethesda, Maryland, telephone 301/496–3213, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.854, National Institutes of Health.)

R. W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 24, 1976.

[FR Doc.76–19490 Filed 7–6–76;8:45 am]

## MATERNAL AND CHILD HEALTH RESEARCH COMMITTEE

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Maternal and Child Health Research Committee, National Institute of Child Health and Human Development, on August 9–10, 1976, in the Landow Building, Room C418, 7910 Woodmont Avenue, Bethesda, Maryland.

The meeting will be open to the public from 9:00 a.m. to 10:00 a.m. on August 9, 1976 to discuss general business of the Committee and for reports from the Director, Center for Research for Mothers and Children, Program Director for Pregnancy and Infancy Branch, Program Director for Growth and Development Branch, and the Executive Secretary of the Committee. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4), 552(b)(5), and 552(b)(6), Title 5, U.S. Code and Section 10(d) of P.L. 92–463, the meeting will be closed to the public from 10:30 a.m. to adjournment for the review, discussion and evaluation of individual initial pending grant applications. The closed portion of the meeting will involve solely the internal expression of views and judgments of the committee members on individual grant applications containing detail research protocols, designs, and other technical information; financial data, such as salaries, and personal information concerning individuals associated with the applications.

Mrs. Marjorie Neff, Committee Management Officer, NICHD, Building 31, Room 2A–04, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496–1848, will provide a summary of the meeting and a roster of committee members. Dr. Nancy Felipe Russo, Executive Secretary of the Maternal and Child Health Research Committee, NICHD, Room C–717, Landow Building, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496–5575, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.317, National Institutes of Health.)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 18, 1976.

[FR Doc.76–19481 Filed 7–6–76;8:45 am]

## MENTAL RETARDATION RESEARCH COMMITTEE

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Mental Retardation Research Committee, National Institute of Child Health and Human Development, on August 12–13, 1976, in the Landow Building, Room C–418, 7910 Woodmont Avenue, Bethesda, Maryland.

The meeting will be open to the public on August 12 from 12:30 p.m. to 2:30 p.m. to discuss items relative to the Committee's activities including announcements by the Chief of the Mental Retardation and Developmental Disabilities Branch and the Executive Secretary of the Committee. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4), 552(b)(5) and 552(b)(6), Title 5, U.S. Code and Section 10(d) of P.L. 92–463, the meeting will be closed to the public on August 12 from 2:30 p.m. to adjournment on August 13 for the review, discussion and evaluation of individual initial pending and renewal grant applications. The closed portion of the meeting will involve solely the internal expression views and judgments of the committee members on individual grant applications containing detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications.

Mrs. Marjorie Neff, Committee Management Officer, NICHD, Building 31, Room 2A–04, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496–1848, will provide a summary of the meeting and a roster of committee members. Dr. Lyle Lloyd, Executive Secretary, Mental Retardation Research Committee, NICHD, Landow Building, Room C–704, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496–1383, will furnish substantive program information.

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 18, 1976.

(Catalog of Federal Domestic Assistance Program No. 13.865, National Institutes of Health.)

[FR Doc.76–19484 Filed 7–6–76;8:45 am]

## NATIONAL CANCER ADVISORY BOARD SUBCOMMITTEE ON CENTERS AND CONSTRUCTION

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Cancer Advisory Board Subcommittee on Centers and Construction, National Cancer Institute, August 13, 1976, National Institutes of Health, Building 31C, Conference Room 8.

The entire meeting will be open to the public from 9:00 a.m. to adjournment to discuss the continuing review and evaluation of cancer centers and a cancer centers program.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496–5708) will furnish summaries of the meeting and a roster of committee members upon request.

Dr. Bernard Keele, Westwood Building, Room 826, National Institutes of Health, Bethesda, Maryland 2016 (301/496–7427) will provide substantive program information.

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 30, 1976.

[FR Doc.76–19485 Filed 7–6–76;8:45 am]

## NATIONAL CANCER INSTITUTE

### Notice of Open Advisory Committee Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of committees advisory to the National Cancer Institute.

These meetings will be entirely open to the public to discuss issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available. Meetings will be held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014, unless otherwise stated.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496–5708) will furnish summaries of the meetings and rosters of committee members upon request.

Other information pertaining to the meeting can be obtained from the Executive Secretary indicated.

Name of committee: Subcommittee on Cost Reimbursement of the Cancer Control and Rehabilitation Advisory Committee.
Dates: August 2, 1976; 8:30 a.m.—adjournment.
Place: Building 31C, Conference Room 8, National Institutes of Health.
Times: Open for the entire meeting.
Agenda: To consider various strategies potentially applicable to the Division of Cancer Control and Rehabilitation's supported projects.
Executive Secretary: Dr. Carlos Caban, address: Blair Building, Room 7A07, National Institutes of Health, phone: 301/427–7944.
Name of Committee: Subcommittee on Prevention of the Cancer Control and Rehabilitation Advisory Committee.
Dates: August 5, 1976; 9:00 a.m.–adjournment.
Place: Blair Building, Conference Room #100 (1st floor), 8300 Colesville Road, Silver Spring, Maryland.
Times: Open for the entire meeting.
Agenda: To consider those interventions which staff of the Division of Cancer Control and Rehabilitation might employ to lower the incidence of cancer through prevention.
Executive secretary: Dr. Robert Browning, address: Blair Building, Room 7A07, National Institutes of Health, phone: 301/427–7944.
Name of committee: President's Cancer Panel.
Dates: August 11, 1976; 9:30 a.m.–adjournment.
Place: Building 31C, Conference Room 7, National Institutes of Health.
Times: Open for the entire meeting.
Agenda: To hear reports from the Director, National Cancer Program, National Cancer Institute, the Chairman, President's Cancer Panel and to review the budget.
Executive secretary: Dr. Richard A. Tjalma, address: Building 31, Room 11A46, National Institutes of Health, phone: 301/496–5854.

R. W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 24, 1976.

[FR Doc.76–19478 Filed 7–6–76;8:45 am]

## NATIONAL HEART AND LUNG ADVISORY COUNCIL

### Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Heart and Lung Advisory Council, National Heart and Lung Institute, August 12, 1976, from 9:00 a.m. to 5:00 p.m. in Building 31, Conference Room 10, Bethesda, Maryland. The meeting will be open to the public from 9:00 a.m. to approximately 9:45 a.m. for general information and closed for the remainder of the day for consideration of special grant applications and, in particular, for those received in response to Request for Applications for studies of "Cardiac and Vascular Disease in Relation to Diabetes Mellitus." Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552(b)(4), 552(b)(5) and 552(b)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92–463, the meeting of the Council will be closed to the public on August 12 from 9:45 a.m. to 5:00 p.m. for the review, discussion and

evaluation of individual initial pending and renewal grant applications. The closed portion of the meeting involves solely the internal expression of views and judgments of committee members on individual grant applications containing detailed research protocols, designs, and other technical information; financial data, such as salaries, and personal information concerning individuals associated with the applications.

Mr. York Onnen, Chief, Public Inquiries and Reports Branch, National Heart and Lung Institute, Building 31, Room 5A03, National Institutes of Health, Bethesda, Maryland 20014 (301) 496–4236, will provide summaries of the meetings and rosters of the Council members.

Dr. Jerome G. Green, Director of Extramural Affairs, NHLI, Westwood Building, Room 5A18 (301) 496–7416, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, 13.838, and 13.839, National Institutes of Health.)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 29, 1976.

[FR Doc.76-19482 Filed 7-6-76;8:45 am]

## NIH PUBLIC ADVISORY COMMITTEES

### Renewal

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463, 86 Stat. 770–776), the National Institutes of Health announces the renewal by the Secretary, HEW, with the concurrence of the Office of Management and Budget Committee Management Secretariat, of the following committees:

| *Committee* | *Rechartering date* |
|---|---|
| National Advisory Dental Research Council | May 31, 1978 |
| National Advisory Neurological and Communicative Disorders and Stroke Council | Do. |

These committees, established by an Act of Congress, shall file a charter upon the expiration of each successive two-year period in accordance with Public Law 92–463. That rechartering date is indicated above.

DONALD S. FREDRICKSON,
*Director,*
*National Institutes of Health.*

JUNE 22, 1976.

[FR Doc.76-19477 Filed 7-6-76;8:45 am]

## RESEARCH GRANT APPLICATIONS, NATIONAL CANCER INSTITUTE

### Meetings for Review

Pursuant to Public Law 92–463, notice is hereby given of the meetings of committees advisory to the National Cancer Institute.

These meetings will be open to the public to discuss administrative details or other issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in Sections 552(b)(4), 552(b)(5) and 552(b)(6) of Title 5, U.S. Code and Section 10(d) of P.L. 92–463, for the review, discussion and evaluation of individual initial pending, supplemental, and renewal grant applications. The closed portions of the meetings involve solely the internal expression of views and judgments of committee members on individual grant applications containing detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301/496–5708) will furnish summaries of the meetings and rosters of committee members upon request. Other information pertaining to the meeting can be obtained from the Executive Secretary indicated. Meetings are held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014, unless otherwise stated.

Name of Committee: National Prostatic Cancer Project Working Cadre.

Dates: August 20–21, 1976; 1:00 p.m.

Place: Roswell Park Memorial Institute, 666 Elm Street (Room 402), Buffalo, New York 14263.

Times: Open: August 21, 8:30 a.m.–Adjournment. Closed: August 20, 1:00 p.m.–5:00 p.m.

Closure reason: To review research grant applications.

Executive secretary: Dr. Andrew Chiaroda, address: Westwood Building, Room 855, National Institutes of Health, phone: 301/496–7194.

(Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395.)

Name of committee: National Pancreatic Cancer Project Working Cadre.

Dates: August 23, 1976: 8:30 a.m.

Place: National Pancreatic Cancer Project Headquarters, 1440 Canal Street, Room 1521, Canal-LaSalle Building, New Orleans, Louisiana 70112.

Times: Open: August 23, 8:30 a.m.–9:00 a.m. Closed: August 23, 9:00 a.m.–Adjournment.

Closure reason: To review research grant applications.

Executive secretary: Dr. David L. Joftes, address: Westwood Building, Room 853, National Institutes of Health, phone: 301/496–7194.

(Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395.)

Name of committee: National Large Bowel Cancer Project Working Cadre.

Dates: August 26–28, 1976: 1:00 p.m.

Place: Anderson Mayfair Hotel, 1600 Holcombe Boulevard, Houston, Texas.

Times: Open: August 26, 1:00 p.m.–1:30 p.m. Closed: August 26, 1:30 p.m.–5:00 p.m. Closed: August 27, 9:00 a.m.–5:00 p.m. Closed: August 28, 9:00 a.m.–Adjournment.

Closure reason: To review research grant applications.

Executive Secretary: Dr. Andrew Chiarodo, address: Westwood Building, Room 855, National Institutes of Health, phone: 301/496–7194.

(Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395.)

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 25, 1976.

[FR Doc.76-19487 Filed 7-6-76;8:45 am]

## WORKSHOP FOR LOW-INCIDENCE POPULATIONS

### Meeting

Notice is hereby given of the "Workshop for Low-Incidence Populations" sponsored by the Division of Cancer Research, Resources and Centers, National Cancer Institute to be held August 19–20, 1976, at the Plaza Conference Center, Snow Bird, Utah 84070.

This meeting will be open to the public on August 19 and 20 from 9:00 A.M. to 5:00 P.M. on both days. Attendance by the public will be limited to space available.

Dr. Genrose D. Copley, Program Director for Epidemiology, Division of Cancer Research, Resources and Centers, 5333 Westbard Avenue, Westwood Building, Room 854, Bethesda, Maryland 20016, Tel. A/C (301) 496–7805 will provide additional information.

RONALD W. LAMONT-HAVERS,
*Deputy Director,*
*National Institutes of Health.*

JUNE 30, 1976.

[FR Doc.76-19486 Filed 7-6-76;8:45 am]

## Office of Education

## COMMUNITY EDUCATION ADVISORY COUNCIL

### Public Meeting

Notice is hereby given, pursuant to section 10(a)(2) of the Federal Advisory Committee Act, Pub. L. 92–634, that the next meeting of the Community Education Advisory Council will be held July 22, 23, and 24, 1976. The meeting will be held in the Colonial Room of the Olympic Hotel located at 4th and Seneca Streets, Seattle, Washington.

The Thursday meeting will begin at 7:00 p.m. and end at 10:00 p.m. On Friday the meeting will begin at 9:00 a.m. and end at 4:30 p.m. The Saturday meeting will begin at 10:00 a.m. and end at 12 Noon.

The Community Education Advisory Council is authorized under Pub. L. 93–380. The Council is established to advise the Commissioner of Education on policy matters relating to the interest of community schools.

The meeting of the Council will be open to the public. The proposed agenda includes:

(1) Discussion of role and function of the Council

(2) Report on Community Education grantees and related activities of future Community Education Program

(3) Reports and Hearings on Community Education activities from the States of Alaska, Idaho, Oregon and Washington

(4) Other administrative matters and related business.

Records shall be kept of all Council proceedings and shall be available for public inspection in Room 5622, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C. 20202.

Signed at Washington, D.C. on July 1, 1976.

JULIE ENGLUND,
*Director, Community Education Program.*

[FR Doc.76-19513 Filed 7-6-76;8:45 am]

## NATIONAL DIRECT STUDENT LOAN, COLLEGE WORK-STUDY AND SUPPLEMENTAL EDUCATIONAL OPPORTUNITY GRANT PROGRAMS

### Approved Lists of Need Analysis Systems

Notice is hereby given that the Commissioner of Education is publishing a list of approved need analysis systems to be used by institutions of higher education in making awards to students for the 1976–77 academic year under the National Direct Student Loan (NDSL), College Work-Study (CWS) and Supplemental Educational Opportunity Grant (SEOG) programs.

On October 21, 1975 there was published in the FEDERAL REGISTER (40 FR 49268–49273) final regulations concerning the approval and use of need analysis systems under the above three programs. These regulations, 45 CFR 144.14 for the NDSL program, 45 175.17 for the CWS SEOG program set forth procedures for an annual review and approval by the Commissioner of need analysis systems for dependent and independent students for use in those programs. In order to be approved, a system to be used for dependent students must generate expected parental contributions for at least 75 percent of the sample cases which are within $50 of the benchmark figures published by the Commissioner for those cases. For independent students, a system must produce expected family contributions which are comparable to those produced by one of the systems specified in paragraph (c)(1) of each section.

Under the above regulatory provisions need analysis systems to be used for applying for funds for the 1976–1977 academic year and for making awards to students for that year should have been published in the FEDERAL REGISTER by September 1, 1975. Because the regulation was not published until October 21, 1975 and did not become effective until that date institutions were advised, in submitting their application for funds for the 1976–1977 academic year, to use need analysis systems approved by the Commissioner for use in determining student awards for the 1975–1976 academic year (40 FR 49268, 49270). However the preamble to those regulations stated that the Commissioner intended to publish a list of approved need analysis systems for making awards to students for the 1976–1977 academic year (40 FR 49268, 49269).

Sections 144.14, 175.17 and 176.13 approved the use of the Income Tax System and the method of determination of expected family contributions used in the Basic Educational Opportunity Grant program (45 CFR 190) for use with dependent students. It also stated approval of the following systems for use with independent students: Basic Educational Opportunity Grant method, the systems of need analysis published by the American College Testing Program, by the College Scholarship Service, by the Graduate and Professional Student Financial Aid Service, and by Financial Aid Service, Inc., a division of Donley, Richardson and Associates. (Systems approved for use with independent students do not have to be submitted on an annual basis). The list set forth below has been approved by the Commissioner for use with dependent and independent students for the academic year 1976–77.

The following additional systems are approved effective immediately with respect to determining awards to students for the academic year 1976–77 under the NDSL, CWS and SEOG programs.

1. Dependent students only.

a. The Income Tax System.

2. Dependent and independent students.

a. Basic Educational Opportunity Grant Program.

b. The system of need analysis published by the College Scholarship Service.

c. The system of need analysis published by the American College Testing Program.

d. The need analysis service published by the Graduate and Professional Student Financial Aid Service.

e. The system of need analysis published by Financial Aid Service, Inc., a division of Donley, Richardson and Associates.

f. The system of need analysis published by Student Assistance Financial Evaluation, a program of Information and Communications, Inc.

g. The system of need analysis published by Financial Analysis Service, a program of Education Methods, Inc.

(20 U.S.C. 1087dd, 42 U.S.C. 2754, and 20 U.S.C. 1070b–1 and 1070–2) (Catalog of Federal Domestic Assistance No. 13.418, Supplemental Educational Opportunity Grant Program; 13.463, College Work-Study Program; and 13.471, National Direct Student Loan Program).

Dated: June 30, 1976.

T. H. BELL,
*Commissioner of Education.*

[FR Doc.76-19511 Filed 7-6-76;8:45 am]

# DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

## Federal Disaster Assistance Administration

[Docket No. NFD–345; FOAA–512–DR]

### NEW YORK

### Major Disaster and Related Determinations

Pursuant to the authority vested in the Secretary of Housing and Urban Development by the President under Executive Order 11795 of July 11, 1974, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D–74–285; and by virtue of the Act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that on June 29, 1976, the President declared a major disaster as follows:

I have determined that the damage in certain areas of the State of New York resulting from flash flooding beginning about June 19, 1976, is of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 93–288. I therefore declare that such a major disaster exists in the State of New York.

Notice is hereby given that pursuant to the authority vested in the Secretary of Housing and Urban Development under Executive Order 11795, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D–74–285, I hereby appoint Mr. Thomas R. Casey, HUD Region II, to act as the Federal Coordinating Officer for this declared major disaster.

I do hereby determine the following areas in the State of New York to have been adversely affected by this declared major disaster:

The Counties of:

Chemung
Steuben

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.)

Dated: June 29, 1976.

THOMAS P. DUNNE,
*Administrator, Federal Disaster Assistance Administration.*

[FR Doc.76-19512 Filed 7-6-76;8:45 am]

## Assistant Regional Administrator for Equal Opportunity

[Docket No. D–76–441]

### BOSTON REGIONAL OFFICE

### Redelegation of Authority With Respect to Fair Housing

Section A. *Authority with respect to fair housing.* The Assistant Regional Administrator for Equal Opportunity, Region I (Boston), is authorized to exercise the power and authority of the Secretary of Housing and Urban Development under Title VIII (Fair Housing) of the Civil Rights Act of 1968 (42 U.S.C. 3601–3619), except the authority to:

1. Make studies and publish reports under Section 808(e) of the Act (42 U.S.C. 3608(d)),

2. Issue rules and regulations.

Section B. *Authority to redelegate.* The Assistant Regional Administrator for Equal Opportunity is further authorized to redelegate any of the authority redelegated under Section A to subordinate employees except the authority to issue a subpoena or interrogatory under Section 811 of the Act (42 U.S.C. 3611).

(Redelegation of Authority by Assistant Secretary for Fair Housing and Equal Opportunity effective April 2, 1976, 41 FR 14208, April 2, 1976 and redelegation of authority by Acting Secretary of Housing and Urban Development effective April 2, 1976, 41 FR 14209, April 2, 1976).

Section C. *Supersedure.* This redelegation of authority supersedes the redelegation published at 36 FR 4517, March 6, 1971.

Effective date: This redelegation of authority is effective on July 7, 1976.

MAURICE E. FRYE, Jr.,
*Regional Administrator,*
*Region I, Boston.*

[FR Doc.76-19538 Filed 7-6-76;8:45 am]

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[Docket No. D-76-442]

## SAN FRANCISCO REGIONAL OFFICE

### Redelegation of Authority With Respect to Fair Housing

Section A. *Authority with respect to fair housing.* The Assistant Regional Administrator for Equal Opportunity, Region IX, San Francisco, is authorized to exercise the power and authority of the Secretary of Housing and Urban Development under Title VIII (Fair Housing) of the Civil Rights Act of 1968, Public Law 90-284 (42 U.S.C. 3601—3619), except the authority to:

1. Make studies and publish reports under Section 808(e) of the Act (42 U.S.C. 3608(d)).

2. Issue rules and regulations.

Section B. *Authority to redelegate.* The Assistant Regional Administrator for Equal Opportunity is authorized to redelegate to subordinate employees any of the authority redelegated under Section A except the authority to issue a subpena or interrogatory under Section 811 of the Act (42 U.S.C. 3611) shall remain with the Assistant Regional Administrator for Equal Opportunity.

Section C. *Supersedure.* This redelegation of authority supersedes the redelegation published at 35 F.R. 14414, September 12, 1970.

(Redelegation of Authority by Assistant Secretary for Fair Housing and Equal Opportunity published at 41 F.R. 14208, April 2, 1976, effective April 2, 1976.)

Effective date: This redelegation of authority shall be effective as of April 5, 1976.

ROBERT H. BAIDA,
*Regional Administrator,*
*Region IX, San Francisco.*

[FR Doc.76-19540 Filed 7-6-76;8:45 am]

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### Office of the Secretary

[Docket No. D-76-443]

## REGIONAL COUNSEL, REGION I, BOSTON

### Delegation of Authority

I hereby designate the Regional Counsel, Region I, to act in my stead, with authority to receive and act upon inquiries, requests for access and requests for correction or amendment of records under the Privacy Act of 1974, enacted December 31, 1974 as P.L. 93-579. The authority for this designation is 40 F.R. 39729 (August 28, 1975), as amended by 41 F.R. 13917 (April 1, 1976).

Effective date: This designation and delegation shall be effective on July 7, 1976.

MAURICE E. FRYE, Jr.,
*Regional Administrator, Region I.*

[FR Doc.76-19539 Filed 7-6-76;8:45 am]

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# CIVIL AERONAUTICS BOARD

[Docket 29160; (Order 76-6-194)]

## INVESTIGATION OF THE LOCAL SERVICE CLASS SUBSIDY RATE CLASS RATE VIII

### Order Reopening Rate

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 30th day of June, 1976.

By Order 76-4-101, dated April 20, 1976, the Board instituted an investigation directed to the establishment of a revised class subsidy rate for the seven local service carriers (Locals) currently operating under Class Rate VII.[1] The order also invited the Locals to file comments on the proposed concept for a new class rate (Class Rate VIII), and required the Locals to supply additional information.

The Board has received the information and the comments requested in Order 76-4-101. However, unexpected problems will delay issuance of a statement of Provisional Findings and Conclusions. Such a statement, reflecting revisions in subsidy calculation as outlined in the order of investigation and containing an updated payment formula, will be forthcoming as soon as possible.

We are therefore reopening as of July 1, 1976, the final subsidy rate presently in effect, Class Rate VII, for the Locals. In line with past practice, the subsidy rates found to be fair and reasonable for each carrier in the fifth review of Class Rate VII (Order 76-2-39, February 11, 1976) will remain in effect as temporary rates which will serve as the bases for interim subsidy payments to each carrier, pending the establishment of final rates in this proceeding.

Accordingly, pursuant to the Federal Aviation Act of 1958, as amended, particularly sections 102, 204, 406, and 1002 (b) thereof,

[1] Class Rate VII as established by Orders 73-7-59, July 13, 1973, 73-10-1, October 1, 1973, and 74-1-123, January 24, 1974.

It is ordered that:

1. The current final local service class subsidy rate is hereby reopened as of July 1, 1976 for the purpose of determining a new final rate or taking such other action as the facts may warrant; and

2. This order shall be served on all the parties to this proceeding and the Postmaster General.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
*Acting Secretary.*

[FR Doc.76-19536 Filed 7-6-76;8:45 am]

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[Docket 29357]

## McGREGOR, SWIRE AIR SERVICES LIMITED FOREIGN AIR FREIGHT FORWARDER RENEWAL (U.K.)

### Notice of Postponement of Prehearing Conference and Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that the prehearing conference and hearing in the above-entitled matter assigned to be held on July 19, 1976, (41 F.R. 23996, June 14, 1976), are postponed indefinitely.

Dated at Washington, D.C., June 30, 1976.

JANET D. SAXON,
*Administrative Law Judge.*

[FR Doc.76-19535 Filed 7-6-76;8:45 am]

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# COMMISSION ON CIVIL RIGHTS

## MISSISSIPPI ADVISORY COMMITTEE

### Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Mississippi Advisory Committee (SAC) to this Commission will convene at 2 p.m. and end at 5:30 p.m. on July 28, 1976, at the Biloxi Hilton, Pacific Room, 3580 West Beach Blvd., Biloxi, Mississippi 39531.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Southern Regional Office of the Commission, Citizens Trust Bank Bldg., Room 362, 75 Piedmont Avenue, NE., Atlanta, Georgia 30303.

The purpose of this meeting: State Employment Study Followup activities; planning for Advisory Committee Education Project for fiscal year 77. Reports of Subcommittee on: Women's Rights developments, administration of Justice, Health.

This meeting will be conducted pursuant to the rules and regulations of the Commission.

Dated at Washington, D.C., June 30, 1976.

ISAIAH T. CRESWELL, Jr.,
*Advisory Committee*
*Management Officer.*

[FR Doc.76-19616 Filed 7-6-76;8:45 am]

## NORTH CAROLINA ADVISORY COMMITTEE

### Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the North Carolina Advisory Committee (SAC) to this Commission will convene at 6 p.m. and end at 10 p.m. on July 23, 1976, at North Lumina Avenue, Wrightsville Beach, North Carolina and will reconvene on July 24, 1976, at 9 a.m. and end at 5:30 p.m., and on July 25, 1976, the meeting will convene at 10 a.m. and end at 2 p.m.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Southern Regional Office of the Commission, Citizens Trust Bank Building, Room 362, 75 Piedmont Avenue, NE., Atlanta, Georgia 30303.

The purpose of this meeting is comprehensive planning session for programs during fiscal 1977. Discuss workshops to define and prioritize civil rights issues for SAC programming. Establishing goals and objectives and timetables for fiscal '77. Reorientation of SAC role and its relationship to the Regional Office and Washington Office.

This meeting will be conducted pursuant to the rules and regulations of the Commission.

Dated at Washington, D.C., June 30, 1976.

ISAIAH T. CRESWELL, JR.,
*Advisory Committee Management Officer.*

[FR Doc.76-19615 Filed 7-6-76;8:45 am]

## PENNSYLVANIA/DELAWARE ADVISORY COMMITTEE

### Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights that a planning meeting of the Pennsylvania/Delaware Advisory Committee (SAC) to this Commission will convene at 10 a.m. and end at 2 p.m. on July 22, 1976, at the Philadelphia Federal Building, 600 Arch Street, 10th Floor, Room 10320, Philadelphia, Pennsylvania.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Mid-Atlantic Regional Office of the Commission, 2120 L Street NW., Room 510, Washington, D.C. 20037.

The purpose of this meeting is to plan future projects.

This meeting will be conducted pursuant to the rules and regulations of the Commission.

Dated at Washington, D.C., June 30, 1976.

ISAIAH T. CRESWELL, JR.,
*Advisory Committee Management Officer.*

[FR Doc.76-19614 Filed 7-6-76;8:45 am]

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### EXEMPT TEXTILE PRODUCTS

### Announcing Requirement That Shipments Be Certified by Exporting Country Government in the Country of Origin

JULY 1, 1976.

The bilateral textile agreements negotiated between the Governments of the United States and Colombia, Haiti, India, Malaysia, Mexico, Pakistan, the Philippines, the Republics of China and Korea, and Thailand provide for the exemption of certain textile products of the cottage industry which have been properly certified by the government of the exporting country.

The purpose of this notice is to clarify for interested parties that shipments of exempt textile products must be certified in the country of origin by designated officials prior to exportation in accordance with procedures established between the Governments of the United States and the country of origin. Exempt certifications issued by embassies cannot be accepted to effect release of shipments. However, embassies may request the Director, Office of Textiles, U.S. Department of Commerce, to advise the U.S. Customs Service that the visa requirement has been waived and the goods may be permitted entry and charged to the applicable levels of restraint.

ALAN POLANSKY,
*Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance, U.S. Department of Commerce.*

[FR Doc.76-19553 Filed 7-6-76;8:45 am]

### REPUBLIC OF KOREA

### Adjusting Import Levels for Certain Cotton and Man-Made Fiber Textile Products Under the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement

JULY 1, 1976.

On September 30, 1975, there was published in the FEDERAL REGISTER (40 FR 44862) a letter dated September 25, 1975 from the Chairman, Committee for the Implementation of Textile Agreements, to the Commissioner of Customs, implementing those provisions of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of June 26, 1975, as amended, between the Governments of the United States and the Republic of Korea, which establish specific export limitations on certain cotton, wool, and man-made fiber textile products, produced or manufactured in the Republic of Korea and exported to the United States during the twelve-month period which began on October 1, 1975. As set forth in that letter, the levels of restraint are subject to adjustment pursuant to paragraphs 5 and 7 of the agreement which provide that within the aggregate and applicable group limits, specific levels of restrain may be increased by designated percentages and that such levels may be increased for carryover and carryforward up to 11 percent of the applicable category limits.

Accordingly, pursuant to the provisions of the bilateral agreement referred to above, there is published below a letter of July 1, 1976 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs amending the levels of restraint applicable to textile products in Categories 26 (duck) and 234 during the twelve-month period which began on October 1, 1975.

ALAN POLANSKY,
*Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance, U.S. Department of Commerce.*

COMMISSIONER OF CUSTOMS,
*Department of the Treasury, Washington, D.C. 20229.*

DEAR MR. COMMISSIONER: On September 25, 1975 the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry during the twelve-month period beginning October 1, 1975 and extending through September 30, 1976 of cotton, wool and man-made fiber textile products in certain specified categories, produced or manufactured in the Republic of Korea, in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, pursuant to paragraphs 5 and 7 of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of June 26, 1975, as amended, between the Governments of the United States and the Republic of Korea, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, you are directed to amend, effective on July 9, 1976 the levels of restraint

[1] The term "adjustment" refers to those provisions of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of June 26, 1975, as amended, between the Governments of the United States and the Republic of Korea which provide, in part, that: (1) within the aggregate and applicable group limits, specific levels of restraint within Categories 1-38, part of 63 (shoe uppers), 64, 200-213, and 241-243 may be exceeded by 10 percent; within Categories 39-62, part of 63 (other than shoe uppers), and 214-240, by 7 percent; and within Categories 101-132, by 5 percent; (2) these same levels may be increased for carryover and carryforward up to 11 percent of the applicable category limit; (3) consultation levels may be increased within the aggregate and applicable group limits upon agreement between the two governments; and (4) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

established for Categories 26 (duck) and 234 to the following:

| Category: | | Amended 12-mo. level of restraint [1] |
|---|---|---|
| 26 (duck) [2] | square yards | 24,872,613 |
| 234 | dozen | 4,321,504 |
| 320 | 01 through 04,06,08 | |
| 321 | 01 through 04,06,08 | |
| 322 | 01 through 04,06,08 | |
| 326 | 01 through 04,06,08 | |
| 327 | 01 through 04,06,08 | |
| 328 | 01 through 04,06,08 | |

[1] The levels of restraint have not been adjusted to reflect any entries made after September 30, 1975.

[2] In Category 26 the T.S.U.S.A. numbers for duck fabric are:

The actions taken with respect to the Government of the Republic of Korea and with respect to imports of cotton and man-made fiber textile products from the Republic of Korea have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ALAN POLANSKY,
*Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance, U.S. Department of Commerce.*

[FR Doc.76-19552 Filed 7-6-76;8:45 am]

## ENVIRONMENTAL PROTECTION AGENCY

[FRL 573-3]

## STATE IMPLEMENTATION PLANS

### Requested Revisions

SYNOPSIS

EPA has worked closely with the States in recent months to determine the sufficiency of State Implementation Plans (SIP's) for the attainment and maintenance of all national ambient air quality standards. In some States, areas which specifically needed SIP revisions for maintenance were identified in early 1975. Where areas are identified today as requiring revisions for attainment, it should be understood that revisions for maintenance will also be submitted. In this notice, the Acting Regional Administrator for EPA Region X finds that the SIP's in the States of Idaho and Oregon are deficient with respect to attainment of certain national ambient air quality standards as indicated in Table I below. He is therefore requesting that these States submit revisions to their plans by July 1, 1977 to correct these deficiencies. In each case, the findings were identified by EPA and the State jointly. The Acting Regional Administrator has confirmed these findings to the Governors of both States in letters dated June 25, 1976.

TABLE I.—*Deficient SIP's—attainment*

| State | AQCR | Area | Pollutant |
|---|---|---|---|
| Idaho | Eastern Washington—Northern Idaho | Shoshone County | TSP |
| Do | Eastern | Bannock County | $SO_2$, TSP |
| Oregon | Portland interstate | Eugene AQMA | TSP [1] |
| Do | Southwest | Medford AQMA | TSP [1] |
| Do | Portland interstate | Portland AQMA | CO, $O_x$ |

[1] Secondary standards only.

In addition, the Acting Regional Administrator finds that portions of the implementation plan in the State of Washington may be deficient with respect to attainment of primary and secondary TSP national ambient air quality standards, as indicated in Table II below. These conclusions were developed by EPA and the State after a joint evaluation of the State plan and studies now under way, but not yet complete. The Acting Regional Administrator has requested that the State complete studies and adopt any necessary plan revisions by July, 1977. These findings were confirmed to the Governor in a letter dated June 25, 1976.

TABLE II.—*Possibly deficient SIP's—attainment*

| State | AQCR | Area | Pollutant |
|---|---|---|---|
| Washington | Eastern Washington—northern Idaho | Spokane | TSP |
| Do | do | Clarkston | TSP |
| Do | Northern | Colville | TSP |

Further, the States of Oregon and Washington are persently in the process of completing analyses for five areas which were designated as Air Quality Maintenance Areas (AQMA's) on April 29, 1975. AQMA's are those areas which are projected to have difficulty maintaining standards once they are attained. These analyses are intended to define whether Air Quality Maintenance Plans (AQMP's) need to be developed and which SIP revisions are necessary to support the AQMP's. There are listed in Table III.

TABLE III.—*Possibly deficient SIP's—maintenance*

| State | AQMA | Geographical composition land area | Pollutant(s) |
|---|---|---|---|
| Oregon | Portland Interstate (Oregon portion). | Columbia Region Association of Governments, 1970 Portland-Vancouver metropolitan transportation study area (Oregon portion), 1,800 km². | TSP, $SO_2$, CO, $O_x$ |
| Do | Eugene-Springfield | Lane Regional Air Pollution Authority, control area C, 277 km². | TSP |
| Do | Medford-Ashland | The Bear Creek urban regional land use planning area, 591 km². | TSP |
| Washington | Portland Interstate (Washington portion). | Columbia Region Association of Governments, 1970 Portland-Vancouver metropolitan transportation study area (Washington portion), 430 km². | TSP, $SO_2$, CO, $O_x$ |
| Do | Spokane | Spokane Regional Planning Conference; study area—1968, 834 km². | TSP |
| Do | Puget Sound | The Washington State Department of Highways, Seattle-Tacoma urban area—1973, 2,453 km². | TSP |

The Acting Regional Administrator is requesting that the AQMA analyses be completed by October 1976. Where warranted on the basis of the AQMA analyses, he is requesting that draft AQMP's be developed and submitted for review by July, 1977 and that final AQMP's and associated plan revisions be adopted by July 1978.

EPA recognizes that in some areas the State's analyses may indicate that attainment of ambient standards is not likely for the next several years due to the difficulty in controlling primarily sources of fugitive particulate matter. In these cases, EPA is requesting that the States submit a schedule by July, 1977 for adopting all practicable control measures for air quality maintenance planning. The date for adopting these regulations should be 3 to 5 years prior to the projected attainment date for ambient standards. Where non-attainment of ambient standards is projected to continue for the foreseeable future, it will be necessary to reassess the present approach to the AQMP problem and schedule for resolv-

DETAILED DISCUSSION OF ACTION

On May 31, 1972 (37 FR 10842), under section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved the implementation plan control strategies for attainment of the national primary and secondary standards for TSP and $SO_2$ for Washington and Oregon. The Oregon CO and $O_3$ control strategies for the Portland Interstate AQCR were approved on November 7, 1973 (38 FR 30825). The Idaho TSP control strategies for primary standards were approved on May 31, 1972 (37 FR 10861). The existing Idaho $SO_2$ control strategy for the Eastern Idaho AQCR was disapproved and a substitute control strategy was promulgated by EPA on June 9, 1976 (41 FR 23200). At the same time, the attainment date for $SO_2$ standards in the Eastern Idaho AQCR was extended to July 31, 1976. Implementation of the other control strategies referenced above was to have assured attainment of national ambient air quality standards by mid-1975, with the exception of the Oregon CO control strategy which was to have assured attainment of standards by May 31, 1976.

Furthermore, on March 8, 1973 (38 FR 6279), in response to a court order, EPA disapproved all implementation plans with respect to maintenance of the national ambient air quality standards. Following this action, on April 29, 1975 (40 FR 18726), EPA identibed five areas (AQMAs) in Region X that have the potential for failing to maintain one or more of the national ambient air quality standards because of future growth. Analyses are now under way for all five areas; preliminary results indicate a maintenance plan will be needed for each AQMA. A more certain determination will be made when Oregon and Washington complete their evaluations. Table III, above, identifies the AQMA's within each State which may need plan revisions to assure maintenance and the pollutants in question.

The Acting Regional Administrator of EPA Region X in conjunction with the States of Oregon and Idaho finds that the presently approved control strategy portion of the implementation plans listed in Table I are deficient as noted. These findings are based on: (a) consideration of recent air quality data for the calendar year 1975 submitted by the States, (b) evaluation of source-receptor relationships and the status of source compliance with the existing implementation plan, and (c) technical reports under preparation by the States analyzing the adequacy of their existing implementation plan conrtol strategies.

The State of Oregon has informed EPA that their analysis of necessary implementation plan revisions for attainment will be completed by August, 1976 and that any necessary new regulations will be submitted to EPA by July 1, 1977. The State of Idaho has informed EPA that their analysis of necessary implementation plan revisions will be completed by March, 1977. Therefore, the Acting Regional Administrator has requested that any necessary new regulations be submitted to EPA by July 1, 1977.

The State of Idaho has indicated that the non-attainment of TSP primary standards in Shoshone and Bannock counties is likely due to industrial process emissions and fugitive dust sources. The State will do further analytical studies to identify specific corrective actions.

The EPA Administrator disapproved the Idaho implementation plan $SO_2$ control strategy for the Eastern Idaho AQCR on June 9, 1976 and promulgated a substitute SO regulation for The J. R. Simplot Company in Bannock County. The Administrator is requesting that Idaho adopt a regulation by July 1977 to bring State regulatory provisions into conformance with those promulgated by EPA as part of the Idaho plan.

The State of Oregon has indicated that the TSP secondary national ambient air quality standard will not be attained in the Medford and Eugene-Springfield AQMA's. The State has also concluded that the CO and $O_x$ standards may not be attained in the Portland AQMA in which case the existing transportation control plan would require revision.

The State of Washington and the EPA have jointly concluded that the Washington plan may be deficient for certain areas as noted in Table II. This tentative conclusion is based on an evaluation of all available air quality and source related data. Washington State is proceeding with detailed studies in each of the noted areas to determine more precisely the nature and extent of these problems. This analysis and subsequent development of any necessary plan revisions is scheduled for completion by March, 1977 and will, upon completion, be made publicly available. Rather than wait for completion of these studies, however, the Acting Regional Administrator is including the status of Washington's efforts in this notice and calling for any necessary plan revisions now so that the State may begin all appropriate studies at once.

To summarize, the Acting Regional Administrator finds that revisions to parts of the Idaho, Oregon and Washington implementation plans may be needed for attainment and maintenance of standards and hereby requests each State to submit the necessary revisions to the respective implementation plans.

EPA is requesting that the States prepare and submit, by July 1, 1977, appropriate plan revisions for attainment of national standards. EPA is also requesting that plans be prepared and submitted by July 1, 1978 for maintenance of national standards. The exceptions to the 1978 date include the areas noted above where fugitive particulate matter sources are causing non-attainment and the Portland Interstate AQMA for TSP. Oregon is presently undertaking an Air Data Base Improvement Project to identify sources of TSP in the Portland area. Due to the timing of this project, it may not be possible for Oregon to fully meet the time schedules listed above. EPA is requesting, for this case, that Oregon adopt and submit regulations that can be identified as necessary and feasible by July, 1978, with the balance to be adopted no later than July 1979.

The requested revisions should include all achievable emission limitations and other necessary measures that are needed to provide for the attainment and maintenance of the national standards. The submittals should also include technical support documentation demonstrating, to the extent possible, the effect of these revisions on ambient air quality.

The completed plan revisions should demonstrate that the total control strategy will maintain the national ambient standards for at least 10 years after attainment.

(Sec. 110 of the Clean Air Act, as amended (42 U.S.C. 1857c-5)).

Dated: June 25, 1976.

L. EDWIN COATE,
*Acting Regional Administrator, Region 10.*

[FR Doc.76-19417 Filed 7-6-76;8:45 am]

## ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

[ERDA-1541]

### LIGHT WATER BREEDER REACTOR PROGRAM

#### Availability of Final Environmental Statement

Notice is hereby given that a five-volume Final Environmental Statement, Light Water Breeder Reactor Program, ERDA-1541, has been issued pursuant to the Energy Research and Development Administration's (ERDA) regulations for implementation of the National Environmental Policy Act of 1969.

The objective of the light water breeder reactor (LWBR) program which began in 1965, is to develop the technology necessary to improve significantly the efficiency of utilization of the energy potentially available in nuclear fuel for pressurized light water reactors including the installation and operation of a breeding reactor core in the ERDA-owned reactor at the Shippingport Atomic Power Station, Shippingport, Beaver County, Pennsylvania. The operation of this, the third reactor core in the Shippingport Station, is expected to confirm that breeding can be achieved in a light water reactor system using the thorium-uranium 233 fuel system. If the LWBR its successful, it will confirm the technical feasibility of operating breeder cores of this type in existing and future light water reactors.

In addition to evaluating the environmental aspects of operating the LWBR core in the Shippingport Station and conducting subsequent LWBR technology development, the statement considers the environmental aspects of a conceptual future commercial application of light water breeder reactors.

The draft environmental statement was issued for public comment on August 8, 1975, and a public hearing was held in Pittsburgh, Pennsylvania, on December 4, 1975, to afford additional opportunity for the public to present views concerning the draft statement. The final statement was prepared taking into consideration the substantive issues and views which were raised in the commenting process. Responses to the comments and the public hearing record are included in the final statement. Based on the results of this environmental review, ERDA does not believe that any issues have been raised which require a change in the LWBR core concept or the LWBR program, including the operation of the LWBR core in the Shippingport Atomic Power Station.

Copies of the final environmental statement are available for public inspection in ERDA's public document rooms at:

ERDA Headquarters, 20 Massachusetts Avenue NW., Washington, D.C.
Albuquerque Operations Office, Kirtland Air Force Base East, Albuquerque, New Mexico.
Chicago Operations Office, 9800 South Cass Avenue, Argonne, Illinois.
Idaho Operations Office, 550 Second Street, Idaho Falls, Idaho.
Nevada Operations Office, 2753 South Highland Drive, Las Vegas, Nevada.
Oak Ridge Operations Office, Federal Building, Oak Ridge, Tennessee.
Richland Operations Office, Federal Building, Richland, Washington.
San Francisco Operations Office, 1333 Broadway, Oakland, California.
Savannah River Operations Office, Savannah River Plant, Aiken, South Carolina.

Copies of the final environmental statement are also available for public inspection at the following locations:

B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania, and designated Federal Depository Libraries.

Copies of the final statement have been furnished to all those who provided comments.

A limited number of single copies of the five-volume final statement are available for distribution by the Technical Information Center, P.O. Box 62, Oak Ridge, Tennessee 37830, 615-483-8611, extension 34672. Copies are also available from the National Technical Information Service, Springfield, Virginia 22161.

Dated at Washington, D.C., this 30th day of June 1976.

For the Energy Research and Development Administration.

JAMES L. LIVERMAN,
*Assistant Administrator for Environment and Safety.*

[FR Doc.76-19449 Filed 7-6-76;8:45 am]

### LIGNITE ADVISORY COMMITTEE

#### Meeting

In accordance with the provisions of P.L. 92-463 (Federal Advisory Committee Act), the Lignite Advisory Committee will meet on July 21, 1976, at ERDA's Grand Forks Energy Research Center, Grand Forks, North Dakota. The meeting will be open to the public and will begin at 9:00 a.m. and end at approximately 4:00 p.m.

The committee will discuss the current program at the Grand Forks Center and the program planned for FY 1977. Subjects to be covered include research programs in combustion, gasification, liquefaction, drying, storage, and a review of the lignite symposia.

The chairman of the committee is empowered to conduct the meeting in a manner that in his judgment will facilitate the orderly conduct of business.

With respect to public participation in the meeting, the following requirements shall apply:

(a) Persons wishing to submit written statements on the subjects to be discussed may do so by mailing 12 copies thereof, postmarked no later than July 15, 1976, to Mr. Gordon H. Gronhovd, Director, Grand Forks Energy Research Center, U.S. Energy Research and Development Administration, 15 North 23rd Street, Grand Forks, North Dakota. Comments shall be based on the above subjects to be discussed at the meeting. Minutes of the meeting will be kept open for 30 days for the receipt of written statements for the record.

(b) Information as to whether the meeting has been rescheduled or relocated can be obtained by a prepaid telephone call on July 19, 1976, to Mr. Gordon H. Gronhovd, Director, Grand Forks Energy Research Center on 701-775-4207 between 8:00 a.m. and 5:00 p.m., central time.

(c) Questions at the meeting may be propounded only by the members of the Lignite Advisory Committee.

(d) Seating to the public will be made available on a first-come, first-served basis.

(e) The use of still, motion picture, and television cameras, the physical installation and presence of which will not interfere with the course of the meeting, will be permitted both before and after the meeting and during any recess. The use of such equipment will not, however, be allowed while the meeting is in session.

(f) Copies of the minutes will be made available for copying, following their certification b ythe Chairman, in accordance with the Federal Advisory Committee Act, at the Grand Forks Energy Research Center, 15 North 23rd Street, Grand Forks, North Dakota, upon payment of all charges required by law.

K. DEAN HELMS,
*Acting Deputy Adivsory Committee Management Officer.*

[FR Doc.76-19667 Filed 7-6-76;8:45 am]

## FEDERAL ADVISORY COUNCIL ON REGIONAL ECONOMIC DEVELOPMENT

### OPEN MEETING

#### Agenda

Notice is given that a meeting of the Federal Advisory Council on Regional Economic Development will be held on Wednesday, August 11, 1976, at 9:30 a.m. to 12 noon, in Room 6802, Department of Commerce, Washington, D.C. 20230.

The Federal Advisory Council was established pursuant to Executive Order 11386. The Council is a cabinet-level committee composed of those Federal agencies most concerned with economic development. Among its responsibilities, the Council advises the Secretary of Commerce, who is Chairman of the Council, in his review of the long-range economic development plans prepared by the Title V Regional Action Planning Commissions.

The purpose of this meeting is to discuss the long-range economic development plan submitted to the Secretary of

Commerce by the Old West Regional Commission. In accordance with the review procedures adopted by the Council, the Old West development plan has been circulated to the members for their review.

Persons wishing to attend this meeting should contact the Acting Executive Secretary of the Council, Office of Regional Economic Coordination, Room 2092, Department of Commerce, Washington, D.C. 20230, telephone (202) 377–5174.

Dated at Washington, D.C., June 30, 1976.

JOHN W. EDEN,
*Acting Special Assistant to the Secretary for Regional Economic Coordination.*

[FR Doc.76–19518 Filed 7–6–76;8:45 am]

## GENERAL ACCOUNTING OFFICE

### REGULATORY REPORTS REVIEW

#### Receipt of Report Proposals

The following requests for clearance of reports intended for use in collecting information from the public were received by the Regulatory Reports Review Staff, GAO, on June 28, 1976 (FCC), and June 29, 1976 (FTC). See 44 U.S.C. 3512 (c) and (d). The purpose of publishing this list in the Federal Register is to inform the public of such receipt.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed FCC and FTC forms are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed forms, comments (in triplicate) must be received on or before July 26, 1976, and should be addressed to Mr. John M. Lovelady, Acting Assistant Director, Regulatory Reports Review, United States General Accounting Office, Room 5216, 425 I Street, NW., Washington, D.C. 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202–376–5425.

FEDERAL COMMUNICATIONS COMMISSION

Request for clearance of an extension (no change) of FCC Form 326–A, Computation of Cable Television Annual Fee. FCC Form 326–A is required to be filed annually for each cable television system with the payment of the cable television annual fee. The use of this form is required by Section 76.406 of the Commission's Rules. The man-hour burden is estimated to average 30 minutes per response. Approximately 8,500 forms are required to be filed annually.

Request for clearance of an extension (no change) of FCC Form 330–R, Application for Renewal of an ITFS and/or Response Station(s) and Low Power Relay Station(s) License. FCC Form 330–R is required to be filed when applying for renewal of an ITFS and/or Response Station(s) and Low Power Relay Station(s) License. The use of this form is required by Section 74.932 of the Commission's Rules. Man-hour burden is estimated to average 2½ hours per response. The FCC receives approximately 36 applications annually.

FEDERAL TRADE COMMISSION

The Federal Trade Commission requests clearance of a new single time voluntary questionnaire designed to be submitted to selected local and state agencies licensing three occupations: television and electronic repair, plumbers, and electricians. The questionnaire is designed to obtain current information concerning specific licensing statutes and regulations, numbers of licensed individuals in these occupations, and requirements for obtaining a license to practice these occupations. The FTC estimates the burden to be 3 hours per questionnaire and anticipates sending it to about 100 city and state licensing boards for TV repair, plumbers and electricians.

The Federal Trade Commission requests clearance of a new voluntary quarterly proposal to gather production information from all manufacturers of home canning equipment. The Bureau intends to inquire about total production per month of each of several types of canning equipment; the relevant functional market these types are to be sold in; the quantity of each type sent to each state; and a description of the firm's allocation plan for future distribution. The potential respondents are the 20 known domestic producers of home canning equipment and any new companies which may enter the industry. This information is to be submitted at the end of each quarter until further notice. The FTC estimates the burden to be 64 hours for each quarterly report or an annual burden for each respondent of 256 hours.

NORMAN F. HEYL,
*Regulatory Reports Review Officer.*

[FR Doc.76–19569 Filed 7–6–76;8:45 am]

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 76–60]

### JAPAN ENGINEERING DEVELOPMENT CO.

#### Intent To Grant Foreign Exclusive Patent License

In accordance with the NASA Foreign Licensing Regulations, 14 CFR 1245.405 (e), the National Aeronautics and Space Administration announces its intention to grant to the Japan Engineering Development Company, Tokyo, Japan, an exclusive patent license in Japan for the four NASA owned inventions covered by the Japanese counterparts of: (1) U.S. Application for Patent Serial No. 634,304 for "Abrasion Resistant Coatings for Plastic Surfaces", filed by NASA on November 21, 1975; (2) U.S. Application for Patent Serial No. 604,374 for "Rechargeable Battery Which Combats Shape Change of the Zinc Anode", filed by NASA on August 13, 1975; (3) U.S. Application for Patent Serial No. 642,083 for "Solar Cell Surface Treatment", filed by NASA on December 18, 1975; and (4) U.S. Application for Patent Serial No. 645,508 for "Silicon Nitride Coated Plastic Covered Solar Cell", filed by NASA on December 30, 1975. Copies of the above U.S. Patent Applications can be purchased from the National Technical Information Service, Springfield, Vigrinia, 22161, at a cost of $3.75 a copy. Interested parties should submit written inquiries or comments within 60 days to the Assistant General Counsel for Patent Matters, Code GP, National Aeronautics and Space Administration, Washington, D.C. 20546.

S. NEIL HOSENBALL,
*General Counsel.*

JUNE 28, 1976.

[FR Doc.76–19469 Filed 7–6–76;8:45 am]

## FEDERAL ENERGY ADMINISTRATION

### CASES FILED WITH THE OFFICE OF EXCEPTIONS AND APPEALS

#### Week of June 18 Through June 25, 1976

Notice is hereby given that during the week of June 18 through June 25, 1976, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Federal Energy Administration's Office of Exceptions and Appeals.

Under the FEA's procedural regulations, 10 CFR, Part 205, any person who will be aggrieved by the FEA action sought in such cases may file with the FEA written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first.

MICHAEL F. BUTLER,
*General Counsel.*

JUNE 30, 1976.

APPENDIX.—*List of cases received by the Office of Exceptions and Appeals, June 18 to June 25, 1976*

| Date | Name and location of applicant | Case No. | Type of submission |
|---|---|---|---|
| June 18, 1976 | Atlantic Richfield Co., Los Angeles, Calif. (If granted: FEA's May 14, 1976, decision and order would be rescinded and Atlantic Richfield Co. would be permitted to recoup certain costs which will be incurred by the firm as a result of the sale of its East Chicago refinery to the C F Petroleum Co.) | FEA-0863 | Appeal of FEA's exception decision and order in Atlantic Richfield Co., 3 FEA par. 83,177 (May 14, 1976). |
| Do | Berry Holding Co., Fresno, Calif. (If granted: Crude oil produced from the firm's Berry & Ewing and Surprise properties would be sold at upper tier ceiling prices.) | FEE-2641 | Price exception (sec. 212.73). |
| Do | Robert E. Hanson, Minneapolis, Minn. (If granted: Crude oil produced from the North Tioga Madison unit would be sold at upper tier ceiling prices.) | FEE-2642 | Price exception (sec. 212.72). |
| June 21, 1976 | Coline Gasoline Corp., Washington, D.C. (If granted: Coline Gasoline Corp. would be permitted to increase its prices for natural gas liquid products produced at its Rincon plant to reflect nonproduct cost increases in excess of $0.005/gal.) | FEE-2644 | Price exception (sec. 212.165). |
| Do | Eagle Oil Co., Columbus, Ohio. (If granted: Eagle Oil Co. would be granted a 3-month extension of the exception relief granted in FEA's Oct. 25, 1974, decision and order.) | FEX-0053 | Extension of exception relief. Eagle Oil Co., 1 FEA par. 20,687 (Oct. 25, 1974). |
| Do | Eason Oil Co., Oklahoma City, Okla. (If granted: Crude oil produced from the Weiner property would be sold at upper tier ceiling prices.) | FEE-2683 | Price exception (sec. 212.74). |
| Do | Oil Development Co., Washington, D.C. (If granted: Oil Development Co. would be permitted to increase its prices for natural gas liquid products produced at its Tarzan plant to reflect nonproduct cost increases in excess of $0.005/gal.) | FEE-2645 | Price exception (sec. 212.165). |
| Do | Rock Island Refining Corp., Indianapolis, Ind. (If granted: Rock Island Refining Corp. would receive a stay of its entitlement purchase obligation pending a final determination of its appeal from the exception decision issued by the FEA on June 17, 1976.) | FES-0864 | Stay request. Rock Island Refining Corp., 3 FEA par.—— (June 17, 1976). |
| Do | Southern California Edison Co., Rosemead, Calif. (If granted: FEA's May 21, 1976, decision and order would be rescinded and Southern California Edison Co. would be permitted to import 114,000,000 bbl of low sulfur fuel oil over a 10-yr period on a license fee-free basis.) | FPI-0102 | Appeal of FEA's exception decision and order in Southern California Edison Co., 3 FEA par. —— (May 21, 1976). |
| Do | Terrible Herbst, Inc., Washington, D.C. (If granted: Terrible Herbst, Inc., would receive a stay of the requirements of 10 CFR 211.9 and would be assigned a lower priced supplier pending a final determination of its exception request.) | FES-2635 | Stay request. |
| Do | The Oil Shale Corp., Los Angeles, Calif. (If granted: The Oil Shale Corp., would be permitted to calculate its May 15, 1973, selling prices for gasoline sold to its wholesale rack and reseller classes of purchaser on the basis of the dates written contrates were entered into rather than on the basis of transaction dates.) | FEE-2684 | Price exception (sec. 212.-83). |
| Do | United Refining Co., Warren, Pa. (If granted: United Refining Co. would receive a stay of the requirements of 10 CFR.31 pending a final determination of its exception request.) | FES-2404 | Stay request. |
| June 22, 1976 | Crystal Oil Co., Washington, D.C. (If granted: FEA's May 24, 1976, decision and order would be rescinded and Crystal Oil Co. would be granted additional price relief.) | FEA-0865 | Appeal of FEA's exception decision, and order in Crystal Oil Co., 3 FEA par. ——— (May 24, 1976). |
| June 23, 1976 | Atlantic Richfield Co., Los Angeles, Calif. (If granted: FEA's June 4, 1976, information request denial would be modified and Atlantic Richfield Co. would receive access to portions of documents which were requested in the firm's Dec. 15, 1975, letter.) | FEA-0871 | Appeal of FEA's information request denial. |
| Do | Atlantic Richfield Co., Los Angeles, Calif. (If granted: FEA's Apr. 28, decision and order would be modified and Atlantic Richfield Co. would not be required to place a certain sum of money which it already refunded to the Ashland Oil Co. of California in an escrow account.) | FEX-0055 | Supplemental to FEA's decision and order. Atlantic Richfield Co., 3 FEA par. 85,030 (Apr. 28, 1976). |
| Do | Continental Oil Co., Houston, Tex. (If granted: FEA's May 21, 1976, assignment order would be rescinded and Continental Oil Co. would not be required to supply 372,000 gal of aviation gasoline per year to Federal Express Corp.) | FEA-0868 | Appeal of FEA's assignment order of May 21, 1976. |
| Do | Continental Oil Co., Houston, Tex. (If granted: FEA's May 21, 1976, assignment order would be rescinded and Continental Oil Co. would not be required to supply 25,000 gal of aviation gasoline to Capitol International Airways, Inc.) | FEA-0869 | Do. |
| Do | Exxon Co., U.S.A., Washington, D.C. (If granted: Exxon Co., U.S.A.'s entitlement purchase obligation for March 1976 would be adjusted to correct for FEA's alleged error in computing old oil receipts.) | FEA-0870 | Appeal of FEA entitlement notice issued May 24, 1976. |
| Do | Gasco Gasoline, Inc., Washington, D.C. (If granted: Gasco Gasoline, Inc., would be assigned a new, lower priced supplier of motor gasoline to replace its base period supplier, Fletcher Oil & Refining Co.) | FEE-2686<br>FES-2686 | Exception to change suppliers. Stay request. |
| Do | G. E. Kadane & Sons, Wichita Falls, Tex. (If granted: Crude oil produced and sold from the Banning lease would be retroactively billed at upper tier ceiling prices.) | FEE-2685 | Price exception (sec. 212.72). |
| Do | Larkin, Hoffman, Daly & Lindgren, Ltd., Minneapolis, Minn. (If granted: FEA's May 4, 1976, information request denial would be rescinded and Larkin, Hoffman, Daly & Lindgren, Ltd., would receive access to FEA information concerning the manner in which the Union Oil Co. of California establishes prices.) | FEA-0866 | Appeal of FEA's information request denial. |
| Do | McDonnell Aircraft Co., St. Louis, Mo. (If granted: McDonnell Aircraft Co. would receive an increase in its base period use of naphtha jet fuel.) | FEE-2687 | Exception to increase its base period use. |
| Do | Mid-Michigan Truck Service, Inc., Grand Rapids, Mich. (If granted: Mid-Michigan Truck Service, Inc., would receive an extension of the exception relief granted in FEA's Feb. 13, 1976, decision and order.) | FEX-0054 | Extension of exception relief. Mid-Michigan Truck Service, Inc., 3 FEA par. 83,100 (Feb. 15, 1976). |
| June 24, 1976 | Beyer Aviation, Dubuque, Iowa. (If granted: Beyer Aviation would receive an increase in its base period use of aviation gasoline.) | FEE-2692 | Exception to increase its base period use. |

| Date | Name and location of applicant | Case No. | Type of submission |
|---|---|---|---|
| Do | BP Oil, Inc., Cleveland, Ohio. (If granted: BP Oil, Inc., would be treated as a separate firm from its parent, the Standard Oil Co. (Sohio), for the purpose of pricing unleaded gasoline under sec. 212.122.) | FEE-2691 | Price exception (sec. 212.112). |
| Do | Sabre Refining, Inc., Bakersfield, Calif. (If granted: Sabre Refining, Inc., would receive an exception from the old oil entitlements program.) | FEE-2689 | Exception to the old oil entitlements program. |
| Do | Spohn Oil Co., Kearney, Nebr. (If granted: Spohn Oil Co. would receive an increase in its base period use of aviation fuels.) | FEE 2688 | Exception to increase its base period use. |
| Do | Texas International Airlines, Houston, Tex. (If granted: Exxon Co., U.S.A., would be assigned as the supplier of aviation fuel to Texas International Airlines, Inc., in lieu of its base period supplier, Texaco, Inc.) | FEE-2690 | Exception to change suppliers (sec. 211.9). |

[FR Doc.76-19447 Filed 7-1-76;10:13 am]

## ENERGY SUPPLY AND ENVIRONMENTAL COORDINATION ACT

### Intention To Issue Construction Orders to Certain Powerplants in the Early Planning Process

The Federal Energy Administration (FEA) hereby gives notice of its intention to issue construction orders pursuant to section 2 of the Energy Supply and Environmental Coordination Act of 1974, as amended (ESECA), and in accordance with 10 CFR Parts 303 and 307, to the following powerplants in the early planning process:

| Docket No. | Owner | Generating station | Unit No. | Location |
|---|---|---|---|---|
| OCU-075-N | Appalachian Power Co | Project 1301 | | New Haven, W. Va. |
| OCU-076-N | Arizona Public Service Co | Intermediate 1983 unit. | | Unknown. |
| OCU-077-N | Basin Electric Power Coop | Beulah plant | 1 | Beulah, N. Dak. |
| OCU-078-N | do | do | 2 | Do. |
| OCU-079-N | do | Laramie River | 1 | Wheatland, Wyo. |
| OCU-080-N | do | do | 2 | Do. |
| OCU-081-N | do | do | 3 | Do. |
| OCU-082-N | Big Rivers Electric Corp | Robert Reid | R-2 | Near Sebree, Ky. |
| OCU-083-N | Central Illinois Light Co | Duck Creek | 2 | Banner Township, Ill. |
| OCU-084-N | do | do | 3 | Do. |
| OCU-085-N | Central Louisiana Electric Co., Inc | Rodemacher | 3 | Near Boyce, La. |
| OCU-086-N | Cincinnati Gas & Electric Co | East Bend | 3 | Near Rabbit Hash, Ky. |
| OCU-087-N | Columbus & Southern Ohio Electric Co | E. M. Poston | 5 | Athens, Ohio. |
| OCU-088-N | do | do | 6 | Do. |
| OCU-089-N | Consumers Power Co | Unassigned unit, 1984 | | Unknown. |
| OCU-090-N | do | Unassigned unit, 1985 | | Do. |
| OCU-091-N | Brazos Electric Power Cooperative, Inc., and South Texas Electric Cooperative, Inc. | San Miguel | 1 | South of Christine, Tex. |
| OCU-092-N | Georgia Power Co | Scherer | 2 | Juliette, Ga. |
| OCU-093-N | do | do | 3 | Do. |
| OCU-094-N | do | do | 4 | Do. |
| OCU-095-N | Hoosier Energy Division, Indiana Statewide REC, Inc. | Merom | 1 | Near Merom, Ind. |
| OCU-096-N | do | do | 2 | Do. |
| OCU-097-N | Idaho Power Co | Pioneer | 1 | Orchard, Idaho. |
| OCU-098-N | do | do | 2 | Do. |
| OCU-099-N | City of Independence (Mo.), Power & Light Department. | Blue Valley | 4 | Independence, Mo. |
| OCU-100-N | Indianapolis Power & Light Co | New plant | 1 | Unknown. |
| OCU-101-N | Intermountain power project | Intermountain power project. | 1 | Near Caineville, Utah. |
| OCU-102-N | do | do | 2 | Do. |
| OCU-103-N | do | do | 3 | Do. |
| OCU-104-N | do | do | 4 | Do. |
| OCU-105-N | Kentucky Utilities Co | Ghent | 3 | Ghent, Ky. |
| OCU-106-N | Lower Colorado River Authority | Fayette power project | 2 | La Grange, Tex. |
| OCU-107-N | Northern States Power Co | 1981 fossil-fueled unit | | Becker, Minn. |
| OCU-108-N | do | 1983 fossil-fueled unit | | Do. |
| OCU-109-N | Pacific Power & Light Co | Roosevelt | 1 | West Roosevelt, Wash. |
| OCU-110-N | Pennsylvania Electric Co. and Jersey Central Power & Light Co. | Seward | 7 | Seward, Pa. |
| OCU-111-N | Potomac Electric Power Co | Dickerson | 4 | Dickerson, Md. |
| OCU-112-N | San Antonio City Public Service Board | Not determined | | South or south central, Texas (indefinite). |
| OCU-113-N | South Carolina Public Service Authority | Winyah | 3 | Georgetown, S.C. |
| OCU-114-N | Southwestern Public Service Co | South Plains | 1 | Lubbock County, Tex. |
| OCU-115-N | do | do | 2 | Do. |
| OCU-116-N | Tampa Electric Co | Beacon Key | 1 | Hillsborough County, Fla. |
| OCU-117-N | do | Big Bend | 4 | Ruskin, Fla. |
| OCU-118-N | Texas Power & Light Co., Texas Electric Service Co., and Dallas Power & Light Co. (Texas Utilities Generating Co., agent/operator). | Forest Grove | 1 | Near Athens, Tex. |
| OCU-119-N | Texas Power & Light Co. and Aluminum Co. of America (Texas Utilities Generating Co., agent/operator). | Sandow | 4 | Near Rockdale, Tex. |
| OCU-120-N | do | Twin Oak | 1 | Near Franklin, Tex. |
| OCU-121-N | do | do | 2 | Do. |
| OCU-122-N | Wisconsin Power & Light Co | Edgewater | 5 | Sheboygan, Wis. |

FEA hereby also gives notice of the opporutnity for written presentation of data, views and arguments regarding these proposed construction orders.

The proposed orders would require each of the above listed powerplants in the early planning process to be designed and constructed to be capable of using coal as its primary energy source.

Prior to issuance of a construction order to a powerplant in the early planning process, section 2(c) of ESECA and FEA's regulations (§§ 303.46(b) and 307.3(b) and (c)) require that FEA find that the powerplant is in the early planning process. They also prohibit FEA from issuing a construction order if FEA finds that (1) such order is likely to result in an impairment of reliability or adequacy of service, or (2) an adequate and reliable supply of coal is not reasonably expected to be available. FEA's initial conclusions and rationales with respect to these findings for each of the powerplants are set out in Section 1 of Appendix A to this notice. These findings, conclusions and rationales may be amended as a result of comments received by FEA pursuant to this notice and other information available to FEA. The findings, conclusions and rationales will be included, with any amendments, in a construction order when it is issued.

In addition, ESECA and FEA's regulations (§§ 303.46(b), 307.3(d)) require that FEA consider certain other factors prior to issuance of a construction order. FEA's initial conclusions, and a brief statement of the rationale for such conclusions, with respect to such considerations also are set out in Section 2 of Appendix A to this notice. The conclusions and rationales may be amended as a result of comments received by FEA pursuant to this notice and other information available to FEA. The conclusions and rationales will be included, with any amendments, in the construction order when it is issued.

Upon completion of the proceedings described in this notice, FEA may determine to issue construction orders to some or all of the above-listed powerplants in the early planning process. These construction orders will not become effective, however, until FEA has considered the environmental impact of any such order, pursuant to 10 CFR 208.3(a)(4) and 307.7, and has served the affected powerplant in the early planning process with a Notice of Effectiveness, as provided in §§ 303.10(b), 303.47(b) and 307.5 of FEA's regulations. Section 307.7 (c) requires that prior to the issuance of a Notice of Effectiveness to a powerplant, FEA shall perform an analysis of the environmental impact of the issuance of such Notice of Effectiveness. That analysis shall result either (1) in a declaration that a specific construction order or group of construction orders, will not, if made effective by a Notice of Effectiveness, be likely to have a significant im-

pact on the quality of the human environment; or, (2) in the preparation by FEA of an environmental impact statement covering significant site-specific impacts that are likely to result from a specific construction order or group of construction orders and that have not been adequately discussed in the programmatic Environmental Impact Statement (FES 75–1, dated April 25, 1975) for the FEA program to implement section 2 of ESECA, or in other official documents made publicly available during the FEA proceedings in connection with issuance of a construction order, or otherwise made available to the public. If FEA prepares an environmental impact statement covering significant site-specific impacts from a construction order or group of such orders, the statement shall be prepared and published for comment in accordance with section 102 (2) (C) of the National Environmental Policy Act of 1969 and prior to issuance of a Notice of Effectiveness. Interested persons may request a public hearing pursuant to § 303.173 of the FEA regulations to comment on the contents of a draft environmental impact statement published pursuant to § 307.7(c) of the FEA regulations.

Public comment on the proposals to issue construction orders to the above-listed powerplants in the early planning process is invited in the form of written presentation of data, views and arguments. Comments should relate to individual docket numbers and should make clear to which docket number the individual comment is addressed.

Comments are solicited addressing (1) the adequacy and validity of each of the proposed findings, and the conclusions and the rationales in support of these findings, as well as the conclusions, and rationales in support of the conclusions, with respect to the other factors FEA must consider; (2) the identification of any site-specific environmental impacts resulting from the proposed construction orders that were not identified or described in the programmatic Environmental Impact Statement for the FEA program to implement section 2 of ESECA; and, (3) any other aspects or impacts of the proposed construction order believed to be relevant. It should be recognized that any such powerplant in the early planning process would have to comply with applicable new source performance standards prescribed by the Environmental Protection Agency under the Clean Air Act, as amended.

Interested persons are invited to submit written comments consisting of data, views, or arguments with respect to a proposed construction order or group of orders to Executive Communications, Federal Energy Administration, Box HU, Washington, D.C. 20461.

Comments and other documents submitted to FEA Executive Communications should be identified on the outside of the envelope in which they are transmitted with the designation "Proposed Construction Order for the _____ Powerplant." Fifteen copies should be submitted.

All written comments received by 4:30 p.m., e.d.t., August 5, 1976 and all other relevant information submitted to or otherwise available to FEA will be considered by FEA prior to issuance of any construction order.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

Copies of the FEA regulations implementing section 2 of ESECA (10 CFR Parts 303 and 307) are available from the FEA Regional Offices:

FEDERAL ENERGY ADMINISTRATION, REGIONAL OFFICES

| *Region* | *Address and Phone* |
|---|---|
| I | Robert Mitchell, Regional Administrator, 150 Causeway St., Room 700, Boston, Mass. 02114; (617) 223–3701. |
| II | Alfred Kleinfeld, Regional Administrator, 26 Federal Plaza, Room 3206, New York, N.Y. 10007; (212) 264–1021. |
| III | J. A. LaSala, Regional Administrator, 1421 Cherry St., Room 1001, Philadelphia, Pa. 19102; (215) 597–3890. |
| IV | Fredric Johnson, Regional Administrator, 1655 Peachtree St., N.E., 8th Floor, Atlanta, Ga. 30309; (404) 526–2837. |
| V | N. Allen Andersen, Regional Administrator, Federal Office Building, 175 West Jackson Blvd., Room A–333, Chicago, Ill. 60604; (312) 353–8420. |
| VI | Delbert Fowler, Regional Administrator, P.O. Box 35228, 2626 West Mockingbird Lane, Dallas, Texas 75235; (214) 749–7345. |
| VII | William H. Smith, Jr., Acting Regional Administrator, Twelve Grand Building, P.O. Box 2208, 112 East 12th St., Kansas City, Mo. 64142; (816) 374–2061. |
| VIII | Dudley Faver, Regional Administrator, P.O. Box 26247, Belmar Branch, 1075 South Yukon St., Lakewood, Colo. 80226; (303) 234–2420. |
| IX | William Arntz, Regional Administrator, 111 Pine Street, San Francisco, Calif. 94111; (415) 556–7216. |
| X | Jack Robertson, Regional Administrator, 1992 Federal Building, 915 Second Avenue, Seattle, Washington 98174; (206) 442–7280. |

Any questions regarding this notice should be directed to the FEA National Office as follows: Federal Energy Administration, Code OCU (Construction Order #2), Washington, D.C. 20461.

(Energy Supply and Environmental Coordination Act of 1974 (Pub. L. 93–319), as amended by Pub. L. 94–163; Federal Energy Administration Act of 1974 (Pub. L. 93–275); E.O. 11790 (39 FR 23185).)

Issued in Washington, D.C., June 30, 1976.

MICHAEL F. BUTLER,
*General Counsel,*
*Federal Energy Administration.*

APPENDIX A

PROPOSED FINDINGS AND CONCLUSIONS

ESECA and the FEA regulations require FEA to make certain findings and consider certain factors before issuing a construction order. FEA's initial findings, as well as its initial conclusions with respect to the factors FEA is required to consider, are set out below with respect to each of the powerplants in the early planning process listed below. Supporting rationales and conclusions are also set forth.

| Docket No. | Owner | Generating station | Unit No. | Location |
|---|---|---|---|---|
| OCU–075–N | Appalachian Power Co | Project 1301 | | New Haven, W. Va. |
| OCU–076–N | Arizona Public Service Co | Intermediate 1983 unit. | | Unknown. |
| OCU–077–N | Basin Electric Power Coop | Beulah plant | 1 | Beulah, N. Dak. |
| OCU–078–N | do | do | 2 | Do. |
| OCU–079–N | do | Laramie River | 1 | Wheatland, Wyo. |
| OCU–080–N | do | do | 2 | Do. |
| OCU–081–N | do | do | 3 | Do. |
| OCU–082–N | Big Rivers Electric Corp | Robert Reid | R–2 | Near Sebree, Ky. |
| OCU–083–N | Central Illinois Light Co | Duck Creek | 2 | Banner Township, Ill. |
| OCU–084–N | do | do | 3 | Do. |
| OCU–085–N | Central Louisiana Electric Co., Inc | Rodemacher | 3 | Near Boyce, La. |
| OCU–086–N | Cincinnati Gas & Electric Co | East Bend | 3 | Near Rabbit Hash, Ky. |
| OCU–087–N | Columbus & Southern Ohio Electric Co | E. M. Poston | 5 | Athens, Ohio. |
| OCU–088–N | do | do | 6 | Do. |
| OCU–089–N | Consumers Power Co | Unassigned unit, 1984 | | Unknown. |
| OCU–090–N | do | Unassigned unit, 1985 | | Do. |
| OCU–091–N | Brazos Electric Power Cooperative, Inc., and South Texas Electric Cooperative, Inc. | San Miguel | 1 | South of Christine, Tex. |
| OCU–092–N | Georgia Power Co | Scherer | 2 | Juliette, Ga. |
| OCU–093–N | do | do | 3 | Do. |
| OCU–094–N | do | do | 4 | Do. |
| OCU–095–N | Hoosier Energy Division, Indiana Statewide REC, Inc. | Merom | 1 | Near Merom, Ind. |
| OCU–096–N | do | do | 2 | Do. |
| OCU–097–N | Idaho Power Co | Pioneer | 1 | Orchard, Idaho. |
| OCU–098–N | do | do | 2 | Do. |
| OCU–099–N | City of Independence (Mo.), Power & Light Department. | Blue Valley | 4 | Independence, Mo. |

| Docket No. | Owner | Generating station | Unit No. | Location |
|---|---|---|---|---|
| OCU-100-N | Indianapolis Power & Light Co. | New plant | 1 | Unknown. |
| OCU-101-N | Intermountain power project | Intermountain power project. | 1 | Near Caineville, Utah. |
| OCU-102-N | do | do | 2 | Do. |
| OCU-103-N | do | do | 3 | Do. |
| OCU-104-N | do | do | 4 | Do. |
| OCU-105-N | Kentucky Utilities Co. | Ghent | 3 | Ghent, Ky. |
| OCU-106-N | Lower Colorado River Authority | Fayette power project. | 2 | La Grange, Tex. |
| OCU-107-N | Northern States Power Co. | 1981 fossil-fueled unit | | Becker, Minn. |
| OCU-108-N | do | 1983 fossil-fueled unit | | Do. |
| OCU-109-N | Pacific Power & Light Co. | Roosevelt | 1 | West Roosevelt, Wash. |
| OCU-110-N | Pennsylvania Electric Co. and Jersey Central Power & Light Co. | Seward | 7 | Seward, Pa. |
| OCU-111-N | Potomac Electric Power Co. | Dickerson | 4 | Dickerson, Md. |
| OCU-112-N | San Antonio City Public Service Board | Not determined | | South or south central, Texas (indefinite). |
| OCU-113-N | South Carolina Public Service Authority | Winyah | 3 | Georgetown, S.C. |
| OCU-114-N | Southwestern Public Service Co. | South Plains | 1 | Lubbock County, Tex. |
| OCU-115-N | do | do | 2 | Do. |
| OCU-116-N | Tampa Electric Co. | Beacon Key | 1 | Hillsborough County, Fla. |
| OCU-117-N | do | Big Bend | 4 | Ruskin, Fla. |
| OCU-118-N | Texas Power & Light Co., Texas Electric Service Co., and Dallas Power & Light Co. (Texas Utilities Generating Co., agent/operator). | Forest Grove | 1 | Near Athens, Tex. |
| OCU-119-N | Texas Power & Light Co. and Aluminum Co. of America (Texas Utilities Generating Co., agent/operator). | Sandow | 4 | Near Rockdale, Tex. |
| OCU-120-N | do | Twin Oak | 1 | Near Franklin, Tex. |
| OCU-121-N | do | do | 2 | Do. |
| OCU-122-N | Wisconsin Power & Light Co. | Edgewater | 5 | Sheboygan, Wis. |

(1) *Proposed Findings.* (a) *The powerplant is in the early planning process.* Based on an analysis of the information submitted to or otherwise available to FEA, including the information provided to FEA by the powerplant on FEA Form C–603–S–O (Identification Report), and information provided by the powerplant in response to subsequent inquiry to assure the continued applicability and currency of such information, FEA proposes to find that the powerplant is in the early planning process. This proposed finding is based on the facts, assumptions and reasoning stated below:

(i) The date by which the powerplant plans to commence the sale and exchange of electric power is not more than 10 years from June 30, 1976, and the driving of the foundation piling, or the equivalent foundation structural event, in accordance with the approved final drawing for the main boiler of the powerplant, has not commenced.

(ii) The powerplant has identified itself as a powerplant in the early planning process by filing with FEA an FEA Form C–603–S–O in accordance with 10 C.F.R. 307.6(b) and with the notice of the requirement to file such report that was published in the FEDERAL REGISTER on May 22, 1975 (40 FR 22309).

(b) *FEA cannot find that the design and construction of the powerplant with the capability of using coal as its primary energy source is likely to result in an impairment of the reliability or adequacy of service.* Based on an analysis of the information submitted to or otherwise available to FEA, FEA proposes that it cannot find that the requirement that the powerplant be designed and constructed to be capable of using coal as its primary energy source is likely to result in an impairment of the reliability or adequacy of service. This proposed conclusion is based on the facts, assumptions and reasoning stated below:

(i) There will not be a delay in the commencement of the sale or exchange of electric power by reason of the FEA requirement that the powerplant be designed and constructed to be capable of using coal as its primary energy source, because such capability is already planned. Specifically, the powerplant stated on FEA Form C–603–S–O that it is being designed and constructed either (1) to burn only coal, or (2) if it is being designed with multiple fuel design, coal is its anticipated primary fuel.

(ii) The fact that there will not be a delay in the commencement of the sale or exchange of electric power by the powerplant by reason of the FEA requirement means that the dispatching system of which the powerplant will be a part cannot be adversely affected, nor can the Gross Reserve Margin for such system be reduced by reason of this requirement. ("Dispatching system" means the group of powerplants for which there is centralized control of power generation scheduling and transmission planning.)

(iii) Because the powerplant is being designed and constructed to burn coal as its primary energy source, FEA assumes that there will be no derating of the powerplant when using coal as its primary energy source that would impair reliability or adequacy of service.

(c) *FEA cannot find that an adequate and reliable supply of coal is not reasonably expected to be available.* Based on analysis of the information submitted to or otherwise available to FEA, FEA proposes that it cannot find that an adequate and reliable supply of coal is not reasonably expected to be available. This proposed conclusion is based on the facts, interpretations and reasoning stated below:

(i) It is 40 or more months before the powerplant can realistically plan to commence the sale or exchange of electric power. Since the length of time prior to the planned commencement of the sale or exchange of electric power is 40 or more months, there is a sufficient period of time for the powerplant to obtain an adequate and reliable supply of coal.

(ii) Because the powerplant stated on FEA Form C–603–S–O that it is being designed and constructed either (1) to burn only coal, or (2) if it is being designed and constructed with multiple fuel design, coal is its anticipated primary fuel, FEA assumes that the powerplant has determined that an adequate and reliable supply of coal will be available at the time the powerplant commences the sale or exchange of electric power.

(2) *Proposed Conclusions Concerning Factors FEA Is Required to Consider.*

(a) *The existence and effects of any contractual commitment for the construction of the powerplant.* The powerplant has not informed FEA, nor is FEA aware, of any contractual commitments for the construction of the powerplant that would be adversely affected by the FEA requirement that the powerplant be designed and constructed to be capable of using coal as its primary energy source. Further, because the powerplant has indicated on FEA Form C–603–S–O that it will be designed and constructed to be capable of using coal as its primary energy source, FEA assumes that the FEA requireemnt will have no independent effect on any contractual commitments for design or construction of the powerplant. FEA therefore proposes to conclude that the FEA requirement that the powerplant be designed and constructed to be capable of using coal as its primary fuel will not affect any contractual commitment for the design or construction of the powerplant, and that as a result there are no such effects which FEA is required to consider.

(b) *The capability of the powerplant to recover any increase in projected capital investment required as a result of a construction order.* In the response to FEA Form C–603–S–O, the powerplant indicated that it would be designed and construced to be capable of using coal as its primary fuel. FEA proposes to conclude, therefore, that the FEA requirement that the powerplant be designed and constructed to be capable of burning coal as its primary energy source will not require any increase in projected capital investment. FEA further proposes to conclude that since no increase in projected capital investment is required, FEA is not required to consider the capability of the powerplant to recover any increase.

(c) *The potential loss of revenue resulting from a delay in commencement of the sale or exchange of electric power, if any, as a result of a construction order.* In response to FEA Form C–603–S–O, the powerplant indicated that it would be designed and constructed to be capable of using coal as its primary fuel. FEA proposes to conclude, therefore, that the FEA requirement that the powerplant be designed and constructed to be capable of using coal as its primary energy source will not result in the delay in the commencement of the sale or exchange of electric power by such powerplant. FEA further proposes to conclude that because no delay will result, it is not necessary or appropriate for FEA to consider the potential for a significant loss of revenue as a result of delay in the commencement of sale or exchange of electric power.

(d) *The relevant regulations or policies of any State or local agency with jurisdiction over the sale or exchange of electric power by the powerplant.* No relevant regulations or policies of any State or local agency with jurisdiction over the sale or exchange of electric power by the powerplant have been brought to FEA's attention that would affect the powerplant as a result of the FEA requirement that the powerplant be designed and constructed to be capable of using coal as its primary energy source, nor is FEA aware of any such regulations or policies. FEA proposes to conclude, therefore, that it is not necessary or appropriate for FEA to consider the effects on the powerplant of such regulations or policies.

[FR Doc.76–19448 Filed 7–1–76;8:45 am]

## EXECUTIVE SUBCOMMITTEE OF THE TRANSPORTATION ADVISORY COMMITTEE

### Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770), notice is hereby given that the Executive Subcommittee of the Transportation Advisory Com-

mittee will meet Thursday, July 22, 1976, at 10:00 a.m., Room 6524, FEA Headquarters, 12th and Pennsylvania Avenue, NW., Washington, D.C.

The Subcommittee was established to make recommendations to the parent Committee with respect to general transportation aspects of interests and problems related to the policy and implementation of programs to meet the continuing energy shortage.

The purpose of the meeting is to develop an agenda for the next meeting of the parent Committee.

The meeting is open to the public. The Chairman of the Committee is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Subcommittee will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Lois Weeks, Director, Advisory Committee Management, (202) 961-7022, at least 5 days prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Further information concerning this meeting may be obtained from the Advisory Committee Management Office.

Minutes of the meeting will be made available for public inspection at the Federal Energy Administration, Washington, D.C.

Issued at Washington, D.C., on July 1, 1976.

MICHAEL F. BUTLER,
*General Counsel.*

[FR Doc.76-19554 Filed 7-1-76;4:16 pm]

## FEDERAL HOME LOAN BANK BOARD

[No. AC-14]

### FIRST SAVINGS AND LOAN ASSOCIATION DEL RIO, TEXAS

#### Approval of Conversion

JUNE 30, 1976.

Notice is hereby given that on June 30, 1976, the Federal Home Loan Bank Board, as the operating head of the Federal Savings and Loan Insurance Corporation, by Resolution No. 76-473, approved the application of First Savings and Loan Association, Del Rio, Texas, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of the Secretary of said Corporation, 320 First Street NW., Washington, D.C. 20552 and the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Little Rock, 1400 Tower Building, Little Rock, Arkansas 72201.

By the Federal Home Loan Bank Board.

J. J. FINN,
*Secretary.*

[FR Doc.76-19514 Filed 7-6-76;8:45 am]

## FEDERAL MARITIME COMMISSION

### THAILAND/PACIFIC FREIGHT CONFERENCE

#### Agreement Filed

*Correction*

In FR Doc. 76-18854 appearing in the Federal Register of Tuesday, June 29, 1976 on page 26748, the beginning of the fifth paragraph should be corrected to read: "Agreement 9474-2 * * *.".

### FARRELL LINES, INC., ET AL.

#### Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street NW., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California, and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before July 27, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

In the matter of: Farrall Lines Incorporated, Hamburg-Suedamerikanische Dampfschifffahrts-Gesellschaft Eggert & Amsinck, trading as Columbus Line Associated Container Transportation (Australia) Ltd. Australia Shipping Commission, trading as The Australian National Line Refrigerated Express Line (A/ASIA) Pty. Ltd.

Notice of Agreement Filed by:

Edward Aptaker, Esq., Morgan, Lewis & Bockius, Counselors at Law, 1800 M Street NW., Washington, D.C. 20036.

Agreement No. 10248, among Farrell Lines Incorporated, Columbus Line, Associated Container Transportation (Australia) Ltd., The Australian National Line, and Refrigerated Express Line (A/Asia) Pty., Ltd., common carriers by water, covers an arrangement for the coordination of the sailings of the parties in the trade from Australia to the East and Gulf Coasts of the United States.

By Order of the Federal Maritime Commission.

Dated: July 1, 1976.

FRANCIS C. HURNEY,
*Secretary.*

[FR Doc.76-19560 Filed 7-6-76;8:45 am]

### FARRELL LINES, INC., ET AL.

#### Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington Office of the Federal Maritime Commission, 1100 L Street NW., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California, and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before June 27, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

In the matter of: Farrell Lines Incorporated Hamburg - Suedamerikanische Dampfschifffahrts-Gesellschaft Eggert & Amsinck, trading as Columbus Line Associated Container Transportation (Australia) Ltd. Australia Shipping Commission, trading as The Australian National Line Refrigerated Express Line (A/Asia) Pty. Ltd.

Notice of Agreement filed by:

Edward Aptaker, Esq., Morgan, Lewis & Bockius, 1800 M Street NW., Washington, D.C. 20036.

Agreement No. 10247, among Farrell Lines Incorporated, Columbus Line, Associated Container Transportation (Australia) Ltd., The Australian National Line and Refrigerated Express Line (A'Asia) Pty. Ltd. provides that a $25 premium will be paid to a party for each

metric ton of meat lifted at Northwest Australian ports (Broome/Wyndham/Dawin range) for destination to ports on the East and Gulf Coasts of the United States from the date the agreement is approved through December 31, 1977. The party shall be paid by the Australian Meat Board through funds collected from the parties to the agreement according to the terms and conditions specified therein.

By Order of the Federal Maritime Commission.

Dated: July 1, 1976.

FRANCIS C. HURNEY,
*Secretary.*

[FR Doc.76-19561 Filed 7-6-76;8:45 am]

## PACIFIC COAST EUROPEAN FREIGHT CONFERENCE

### Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street NW., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California, and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before July 27, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:
David C. Nolan, Esquire, Graham & James, One Maritime Plaza, San Francisco, California 94104.

Agreement No. 5200-30, among the member lines of the above-named conference, provides (1) that self-policing and enforcement pursuant to conference activity in the trade from the U.S. West Coast to the United Kingdom, Republic of Ireland, the Scan/Baltic area, Continental ports and interior ports served thereby will be provided by the Executive Director of the Associated North Atlantic Freight Conferences and (2) that self-policing for the Mediterranean and African portions of the conference scope shall be provided by an Executive Representative Panel, consisting of representatives of each member line serving the trades, one of whom is to be chosen chairman and one vice chairman.

By Order of the Federal Maritime Commission.

Dated: June 30, 1976.

FRANCIS C. HURNEY,
*Secretary.*

[FR Doc.76-19559 Filed 7-6-76;8:45 am]

## INDEPENDENT OCEAN FREIGHT FORWARDER LICENSES

### Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as independent ocean freight forwarders pursuant to Section 44(a) of the Shipping Act, 1916, (Stat. 552 and 46 U.S.C. 841(b)).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to communicate with the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, D.C. 20573.

Quickways Forwarding Services (Khawaja M. Razavi, d/b/a), 6029 Carlton Way #9, Hollywood, L.A., California 90026.

Pacific Northwest Motor Freight Lines, Inc., 600 South Edmunds Street, Seattle, WA 98108. Officers: L. H. Doolittle, President/Treasurer, Helen E. Doolittle, Vice President/Secretary.

Romat Shipping Corp., 1536 Dieman Lane, E. Madison, L.I., New York 1154. Officers: Daniel Rosen, President, Jose Mateus, Vice President, Adele Rosen, Secretary/Treasurer, Elizabeth Mateus, Vice President.

5 Star Air Freight Corporation, 1414 Calcon Hook Road, Sharon Hill, PA 19079. Officers: Salvatore Sorace, President, Donald A. Pettinelli, Exec. Vice President.

Donnell Customs Services, Inc., 53 West Jackson Blvd., Chicago, IL 60604. Officers: Lawrence J. McCann, Vice President/Treasurer, Arthur B. Parker, Vice President/Secretary, Joseph P. Donnell, President.

Westwind Overseas Limited, 3 Sheridan Square, Apt. No. 5C, New York, N.Y. 10014. Officer: Peter D. Wolf, President.

Export Service Priorities, Inc., P.O. Box 161223, Memphis, TN 38116. Officers: Jerry W. Gillentine, President, Arthur N. Barnes, Vice President, Carol M. Barnes, Secretary/Treasurer, Peggie H. Gillentine, Assistant Secretary.

Ven-Air Service, Inc., P.O. Box 520371, Miami, FL 33152. Officers: Enrique C. Garcia, President, Ernest Romero, Vice President, Nestor Morales, Secretary, Eileen Romero, Treasurer.

World Cargo Ltd., 3985 Newport Street, Unit C, Denver, Colorado 80207. Officers: Rosalie H. Kent, Operations Director, Earl A. Hager, Managing Director.

A. N. Deringer, Inc., 64-66 No. Main St., St. Albans, Vermont 05478. Officers: Helen G. Deringer, President/Treasurer, Kenneth J. Holzscheiter, Vice President, L. W. Kelley, Vice President, Maurice R. Greene, Vice President.

By the Federal Maritime Commission.

Dated: June 30, 1976.

FRANCIS C. HURNEY,
*Secretary.*

[FR Doc.76-19558 Filed 7-6-76;8:45 am]

# FEDERAL POWER COMMISSION

[Docket Nos. RP73-107, RP74-90 and RP75-91]

## CONSOLIDATED GAS SUPPLY CORP.

### Informal Conference

JUNE 29, 1976.

Take notice that an informal conference for the purpose of resolving the issues in the referenced dockets will be convened at 10:30 A.M. (EDT) on July 6, 1976 in Room 5200 of the Federal Power Commission, 825 N. Capitol Street NE., Washington, D.C. 20426.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19457 Filed 7-6-76;8:45 am]

[Docket Nos. RP71-15 and RP75-28 (PGA76-4 and DCA76-2)]

## EAST TENNESSEE NATURAL GAS CO.

### Pipeline Rates; Order Accepting for Filing and Suspending Proposed Tariff Sheet, Subject to Condition

JUNE 28, 1976.

On May 14, 1976, East Tennessee Natural Gas Company (East Tennessee) tendered proposed changes[1] in its FPC Gas Tariff, Sixth Revised Volume No. 1. The filing tracks rate increases tendered on that date by East Tennessee's pipeline supplier, Tennessee Gas Pipeline Company (Tennessee). The proposed changes will be accepted for filing, suspended for one day, and permitted to become effective, on July 2, 1976, subject to refund and to the condition that East Tennessee file appropriate revised tariff sheets tracking any adjustments by Tennessee to its rate increase filing.

East Tennessee's filing includes a purchased gas cost (PGA) adjustment of 2.88¢ per Mcf and a reduction in the demand charge adjustment surcharge (DCA) of 2.68¢ per Mcf to 4.16¢ per Mcf to recoup $0.8 million in East Tennessee's deferred account. An effective date of July 1, 1976 is requested.

Public notice of this filing was issued on May 25, 1976, with all comments, protests and petitions to intervene due on or before June 16, 1976. No responses have been received.

[1] Sixteenth Revised Sheet No. 4. East Tennessee also tendered an alternative, lower, PGA adjustment, Alternate sixteenth Revised Sheet No. 4.

This filing tracks proposed changes by Tennessee including an allowance for curtailment credits. The propriety of East Tennessee's method for tracking Tennessee's curtailment adjustment has not been established and is an issue being litigated in Docket Nos. RP71–15 and RP75–28. For that reason, the Commission has determined that the proposed rates have not been shown to be just and reasonable, and may be unjust, unreasonable, unduly discriminatory or otherwise unlawful. The tendered tariff sheet will be accepted for filing, and suspended for one day until July 2, 1976, when it will be permitted to become effective, subject to refund and to the final outcome of these proceedings.

This filing will be accepted subject to a condition that East Tennessee file appropriate revisions to these tariff sheets to track any revisions filed by Tennessee eliminating from Tennessee's filing of May 14, 1976, any producer rate increases not yet in effect on July 2, 1976.

*The Commisison finds:* It is necessary and appropriate to aid in the enforcement of the Natural Gas Act that East Tennessee's tender, on May 14, 1976, of Sixteenth Revised Sheet No. 4 be accepted for filing and suspended for one day until July 2, 1976, when it shall become effective, subject to refund.

*The Commission orders:* (A) East Tennessee's tender in these dockets of Sixteenth Revised Sheet No. 4 is hereby accepted for filing, suspended for one day, or until July 2, 1976, when it shall become effective, subject to refund and upon condition that East Tennessee file a revised tariff sheet tracking any revisions by Tennessee to Tennessee's PGA filing of May 14, 1976.

(B) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19450 Filed 7–6–76;8:45 am]

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[Docket No. CP75–96, et al]

## EL PASO ALASKA CO., ET AL.

### Proposed Inspection Trip

JUNE 29, 1976.

This is to advise that on or about August 1, 1976, the members of this Commission will conduct a survey of the Alaskan Natural Gas Transmission facilities which are contemplated in the above-styled proceedings. In doing so, the Commission members will utilize transportation and other physical facilities provided by the Federal government, in addition to commercial facilities or transportation arrangements. All expenses will be borne by the Commission.

Attention is directed to Section 1.4 of the Commission's Rules of Practice and Procedure, 18 CFR 1.4. Consistent with those requirements all public and private interests are prohibited from engaging in communications of an ex parte nature with the Commission.

The Commission members will undertake this trip unaccompanied by any representative of any party to the above-styled proceedings. Officials of United States Federal Departments or Agencies other than parties will assist the Commission members in certain physical aspects of the tour.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19456 Filed 7–6–76;8:45 am]

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[Docket No. RP73–23 (PGA 76–4)]

## LAWRENCEBURG GAS TRANSMISSION CORP.

### Filing of Tariff Sheets

JUNE 29, 1976.

Take notice that on June 21, 1976, Lawrenceburg Gas Transmission Corporation (Lawrenceburg) tendered for filing two (2) revised gas tariff sheets to its FPC Gas Tariff, First Revised Volume No. 1, identified as Fourth Revised Sheet No. 4 and Fourth Revised Sheet No. 18.

Lawrenceburg states that these revised tariff sheets are being filed to reflect a change in its cost of gas purchased from Texas Gas Transmission Corporation (Texas Gas), pursuant to Lawrenceburg's Purchase Gas Adjustment Clause in its FPC Gas Tariff, First Revised Volume No. 1. Lawrenceburg requests an effective date of August 1, 1976, and a "Waiver of Notice Requirements" of the Commission's Regulations so that the tariff sheets can become effective on the requested date. The proposed change in rates would increase revenues from jurisdictional sales and service by $213,473 based on the 12-month period ended May 31, 1976.

Lawrenceburg states that copies of this filing have been mailed to its two wholesale customers and to the interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 16, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19453 Filed 7–6–76;8:45 am]

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[Docket No. RP76–100]

## MICHIGAN WISCONSIN PIPE LINE CO.

### Pipeline Rates; Order Granting Petition To Intervene and Amending Prior Order

JUNE 28, 1976.

On May 28, 1976, the Commission accepted for filing and suspended tariff sheets proposing increased rates filed by Michigan Wisconsin Pipe Line Company in the captioned docket. Public notice of the filing had been issued on May 13, 1976, with comments, protests, and petitions to intervene due on or before May 21, 1976. Untimely petitions to intervene were filed by Michigan Consolidated Gas Company, Columbia Gas Transmission Corporation, Michigan Public Service Commission, and Illinois Commerce Commission. The Commission believes that the interest of those petitioners in the instant proceeding is sufficient to warrant intervention herein. Accordingly, the petitions will be granted.

In Appendix A of the order of May 28, 1976, the Missouri Public Service Corporation was incorrectly designated as having filed a petition to intervene. Reference to that company was incorrect and should be corrected to indicate that the Wisconsin Public Service Corporation petitioned to intervene. The order will be so amended.

*The Commission finds:* (1) It is desirable and in the public interest to permit the above name petitioner to intervene.

*The Commission orders:* (A) The above-named petitioners are hereby permitted to intervene in these proceedings subject to the rules and regulations of the Commission; *Provided, however,* That participation of such intervenors shall be limited to matters affecting asserted rights and interests as specifically set forth in their petitions to intervene; and *Provided, further,* that the admission of such intervenors shall not be construed as recognition by the Commission that they might be aggrieved because of any order or orders of the Commission entered in this proceeding.

(B) The interventions granted herein shall not be the basis for delaying or deferring any procedural schedules heretofore established for the orderly and expeditious disposition of this proceeding.

(C) The Commission's order of May 28, 1976, is hereby amended so as to delete reference to the Missouri Public Service Corporation from Appendix A thereof and to substitute therefor the Wisconsin Public Service Corporation.

(D) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19451 Filed 7–6–76;8:45 am]

[Docket Nos. RP71-16 (PGA76-4) and RP74-29 (DCA76-2)]

## MIDWESTERN GAS TRANSMISSION CO.

### Filing Pursuant to Tariff Rate Adjustment Provisions

JUNE 29, 1976.

Take notice that on June 16, 1976, Midwestern Gas Transmission Company (Midwestern) tendered for filing Fourteenth Revised Sheet No. 5 to its FPC Gas Tariff, Third Revised Volume No. 1, to be effective August 1, 1976. Midwestern states that the sole purpose of the revised tariff sheet is to reflect adjustments to its rates pursuant to rate adjustment provisions in Article XVII, XVIII, and XIX of the General Terms and Conditions of its tariff.

Midwestern states that as to the Southern System, Fourteenth Revised Sheet No. 5 reflects (1) a Current Purchased Gas Cost Rate Adjustment pursuant to Section 2 of Article XVII which is based on rate changes filed by Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee) on May 14, 1976, in Docket Nos. RP73-114, RP74-24, and RP74-73, and (2) a revised Surcharge for Amortizing the Unrecovered Purchased Gas Cost Account for the Southern System pursuant to Section 3 of Article XVII. Midwestern states that the calculation of the Surcharge is based on the balance in the account as of April 30, 1976, three months prior to the effective date of adjustment as specified by Section 3.4 of Article XVII. According to Midwestern, the revised tariff sheet also reflects a Current Rate Adjustment to reflect curtailment demand charge credits applicable to the Southern System pursuant to Section 9 of Article XIX.

Midwestern states that as to the Northern System, Fourteenth Revised Sheet No. 5 reflects a revised Surcharge for Amortizing the Unrecovered Purchased Gas Cost Account for the Northern System pursuant to Section 3 of Article XVIII.

Midwestern states that copies of the filing have been mailed to all of its jurisdictional customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 9, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19462 Filed 7-6-76;8:45 am]

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[Docket No. RP72-149 (PGA 76-11)]

## MISSISSIPPI RIVER TRANSMISSION CORP.

### Proposed Change in Rates

JUNE 29, 1976.

Take notice that Mississippi River Transmission Corporation ("Mississippi") on June 23, 1976, submitted for filing Forty-Third Revised Sheet No. 3A to its FPC Gas Tariff, First Revised Volume No. 1, to become eeffctive August 1, 1976.

The instant filing is being made pursuant to the provisions of Mississippi's purchased gas cost adjustment clause to track a rate change filing of Trunkline Gas Company ("Trunkline") made pursuant to the terms of the PGA provisions of its tariff and the Advance Payment and Transportation tracking provisions of its Agreement as to Rates and Related Matters at Docket No. RP74-89.

Mississippi submitted schedules containing computations supporting the rate changes to be effective August 1, 1976. Mississippi states that copies of its filing were served on Mississippi's jurisdictional customers and the State Commissions of Arkansas, Illinois and Missouri.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 12, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene unless such petition has previously been filed. Copies of the filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19460 Filed 7-6-76;8:45 am]

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[Docket Nos. RP73-114, RP74-24, and RP74-73 (PGA 76-3, DCA76-2, and R&D76-2)]

## TENNESSEE GAS PIPELINE CO.

### Pipeline Rates; Order; Tariff Sheets

JUNE 28, 1976.

On May 14, 1976, Tennessee Gas Pipeline Company (Tennessee) tendered for filing proposed changes and alternate proposed changes[1] to its FPC Gas Tariff, Ninth Revised Volume No. 1, to reflect increases in purchased gas costs and in research and development (R&D) expenditures, and to recoup additional curtailment demand charge credits through its commodity surcharge. As will be discussed herein, the Commission shall accept the proposed changes for filing, suspend their effectiveness for one day, and permit them to become effective subject to refund on July 2, 1976. This filing will be accepted subject to the condition that Tennessee file revised tariff sheets eliminating any anticipated producer rate increases which will not be in effect on July 2, 1976.

Tennessee's alternate proposed changes, which reflect the elimination of purchased gas costs in excess of the rate level established by Opinion No. 742, will be accepted for filing and permitted to become effective without suspension on July 1, 1976, provided that Tennessee file appropriate revisions to eliminate the effects of any anticipated producer rate increases which will not be in effect on July 1, 1976.

Tennessee's filing of May 14, 1976 in these dockets includes: (a) a PGA rate increase of 2.57¢ per Mcf tracking increased gas costs of 4.18¢ per Mcf less 1.61¢ per Mcf reducing the surcharge to 2.64¢ per Mcf to recoup $14 million in the Deferred Purchased Gas Cost Account; (b) separate rate changes for each zone to recover the revised balance of $9.8 million in the account for the curtailment credit to demand charges; and (c) a rate increase of 0.05¢ per Mcf to recover an additional $0.6 million of R&D expenses attributable to existing projects. An effective date of July 1, 1976 is requested.

Public notice of the filing was issued on June 7, 1976 with all comments, protests or petitions to intervene due on or before June 24, 1976.

The Commission's review of Tennessee's filing indicates that the proposed rates contain small producer purchases in excess of the rate levels prescribed in Opinion No. 742. Also, the proposed rates appear to reflect producer rate increases which have not yet been filed and may not be in effect on July 1, 1976. Further, this filing reflects R&D expenditures attributable to projects which have not yet been found to be eligible for R&D expense tracking. For these reasons, the proposed rates have not been shown to be just and reasonable and may be unjust, unreasonable, unduly discriminatory or otherwise unlawful. Therefore, the proposed tariff sheets will be accepted for filing and their use will be suspended for one day, until July 2, 1976, when they may be permitted to become effective subject to refund. This filing will be ac-

[1] Twelfth Revised Sheets Nos. 12A and 12B; and Alternate Twelfth Revised Sheets Nos. 12A and 12B.

cepted subject to the condition that Tennessee file revised tariff sheets reflecting the elimination of any producer rate increases not effective as of July 1, 1976.

In regard to the above described issue concerning small producer purchases, the establishment of a hearing schedule will be deferred pending Commission action on rehearing of Opinion No. 742[2] and the proposed rulemaking in Docket No. RM76-5[3]

With respect to the inclusion of increased R&D expenditures the Commission notes that the expenditures are attributable to projects which have not yet been found to be eligible for R&D expense tracking. Since this issue is before the Commission in the proceeding in Docket Nos. RP75-13 and RP75-113, the expenditures in the instant filing will be determined by the outcome of the proceedings in those dockets. All amounts in the instant filing associated with these R&D projects will be subject to refund pending final Commission decision on this issue.

Tennessee, in its May 14, 1976 filing, additionally tendered Alternate Twelfth Revised Sheet Nos. 12A and 12B. Tennessee requests these alternate sheets be permitted to become effective on July 1, 1976 in the event the Commission suspends the effectiveness of Twelfth Revised Sheet Nos. 12A and 12B. This alternative filing includes a lower PGA adjustment of 2.06¢ per Mcf which reflects elimination of cost increases due to purchases at rates in excess of the levels prescribed by Opinion No. 742. The Alternate sheets reflects producer rate increases which may not be in effect on July 1, 1976.

The remainder of Tennessee's alternate filing appears to comply with the standards set forth in Docket No. R-406 and should be approved. Therefore, the alternate tariff sheets will be accepted for filing and permitted to become effective July 1, 1976, subject to a condition that Tennessee file revised alternate tariff sheets reflecting the elimination of the portion of its PGA increases attributable to producer rate increases which may not be effective as of July 1, 1976.

*The Commission finds:* (1) It is necessary and appropriate to aid in the enforcement of the Natural Gas Act that the hearing procedures on the issue of small producer purchases be deferred pending further Commission order.

*The Commission orders:* (A) Tennessee's tender, on May 14, 1976, of Twelfth Revised Sheet Nos. 12A and 12B is hereby accepted for filing, suspended for one day, or until July 2, 1976, when they shall become effective subject to refund, and subject to the condition that Tennessee file, revised tariff sheets reflecting the elimination of any producer cost increases not in effect on July 2, 1976.

(B) Tennessee's Alternate Twelfth Revised Sheets Nos. 12A and 12B are hereby accepted for filing and permitted to become effective on July 1, 1976, subject to the condition that Tennessee file revised alternate tariff sheets reflecting the elimination of any producer cost increases not in effect on July 1, 1976.

(C) Hearing procedures on the issue of small producer purchases in excess of the rate levels prescribed in Opinion No. 742 are hereby deferred pending further Commission order.

(D) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19452 Filed 7-6-76;8:45 am]

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[Docket Nos. RP74-20 and RP74-83]

## UNITED STATES PIPE LINE CO.

### Petition To Require Refunds at Lawful Interest Rate

JUNE 29, 1976.

Take notice that, on June 15, 1976, the United Municipal Distributors Group (Distributors) filed a petition that requests the Commission to issue an order requiring that all overcharges collected by United Gas Pipe Line Company from April 6, 1974 in this proceeding be assessed interest at a 9% interest rate from October 10, 1974, rather than the 7% interest rate reflected in the Stipulation and Agreement now pending before the Commission. The Distributors state that this Stipulation and Agreement should be modified to reflect the judgment of the United States Court of Appeals of the District of Columbia, on May 19, 1976, in *A.P.C.A.* v. *F.P.C.* that concerns Order No. 513.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 9, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19459 Filed 7-6-76;8:45 am]

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[Docket No. ER76-749]

## WEST TEXAS UTILITIES CO.

### Filing of Rate Schedule

JUNE 29, 1976.

Take notice that on June 18, 1976, West Texas Utilities Company (WTU) tendered for filing a rate schedule covering interconnection of facilities, firm and emergency power, and unintentional and economy energy service with Texas Electric Service Company.

WTU states that this rate schedule is being filed because of changes in its operations on May 4, 1976, and that such changes are described in an application filed in Docket No. E-9558.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 7, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19461 Filed 7-6-76;8:45 am]

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[Docket No. ER76-751]

## WEST TEXAS UTILITIES CO.

### Filing of Rate Schedule

JUNE 29, 1976.

Take notice that on June 18, 1976, West Texas Utilities Company (WTU) tendered for filing a rate schedule covering exchange of temporary energy with Central Power and Light Company.

WTU states that this rate schedule is being filed because of changes in its operations on May 4, 1976, and that such changes are described in an application filed in Docket No. E-9558.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 9, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76-19458 Filed 7-6-76;8:45 am]

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[Docket No. ER76-752]

## WEST TEXAS UTILITIES CO.

### Filing of Rate Schedule

JUNE 29, 1976.

Take notice that on June 18, 1976, West Texas Utilities Company (WTU) ten-

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[2] ____ FPC ____, issued August 28, 1975, in Docket No. R-393.

[3] Small Producers, Docket No. RM76-5, Notice of Proposed Rulemaking, issued August 28, 1975.

dered for filing a rate schedule covering the lease of transmission facilities and firm power and energy service with Community Public Service Company.

WTU states that this rate schedule is being filed because of changes in its operations on May 4, 1976, and that such changes are described in an application filed in Docket No. E–9558.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 9, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19454 Filed 7–6–76;8:45 am]

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[Docket No. ER76–753]

### WEST TEXAS UTILITIES CO.

#### Filing of Rate Schedule

JUNE 29, 1976.

Take notice that on June 18, 1976, West Texas Utilities Company (WTU) tendered for filing a rate schedule covering wholesale service with Western Farmers Electric Cooperative.

WTU states that this rate schedule is being filed because of changes in its operations on May 4, 1976, and that such changes are described in an application filed in Docket No. E–9558.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 9, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19455 Filed 7–6–76;8:45 am]

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[Docket Nos. CP69–41, etc.]

### ALGONQUIN GAS TRANSMISSION CO., ET AL.

#### Certification of Offer of Settlement

JULY 2, 1976.

Take notice that on May 3, 1976, Presiding Administrative Law Judge Isaac Benkin certified to the Commission an Offer of Settlement filed by Algonquin Gas Transmission Company as a proposed settlement of issues raised in the proceedings in Docket Nos. CP69–41, et al., instituted by Commission order of January 16, 1976, to the extent that such proceedings involve Algonquin's rates and service under Rate Schedule SNG–1, and of all matters in dispute in case Nos. 75–1460, 76–1043, 76–1116, and 76–1220 before the United States Court of Appeals for the District of Columbia Circuit. The settlement proposal is a result of a series of discussions among Algonquin, the Commission Staff, and Algonquin's regular system customers, and was presented to the judge and parties and made the subject of a motion to certify at a post-hearing conference held on April 20, 1976.

The proposed Offer of Settlement contains terms and conditions under which Algonquin Gas shall be authorized to sell volumes from its synthetic natural gas (SNG) plant at Freetown, Massachusetts. The proposal amends Opinion Nos. 637 and 637–A, issued December 7, 1972 and February 6, 1973 in Algonquin SNG, Inc., et al., under which Algonquin was authorized to sell for resale its SNG volumes, by deleting condition 6(iv) of the original certificate therein and adding new substitute provisions. Under the proposed amendments, Algonquin would be authorized to sell excess SNG capacity during the winters of 1976–77, 1977–78, and 1978–79, to off-system customers on a firm pro-rata basis and under the same SNG–1 Rate Schedule that applies to its regular on-system customers, and any rate increase filings during that same period shall reflect Contract Demands of 118,200 MMBtu per day times the number of demand billing periods in a contract year. In addition, the Offer of Settlement authorizes Algonquin to modify Rate Schedule SNG–1 concerning daily and seasonal makeup flexibility provisions, and directs Algonquin to file a Demand Charge of $1.353 under Rate Schedule SNG–1.

A more detailed description of the Settlement proposal, including certain additional minor provisions contained therein, may be found in the Offer of Settlement, which is on file and available for public inspection in the Commission's Office of Public Information.

At the conference of April 20, 1976, the parties agreed to a request for a shortened comment period. Therefore, any person, including the parties, may file comments on the proposed Offer of Settlement on or before July 13, 1976.

KENNETH F. PLUMB,
*Secretary.*

[FR Doc.76–19633 Filed 7–2–76;1:14 pm]

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## INTERNATIONAL TRADE COMMISSION

[AA1921–155]

### HOLLOW OR CORED CERAMIC BRICK AND TILE

#### Amendment of Notice of Investigation

On the basis of advice from the Department of the Treasury in a letter received June 21, 1976, and a notice of "Clarification of Determination of Sales at Less Than Fair Value" received June 22, 1976 (41 FR 26037), notice is hereby given that the United States International Trade Commission's Notice of Investigation and Hearing on Hollow or Cored Ceramic Brick and Tile from Canada, investigation No. AA1921–155 under section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)) (41 FR 19383, 41 FR 20454, and 41 FR 21224), is further amended by changing the last sentence of the first paragraph to read as follows:

Such brick is of greater than 25 percent void.

Issued: July 1, 1976.

By order of the Commission.

KENNETH R. MASON,
*Secretary.*

[FR Doc.76–19566 Filed 7–6–76;8:45 am]

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## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### ARCHITECTURE + ENVIRONMENTAL ARTS ADVISORY PANEL

#### Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given that a closed meeting of the Architecture + Environmental Arts Advisory Panel to the National Endowment for the Arts will be held on July 27–28, 1976 in room 1133 of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. The hours will be from 9:30 a.m.–5:30 p.m. on both days.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of June 16, 1975, this meeting, which involves matters exempt from the requirements of public disclosure under the provisions of the Freedom of Information Act (5 U.S.C. 552(b), (4), (5), and (6)) will not be open to the public.

Further information with reference to this meeting can be obtained from Mr. Robert M. Sims, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6377.

ROBERT M. SIMS,
*Administrative Officer, National Endowment for the Arts, National Foundation on the Arts, and the Humanities.*

[FR Doc.76–19506 Filed 7–6–76;8:45 am]

## OFFICE OF MANAGEMENT AND BUDGET

### U.S. OIL AND NATURAL GAS RESERVES DATA COLLECTION

#### Public Hearing

Notice is hereby given of a public hearing to be held by the Office of Management and Budget under the provisions of the Federal Reports Act of 1942 (44 U.S.C. 3504 and 3506).

The purpose of the hearing is to solicit the views of the public concerning the collection of data on U.S. reserves of oil and natural gas.

The discussion at the hearing will focus on several options for collecting oil and gas reserves data including: (1) A joint government-industry sponsored survey; (2) industry survey with selective government audits; (3) single lead government agency collecting data for several agencies; (4) several government agencies collecting data in a coordinated fashion; or (5) other options. Some additional questions to be discussed will include: What level of accuracy is necessary? What type of audit or verification program is needed? What degree of confidentiality shall be assigned to specific reserves data?

Representatives of several government agencies which collect or use reserves data and which comprise the Ad Hoc Interagency Committee on Oil and Gas Reserves Surveys will participate in the discussion. Representatives of the reserves committees of the American Petroleum Institute and American Gas Association, public interest groups, Congressional staffs and any other interested persons are invited to attend and to present their views. The hearing will be open to public observation and participation.

The hearing will be held in Room 2010, New Executive Office Building, 726 Jackson Place NW., Washington, D.C. on July 22, 1976, at 9:30 a.m. Further information regarding the hearing may be obtained from the Statistical Policy Division, Office of Management and Budget, Room 10208, New Executive Office Building, Washington, D.C. 20503, Telephone (202) 395-4730.

VELMA N. BALDWIN,
*Assistant to the Director for Administration.*

[FR Doc.76-19533 Filed 7-6-76;8:45 am]

## PRIVACY PROTECTION STUDY COMMISSION

### HEARINGS

The Privacy Protection Study Commission will hold public hearings between 10 a.m., and 5:30 p.m. on August 3, 1976, and between 9:00 a.m., and 5:30 p.m., on August 4 and 5, 1976. The hearings will be held in Room 1318, Dirksen (New Senate Office) Building, Washington, D.C. *The hearings form part of the Commission's examination of the record-keeping practices of consumer- and commercial-reporting agencies (i.e., organizations that supply both credit and investigative reports on individual consumers and businesses) and check-cashing and credit-card verification and authorization services.* Pursuant to section 5 of the Privacy Act of 1974 (Pub. L. 93-579), the Commission will consider whether the principles and requirements of the Act should be extended to these organizations and whether other legislative recommendations may be necessary.

To assist in the development of its inquiry, the Commission, prior to these hearings, wishes to learn about the experiences and views of interested parties regarding the areas of inquiry described herein. Submissions should be made in writing to the Executive Director, Privacy Protection Study Commission, Suite 424, 2120 L Street N.W., Washington, D.C. 20506, and should be received no later than July 16, 1976.

Several aspects of consumer-reporting, commercial-reporting and check and credit-card verification and authorization services warrant this inquiry:

(i) Virtually every individual who participates in commerce—whether by applying for credit, insurance, or employment, or by making payment for goods and services by check or other payment device—is affected by consumer reporting, payment authorization services, and, in some instances, by commercial reporting;

(ii) The primary function of consumer-reporting agencies and of check and credit-card verification and authorization services is the collection, collation, evaluation, and distribution of personal information to assist in making important decisions about individuals;

(iii) Consumer- and commercial-reporting agencies and verification and authorization services have no direct market relationship with the individuals who are the subjects of their records;

(iv) There is substantial controversy about the adequacy of the Fair Credit Reporting Act as it now applies to consumer-reporting agencies;

(v) Commercial reporting and check and credit-card verification and authorization services, which involve the collection, collation, evaluation, and distribution of personal information to assist in making decisions about individuals, are not now subject to the Fair Credit Reporting Act.

(vi) The record-keeping practices of consumer-reporting agencies are subject to the requirements of both Federal and State fair credit-reporting statutes which are not identical in their requirements.

The Privacy Protection Study Commission seeks information and comments concerning the following aspects of consumer- and commercial-reporting and check and credit-card verification and authorization services:

(i) The categories of clients in the public and private sector that use such services, and the nature of the contracts that govern the provision of such services;

(ii) The types of services available to a client, such as preparation of reports, pre-screening, monitoring of individuals' activities, collection of delinquent accounts, processing insurance claims, and authorizing or insuring checks or other forms of payment;

(iii) The specific information, including type and source, necessary for the various services available to the clientele;

(iv) Procedures for collecting, updating, archiving, and purging information which affect the accuracy and timeliness of information, including information collected from public records;

(v) The development of automated systems to facilitate interchange of information among consumer-reporting agencies, collection agencies, and providers of payment authorization services;

(vi) Means by which affected organizations comply with the requirements of the Federal Fair Credit Reporting Act; and State credit-reporting statutes to which they may be subject; and

(vii) The desirability and feasibility of applying the principles and requirements of the Privacy Act of 1974 to consumer- and commercial-reporting agencies and providers of verification and authorization services in areas where this would result in strengthening the Fair Credit Reporting Act or in areas where this would result in strengthening the Fair Credit Reporting Act or in areas where the FCRA does not now apply.

The Commission has held hearings covering the recordkeeping practices of the mailing-list industry, credit-card issuers, maintainers of reservation systems, depository and lending institutions, insurance institutions, and health-care providers and institutions. As a result of these hearings, the Commission seeks information and comments in response to certain questions raised by their use of credit-reporting, commercial-reporting and verification and authorization services, to wit—

(i) What responsibility to the individual do consumer- and commercial-reporting agencies and providers of payment authorization services have with respect to (a) assuring the accuracy, timeliness, and relevance of information they maintain about individuals, and (b) the uses to which that information is put?

(ii) Should there be limitations on the disclosure of certain types of information, such as "balance owing" to consumer-reporting agencies; or should there be limitations on the use of such information by consumer-reporting agencies?

(iii) Should an individual have a right in law to obtain a copy of a consumer or commercial credit report that pertains to him from: (a) the reporting agency that maintains the report; and (b) an organization or individual that receives the report from the reporting agency?

(iv) Should an individual have a right in law to access to the medical information about him that is maintained by a consumer-reporting agency?

(v) Should the preparation of a consumer investigative report require the prior authorization of the individual who is to be investigated and should the individual have the ability to limit his authorization with respect to time and type of information to be collected?

(vi) Should a Federal agency be required to notify an individual when a credit report has been obtained on him, and to advise the individual of his rights pursuant to the Privacy Act of 1974?

(vii) Should the Fair Credit Reporting Act apply to the preparation of reports which are used in processing insurance claims?

(viii) Should the Federal Trade Commission be granted rule-making authority with respect to substantive implementation of the Fair Credit Reporting Act?

DAVID F. LINOWES,
*Chairman.*

CAROLE W. PARSONS,
*Executive Director.*

JUNE 30, 1976.

[FR Doc.76-19419 Filed 7-6-76;8:45 am]

## SECURITIES AND EXCHANGE COMMISSION

[File Nos. 3-5041; 2-37401, (22-6087); 2-26527, (22-4481); 2-55595, (22-8754)]

### AMERICAN AIRLINES, INC. AND C.I.T. FINANCIAL CORP.

### Application and Opportunity for Hearing

JUNE 30, 1976.

Notice is hereby given that American Airlines, Inc. and C.I.T. Financial Corporation (the "Applicants") have filed an application under clause (ii) of Section 310(b)(1) of the Trust Indenture Act of 1939 (the "Act") for a finding that the trusteeship of Bankers Trust Company under certain existing indentures involving American Airlines, Inc. ("American") hereinafter described, under certain existing indentures of C.I.T. Financial Corporation ("CIT") hereinafter described, and under a new indenture (the "New Indenture") of American not to be qualified under the Act is not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify Bankers Trust Company from acting as trustee under one of such indentures.

Section 310(b) of the Act provides, in part, that if a trustee under an indenture qualified under the Act has or shall acquire any conflicting interest, it shall within ninety days after ascertaining that it has such conflicting interest, either eliminate such conflicting interest or resign. Subsection (1) of such Section provides, in effect, with certain exceptions that a trustee under a qualified indenture shall be deemed to have a conflicting interest if such trustee is trustee under another indenture under which any other securities of the same issuer are outstanding. However, under clause (ii) of subsection (1), there may be excluded from the operation of this provision another indenture under which other securities of the issuer are outstanding, if the issuer shall have sustained the burden of proving, on application to the Commission and after opportunity for hearing thereon, that trusteeship under such qualified indenture and such other indenture is not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify such trustee from acting as trustee under either of such indentures.

The Applicants allege the following:

(1) American, a Delaware Corporation, intends to finance the acquisition of three Boeing Model 727-223 aircraft (the "Aircraft") in a leveraged lease transaction which will include the placement with several institutional investors of approximately $18 million principal amount of debt certificates which certificates are expected to be issued pursuant to the New Indenture. It is anticipated that the certificates to be issued under the New Indenture will consist, to the extent of approximately 48.72 percent of the aggregate principal amount, of Short Term Loan Certificates (8½ year maturity) and to the extent of approximately 51.28 percent of the aggregate principal amount of Long Term Loan Certificates (14 year maturity). The Short Term Loan Certificates and the Long Term Certificates will be secured ratably by the Aircraft and a lease thereof to American. Included in the financing documents to be executed in connection with the New Indenture is a Participation Agreement which contains a provision in which C.I.T. Corporation, a subsidiary of CIT, guarantees directly to the holders of the Long Term Loan Certificates the payment of the principal and interest of such Long Term Loan Certificates through the mechanism of an unconditional obligation of C.I.T. Corporation to purchase such Long Term Loan Certificates upon the occurrence of certain specified events. This guaranty or purchase obligation of C.I.T. Corporation is further guaranteed by CIT. Although the financing documents do not provide that such purchase obligation is to be enforced by Bankers Trust Company as trustee under the New Indenture, but rather by the holders of the Long Term Loan Certificates individually, Bankers Trust Company is involved in certain notification procedures and accordingly CIT is arguably an "obligor" with respect to the Long Term Loan Certificates to be issued under the New Indenture. American concedes that it is an "obligor" with respect to the Short Term Loan Certificates and the Long Term Loan Certificates to be so issued. Copies of the proposed New Indenture will be filed by an amendment to the Applicants' Application promptly upon its availability.

(2) Applicants desire to appoint Bankers Trust Company, a New York Corporation, to act as trustee under the New Indenture.

(3) Bankers Trust Company presently is acting as trustee under the following indentures of American: (a) a trust agreement dated as of October 20, 1967 ("1967 Indenture"), (b) a trust agreement dated as of September 15, 1969 ("1969 Indenture"), (c) a trust indenture and mortgage dated as of June 1, 1970, as amended and supplemented ("1970 Indenture"), (d) a trust agreement dated as of November 15, 1971 ("1971 Indenture"), (e) a trust indenture and mortgage dated as of April 1, 1975 (the "1975 Indenture") and (f) a trust indenture and mortgage dated as of April 1, 1976 (the "1976 Indenture"), relating to the financing of twenty-seven Boeing Model 727-223 Aircraft, two Boeing Model 727-223 Aircraft, seven Boeing Model 747-123 Aircraft, two McDonnell Douglas DC-10 Aircraft, six Boeing Model 727-223 Aircraft and five Boeing Model 727-223 Aircraft, respectively, leased to American which constitute six of American's sixteen presently existing flight equipment lease transactions. 6½% Equipment Trust Loan Certificates weer issued under the 1967 Indenture in the original principal amount of $114,371,636.03 of which $80,212,242.89 remain outstanding; final payment is due on January 1, 1987. 9½% Equipment Trust Loan Certificates were issued under the 1969 Indenture in theoriginal principal amount of $9,079,642.40 of which $6,698,158.88 remain outstanding; final payment is due July 29, 1984. Guaranteed Loan Certificates, Series A, B, Interim C, Second Interim C and C, were issued under the 1970 Indenture and remain outstanding in the following respective principal amounts:

$47,850,000 original principal amount of 11% Series A, due December 1, 1988, presently outstanding in the principal amount of $41,089,000.00; $31,800,000 original principal amount of 10⅞% Series B, due December 1, 1988, presently outstanding in the principal amount of $27,251,000.00; $15,564,000 original principal amount of 9½% Interim Series C, due June 1, 1989, none of which is presently outstanding; $15,689,000 original principal amount of 9½% Second Interim Series C, due June 1, 1989, none of which is presently outstanding; $15,689,000 original principal amount of 9½% Second Interim Series C, due June 1, 1989, none of which is presently outstanding; $15,689,000 original principal amount of 9½% Second Interim Series C, due June 1, 1989, none of which is presently outstanding; and $32,000,000 original principal amount of 10% Series C, due June 1, 1989, presently outstanding in the principal amount of $27,746,000.00 9¼% Equipment Trust Loan Certificates were issued under the 1971 Indenture in the original principal amount of $19,513,754.67 of which $18,530,197.45 remain outstanding. 11⅝% Equipment Trust Loan Certificates were issued under the 1975 Indenture in the original principal amount of $32,031,409.80 of which $31,028,459.23 remain outstanding. 11% Short Term Equipment Trust Loan Certificates were issued under the 1976 Indenture in the original principal amount of $14,039,261.05, all of which remain outstanding and 9⅛% Long Term Equipment Trust Loan Certificates were issued under the 1976 Indenture in the original principal amount of $14,778,166.51, all of which remain outstanding. Copies of the trust agreement, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1967 Indenture were filed as Exhibit 2 to American's Application dated March 3, 1970 under Section 310(b)(1)(ii) of the Act in connection with American's Registration Statement on Form S-7 under the Securities Act of 1933 (No. 2-37401) and are incorporated herein by reference. Copies of the trust agreement, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1967 Indenture were filed as Exhibit 2 to American's Application dated March 3, 1970 under Section 310(b)(1)(ii) of the Act in connection with American's Registration Statement on Form S-7 under the Securities Act of 1933 (No. 2-37401) and are incorporated herein by reference.

Copies of the trust agreement, lease and other documents (combined as a singel document) setting forth the terms and provisions governing the certificates issued under the 1969 Indenture were filed as Exhibit 3 to such Application dated March 3, 1970 and are incorporated herein by reference. Copies of the trust indenture and mortgage, lease and other documents, as amended and supplemented, setting forth the terms and

provisions governing the certificates issued under the 1970 Indenture were filed as exhibits to American's Registration Statements under the Securities Act of 1933 (Nos. 2–37401, 2–38352 and 2–39380) and are incorporated herein by reference. Copies of the trust agreement, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1971 Indenture were filed as Exhibit A to American's Application dated March 25, 1975 under Section 310 (b)(1)(ii) and are incorporated herein by reference. Copies of the trust indenture and mortgage, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1975 Indenture were filed as Exhibit A to American's Application dated April 2, 1976 under Section 310(b)(1)(ii) of the Act. Copies of the trust indenture and mortgage, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1975 Indenture were filed as Exhibit A to American's Application dated April 2, 1976 under Section 310(b)(1)(ii) of the Act. Copies of the trust indenture and mortgage, lease and other documents (combined as a single document) setting forth the terms and provisions governing the certificates issued under the 1976 Indenture were filed as Exhibit to the Applicants' Application dated June 8, 1976 under Section 310(b)(1)(ii) of the Act, and are incorporated herein by reference. The 1970 Indenture is qualified under the Act and the Commission has determined in response to applications of American that Bankers Trust Company's trusteeship under the other indentures of American refererred to above is not so likely to involve a material conflict of interest as to make it necessary to disqualify Bankers Trust Company from acting as trustee under such indentures.

(4) The certificates issued under the 1967 Indenture, the 1969 Indenture, the 1970 Indenture, the 1971 Indenture, the 1975 Indenture and the 1976 Indenture (which in the case of the Long Term Loan Certificates are also secured by the letter of credit referred to in the 1976 Indenture) are, and the certificates to be issued under the New Indenture (which in the case of the Long Term Certificates are also secured by the purchase obligation of C.I.T. Corporation referred to above) will be, secured by a separate lot of identified Aircraft, so that should the trustee have occasion to proceed against the security under one of these trusts, such action would not affect the security, or the use of any security, under any other trust. Thus, the existence of the other trusteeships should in no way inhibit or discourage the trustee's actions.

(5) American is not in default under any of its equipment obligations.

(6) Bankers Trust Company is presently acting as trustee under three indentures of CIT, one dated as of October 1, 1967 and two dated as of April 1, 1976. All of such indentures relate to unsecured indebtedness of CIT and all are qualified under the Act. 6⅜% debentures due October 1, 1986 were issued under the October 1, 1967 Indenture in the principal amount of $75,000,000 all of which remain outstanding. One of the April 1, 1976 Indentures relates to $100,000,000 principal amount of 7⅞% debentures due April 1, 1986 all of which remain outstanding and the other relates to $100,000,000 principal amount of 8¾% debentures due April 1, 2001 all of which remain outstanding. The form of the 1967 Indenture was filed as an Exhibit to CIT's Registration Statement under the Securities Act of 1933 (No. 2–26527). Copies of the form of the two April 1, 1976 Indentures were filed as Exhibits to CIT's Registration Statement under the Securities Act of 1933 (No. 2–55595).

(7) If the New Indenture were qualified under the Act Bankers Trust Company would not be disqualified by the terms of the Act from acting as trustee thereunder since the obligation of CIT guaranteeing the purchase obligation of CIT Corporation is wholly unsecured. (Act Section 310(b)(1)(i)). Furthermore, the purchase obligation of CIT Corporation is not set forth in the New Indenture, but rather in an ancillary document and is not enforceable by Bankers Trust Company as trustee under the New Indenture. Accordingly, the existence of the CIT guaranty in the financing documents connected with the New Indenture should in no way discourage or inhibit the trustee's actions under the existing CIT Indentures.

(8) CIT is not in default under its existing indentures.

The Applicants have waived notice of hearing, hearing on the issues raised by its application and all rights to specify procedures under Rule 8(b) of the Rules of Practice of the Securities and Exchange Commission in connection with this matter.

For a more detailed statement of the matters of fact and law asserted, all persons are referred to said application, which is a public document on file in the Commission's Public Reference Section, 1100 L Street NW., Washington, D.C. 20549.

Notice is further given that any interested person may, not later than July 27, 1976 request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application which he desires to controvert, or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. At any time after said date, the Commission may issue an order granting the application, upon such terms and conditions as the Commission may deem necessary or appropriate in the public interest and the interest of investors, unless a hearing is ordered by the Commission.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76–19527 Filed 7–6–76;8:45 am]

[File No. 500–1]

## DIVERSIFIED INDUSTRIES, INC.

### Suspension of Trading

JUNE 29, 1976.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the securities of Diversified Industries, Inc. being traded on a national securities exchange or otherwise is required in the public interest and for the protection of investors;

Therefore, pursuant to Section 12(k) of the Securities Exchange Act of 1934, trading in such securities on a national securities exchange or otherwise is suspended, for the period from June 30, 1976 through July 9, 1976.

By the Commission.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76–19528 Filed 7–6–76;8:45 am]

[File No. 500–1]

## EQUITY FUNDING CORP. OF AMERICA AND ORION CAPITAL CORP.

### Suspension of Trading

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the securities of Equity Funding Corporation of America, including Orion Capital Corporation, being traded on a national securities exchange or otherwise, is required in the public interest and for the protection of investors;

Therefore, pursuant to Section 12(k) of the Securities Exchange Act of 1934, trading in such securities on a national securities exchange or otherwise is suspended, for the period from June 30, 1976 through July 9, 1976.

By the Commission.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76–19529 Filed 7–6–76;8:45 am]

[Release No. 12583; SR–MSE–76–4]

## MIDWEST STOCK EXCHANGE, INC.

### Purchase Transactions on Margin

JUNE 29, 1976.

On March 22, 1976, the Midwest Stock Exchange, 120 South LaSalle Street, Chicago, Illinois 60603, filed with the Commission, pursuant to Section 19(b) of the Securities Exchange Act of 1934 (the "Act"), as amended by the Securities Acts Amendments of 1975, and Rule 19b–4 thereunder, copies of a proposed rule change. The proposed rule change is intended to transform the Exchange's treatment of purchase transactions on margin into formal Exchange rules.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 12365

(April 23, 1976)) and by publication in the FEDERAL REGISTER (41 FR 18478 (May 4, 1976)).

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to National securities exchanges, and in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and it hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76-19530 Filed 7-6-76;8:45 am]

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[Release No. 12582; SR-PBWSE-76-9]

## PHILADELPHIA STOCK EXCHANGE

### Margin Requirements

JUNE 29, 1976.

On March 22, 1976, the Philadelphia Stock Exchange, 17th Street and Stock Exchange Place, Philadelphia, Pennsylvania 19103, filed with the Commission, pursuant to Section 19(b) of the Securities Exchange Act of 1934 (the "Act"), as amended by the Securities Acts Amendments of 1975, and Rule 19b-4 thereunder, copies of a proposed rule change. The proposed rule change would amend Exchange Rule 722, pertaining to margin requirements, and would rescind Exchange Rule 1054.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 12367 (April 23, 1976)) and by publication in the FEDERAL REGISTER (41 FR 18369, May 3, 1976).

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges, and in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and it hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76-19531 Filed 7-6-76;8:45 am]

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[Release No. 1258; SR-NYSE-76-21]

## NEW YORK STOCK EXCHANGE, INC.

### Margin Requirements

JUNE 29, 1976.

On March 22, 1976, the New York Stock Exchange, Eleven Wall Street, New York, New York 10005, filed with the Commission, pursuant to section 19(b) of the Securities Exchange Act of 1934 (the "Act"), as amended by the Securities Acts Amendments of 1975, and Rule 19b-4 thereunder, copies of a proposed rule change. The proposed rule change would amend Exchange Rule 431 in respect of the margin requirements for positions involving put options.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 12366 (April 23, 1976)) and by publication in the FEDERAL REGISTER (41 FR 18374 (May 3, 1976)).

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to National securities exchanges, and in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and it hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76-19532 Filed 7-6-76;8:45 am]

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# DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

## FEDERAL ADVISORY COUNCIL ON OCCUPATIONAL SAFETY AND HEALTH

### Meeting

Notice is hereby given that the Federal Advisory Council on Occupational Safety and Health, established under Section 3(a) of Executive Order 11612 of July 26, 1971 and continued under 4 (a) of Executive Order 11807 of September 28, 1974, Occupational Safety and Health Programs for Federal Employees, will meet on Wednesday, July 21, starting at 9:30 a.m., in Room S5215 ABC, New Department of Labor Building, Third Street and Constitution Avenue NW., Washington, D.C. The meeting will be open to the public.

The agenda provides for:

I. Proposed addition to 29 CFR Part 1960, review approval of draft proposing a new subpart on Program Evaluation Criteria.

II. Proposed expansion to 29 CFR Part 1960, review and approval of draft expanding subpart F—Field Federal Safety and Health Councils.

III. Reports. A. Committee to review House Report (January 26, 1976) on Safety in the Federal Workplace.

B. Proposed Amendment to 29 CFR Part 1960 adding § 1960.20—Agency Safety and Health Training Guidelines. Published in the Federal Register of June 11, 1976. (41 FR 23722)

C. Final report on Calendar year 1976 Regional Federal Safety and Health Conferences.

The Council welcomes written data, views or comments concerning safety and health programs for Federal employees, including comments on the agenda items. All such submissions, together with 20 copies thereof, received by the close of business July 19 will be provided to members of the Council and included in the record of the meeting.

The Council will consider oral presentations related to agenda items. Persons wishing to orally address the Council at the meeting should submit a written request to be heard, together with 20 copies thereof by the close of business July 16. The request must include the name and address of the person wishing to appear, the capacity in which appearance will be made, a short summary of the intended presentation and an estimate of the amount of time needed.

All communications regarding this Advisory Council should be addressed to Mr. Walter J. Mason, Executive Director, FACOSH, Room N3673, Department of Labor, OSHA, Third Street and Constitution Avenue NW., Washington, D.C. 20210, telephone (202) 523-7125.

Signed at Washington, D.C. this 2nd day of July 1976.

MORTON CORN,
*Assistant Secretary of Labor.*

[FR Doc.76-19585 Filed 7-6-76;8:45 am]

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## NATIONAL ADVISORY COMMITTEE ON OCCUPATIONAL SAFETY AND HEALTH, SUBGROUPS ON STANDARDS AND POLICY AND ISSUES

### Meeting

Notice is hereby given that the Subgroups on Standards and Policy and Issues, National Advisory Committee on Occupational Safety and Health (NACOSH), will meet on July 22, 1976 in Room S-5215, Department of Labor Building, Third Street and Constitution Avenue NW., Washington, D.C. 20210.

The National Advisory Committee was established under section 7(a) of the Occupational Safety and Health Act of 1970 to advise the Secretary of Labor and the Secretary of Health, Education and Welfare on matters relating to the administration of the Act.

The meeting will begin at 9 a.m. The public is invited to attend. The Subgroups will discuss methods to revise and update OSHA consensus safety standards that primarily were adopted under Section 6(a) of the Act in the first two years of the agency's existence. In particular, the Subgroups will discuss the organization and work plan of the President's Task Force on Improving OSHA Regulations which will assist OSHA in accelerating the program to simplify and clarify its safety standards. The issue of the best method to revise safety standards follows-up and expands on previous discussions of the Subgroup on Standards in early 1976.

If time permits, the Subgroups also will continue their discussion of inflationary impact assessment of OSHA standards.

For additional information on the Subgroups' agenda, please contact:

Nancy L. Hucke, National Advisory Committee on Occupational Safety and Health, Department of Labor-OSHA, Committee Management Office, Room N-3635, Third Street and Constitution Avenue, NW, Washington, D.C. 20210. Phone: (202) 523-8024.

Any written data or views concerning this agenda item or suggestions for future agenda items which are received by the Committee Management Office before the meeting, preferably with 20 copies, will be presented to the Subgroups and included in the official record of the meeting.

Anyone wishing to request an oral presentation should notify the Committee Management Office before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the content of the presentation. Oral presentations will be scheduled at the discretion of the Subgroups' Chairmen, depending on the extent to which time permits.

Official records of the meeting will be available for public inspection at the above address.

Signed at Washington, D.C. this day of July 1976.

JOANNE L. GOODELL,
*Executive Secretary.*

[FR Doc.76-19617 Filed 7-6-76;8:45 am]

## INTERSTATE COMMERCE COMMISSION

[Notice No. 86]

### ASSIGNMENT OF HEARINGS

JULY 1, 1976.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 141521, TCI, Inc., now being assigned October 4, 1976 (1 Week), at Columbus, Ohio, in a hearing room to be later designated.

MC-F 12708, Murrow's Transfer, Inc.—Purchase—D & D Trucking Co. (Louis J. Fisher, Jr., Receiver) and MC 111936 (Sub 15), Murrow's Transfer, Inc. now being assigned October 19, 1976 at the Offices of the Interstate Commerce Commission in Washington, D.C.

FD 27804, Chicago and Northwestern Transportation Company Petition for Investigation and Declaratory Order, FD 27861, Chicago, Milwaukee, St. Paul & Pacific Railroad Company—Trackage Rights, County, Illinois and FD 27862, Chicago, Milwaukee, St. Paul & Pacific Railroad Company—Application for an Order Under Section 3 (5) of the Interstate Commerce Act now being assigned September 9, 1976 (for pre-hearing conference) at the Offices of the Interstate Commerce Commission in Washington, D.C.

I & S M 29049, General Increase, New York Movers Tariff Bureau Inc., Agent, now assigned July 27, 1976, at Washington, D.C., is cancelled. The rates are being cancelled.

MC 2860 (Sub 150), National Freight, Inc. now being assigned September 28, 1976 (2 days) at Atlanta, Georgia in a hearing room to be later designated.

MC 119789 (Sub 270), Caravan Refrigerated Cargo, Inc. now being assigned September 30, 1976 (1 day) at Atlanta, Georgia in a hearing room to be later designated.

MC 106674 (Sub 176), Schilli Motor Lines, Inc. now being assigned October 1, 1976 (1 day) at Atlanta, Georgia in a hearing room to be later designated.

MC 107515 (Sub 1002), Refrigerated Transport Co., Inc. now being assigned October 4, 1976 (1 week) at Atlanta, Georgia in a hearing room to be later designated.

ROBERT L. OSWALD,
*Secretary.*

[FR Doc.76-19565 Filed 7-6-76;8:45 am]

[Rule 19; Ex Parte No. 241; Exemption No. 95, Amdt. 6]

### BESSEMER AND LAKE ERIE RAILROAD CO. AND NORFOLK AND WESTERN RAILWAY CO.

#### Exemption Under Provision of Mandatory Car Service Rules

To: Bessemer and Lake Erie Railroad Company, Norfolk and Western Railway Company.

Upon further consideration of Exemption No. 95 issued February 5, 1975.

*It is ordered*, That, under the authority vested in me by Car Service Rule 19, Exemption No. 95 to the Mandatory Car Service Rules ordered in Ex Parte No. 241, be, and it is hereby amended to expire September 30, 1976.

This amendment shall become effective June 30, 1976.

Issued at Washington, D.C., June 24, 1976.

INTERSTATE COMMERCE COMMISSION,
LEWIS R. TEEPLE,
*Agent.*

[FR Doc.76-19567 Filed 7-6-76;8:45 am]

[Rule 19; Ex Parte No. 241; Exemption No. 85, Amdt. 7]

### CHICAGO, MILWAUKEE, ST. PAUL AND PACIFIC RAILROAD CO.

#### Exemption Under Provision of Mandatory Car Service Rules

To: Chicago, Milwaukee, St. Paul and Pacific Railroad Co., Missouri Pacific Railroad Company, Southern Railway Company.

Upon further consideration of Exemption No. 85 issued September 11, 1974.

*It is ordered*, That, under the authority vested in me by Car Service Rule 19, Exemption No. 85 to the Mandatory Car Service Rules ordered in Ex Parte No. 241, be, and it is hereby amended to expire September 30, 1976.

This amendment shall become effective June 30, 1976.

Issued at Washington, D.C., June 24, 1976.

INTERSTATE COMMERCE COMMISSION,
LEWIS R. TEEPLE,
*Agent.*

[FR Doc.76-19568 Filed 7-6-76;8:45 am]

[Notice No. 82]

### MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

JULY 1, 1976.

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 C.F.R. § 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the I.C.C. Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 40978 (Sub-No. 26TA), filed June 23, 1976. Applicant: CHAIR CITY MOTOR EXPRESS COMPANY, 3321 Highway 141 South, P.O. Box 686, Sheboygan, Wis. 53081. Applicant's representative: William C. Dineen, 710 North Plankinton Ave., Wilwaukee, Wis. 53203. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Doors*, from the plantsite of Curtis Corporation, at New London, Wis., to points in Alabama, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine,

Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and the District of Columbia; and (2) *Equipment, materials and supplies* used in the manufacture and distribution of doors (except commodities in bulk), from points in the District of Columbia and points in the above-named destination states to the plantsite of Curtis Corporation, at New London, Wis., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Curtis Corporation, 313 West Wolf River Ave., New London, Wis. 54961. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 135 West Wells St., Room 807, Milwaukee, Wis. 53203.

No. MC 123061 (Sub-No. 80TA), filed June 21, 1976. Applicant: LEATHAM BROTHERS, INC., 46 Orange St., Salt Lake City, Utah 84104. Applicant's representative: Harry D. Pugsley, 315 East 2nd South, Salt Lake City, Utah 84111. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Boxes or sheets*, corrugated or not corrugated K.D.F., from the plantsite of Boise Cascade Corporation, at or near Nampa, Idaho, to Cedar City, Logan, Wellsville, and Riverton, Utah, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Boise Cascade Corporation, P.O. Box 7747, Boise, Idaho 83704. Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 5301 Federal Bldg., 125 South State St., Salt Lake City, Utah 84138.

No. MC 124160 (Sub-No. 12TA), filed June 23, 1976. Applicant: SAVAGE BROTHERS, INCORPORATED, 585 South 500 East, American Fork, Utah 84003. Applicant's representative: Lon Rodney Kump, 333 East Fourth South, Salt Lake City, Utah 84111. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Sand*, from points in Box Elder County, Utah, to points in Oneida County, Idaho, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Acme Vickrey, E. 4007 Grace, Spokane, Wash. Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 5301 Federal Bldg., 125 South State St., Salt Lake City, Utah 84138.

No. MC 135231 (Sub-No. 19TA), filed June 23, 1976. Applicant: NORTH STAR TRANSPORT, INC., Route 1, Highway 1 and 59 West, Thief River Falls, Minn. 56701. Applicant's representative: Robert P. Sack, 33 E. Wentworth, West St. Paul, Minn. 55118. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise* as is dealt in by mail order houses (except commodities in bulk and foodstuffs), from St. Cloud, Minn., to Lexington, Ky., restricted to transportation of shipments originating at the facilities of Fingerhut Manufacturing Co. Service, Inc., for immediate and subsequent movement by U.S. Mail or by United Parcel Service, Inc., for 180 days. Supporting shipper: Fingerhut Manufacturing Co., 11 McLeland Road, St. Cloud, Minn. 56395. Send protests to: Ronald R. Mau, District Supervisor, Bureau of Operations, Interstate Commerce Commission, P.O. Box 2340, Fargo, N. Dak. 58102.

No. MC 136267 (Sub-No. 6TA), filed June 21, 1976. Applicant: BELS PRODUCE CO., INC., 11357 Vienna Road, P.O. Box 348, Montrose, Mich. 48457. Applicant's representative: Andrew J. Haliw, III, 22375 Haggerty Road, P.O. Box 400, Northville, Mich. 48167. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pickles and related pickle products* (except refrigerated and in bulk), from the facilities of Vlasic Foods, Inc., at Greenville, Miss., to points in Florida, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Vlasic Foods, Inc., Manager of Traffic, Ernest P. Szwarc, 33200 W. 14 Mile Road, W. Bloomfield, Mich. 48033. Send protests to: Melvin F. Kirsch. District Supervisor, Interstate Commerce Commission, Bureau of Operations 1110 Broderick Tower, 10 Witherell Ave., Detroit, Mich. 48226.

No. MC 138003 (Sub-No. 8TA), filed June 23, 1976. Applicant: ROBERT F. KAZIMOUR, 1200 Norwood Drive, S.E., P.O. Box 2011, Cedar Rapids, Iowa 52403. Applicant's representative: Robert A. Wichser, 5000 South Lewis Blvd., Sioux City, Iowa 51102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Appliances, and parts, materials, and supplies* used in the manufacture, repair, and distribution of such commodities, between Webster City, Iowa, Fort Dodge, Iowa, Des Plains, Ill., and Milwaukee, Wis., under a continuing contract with Franklin Manufacturing Company, for 180 days. Supporting shipper: Franklin Manufacturing Company, 600 Stockdale St., Webster City, Iowa. Send protests to: Herbert W. Allen, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 518 Federal Bldg., Des Moines, Iowa 50309.

No. MC 139968 (Sub-No. 2TA), filed June 23, 1976. Applicant: NATIONAL CONSTRUCTION CORP., 12050 N.W. South River Drive, Miami, Fla. 33012. Applicant's representative: Bernard C. Pestcoe, 511 Biscayne Bldg., 19 West Flagler St., Miami, Fla. 33130. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Cement clinker, gypsum and bunker C fuel*, between points in Dade and Broward Counties, Fla., restricted to transportation having a prior or subsequent movement in interstate or foreign commerce, under a continuing contract with Maule Industries, Inc., for 180 days. Supporting shipper: Maule Industries, Inc., 100 Biscayne Blvd., Miami, Fla. Send protests to: Joseph B. Teichert, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Monterey Bldg., Suite 101, 841 N.W. 53rd Terrace, Miami, Fla. 33166.

No. MC 140104 (Sub-No. 3TA), filed June 21, 1976. Applicant: TOLEDO FRIGID LINES, INC., 4117 Fitch Road, Toledo, Ohio 43613. Applicant's representative: David L. Pemberton, 50 West Broad St., Columbus, Ohio 43215. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Bakery goods, ice cream, ice cream confections, ice confections, ice water confections, and frozen desserts*, in vehicles equipped with mechanical refrigeration, from Toledo, Ohio, to points in Louisiana; and (2) *Materials, ingredients, equipment and supplies* used in the manufacture of the aforementioned commodities, from points in Louisiana, to Toledo, Ohio, under a continuing contract with Vroman Foods, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Vroman Foods, Inc., 4117 Fitch Road, Toledo, Ohio 43613. Send protests to: Keith D. Warner, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 313 Federal Office Bldg., 234 Summit St., Toledo, Ohio 43604.

No. MC 140176 (Sub-No. 4TA), filed June 25, 1976. Applicant: RILEY WAYNE POWELL, doing business as POWELL TRUCKING COMPANY, Route 3, Sumrall, Miss. 39482. Applicant's representative: Fred W. Johnson, Jr., 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, Miss. 39205. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Poles and pilings*, from the facilities of Fernwood Industries, at Fernwood, Miss., to points in Alabama, Arkansas, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Missouri, Nebraska, New Mexico, New York, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Wisconsin, and Wyoming, under a continuing contract with Fernwood Industries, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Fernwood Industries, P.O. Box 90, Fernwood, Miss. 39635. Send protests to: Alan C. Tarrant, District Supervisor, Interstate Commerce Commission, Room 212, 145 East Amite Bldg., Jackson, Miss. 39201.

No. MC 140693 (Sub-No. 4TA), filed June 21, 1976. Applicant: BEER TRANSPORTATION COMPANY, 1120 Germantown Ave., Philadelphia, Pa. 19123. Applicant's representative: Leonard A.

Jaskiewicz, 1730 M St. NW., Suite 501, Washington, D.C. 20036. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages (beer) and related advertising materials*, from South Volney, N.Y., to points in Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York and West Virginia; and (2) *Returned empty malt beverage containers*, from points in Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York and West Virginia to South Volney, N.Y., for 180 days. Supporting shipper: Miller Brewing Company, 4000 West State St., Milwaukee, Wis. 53208. Send protests to: Monica A. Blodgett Transportation Assistant, Interstate Commerce Commission, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

No. MC 141804 (Sub-No. 14TA), filed June 22, 1976. Applicant: WESTERN EXPRESS, Box 422, Goodlettsville, Tenn. 37072. Applicant's representative: R. Connor Wiggins, Jr., 100 North Main Bldg., Suite 909, Memphis, Tenn. 38103. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lawn mowers and yard equipment and parts*, from the plantsite and storage facilities of McDonough Power Equipment Company, located at or near McDonough, Ga., to the plantsite and storage facilities of Tru-Cut, Inc., located at or near Pacoima, Calif., for 180 days. Supporting Shipper: Tru-Cut, Inc., 10487 San Fernando Road, Pacoima, Calif. 91331. Send protests to: Joe J. Tate, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Suite A–422, P.S. Courthouse, 801 Broadway, Nashville, Tenn. 37203.

No. MC 142055 (Sub-No. 2TA), filed June 16, 1976. Applicant: THOMAS H. PRESLEY, doing business as PRESLEY'S TRUCKING SERVICE, P.O. Box 46, Shuqualak, Miss. 39361. Applicant's representative: John A. Crawford, 1700 Deposit Guaranty Plaza, P.O. Box 22567, Jackson, Miss. 39205. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Brick and structural tile*, from the plant and facilities of Delta Brick & Tile Company, Inc., at or near Indianola, Miss., to points in Alabama, Arkansas, Louisiana, Tennessee, and Texas, under a continuing contract with Delta Brick & Tile Company, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Delta Brick & Tile Company, Inc., P.O. Box 539, Indianola, Miss. 38751. Send protests to: Alan C. Tarrant, District Supervisor, Interstate Commerce Commission, Room 212, 145 East Amite Bldg., Jackson, Miss. 39201.

No. MC 142056 (Sub-No. 1TA) (Correction), filed May 28, 1976, published in the FEDERAL REGISTER issue of June 22, 1976, and republished as corrected this issue. Applicant: JOHN RAGO, 1006 Neptune Blvd., Lynn, Mass. 01905. Applicant's representative: Ronald F. Shapess, 450 Seventh Ave., New York, N.Y. 10001. Authority sought to operate as a *commoncarrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and brewery supplies*, between Merrimack, N.H., and Newark, N.J., on the one hand, and, on the other, West Roxbury, Plymouth, and Danvers, Mass., and Patchogue, Poughkeepsie, and New York, N.Y., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shippers: Jing Beer Dist. Corp., 1213 Grand St., Brooklyn, N.Y. 11211, United Liquors Ltd., 99 Rivermoor St., W. Roxbury, Mass. 02132, Dutchess Beer Distributors, Inc., 84 Dutchess Turnpike, Box 1129, Poughkeepsie, N.Y. 12602, Seabrook Products, Inc., Zero Beechwood Place, Danver, Mass. 01923, L. Knife & Son, Inc., Sandri Drive, Plymouth, Mass. 02360. Send protests to: Max Gorenstein, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 150 Causeway St., Boston, Mass. 02114. The purpose of this republication is to add the name and address of Bureau Field Representative.

No. MC 142075 (Sub-No. 1TA) (Correction), filed June 2, 1976, published in the FEDERAL REGISTER issue of June 22, 1976, and republished as corrected this issue. Applicant: D. C. LARSON TRUCKING, INC., 701 Highway 75 North, Moorhead, Minn. 56560. Applicant's representative: Charles E. Johnson, 425 Gate City Bldg., Fargo, N. Dak. 58102. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Incandescent and fluorescent light bulbs and tubes, from Warren, Pa., to Fargo, N. Dak., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shippers: Maintenance Engineering, Ltd., P.O. Box 2811, Fargo, N. Dak. 58102. Solar Electric, P.O. Box 988, Warren, Pa. 16365. Send protests to: District Supervisor, Bureau of Operations, Interstate Commerce Commission, P.O. Box 2340, Fargo, N. Dak. 58102. The purpose of this republication is to correct the territorial description.

No. MC 142182TA, filed June 22, 1976. Applicant: B & S TRUCKING, INC., 117 Ramsey Lane, Ballwin, Mo. 63011. Applicant's representative: Joseph E. Rebman, 314 N. Broadway, Suite 1230, St. Louis, Mo. 63102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Household appliances, television sets, radios, refrigerators, freezers, stereos and stereo speakers, tape recorders, calculators, ovens and ranges* (including microwave ovens and ranges), *washers, dryers, disposals, dishwashers, air conditioners, carpets, padding, floor tile, sheet vinyl, CB radios* (for automobile installation or otherwise, between the warehouses and shipping facilities of Brightman Distributing Co., Inc., at or near St. Louis, Mo., and Springfield, Mo., on the one hand, and, on the other, points in Adams, Alexander, Bond, Brown, Calhoun, Cass, Champaign, Christian, Clark, Clay, Clinton, Coles, Crawford, Cumberland, DeWitt, Douglas, Edgar, Edwards, Effingham, Fayette, Franklin, Fulton, Green, Gallatin, Hamilton, Hardin, Hancock, Henderson, Henry, Jackson, Jasper, Jefferson, Jersey, Johnson, Knox, Lawrence, Logan, McLean, McDonough, Macon, Macoupin, Madison, Marion, Mason, Massac, Menard, Mecer, Monroe, Montgomery, Morgan, Perry, Piatt, Pike, Pope, Pulaski, Randolph, Richland, St. Clair, Saline, Sangamon, Scott, Schuyler, Shelby, Starke, Sullivan, Tazewell, Union, Vermillion, Wabash, Warren, Washington, Wayne, White, and Williamson Counties, Ill., under a continuing contract with Brightman Distributing Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Brightman Distributing Co., 10411 Baur Blvd., St. Louis, Mo. 63132. Send protests to: J. P. Werthmann, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 1465, 210 N. 12th St., St. Louis, Mo. 63101.

No. MC 94742 (Sub-No. 38TA) (Correction), filed May 26, 1976, published in the FEDERAL REGISTER issue of June 23, 1976, and republished as corrected this issue. Applicant: MICHAUD BUS LINES, INC., 61–63 Jefferson Ave., Salem, Mass. 01970. Applicant's representative: J. Alex Michaud (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and their baggage*, in round-trip special operations, in sightseeing and pleasure tours, offering door to door service, from and to outlying areas to convenient central point of departure, Massachusetts: Commercial Zone of Boston as defined by the Commission (except the City of Boston) and the additional cities and towns: Reading, Wilmington, Winchester, Burlington, Belmont, Stoneham, Lexington, Lincoln, Concord, Waltham, Bedford, Arlington, Melrose, Woburn, Dover, Westwood, Norwood, Weymouth, Braintree, Wellesley, Canton, Stoughton, Framingham, and Natick; New Hampshire Counties of Rockingham, Strafford, Merrimack, and Hillsboro; Maine County of York, to all points in the United States. Applicant intends to tack authority applied for to authority presently held, for 150 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shippers: There are approximately 36 statements of support attached to the application, which may be examined at the Interstate Commerce Commission in Washington, D.C., or copies thereof which may be examined at the field office named below. Send protests to: Max Gorenstein, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 150 Causeway St., Boston, Mass. 02114. The purpose of this republication is to correct the territorial description in this proceeding.

By the Commission.

ROBERT L. OSWALD,
*Secretary.*

[FR Doc.76–19564 Filed 7–6–76;8:45 am]

federal register

WEDNESDAY, JULY 7, 1976




PART II:

# DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## National Institutes of Health

■

# RECOMBINANT DNA RESEARCH

## Guidelines

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### National Institutes of Health

### RECOMBINANT DNA RESEARCH

### Guidelines

On Wednesday, June 23, 1976, the Director, National Institutes of Health, with the concurrence of the Secretary of Health, Education, and Welfare, and the Assistant Secretary for Health, issued guidelines that will govern the conduct of NIH supported research on recombinant DNA molecules. The NIH is also undertaking an environmental impact assessment of these guidelines for recombinant DNA research in accordance with the National Environmental Policy Act of 1969.

The NIH Guidelines establish carefully controlled conditions for the conduct of experiments involving the production of such molecules and their insertion into organisms such as bacteria. These Guidelines replace the recommendations contained in the 1975 *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*. The latter would have permited research under less strict conditions than the NIH Guidelines.

The chronology leading to the present Guidelines is described in detail in the NIH Director's decision document that follows. In summary, scientists engaged in this research called, in 1974, for a moratorium on certain kinds of experiments until an international meeting could be convened to consider the potential hazards of recombinant DNA molecules. They also called upon the NIH to establish a committee to provide advice on recombinant DNA technology.

The international meeting was held at the Asilomar Conference Center, Pacific Grove, California, in February 1975. The consensus of this meeting was that certain experiments should not be done at the present time, but that most of the work on construction of recombinant DNA molecules should proceed with appropriate physical and biological barriers. The Asilomar Conference report also made interim assignments of the potential risks associated with different types of experiments. The NIH then assumed responsibility for translating the broadly based Asilomar recommendations into detailed guidelines for research.

The decision by the NIH Director on these Guidelines was reached after extensive scientific and public airing of the issues during the sixteen months which have elapsed since the Asilomar Conference. The issues were discussed at public meetings of the Recombinant DNA Molecule Program Advisory Committee (Recombinant Advisory Committee) and the Advisory Committee to the NIH Director. The Recombinant Advisory Committee extensively debated three different versions of the Guidelines during this period.

The Advisory Committee to the NIH Director, augmented with consultants representing law, ethics, consumer affairs and the environment, was asked to advise as to whether the proposed Guidelines balanced responsibilty to protect the public with the potential benefits through the pursuit of new knowledge. The many different points of view expressed at this meeting were taken into consideration in the decision.

The NIH recognizes a special obligation to disseminate information on these guidelines as widely as possible. Accordingly, the Guidelines will be sent to all of the approximately 25,000 NIH grantees and contractors. Major professional societies which represent scientists working in this area will also be asked to endorse the Guidelines. The Guidelines will be sent to medical and scientific journals and editors of these journals will be asked to request that investigators include a description of the physical and biological containment procedures used in any recombinant research they report on. International health and scientific organizations will also receive copies of the guidelines for their review.

Filing of an environmental impact statement will provide opportunity for the scientific community, Federal, State and local agencies and the general public to address the potential benefits and hazards of this research area. In order for there to be further opportunity for public comment and consideration, these guidelines are being offered for general comment in the FEDERAL REGISTER. It must be clearly understood by the reader that the material that follows is *not* proposed rulemaking in the technical sense, but is a document on which early public comment and participation is invited.

Please address any comments on these draft policies and procedures to the Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments should be received by November 1, 1976.

Additional copies of this notice are available from the Acting Director, Office of Recombinant DNA Activities, National Institute of General Medical Sciences, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014.

DONALD S. FREDRICKSON,
*Director,*
*NIH National Institutes of Health.*

JUNE 25, 1976.

### DECISION OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH TO RELEASE GUIDELINES FOR RESEARCH ON RECOMBINANT DNA MOLECULES

JUNE 23, 1976.

INTRODUCTION

I. General Policy Considerations.
A. Science Policy.
B. Implementation Within the NIH.
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#### INTRODUCTION

Today, with the concurrence of the Secretary of Health, Education, and Welfare and the Assistant Secretary for Health, I am releasing guidelines that will govern the conduct of NIH-supported research on recombinant DNA molecules (molecules resulting from the recombination in cell-free systems of segments of deoxyribonucleic acid, the material that determines the hereditary characteristics of all known cells). These guidelines establish carefully controlled conditions for the conduct of experiments involving the insertion of such recombinant genes into organisms, such as bacteria. The chronology leading to the present glidelines and the decision to release them are outlined in this introduction.

In addition to developing these guidelines, NIH has undertaken an environmental impact assessment of these guidelines for recombinant DNA research in accordance with the National Environmental Policy Act of 1969 (NEPA). The guidelines are being released prior to completion of this assessment. They will replace the current Asilomar guidelines, discussed below, which in many instances allow research to proceed under less strict conditions. Because the NIH guidelines will afford a greater degree of scrutiny and protection, they are being released today, and will be effective while the environmental impact assessment is under way.

Recombinant DNA research brings to the fore certain problems in assessing the potential impact of basic science on society as a whole, including the manner of providing public participation in those asessments. The field of research involved is a rapidly moving one, at the leading edge of biological science. The experiments are extremely technical and complex. Molecular biologists active in this research have means of keeping informed, but even they may fail to keep abreast of the newest developments. It is not surprising that scientists in other fields and the general public have difficulty in understanding advances in recombinant DNA research. Yet public awareness and understanding of this line of investigation is vital.

It was the scientists engaged in recombinant DNA research who called for a moratorium on certain kinds of experiments in order to assess the risks and devise appropriate guidelines. The capability to perform DNA recombinations, and the potential hazards, had become apparent at the Gordon Research Conference on Nucleic Acids in July 1973. Those in attendance voted to send an open letter to Dr. Philip Handler, President of the National Academy of Sciences, and to Dr. John R. Hogness, President of the Institute of Medicine, NAS. The letter, appearing in *Science 181*, 1114, (1973), suggested "that the Academies

[*sic*] establish a study committee to consider this problem and to recommend specific actions or guidelines, should that seem appropriate."

In response, NAS formed a committee, and its members published another letter in *Science 185*, 303, (1974). Entitled "Potential Biohazards of Recombinant DNA Molecules," the letter proposed:

> First, and most important, that until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread, scientists throughout the world join with the members of this committee in voluntarily deferring * * * [certain] experiments * * *.
>
> Second, plans to link fragments of animal DNAs to bacterial plasmid DNA or bacteriophage DNA should be carefully weighted * * *.
>
> Third, the Director of the National Institutes of Health is requested to give immediate consideration to establishing an advisory committee charged with (i) overseeing an experimental program to evaluate the potential biological and ecological hazards of the above types of recombinant DNA molecules; (ii) developing procedures which will minimize the spread of such molecules within human and other populations; and (iii) devising guidelines to be followed by investigators working with potentially hazardous recombinant DNA molecules.
>
> Fourth, an international meeting of involved scientists from all over the world should be convened early in the coming year to review scientific progress in this area and to further discuss appropriate ways to deal with the potential biohazards of recombinant DNA molecules.

On October 7, 1974, the NIH Recombinant DNA Molecule Program Advisory Committee (hereafter "Recombinant Advisory Committee") was established to advise the Secretary, HEW, the Assistant Secretary for Health, and the Director, NIH, "concerning a program for developing procedures which will minimize the spread of such molecules within human and other populations, and for devising guidelines to be followed by investigators working with potentially hazardous recombinants."

The international meeting proposed in the *Science* article (*185*, 303, 1974) was held in February 1975 at the Asilomar Conference Center, Pacific Grove, California. It was sponsored by the National Academy of Sciences and supported by the National Institutes of Health and the National Science Foundation. One hundred and fifty people attended, including 52 foreign scientists from 15 countries, 16 representatives of the press, and 4 attorneys.

The conference reviewed progress in research on recombinant DNA molecules and discussed ways to deal with the potential biohazards of the work. Participants felt that experiments on construction of recombinant DNA molecules should proceed, provided that appropriate biological and physical containment is utilized. The conference made recommendations for matching levels of containment with levels of possible hazard for various types of experiments. Certain experiments were judged to pose such serious potential dangers that the conference recommended against their being conducted at the present time.

A report on the conference was submitted to the Assembly of Life Sciences, National Research Council, NAS, and approved by its Executive Committee on May 20, 1975. A summary statement of the report was published in *Science 188*, 991 (1975), *Nature 225*, 442, (1975), and the *Proceedings of the National Academy of Sciences 72*, 1981, (1975). The report noted that "in many countries steps are already being taken by national bodies to formulate codes of practice for the conduct of experiments with known or potential biohazard. Until these are established, we urge individual scientists to use the proposals in this document as a guide."

The NIH Recombinant Advisory Committee held its first meeting in San Francisco immediately after the Asilomar conference. It proposed that NIH use the recommendations of the Asilomar conference as guidelines for research until the committee had an opportunity to elaborate more specific guidelines, and that NIH establish a newsletter for informal distribution of information. NIH accepted these recommendations.

At the second meeting, held on May 12–13, 1975, in Bethesda, Maryland, the committee received a report on biohazard-containment facilities in the United States and reviewed a proposed NIH contract program for the construction and testing of microorganisms that would have very limited ability to survive in natural environments and would thereby limit the potential hazards. A subcommittee chaired by Dr. David Hogness was appointed to draft guidelines for research involving recombinant DNA molecules, to be discussed at the next meeting.

The NIH committee, beginning with the draft guidelines prepared by the Hogness subcommittee, prepared proposed guidelines for research with recombinant DNA molecules at its third meeting, held on July 18–19, 1975, in Woods Hole, Massachusetts.

Following this meeting, many letters were received which were critical of the guidelines. The majority of critics felt that they were too lax, others that they were too strict. All letters were reviewed by the committee, and a new subcommittee, chaired by Dr. Elizabeth Kutter, was appointed to revise the guidelines.

A fourth committee meeting was held on December 4–5, 1975, in La Jolla, California. For this meeting a "variorum edition" had been prepared, comparing line-for-line the Hogness, Woods Hole, and Kutter guidelines. The committee reviewed these, voting item-by-item for their preference among the three variations and, in many cases, adding new material. The result was the "Proposed Guidelines for Research Involving Recombinant DNA Molecules, "which were referred to the Director, NIH, for a final decision in December 1975.

As Director of the National Institutes of Health, I called a special meeting of the Advisory Committee to the Director to review these proposed guidelines. The meeting was held at NIH, Bethesda, on February 9–10, 1976. The Advisory Committee is charged to advise the Director, NIH, on matters relating to the broad setting—scientific, technological, and socioeconomic—in which the continuing development of the biomedical sciences, education for the health professions, and biomedical communications must take place, and to advise on their implications for NIH policy, program development, resource allocation, and administration. The members of the committee are knowledgeable in the fields of basic and clinical biomedical sciences, the social sciences, physical sciences, research, education, and communications. In addition to current members of the committee, I invited a number of former committee members as well as other scientific and public representatives to participate in the special February session.

The purpose of the meeting was to seek the committee's advice on the guidelines proposed by the Recombinant Advisory Committee. The Advisory Committee to the Director was asked to determine whether, in their judgment, the guidelines balanced scientific responsibility to the public with scientific freedom to pursue new knowledge.

Public responsibility weighs heavily in this genetic research area. The scientific community must have the public's confidence that the goals of this profoundly important research accord respect to important ethical, legal, and social values of our society. A key element in achieving and maintaining this public trust is for the scentific community to ensure an openness and candor in its proceedings. The meetings of the Director's Advisory Committee, the Asilomar group, and the Recombinant Advisory Committee have reflected the intent of science to be an open community in considering the conduct of recombinant DNA experiments. At the Director's Advisory Committee meeting, there was ample opportunity for comment and an airing of the issues, not only by the committee members but by public witnesses as well. All major points of view were broadly represented.

I have been reviewing the guidelines in light of the comments and suggestions made by participants at that meeting, as well as the written comments received afterward. As part of that review I asked the Recombinant Advisory Committee to consider at their meeting of April 1–2, 1976, a number of selected issues raised by the commentators. I have taken those issues and the response of the Recombinant Advisory Committee into account in arriving at my decision on the guidelines. An analysis of the issues and the basis for my decision follow.

### I. GENERAL POLICY CONSIDERATIONS

A word of explanation might be interjected at this point as to the nature of the studies in question. Within the past decade, enzymes capable of breaking DNA strands at specific sites and of coupling the broken fragments in new combinations were discovered, thus making possible the insertion of foreign genes into viruses or certain cell particles (plas-

mids). These, in turn, can be used as vectors to introduce the foreign genes into bacteria or into cells of plants or animals in test tubes. Thus transplanted, the genes may impart their hereditary properties to new hosts. These cells can be isolated and cloned—that is, bred into a genetically homogeneous culture. In general, there are two potential uses for the clones so produced: as a tool for studying the transferred genes, and as a new useful agent, say for the production of a scarce hormone.

Recombinant DNA research offers great promise, particularly for improving the understanding and possibly the treatment of various diseases. There is also a potential risk—that microorganisms with transplanted genes may prove hazardous to man or other forms of life. Thus special provisions are necessary for their containment.

All commentators acknowledged the exemplary responsibility of the scientific community in dealing publicly with the potential risks in DNA recombinant research and in calling for a self-imposed moratorium on certain experiments in order to assess potential hazards and devise appropriate guidelines. Most commentators agreed that the process leading to the formulation of the proposed guidelines was a most responsible and responsive one. Suggestions by the commentators on broad policy considerations are presented below. They relate to the science policy aspects of the guidelines, the implementation of the guidelines for NIH grantees and contractors, and the scope and impact of the guidelines nationally and internationally.

*A. Science policy considerations*

Commentators were divided on how best to steer a course between stifling research through excessive regulation and allowing it to continue with sufficient controls. Several emphasized that the public must have assurance that the controls afford adequate protection against potential hazards. In the views of these commentators, the burden is on the scientific community to show that the danger is minimal and that the benefits are substantial and far outweigh the risks.

Opinion differed on whether the proposed guidelines were an appropriate response to the potential benefits and hazards. Several found the guidelines to so exaggerate safety procedures that inquiry would be unnecessarily retarded, while others found the guidelines weighted toward promoting research. The issue was how to strike a reasonable balance—in fact, a proper policy "bias"—between concerns to "go slow" and those to progress rapidly.

There was strong disagreement about the nature and level of the possible hazards of recombinant DNA research. Several commentators believed that the hazards posed were unique. In their view, the occurrence of an accident or the escape of a vector could initiate an irreversible process, with a potential for creating problems many times greater than those arising from the multitude of genetic recombinations that occur spontaneously in nature. These commentators stress the moral obligation on the part of the scientific community to do no harm.

Other commentators, however, found the guidelines to be adequate to the hazards posed. In their view, the guidelines struck an appropriate balance so that research could proceed cautiously. Still other commentators found the guidelines too onerous and restrictive in light of the potential benefits of this research for medicine, agriculture, and industry. Some felt that the guidelines are perhaps more stringent than necessary given the available evidence on the likelihood of hazards, but supported them as a compromise that would best serve the scientific community and the public at large. Many commentators urged that the guidelines be adopted as soon as possible to afford more specific direction to this research area.

I understand and appreciate the concerns of those who urge that this research proceed because of the benefits and of those who urge caution because of potential hazards. The guidelines issued today allow the research to go forward in a manner responsive and appropriate to hazards that may be realized in the future.

The object of these guidelines is to ensure that experimental DNA recombination will have no ill effects on those engaged in the work, on the general public, or on the environment. The essence of their construction is subdivision of potential experiments by class, decision as to which experiments should be permitted at present, and assignment to these of certain procedures for containment of recombinant organisims.

Containment is defined as physical and biological. Physical containment involves the isolation of the research by procedures which have evolved over many years of experience in laboratories studying infectious microorganisms. P1 containment—the first *physical* containment level—is that used in most routine bacteriology laboratories. P2 and P3 afford increasing isolation of the research from the environment P4 represents the most extreme measures used for containing virulent pathogens, and permits no escape of contaminated air, wastes, or untreated materials. *Biological* containment is the use of vectors or hosts that are crippled by mutation so that the recombinant DNA is incapable of surviving under natural conditions.

The experiments now permitted under the guidelines involve no known additional hazard to the workers or the environment beyond the relatively low risk known to be associated with the source materials. The additional hazards are speculative and therefore not quantifiable. In a real sense they are considerably less certain than are the benefits now clearly derivable from the projected research.

For example, the ability to produce, through "molecular cloning," relatively large amounts of pure DNA from the chromosomes of any living organism will have a profound effect in many areas of biology. No other procedure, not even chemical synthesis, can provide pure material corresponding to particular genes. DNA "probes," prepared from the clones will yield precise evidence on the presence or absence, the organization, and the expression of genes in health and disease.

Potential medical advances were outlined by scientists active in this research area who were present at the meeting of the Director's Advisory Committee. Of enormous importance, for example, is the opportunity to explore the malfunctioning of cells in complicated diseases. Our ability to understand a variety of hereditary defects may be significantly enhanced, with amelioration of their expression a real possibility. There is the potential to elucidate mechanisms in certain cancers, particularly those that might be caused by viruses.

Instead of mere propagation of foreign DNA, the expression of the genes of one organism by the cell machinery of another may alter the new host and open opportunities for manipulating the biological properties of cells. In certain prokaryotes (organisms with a poorly developed nucleus, like bacteria), this exchange of genetic information occurs in nature. Such exchange explains, for instance, an important mechanism for the changing and spreading of resistance to antibiotics in bacteria. Beneficial effects of this mechanism might be the production of medically important compounds for the treatment and control of disease. Examples frequently cited are the production of insulin, growth hormone, specific antibodies, and clotting factors absent in victims of hemophilia.

Aside from the potential medical benefits, a whole host of other applications in science and technology have been envisioned. Examples are the large-scale production of enzymes for industrial use and the development of bacteria that could ingest and destroy oil spills in the sea. Potential benefits in agriculture include the enhancement of nitrogen fixation in certain plants, permitting increased food production.

While the projected research offers the possibility of many benefits, it must proceed only with assurance that potential hazards can be controlled or prevented. Some commentators are concerned that nature may maintain a barrier to the exchange of DNA between prokaryotes and eukaryotes (higher organisms, with a well-formed nucleus)—a barrier that can now be crossed by experimentalists. They further argue that expression of the foreign DNA may alter the host in unpredictable and undesirable ways. Conceivable harm could result if the altered host has a competitive advantage that would foster its survival in some niche within the ecosystem. Other commentators believe that the endless experiments in recombination of DNA which nature has conducted since the beginning of life on the earth, and which have accounted in part for the evolution of species, have most likely involved exchange of DNA between widely disparate species. They

argue that prokaryotes such as bacteria in the intestines of man do exchange DNA with this eukaryotic host and that the failure of the altered prokaryotes to be detected attests to a sharply limited capacity of such recombinants to survive. Thus nature, this argument runs, has already tested the probabilities of harmful recombination and any survivors of such are already in the ecosystem. The fact is that we do not know which of the above-stated propositions is corrected.

The interntaional scientific community, as exemplified by the Asilomar conference and the deliberations attendant upon preparation of the present guidelines, has indicated a desire to proceed with research in a conservative manner. And most of the considerable public commentary on the subject, while urging caution, has also favored proceeding. Three European groups have independently arrived at the opinion that recombinant DNA research should proceed with caution. These are the Working Party on Experimental Manipulation of the Genetic Composition of Micro-Organisms, whose "Ashby Report" was presented to Parliament in the United Kingdom by the Secretary of State for Education and Science in January 1975; the Advisory Committee on Medical Research of the World Health Organization, which issued a press release in July 1975; and the European Molecular Biology Organization Standing Committee on Recombinant DNA, meeting in February 1976.

There is no means for a flat proscription of such research throughout the world community of science. There is also no need to attempt it. It is likely that the evaluation engendered in the preparation and application of these guidelines will lead to beneficial review of some of the containment practices in other work that is not technically defined as recombinant DNA research.

Recombinant DNA research with which these guidelines are concerned involves microorganisms such as bacteria or viruses or cells of higher organisms growing in tissue culture. It is extremely important for the public to be aware that this research is not directed to altering of genes in humans although some of the techniques developed in this research may have relevance if this is attempted in the future.

NIH recognizes its responsibility to conduct and support research designed to determine the extent to which certain potentially harmful effects from recombinant DNA molecules may occur. Among these are experiments, to be conducted under maximum containment, that explore the capability of foreign genes to alter the character of host or vector, rendering it harmful, as through the production of toxic products.

Given the general desire that no rare and unexpected event arising from this research shall cause irreversible damage, it is obvious that merely to establish conservative rules of conduct for one group of scientists is not enough. The precautions must be uniformly and unanimously observed. Second, there must be full and timely exchange of experiences so that guidelines can be altered on the basis of new knowledge. The guidelines must also be implemented in a manner that protects all concerned—the scientific workers most likely to encounter unexpected hazards and all forms of life within our biosphere. The responsibility of the scientists involved is as inescapable and extreme as is their opportunity to beneficially enrich our understanding.

*B. Implementation considerations within the NIH*

All the commentators had suggestions concerning the structure and function of decision making as it relates to the principal investigator, the local biohazards committee, the peer review group, and the NIH Recombinant Advisory Committee. These comments and my response on the section of the guidelines relating to roles and responsibilities of investigators, their institutions, and the National Institutes of Health are presented below.

Of considerable concern to all commentators was the process by which NIH would proceed to implement the guidelines. The scientific community generally urged that there be no Federal regulations, while some of the public commentators recommended the regulatory process.

Many who opposed changing the proposed guidelines into Federal regulations expressed concern for flexibility and administrative efficiency, which could best be achieved, in their view, through voluntary compliance. Other commentators, however, believed it imperative to proceed toward regulation. In their view, the guidelines could be implemented for purposes of NIH funding and would govern the conduct of experiments until regulations were in effect. Another commentator who thought regulation would be harmful rather than helpful suggested that if there were to be regulations, they should be along lines similar to those that govern the sale, distribution, use, and disposal of radioisotopes.

The question of how best to proceed now that the guidelines have been released deserves careful attention. I share the concern of those who feel that the guidelines must remain flexible. It is especially important that there be opportunity to change them quickly, based on new information relating to scientific evidence, potential risks, or safety aspects of the research program.

The suggestions for regulation need further attention at this time. The process for regulation not only involves the Director of NIH, but also the Assistant Secretary for Health and the Secretary of Health, Education, and Welfare. These guidelines are being promulgated now in order to afford additional protection to all concerned. Consideration of their conversion to regulations can proceed with continuing review of their content and present and future implications. Meanwhile, the NIH shall continue to provide the opportunity for public comment and participation at least equivalent to that provided if steps towards regulations were to proceed immediately. The guidelines will be published in the FEDERAL REGISTER forthwith to allow for further public comment.

*C. Implementation considerations beyond the purview of NIH*

Special concern has been expressed by many commentators regarding the application of the guidelines to research outside NIH by investigators other than its grantees or contractors. It has been urged that the guidelines be made applicable to recombinant DNA research conducted or supported by other agencies in HEW and by NSF, ERDA, DoD, and other governmental departments. Most commentators believe that these or similar guidelines should also govern research in the private sector, including industry, voluntary organizations, and foundations. Many feel that experiments conducted in colleges, universities, and even in high schools require some form of monitoring. And finally, all agree that in view of the potential hazards of recombinant DNA research to the biosphere, some form of international understanding on guidelines for the research is essential.

The committee, in the proposed guidelines, has suggested as one means of control that a description of the physical and biological containment procedures practiced in a research project be included in the publication of research results. In the scientfic community this can be a powerful force for conformity, and we will undertake to present the recommendation to all appropriate journals. We are also prepared to take steps to disseminate the guidelines widely, and to arrange for a continual flow of information outward concerning the activities of the Recombinant Advisory Committee and the Advisory Committee to the Director, NIH, in the evolution of the guidelines and their implementation.

In response to these suggestions, I have already held a meeting with relevant HEW agencies and with representatives from other departments of the Federal Government. The purpose of the meeting was to exchange information on recombinant DNA research and to discuss the NIH guidelines. It served as an important beginning to address a common concern of these public institutions. A number of the representatives indicated that various departments might very well adopt the guidelines for research conducted both in-house and supported outside. Following up, I have begun preliminary discussions with the Assistant Secretary for Health and the Secretary of HEW, to determine possible methods to ensure adoption of the guidelines by all Federal agencies. Encouraged by these efforts, we held a meeting on June 2 with representatives of industry to provide them with full information about the guidelines and to help determine the present and future interests of industrial laboratories in this type of research. The meeting provided one of the first opportunities for industry representatives to convene for a discussion of this research area, and an industry com-

mittee under the auspices of the Pharmaceutical Manufacturers Association will be formed to review the guidelines for potential application to the drug industry. Further meetings will be scheduled with other groups that have an active interest in recombinant DNA research.

It is my hope that the guidelines will be voluntarily adopted and honored by all who support or conduct such research throughout the United States, and that at least very similar guidelines will obtain throughout the rest of the world. NIH places the highest priority on efforts to inform and to work with international organizations, such as the World Health Organization and the International Council of Scientific Unions, with a view to achieving a consensus on safety standards in this most important research area.

There has been considerable international cooperation and activity in the past, and I expect it to continue in the future. The aforementioned Ashby Report, presented to Parliament in January 1975, describes the advances in knowledge and possible benefits to society of the experiments involving recombinant DNA molecules, and attempts to assess the hazards in these techniques. The Asilomar meeting also had a number of international representatives, as mentioned previously. The European Molecular Biology Organization (EMBO) has been involved in considering guidelines for recombinant DNA research. They have closely followed the activities of NIH, and will thus be encouraged, I believe, to monitor their research with augmented cooperation and coordination. For example, EMBO recently announced plans for a voluntary registry of recombinant DNA research in Europe. Following this EMBO initiative, NIH shall similarly maintain a voluntary registry of investigators and institutions engaged in such research in the United States. Plans for establishing this registry are under way.

*D. Environmental policy considerations*

A number of commentators urged NIH to consider preparing an environmental impact statement on recombinant DNA research activity. They evoked the possibility that organisms containing recombinant DNA molecules might escape and affect the environment in potentially harmful ways.

I am in full agreement that the potentially harmful effects of this research on the environment should be assessed. As discussed throughout this paper, the guidelines are premised on physical and biological containment to prevent the release or propagation of DNA recombinants outside the laboratory. Deliberate release of organisms into the environment is prohibited. In my view, the stipulated physical and biological containment ensures that this research will proceed with a high degree of safety and precaution. But I recognize the legitimate concern of those urging that an environmental impact assessment be done. In view of this concern and ensuing public debate, I have reviewed the appropriateness of such an assessment and have directed that one be undertaken.

The purpose of this assessment will be to review the environmental effects, if any, of research that may be conducted under the guidelines. The assessment will provide further opportunity for all concerned to address the potential benefits and hazards of this most important research activity. I expect a draft of the environmental impact statement should be completed by September 1 for comment by the scientific community, Federal and State agencies, and the general public.

It should be noted that the development of the guidelines was in large part tantamount to conducting an environmental impact assessment. For example, the objectives of recombinant DNA research, and alternate approaches to reach those objectives, have been considered. The potential hazards and risks have been analyzed. Alternative approaches have been thoroughly considered, to maximize safety and minimize potential risk. And an elaborate review structure has been created to achieve these safety objectives. From a public policy viewpoint, however, the environmental impact assessment will be yet another review that will provide further opportunity for the public to participate and comment on the conduct of this research.

II. METHODS OF CONTAINMENT

Comments on the containment provisions of the proposed guidelines were directed to the definition of both physical and biological containment and to the safety and effectiveness of the prescribed levels. Several commentators found the concept of physical containment imprecise and too subject to the possibility for human error. Others questioned the concept of biological containment in terms of its safety and purported effectiveness in averting potential hazards. The commentators were divided on which method of containment would provide the most effective and safe system to avoid hazards. Several suggested that each of the physical containment levels be more fully explained.

W. Emmett Barkley, Ph.D., Director of the Office of Research Safety, National Cancer Institute, was asked to review the section on physical containment in light of these comments. Dr. Barkley convened a special committee of safety and health experts, who met to consider not only this section of the guidelines but also the section on the roles and responsibilities of researchers and their institutions. The committee thoroughly reviewed the section on physical containment and recommended a number of changes. The Recombinant Advisory Committee, meeting on April 1–2, 1976, reviewed the recommendations of the Barkley group. These are incorporated, with editorial revisions, in the final version of the guidelines.

The present section on physical containment is directly responsive to those commentators who asked for greater detail and explanation. Although different in detail, the four levels of containment approximate those given by the Center for Disease Control for human etiologic agents and by the National Cancer Institute for oncogenic viruses. For each of the proposed levels, optional items have been excluded, and only those items deemed absolutely necessary for safety are presented. Necessary facilities, practices, and equipment are specified. To give further guidance to investigators and their institutions, a supplement to the guidelines explains more fully safety practices appropriate to recombinant DNA research. And a new section has been added to ensure that shipment of recombinant DNA materials conforms, where appropriate, to the standards, prescribed by the U.S. Public Health Service, the Department of Transportation, and the Civil Aeronautics Board.

The section on physical containment is carefully designed to offer a constructive approach to meeting potential hazards for recombinant experiments at all levels of presumed risk. Certain commentators had suggested that the first level of physical containment (P1) be merged with the second level (P2). This suggestion, however, would tend to apply overly stringent standards for some experiments and might result in a lowering of standards necessary at the second level. I believe the level of control must be consistent with a reasonable estimate of the hazard; and the section on physical containment does provide this consistency. Accordingly, the first and second levels of physical containment remain as separate sections in the guidelines.

Because of the nature and operation of facilities required for experiments to be done at the fourth level of containment (P4), a provision has been included that the NIH shall review such facilities prior to funding them for recombinant DNA studies. The situation merits the special attention of experts who have maximum familiarity with the structure, operation, and potential problems of P4 installations. Several commentators advocated that NIH arrange for sharing of P4 facilities, both in the NIH intramural program and in institutions supported through NIH awards. In response to these suggestions, we are currently reviewing our facilities, including those at the Frederick Cancer Research Center (Fort Detrick), to determine how such a program can best be devised. It is most important that P4 facilities be made available to investigators. It should be noted that incidents of infection by even the most highly infectious and dangerous organisms are extremely infrequent at P4 facilities, and therefore the potential for hazard in certain complex experiments in recombinant DNA research is considerably reduced.

III. PROHIBITED EXPERIMENTS

1. Practically all commentators supported the present prohibition of certain experiments. There were suggestions for a clearer definition of the prohibition of certain experiments where increased antibiotic resistance may result. And it

was urged by some that the prohibition be broadened to include experiments that result in resistance to any antibiotic, irrespective of its use in medicine or agriculture. Consideration of such a suggestion must take into account that antibiotic resistance occurs naturally among bacteria, and that resistance is a valuable marker in the study of microbial genetics in general, and recombinants in particular.

In view of these concerns, however, the Recombinant Advisory Committee was asked to reconsider carefully the prohibition and related sections concerning antibiotic resistance. The committee noted that the prohibition relating to drug resistance was intended to ban those experiments that could compromise drug use in controlling disease agents in veterinary as well as human medicine and this is now clearly stated.

In the draft guidelines there were two statements concerning resistance to drugs which related to experiments with *E. coli*. The statements appeared to allow experiments that would extend the range of resistance of this bacterium to therapeutically useful drugs and disinfectants, and thus seemed to be in conflict with the general prohibition on such research. There are numerous reports in the scientific literature indicating that *E. coli* can acquire resistance to all antibiotics known to act against it. Since *E. coli* acquires resistance naturally, the prohibition directed against increasing resistance does not apply. The ambiguous statements have been deleted from the present guidelines. On the other hand, new language has been inserted in the section dealing with other prokaryote species to set containment levels for permitted experiments.[1]

2. The Recombinant Advisory Committee was also asked to clarify whether the prohibition of use of DNA derived from pathogenic organisms (those classified as 3, 4, and 5 by the Center for Disease Control, USPHS) also included the DNA from any host infected with these organisms. The committee explained that this prohibition did extend to experiments with cells known to be so infected. To avoid misunderstanding, the prohibition as now worded includes such cells. In addition, the prohibitions have been extended to include moderate-risk oncogenic viruses, as defined by the National Cancer Institute, and cells known to be infected with them.

3. Two other issues relating to the section on prohibited experiments were raised by Roy Curtiss III, Ph.D., Professor, Department of Microbiology, University of Alabama School of Medicine, Birmingham, who is a member of the Recombinant Advisory Committee. Dr. Curtiss noted that for the class of experiments prohibited on the basis of production of highly toxic substances, only substances from micro-organisms were cited as examples. He suggested that other examples be included, such as venoms from insects and snakes. The committee approved the suggestion and I concur.

In the proposed guidelines, release of organisms containing recombinant DNA molecules into the environment was prohibited unless a series of controlled tests had been done to leave no reasonable doubt of safety. Dr. Curtiss felt that the guidelines should provide greater specificity for testing and should include some form of review prior to release of the organism. I have decided that the guidelines should, for the present, prohibit any deliberate release of organisms containing recombinant DNA into the environment. With the present limited state of knowledge, it seems highly unlikely that there will be in the near future, any recombinant organism that is universally accepted as being beneficial to introduce into the environment. When the scientific evidence becomes available that the potential benefits of recombinant organisms, particularly for agriculture, are about to be realized, then the guidelines can be altered to meet the needs for release. It is most important that the potential environmental impact of the release be considered.

### IV. PERMISSIBLE EXPERIMENTS: E. COLIK-12 HOST-VECTOR SYSTEMS

The continued use of *E. coli* as a host has drawn considerable comment, in cluding some suggestions that its use be prohibited presently or within a specified time limit. It should be stressed that the use of *E. coli* as detailed in the guidelines is limited to *E. coli* K-12, a strain that has been carried in the laboratory for decades and does not involve the use of any strain of *E. coli* that is freshly isolated from a natural source. *E. coli* K-12 does not usually colonize the normal bowel, even when given in large doses, and exhibits little if any multiplication while passing through the alimentary canal. For years it has been the subject of more intense investigation than any other single organism, and knowledge of its genetic makeup and recombinant behavior exceeds greatly that pertaining to any other organism. I believe that because of this experience, *E. coli* K-12 will provide a host-vector system that is safer than other candidate microorganisms.

NIH recognizes the importance of supporting the development of alternative host-vector systems (such as *B. subtilis*, which has no ecological niche in man) and will encourage such development. It should be noted, however, that for each new host-vector system, the same questions of risk from altered properties attendant upon the presence of recombinant genes will apply as apply to *E. coli*. NIH does not believe it wise to set a time limit on replacement of *E. coli* systems by other organisms.

There were specific suggestions concerning the three levels of biological containment prescribed for use of *E. coli* K-12 host-vectors. Some commentators requested a more detailed explanation of the adequacy of protection for laboratory personnel with the first level of containment (EK1).[2] Sections of the guidelines dealing with physical containment and roles and responsibilities now specify the need for safety practices and accident plans.

For the second level of containment (EK2), it is required that a cloned DNA fragment be contained in a host-vector system that has no greater than a $10^{-8}$ probability of survival in a nonpermissive or natural environment. It was suggested that the selection of this level of biological containment and the appropriate tests for verification be more fully explained in the guidelines. The committee, in responding to a request for further examination of this point, reviewed at considerable length the testing for an EK2 system and recommended certain modifications. We have accepted the committee's new language that better explains testing of survival of a genetic marker carried on the vector, preferably on an inserted NDA fragment.

Possible tests to determine the level of biological containment afforded by these altered host-vector systems are outlined in this section. Because this is such a new area of scientific research and development, however, it is inappropriate to standardize such testing at the present time. Standards will gradually be set as more experience with EK2 host-vector systems is acquired. The committee, for example, during its April 1976 meetings gave its first approval to an EK2 host-vector system. What is necessary is that new and more effective tests be devised by investigators, and this effort is very likely to occur under the present guidelines. For example, one task recognized by the committee is to clarify how survival of the organism and the cloned DNA should be defined in terms of temperature, medium, and other variables.

It is also very important to note here that the stringent requirements set by the committee for EK2 biological containment jeopardize considerably the capacity of such crippled organisms to survive and replicate even under permissive laboratory conditions. More experience will be required to determine whether EK2 containment will permit some lines of important research to be followed.

Several commentators suggested that methods and procedures to confirm an

[1] Specifically, experiments that would extend resistance to therapeutically useful drugs must use P3 physical containment plus a host-vector comparable to EK1, or P2 containment plus a host-vector comparable to EK2.

[2] The EK1 system presently consists of a battery of different vectors and of *E. coli* K-12 mutants, all of which afford a considerable degree of biological containment. The diversity of vectors and of host mutants in this battery has permitted a wide range of important scientific questions to be attacked. For example, the availability of different vectors with cleavage sites for different restriction endonucleases have increased the kind of DNA segments that can be cloned. By contrast, the first EK2 host-vector systems are only now being considered by the Recombinant Advisory Committee. While NIH is supporting the development of more EK2 host-vector systems, it is not expected that a battery equivalent to that available for the EK1 system will be certified by the Recombinant Advisory Committee in the near future.

EK system at the third level of containment (EK3) be more fully explained. The Recombinant Advisory Committee was asked to consider this suggestion. After considerable discussion the committee declined to define the procedures more fully at this time, because development of an EK3 system is still far enough in the future not to warrant specific testing procedures. Further, it is not clear what tests are best suited. The language, therefore, remains general. The committee, however, is aware of the concerns for a more completely defined system of testing, and has considered the possibility of organizing a symposium for purposes of designating tests. In my view, more fully developed protocols for testing EK3 systems are warranted, and it is necessary that guidelines here be more fully developed before the committee proceeds to certify such a system. In this regard the NIH is prepared through the National Institute of Allergy and Infectious Diseases to support contracts to accomplish this task. We will seek the advice and assistance of the committee to define the scope of necessary work.

These guidelines also include a statement that for the time being no EK2 or EK3 host-vector system will be considered *bona fide* until the Recombinant Advisory Committee has certified it. I share the concern of the commentators that new host-vector systems require the highest quality of scientific review and scrutiny. At this early stage of development, it is most important that the committee provide that scrutiny. Further, I believe that until more experience has been gained, the committee should encourage and the NIH support research that will independently confirm and augment the data on which certification of EK2 host-vector systems are based.

V. CLASSIFICATION OF EXPERIMENTS USING THE E. COLI K–12 CONTAINMENT SYSTEMS

The guidelines assign different levels of containment for experiments in which DNA from different sources is to be introduced into an *E. coli* K–12 host-vector system. The variation is based on both facts and assumptions. There are some prokaryotes (bacteria) which constantly exchange DNA with *E. coli*. Here it is assumed that experimental conditions beyond those obtained in careful, routine microbiology laboratories are superfluous, because any exchange experiments have undoubtedly been performed already in nature.

In every instance of artificial recombination, consideration must be given to the possibility that foreign DNA may be translated into protein (expressed), and also to the possibility that normally repressed genes of the host may be expressed and thus change, undesirably, the characteristics of the cell. It is assumed that the more similar the DNAs of donor and host, the greater the probability of expression of foreign DNA, or of possible derepression of host genes. In those cases where the donor exchanges DNA with *E. coli* in nature, it is unlikely that recombination experiments will create new genetic combinations. When prokaryote donors not known to exchange DNA with *E. coli* in nature are used, however, there is a greater potential for new genetic combinations to be formed and be expressed. Therefore, it is required that experiments involving prokaryotic DNA from a donor that is not known to exchange DNA with *E. coli* in nature be carried out at a higher level of containment. Recombination using prokaryotic DNA from an organism known to be highly pathogenic is prohibited.

There are only limited data available concerning the expression of DNA from higher forms of life (eukaryotes) in *E. coli* (or any other prokaryote). Therefore, the containment prescriptions for experiments inserting eukaryotic DNA into prokaryotes are based on risks having quite uncertain probabilities.

On the assumption that a prokaryote host might translate eukaryotic DNA, it is further presumed that the product of that foreign gene would be most harmful to man if it were an enzyme, hormone, or other protein that was similar (homologous) to proteins already produced by or active in man. An example is a bacterium that could produce insulin. Such a "rogue" bacterium could be of benefit if contained, a nuisance or possibly dangerous if capable of surviving in nature. This is one reason that the higher the phylogenetic order of the eukaryote, the higher the recommended containment, at least until the efficiency of expression of DNA from higher eukaryotes in prokaryotes can be determined.

There is a second, more concrete reason for scaling containment upward as the eukaryote host becomes similiar to man. This is the concern that viruses capable of propagating in human tissue, and possibly causing diseases, can contaminate DNA, replicate in prokaryote hosts and infect the experimentalist. Such risks are greatest when total DNA from donor tissue is used in "shotgun" recombinant experiments; it diminishes to much lower levels when pure cloned DNA is used.

The commentators were clearly divided on the classification of containment criteria for different kinds of recombinant DNAs. Many commentators considered the guidelines too stringent and rigid. Others viewed the guidelines in certain instances as too permissive. And still others endorsed the guidelines as sensible and reasonable, affording the public an enormous degree of protection from the speculative risks. Several suggestions were made for the specific classes of experiments, and they follow:

1. Comment on the use of DNA from animals and plants in recombinant experiments varied widely. Some commentators suggested banning the use of DNA from primates, other mammals, and birds. Others suggested that higher levels of containment be used for all such experiments. Still others believed that the guidelines were too strict for experiments of this class. I have carefully reviewed the issues raised by the commentators and the responses of the committee to certain queries concerning use of animal and plant DNA in these experiments.

In my view, the classification for the use of DNA from primates, other mammals, and birds is appropriate to the potential hazards that might be posed. The physical and biological containment levels are very strict. For example, biological containment levels are at EK2 or EK3, and will effectively preclude experimentation until useful EK2 and EK3 systems are available. EK2 systems are still in the initial stages of development, and the first system was only certified at the most recent meeting of the Recombinant Advisory Committee. An EK3 host-vector system has yet to be tested, and its certification is far enough in the future to place a moratorium on those experiments requiring biological containment at an EK3 level. The physical containment levels of P3 or P4 themselves afford a very high degree of protection. I am satisfied that the guidelines demonstrate the caution and prudence that must govern the conduct of experiments in this category.

The guidelines allow reduced containment levels for primate DNA when it is derived from embryonic tissue or germline cells. This is based on evidence that embryonic material is less likely to contain viruses than is tissue from the adult. Obviously, the embryonic tissue must be free of adult tissue, and the present guidelines so indicate.

I have also carefully considered the special concerns arising from the use of DNA from cold-blooded vertebrates and other cold-blooded animals, because several commentators questioned the basis of lower physical and biological containment levels for DNA from these species. The Recombinant Advisory Committee has debated this extensively, and they were asked to do so once again in April.[3] The committee has now recommended high containment levels (P3+EK2) when the DNA is from a cold-blooded vertebrate known to produce a potent toxin. That recommendation is included in the present guidelines. Where no toxin is involved the committee supported lower

[3] A committee member, David S. Hogness, Ph. D., Professor, Department of Biochemistry, Stanford University, California, submitted a statement in support of lower containment levels based on current scientific evidence. That evidence is based on certain differences between cold- and warm-blooded vertebrates. One of the criteria used for the evaluation of the relative risk that might be encountered with different levels of shotgun experiment is the degree of sequence homology between the DNA of the given species and that of humans. This criterion is used to estimate the likelihood that segments of DNA from the given species might be integrated into the human genome by recombination; the greater the homology, the greater the likelihood of integration. Studies of sequence homologies indicate that there is a considerable degree of homology between human DNA and DNA from other primates, much less homology between primates and other mammals, and even lower but detectable homology between birds and primates. By contrast, no significant homologies between cold-blooded vertebrates and primates have been detected.

containment levels. The guidelines specify P2+EK2 levels for such work. There was considerable discussion concerning the advisability of recommending lower containment (P2+EK1) when the DNA is isolated from embryonic tissue or germ-line cells from cold-blooded vertebrates. Those supporting lower containment levels argued that the justification for P2+EK2 was the possibility that cold-blooded vertebrates may carry viruses and that the distinction between adult and germ-cell tissue is real. Others argued that, contrary to the situation with primate DNA, viruses are not a central problem with cold-blooded vertebrates and therefore no distinction should be made on the basis of tissue origin. Finally, the committee recommended, on a divided vote (8 to 4), to adopt P2+EK1 when the cold-blooded vertebrate DNA is isolated from embryonic tissue or germ-line cells. Upon reviewing these considerations, I have decided to retain the containment levels for embryonic or germ-line DNA from cold-blooded vertebrates as recommended by the committee.

In April the committee also reviewed, at our request, the classification of experiments where DNA is derived from other cold-blooded animals or lower eukaryotes. Several commentators, for example, had been concerned about the fact that insects are known to carry agents pathogenic to man. In the committee review, it was noted that viruses carried by insects and known to transmit disease to man are RNA rather than DNA viruses and do not reproduce via DNA copied from RNA. In order, however, to make the intent clearer, the guidelines have been rewritten for experiments of this class. New language is inserted to ensure that strict containment levels are employed when the DNA comes from known pathogens or species known to carry them. Further, to reduce the potential hazards, we have also included in the guidelines the requirement that any insect must be grown under laboratory conditions for at least 10 generations prior to its use as a DNA source.

2. As alluded to above, certain commentators expressed concern that when *E. coli* becomes the host of recombinant DNA from prokaryotes with which DNA is not usually exchanged, there is hazard of altered host characteristics resulting from translation of the DNA into functioning proteins. The committee was asked to review the guidelines and take into account this potential hazard. They agreed that the containment levels should be increased for this category of experiment, from P2+EK1 to either P2+EK2 or P3+EK1. That recommendation is included in the present guidelines.

Comments were made concerning that class of experiments in which the recombinant DNA, regardless of source, has been cloned. A clone is a population of cells derived from a single cell and therefore all the cells are presumed to be genetically identical. As outlined in the proposed guidelines, clones could be used at lower containment levels if they had been rigorously characterized and shown to be free of harmful genes. Several commentators inquired how the characterization was to be performed and the freedom from harmful genes demonstrated. Although the committee acknowledges that these terms are unavoidably vague, they do cite appropriate scientific methods to make relevant determinations. Again, this is a rapidly changing area and more clarity and precision can be expected with experience. Reduced containment requirements for this class of experiment are warranted because of the purified nature of clones. Further, the granting agency must approve the clone before containment conditions can be reduced, thus providing an additional element of review.

4. Another comment was related to the use of DNA from organelles (intracellular elements that contain special groups of genes for particular cell functions). Concern was expressed about the potential contamination of purified organelle DNA with DNA from viruses because of the similarity of their structures. The committee agrees, and the guidelines now specify a requirement, that the organelles be isolated prior to extracting DNA, as a further means of reducing the hazard of viral contamination.

5. Some commentators were troubled about the lowering of containment for that class of experiments involving recombinations with cell DNA segments purified by chemical or physical methods. They asked that procedures for determining the state of purification be more fully detailed and that the Recombinant Advisory Committee certify the purity. There are, however, appropriate techniques, such as gel electrophoresis, with which a purity of 99 percent by mass can be achieved and ascertained. There is no way for the committee to certify these results beyond repeating the experiments themselves. These techniques are well documented and described in the literature. I do not believe it is necessary or feasible for the committee to review each procedure for purification of DNA.

6. Comments were made concerning the use of DNA derived from animal viruses. It was urged that containment levels for this class of experiment be increased. On the basis of my review, I find the containment conditions appropriate to the potential hazard posed. As defined in the guidelines, experiments are to be done at very strict levels of containment and these can be lowered only when the cloned DNA recombinants have been shown to be free of possibly harmful genes by suitable biochemical and biological tests. This also pertains to DNA that is copied from RNA viruses. In no instance are the guidelines more lenient, and in most instances they are more stringent than conditions obtaining in many laboratories where such viruses are studied in non-DNA-recombinant experiments.

VI. CLASSIFICATION OF EXPERIMENTS USING CONTAINMENT SYSTEMS OTHER THAN E. COLI K–12

1. No issue with regard to these guidelines raised more comment than the use of animal viruses as vectors. Of special concern to many commentators was the use of the simian (monkey) virus 40 (hereafter "SV40"). Some suggested a complete ban on the use of this virus; others urged its retention as a vector. SV40 is not known to produce any disease in man, although it can be grown in human cells and on very rare occasions has been isolated from humans. Many humans have received SV40 virus inadvertently in vaccines prepared from virus grown in monkey kidney-cell cultures. An intensive search has been made and is continuing for evidence that SV40 might cause cancer or be otherwise pathogenic for man. At present, it is my view that the extensive knowledge we have of SV40 virus provides us with sufficient sophistication to ensure its safe handling under the conditions developed for its use in the guidelines.

I believe work with SV40 should continue under the cost careful conditions, but I do recognize and appreciate the concerns expressed over its possible harmful effects in humans. In light of these concerns, I asked the Recombinant Advisory Committee to review this section of the guidelines. The committee reconsidered the containment conditions for this class of experiments and judged them appropriate to meet the potential hazards.[4]

This class of experiments will proceed under the most careful and stringent conditions. Work with SV40 virus will be done at the maximum level of physical containment (P4). The extraordinary precautions required in a P4 facility lessen the likelihood of a potential hazard from this work. Only defective SV40 virus will be used as vector; that is, the SV40 virus particles that carry the foreign DNA cannot multiply by themselves. When a number of strict conditions are met, this work will be permitted to go on at the third level of containment (P3), which in itself requires care and precision. It should be noted that SV40 virus and its DNA can be efficiently disinfected by Clorox and autoclaving. These are customary procedures for disinfecting glassware and other items used in SV40 animal-cell work.

Some commentators suggested that the containment criteria for experiments using polyoma virus as the vector be strengthened. There is no evidence that polyoma infects humans or replicates to any significant extent in human cells. It holds promise as a vector, as is more fully documented in an appendix to these guidelines.

2. Several commentators found the guidelines inadequate regarding experiments with plant host-vector systems. Because NIH shared these concerns, a group with extensive experience with plants was appointed to review this section. The group met concurrently with

[4] One member dissented from this position. During the discussion, additional language was recommended (and adopted) to ensure that the defective SV40–virus/helper-virus system, with its inserted non-SV40 DNA segment, does not replicate in human cells with significantly more efficiency than does SV40.

the Recombinant Advisory Committee in April 1976 and made several modifications. The suggested revisions were acceptable to the full committee, and we have included them in the guidelines.

The modifications are responsive to the stated concerns of the commentators. A description of greenhouse facilities is given, and physical containment conditions have been modified to take into account operations with whole plants. On the whole, the respective portions of the guidelines relating to plants are more fully explained and the intent is clarified.

I have also accepted the recommendation of the subcommittee to lower the biological containment level from EK2 to EK1 for experiments in which the DNA from plants is used in conjunction with the *E. coli* K-12 host-vector system, thereby setting containment in this instance at the same level required for experiments with lower-eukaryote DNA.

VII. ROLES AND RESPONSIBILITIES

1. Most commentators had suggestions for the section on the roles and responsibilities of investigators, their local institutions, and NIH. Commentators generally urged openness, candor, and public participation in the process, emphasizing shared responsibility and accountability from the local to the national level. We reviewed that section of the guidelines in light of these comments and have asked the Recombinant Advisory Committee to review certain issues.

It is clear that much of the success of the guidelines will lie in the wisdom with which they are implemented. Because of the importance of this section, especially in terms of safety programs and plans, we have carefully weighed the comments and suggestions made in this regard. NIH has a special responsibility to take a leading role in ensuring that safety programs are part of all recombinant DNA research. Dr. Barkley and a specially convened committee were asked to provide greater detail for safety, accident, and training plans for this section of the guidelines. Based on their recommendations, the section has been extensively rewritten to clarify the respective responsibilities of the principal investigator, the institution (including the institutional biohazards committee), the NIH inital review group (study section), the NIH Recombinant DNA Molecule Program Advisory Committee, and NIH staff.

This section has a definitive administrative framework for assuring that safety is an essential and integrated component of research involving recombinant DNA molecules. The guidelines require investigators to institute, monitor, and evaluate containment and safety practices and procedures. Before research is done, the investigator must have safety and accident plans in place and training exercises for the staff well under way.

Some commentators suggested that the investigator be required to obtain informed consent of laboratory personnel prior to their participation. Rather than rely explicitly on an informed consent document, the guidelines now make the investigator responsible for advising his program and support staff as to the nature and assessment of the real and potential biohazards. He must explain and provide for any advised or requested precautionary medical policies, vaccinations, or serum collections. Further, an appendix to the guidelines includes detailed explanations for dealing with accidents, as well as instructions for the training of staff in safety and accident procedures.

In response to suggestions for epidemiological monitoring, the guidelines now require the principal investigator to report certain categories of accidents, in writing, to appropriate officials. NIH is investigating procedures for long-term surveillance of workers engaged in recombinant DNA research.

2. A number of comments on the role and responsibilities of the institutional biohazards committee were received. Comments were directed to the structure of the committee, the scope of its responsibility, and the methods for operation. Comments on structure included suggestions that the committee have a broadly based representation, especially in terms of health and safety expertise. Some others suggested NIH require certain classes of representation. In response to these suggestions, the guidelines now recommend membership from a diversity of disciplines relevant to recombinant DNA molecule technology, biological safety, and engineering.

For broader representation beyond the immediate scientific expertise, the guidelines now recommend that local committees should possess, or have available, the competence necessary to determine the acceptability of their findings in terms of applicable laws, regulations, standards of practice, community attitudes, and health and environmental considerations. The names of and relevant background information on the committee members will be reported to NIH.

In response to suggestions that decisions of the committee be made publicly available, the guidelines now recommend that minutes of the meetings should be kept and made available for public inspection.

Commentators generally approved of the responsibility given to the institutional biohazards committee to serve as a source of advice and reference to the investigator on scientific and safety questions. It was further suggested that the committee's responsibility be broadened in the development, monitoring, and evaluation of safety standards and procedures. In response to these suggestions, the guidelines now indicate that the institutional biohazards committee has the responsibility to certify, and recertify annually, to NIH that the facilities, procedures, practices, training, and expertise of involved personnel have been reviewed and approved. The Recombinant Advisory Committee suggested that examination might be unnecessary for P1 facilities, but we believe that all facilities should be reviewed to emphasize the importance of safety programs.

Some commentators suggested that the guidelines should stipulate that the local committees be required to determine the containment conditions to be imposed for a given project (which the draft guidelines specifically noted was not their responsibility). The Recombinant Advisory Committee took exception to this suggestion. They urged NIH not to include these conditions as local requirements, arguing among other things that review by the NIH study sections would provide the necessary scrutiny at the national level and assure uniformity of standards in application of the guidelines. I do not believe that NIH should require the local institution to have its biohazards committee assess what containment conditions are required for a given project. On the other hand, the guidelines should not prohibit the local institution from having its biohazards committee perform this function. Accordingly, I have deleted the prohibition that appeared in the proposed guidelines.

Another suggestion was that the local committee ensure that research is carried out in accordance with standards and procedures under the Occupational Safety and Health Act (OSHA). This is an area of importance to the local institutions under Federal and State law, but need not be included as a requirement in the guidelines. NIH will maintain liaison with the Occupational Safety and Health Administration (Department of Labor) to ensure maximum Federal cooperation in this venture.

I would also encourage all institutions, as suggested by several commentators, to review their insurance compensation programs to determine whether their laboratory personnel, in the research area, are covered for injuries.

3. The commentators approved of having the NIH study sections responsible for making an independent evaluation of the classification of the proposed research under the guidelines, along with the customary judgment of the scientific merit of each grant application. This additional element of review will ensure careful attention to potential hazards in the research activity. The study sections will also scrutinize the proposed safeguards. Biological safety expertise shall be available to the study section for consultation and guidance in this regard.

4. Several commentators made suggestions concerning the structure, function, and scope of responsibility of the NIH Recombinant DNA Molecule Program Advisory Committee.

Comments on possible structural mechanisms for decision making included suggestions that there be a scientific and technical committee and a general advisory public policy committee. It was also suggested that the scientific committee include scientists who are not actively engaged in recombinant research, and that the public policy committee have a broad scientific and public representation.

I have carefully reviewed these comments and suggestions. In response, the following structure has been devised. The Recombinant Advisory Committee shall serve as the scientific and technical committee. Its membership shall continue to

include scientists who represent disciplines actively engaged in recombinant DNA research. In my view, it is most important that this committee have the necessary expertise to assure that the guidelines are of the highest scientific quality. The committee has provided this expertise in the past, and it must continue to do so. The committee shall also include members from other scientific disciplines.

It should be noted that the present committee recommended on its own initiative that a nonscientist be appointed. Emmette S. Redford, Ph.D., LL.D., Ashbel Smith Professor of Government and Public Affairs at the Lyndon B. Johnson School of Public Affairs, University of Texas at Austin, serves in that capacity. An ethicist has also been nominated for appointment.

The Advisory Committee to the Director, NIH, shall serve to provide the broader public policy perspectives. This committee, at its meeting on February 9–10, 1976, reviewed the proposed guidelines with the participation of public witnesses, and shall continue to provide such review for future activities of the Recombinant Advisory Committee.

In response to suggestions, the responsibilities of the Recombinant Advisory Committee have been expanded. In addition to reviewing the guidelines for possible modification as scientific evidence warrants, the committee will certify EK2 and EK3 systems. In response to requests by the investigator, local committee, or study section, the committee will also provide evaluation and review in order to advise on levels of required containment, on lowering of requirements when cloned recombinants are to be used, and on questions concerning potential biohazard and adequacy of containment provisions.

Commentators also asked that the committee review ongoing research initiated prior to the implementation of the guidelines. Now that the guidelines are being released, NIH-funded investigators in this field will be asked to give assurance, within a given period, that they will comply. Any investigators who constructed clones under the Asilomar guidelines will be asked to petition NIH for special consideration of their case, if the new guidelines require higher containment than did the Asilomar guidelines. Here the advice of the Recombinant Advisory Committee will be sought.

There were also suggestions that the committee certify chemical purification of recombinant DNA, but as I indicated earlier, these procedures are too well known to require NIH monitoring.

5. In light of comments received, NIH will provide review, through appropriate NIH offices, of data from institutional biohazards committees (including accident reports) and will ensure dissemination of these findings as appropriate. Dr. William Gartland will head the newly created NIH Office of Recombinant DNA Activities for these purposes. In addition, NIH will provide for rapid dissemination of information through its Nucleic Acid Recombinant Scientific Memoranda (NARSM), distributed by the National Institute for Allergy and Infectious Diseases. NIH will also provide an appropriate mechanism for approving and certifying clones before containment conditions can be lowered.

With these extended modifications, the section of the guidelines dealing with roles and responsibilities now sets forth a more fully developed review structure involving the principal investigator, local biohazards committees, and the Recombinant Advisory Committee, as well as peer review committees. Guidelines now provide extensive opportunity for advice, from the local to the national level. Several levels of review and scrutiny are provided, ensuring the highest standards for scientific merit and conditions for safety.

The Recombinant Advisory Committee in conjunction with the Director's Advisory Committee shall continue to serve as an ongoing forum for examining progress in the technology and safety of recombinant DNA research. Their responsibility, and that of the NIH Director, is to ensure that the guidelines, through modification when called for, reflect the soundest scientific and safety evidence as it accrues in this area. Their task, in a sense, is just beginning.

DONALD S. FREDRICKSON,
*Director,*
*National Institute of Health.*

## GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

JUNE 1976.

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### I. INTRODUCTION

The purpose of these guidelines is to recommend safeguards for research on recombinant DNA molecules to the National Institutes of Health and to other institutions that support such research. In this context we define recombinant DNAs as molecules that consist of different segments of DNA which have been joined together in cell-free systems, and which have the capacity to infect and replicate in some host cell, either autonomously or as an integrated part of the host's genome.

This is the first attempt to provide a detailed set of guidelines for use by study sections as well as practicing scientists for evaluating research on recombinant DNA molecules. We cannot hope to anticipate all possible lines of imaginative research that are possible with this powerful new methodology. Nevertheless, a considerable volume of written and verbal contributions from scientists in a variety of disciplines has been received. In many instances the views presented to us were contradictory. At present, the hazards may be guessed at, speculated about, or voted upon, but they cannot be known absolutely in the absence of firm experimental data—and, unfortunately, the needed data were, more often than not, unavailable. Our problem then has been to construct guidelines that allow the promise of the methodology to be realized while advocating the considerable caution that is demanded by what we and others view as potential hazards.

In designing these guidelines we have adopted the following principles, which are consistent with the general conclusions that were formulated at the International Conference on Recombinant DNA Molecules held at Asilomar Conference Center, Pacific Grove, California, in February 1975 (3): (i) There are certain experiments for which the assessed potential hazard is so serious that they are not to be attempted at the present time. (ii) The remainder can be undertaken at the present time provided that the experiment is justifiable on the basis that new knowledge or benefits to humankind will accrue that cannot readily be obtained by use of conventional methodology and that appropriate safeguards are incorporated into the design and execution of the experiment. In addition to an insistence on the practice of good microbiological techniques, these safeguards consist of providing both physical

and biological barriers to the dissemination of the potentially hazardous agents. (iii) The level of containment provided by these barriers is to match the estimated potential hazard for each of the different classes of recombinants. For projects in a given class, this level is to be highest at initiation and modified subsequently only if there is a substantiated change in the assessed risk or in the applied methodology. (iv) The guidelines will be subjected to periodic review (at least annually) and modified to reflect improvements in our knowledge of the potential biohazards and of the available safeguards.

In constructing these guidelines it has been necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. We recognize that these definitions do not take into account existing and anticipated special procedures and information that will allow particular experiments to be carried out under different conditions than indicated here without sacrifice of safety. Indeed, we urge that individual investigators devise simple and more effective containment procedures and that study sections give consideration to such procedures which may allow change in the containment levels recommended here.

It is recommended that all publications dealing with recombinant DNA work include a description of the physical and biological containment procedures practiced, to aid and forewarn others who might consider repeating the work.

## II. CONTAINMENT

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information therefore already exists for the design of physical containment facilities and the selection of laboratory procedures applicable to organisms carrying recombinant DNAs (4–17). The existing programs rely upon mechanisms that, for convenience, can be divided into two categories: (i) a set of standard practices that are generally used in microbiological laboratories, and (ii) special procedures, equipment, and laboratory installations that provide physical barriers which are applied in varying degrees according to the estimated biohazard.

Experiments on recombinant DNAs by their very nature lend themselves to a third containment mechanism—namely, the application of highly specific biological barriers. In fact, natural barriers do exist which either limit the infectivity of a vector or vehicle (plasmid, bacteriophage or virus) to specific hosts, or its dissemination and survival in the environment. The vectors that provide the means for replication of the recombinant DNAs and/or the host cells in which they replicate can be genetically designed to decrease by many orders of magnitude the probability of dissemination of recombinant DNAs outside the laboratory.

As these three means of containment are complementary, different levels of containment appropriate for experiments with different recombinants can be established by applying different combinations of the physical and biological barriers to a constant use of the standard practices. We consider these categories of containment separately here in order that such combinations can be conveniently expressed in the guidelines for research on the different kinds of recombinant DNA (Section III).

A. *Standard practices and training.* The first principle of containment is a strict adherence to good microbiological practices (4–13). Consequently, all personnel directly or indirectly involved in experiments on recombinant DNAs must receive adequate instruction. This should include at least training in aspectic techniques and instruction in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

Any research group working with agents with a known or potential biohazard should have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or environment. The principal investigator must ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If a research group is working with a known pathogen for which an effective vaccine is available, all workers should be immunized. Serological monitoring, where appropriate, should be provided.

B. *Physical containment levels.* A variety of combinations (levels) of special practices, equipment, and laboratory installations that provide additional physical barriers can be formed. For example, 31 combinations are listed in "Laboratory Safety" at the Center for Disease Control" (4); four levels are associated with the "Classification of Etiologic Agents on the Basis of Hazard" (5), four levels were recommended in the "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules" (3); and the National Cancer Institute uses three levels for research on oncogenic viruses (6). We emphasize that these are an aid to, and not a substitute for, good technique. Personnel must be competent in the effective use of all equipment needed for the required containment level as described below. We define only four levels of physical containment here, both because the accuracy with which one can presently assess the biohazards that may result from recombinant DNAs does not warrant a more detailed classification, and because additional flexibility can be obtained by combination of the physical with the biological barriers. Though different in detail, these four levels (P1<P2<P3<P4) approximate those given for human etiologic agents by the Center for Disease Control (i.e., classes 1 through 4; ref. 5), in the Asilomar summary statement (i.e., minimal, low, moderate, and high; ref. 3), and by the National Cancer Institute for oncogenic viruses (i.e., low, moderate, and high; ref. 6), as is indicated by the P-number or adjective in the following headings. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing approaches to containment of hazardous organisms.

We anticipate, and indeed already know of, procedures (14) which enhance physical containment capability in novel ways. For example, miniaturization of screening, handling, and analytical procedures provides substantial containment of a given host-vector system. Thus, such procedures should reduce the need for the standard types of physical containment, and such innovations will be considered by the Recombinant DNA Molecule Program Advisory Committee.

The special practices, equipment and facility installations indicated for each level of physical containment are required for the safety of laboratory workers, other persons, and for the protection of the environment. Optional items have been excluded; only those items deemed absolutely necessary for safety are presented. Thus, the listed requirements present basic safety criteria for each level of physical containment. Other microbiological practices and laboratory techniques which promote safety are to be encouraged. Additional information giving further guidance on physical containment is provided in a supplement to the guidelines (Appendix D).

*P1 Level (Minimal).* A laboratory suitable for experiments involving recombinant DNA molecules requiring physical containment at the P1 level is a laboratory that possesses no special engineering design features. It is a laboratory commonly used for microorganisms of no or minimal biohazard under ordinary conditions of handling. Work in this laboratory is generally conducted on open bench tops. Special containment equipment is neither required nor generally available in this laboratory. The laboratory is not separated from the general traffic patterns of the building. Public access is permitted.

The control of biohazards at the P1 level is provided by standard microbiological practices of which the following are examples: (i) Laboratory doors should be kept closed while experiments are in progress. (ii) Work surfaces should be decontaminated daily and following spills of recombinant DNA materials. (iii) Liquid wastes containing recombinant DNA materials should be decontaminated before disposal. (iv) Solid wastes contaminated with recombinant DNA materials should be decontaminated or packaged in a durable leakproof container before removal from the laboratory. (v) Although pipetting by mouth is permitted, it is preferable that mechanical pipetting devices be used. When pipetting by mouth, cotton-plugged pipettes shall be employed. (vi) Eating, drinking, smoking, and storage of food in the working area should be discouraged. (vii) Facilities to wash hands should be available. (viii) An insect and rodent control program should be provided. (ix) The use of laboratory gowns, coats, or uniforms is discretionary with the laboratory supervisor.

*P2 Level (Low)*. A laboratory suitable for experiments involving recombinant DNA molecules requiring physical containment at the P2 level is similar in construction and design to the P1 laboratory. The P2 laboratory must have access to an autoclave within the building; it may have a Biological Safety Cabinet.[1] Work which does not produce a considerable aerosol is conducted on the open bench. Although this laboratory is not separated from the general traffic patterns of the building, access to the laboratory is limited when experiments requiring P2 level physical containment are being conducted. Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory.

The P2 laboratory is commonly used for experiments involving microorganisms of low biohazard such as those which have been classified by the Center for Disease Control as Class 2 agents (5).

The following practices shall apply to all experiments requiring P2 level physical containment: (i) Laboratory doors shall be kept closed while experiments are in progress. (ii) Only persons who have been advised of the potential biohazard shall enter the laboratory. (iii) Children under 12 years of age shall not enter the laboratory. (iv) Work surfaces shall be decontaminated daily and immediately following spills of recombinant DNA materials. (v) Liquid wastes of recombinant DNA materials shall be decontaminated before disposal. (vi) Solid wastes contaminated with recombinant DNA materials shall be decontaminated or packaged in a durable leak-proof container before removal from the laboratory. Packaged materials shall be disposed of by incineration or sterilized before disposal by other methods. Contaminated materials that are to be processed and reused (i.e., glassware) shall be decontaminated before removal from the laboratory. (vii) Pipetting by mouth is prohibited; mechanical pipetting devices shall be used. (viii) Eating, drinking, smoking, and storage of food are not permitted in the working area. (ix) Facilities to wash hands shall be available within the laboratory. Persons handling recombinant DNA materials should be encouraged to wash their hands frequently and when they leave the laboratory. (x) An insect and rodent control program shall be provided. (xi) The use of laboratory gowns, coats, or uniforms is required. Such clothing shall not be worn to the lunch room or outside the building. (xii) Animals not related to the experiment shall not be permitted in the laboratory. (xiii) Biological Safety Cabinets [1] and/or other physical containment equipment shall be used to minimize the hazard of aerosolization of recombinant DNA materials from operations or devices that produce a considerable aerosol (e.g., blender, lyophilizer, sonicator, shaking machine, etc.). (xiv) Use of the hypodermic needle and syringe shall be avoided when alternate methods are available.

[1] Footnotes at end of article.

*P3 Level (Moderate)*. A laboratory suitable for experiments involving recombinant DNA molecules requiring physical containment at the P3 level has special engineering design features and physical containment equipment. The laboratory is separated from areas which are open to the general public. Separation is generally achieved by controlled access corridors, air locks, locker rooms or other double-doored facilities which are not available for use by the general public. Access to the laboratory is controlled. Biological Safety Cabinets [1] are available within the controlled laboratory area. An autoclave shall be available within the building and preferably within the controlled laboratory area. The surfaces of walls, floors, bench tops, and ceilings are easily cleanable to facilitate housekeeping and space decontamination.

Directional air flow is provided within the controlled laboratory area. The ventilation system is balanced to provide for an inflow of supply air from the access corridor into the laboratory. The general exhaust air from the laboratory is discharged outdoors and so dispersed to the atmosphere as to prevent reentry into the building. No recirculation of the exhaust air shall be permitted without appropriate treatment.

No work in open vessels involving hosts or vectors containing recombinant DNA molecules requiring P3 physical containment is conducted on the open bench. All such procedures are confined to Biological Safety Cabinets.[1]

The following practices shall apply to all experiments requiring P3 level physical containment: (i) The universal biohazard sign is required on all laboratory access doors. Only persons whose entry into the laboratory is required on the basis of program or support needs shall be authorized to enter. Such persons shall be advised of the potential biohazards before entry and they shall comply with posted entry and exit procedures. Children under 12 years of age shall not enter the laboratory. (ii) Laboratory doors shall be kept closed while experiments are in progress. (iii) Biological Safety Cabinets [1] and other physical containment equipment shall be used for all procedures that produce aerosols of recombinant DNA materials (e.g., pipetting, plating, flaming, transfer operations, grinding, blending, drying, sonicating, shaking, etc.). (iv) The work surfaces of Biological Safety Cabinets [1] and other equipment shall be decontaminated following the completion of the experimental activity contained within them. (v) Liquid wastes containing recombinant DNA materials shall be decontaminated before disposal. Solid wastes contaminated with recombinant DNA materials shall be decontaminated or packaged in a durable leak-proof container before removal from the laboratory. Packaged material shall be sterilized before disposal. Contaminated materials that are to be processed and reused (i.e., glassware) shall be sterilized in the controlled laboratory area or placed in a durable leak-proof container before removal from the controlled laboratory area. This container shall be sterilized before the materials are processed. (vii) Pipetting by mouth is prohibited; mechanical pipetting devices shall be used. (vii) Eating drinking, smoking, and storage of food are not permitted in the laboratory. (ix) Facilities to wash hands shall be available within the laboratory. Persons shall wash hands after experiments involving recombinant DNA materials and before leaving the laboratory. (x) In insect and rodent control program shall be provided. (xi) Laboratory clothing that protects street clothing (i.e., long sleeve solid-front or wrap-around gowns, no-button or slipover jackets, etc.) shall be worn in the laboratory. FRONT-BUTTON LABORATORY COATS ARE UNSUITABLE. Gloves shall be worn when handling recombinant DNA materials. Provision for laboratory shoes is recommended. Laboratory clothing shall not be worn outside the laboratory and shall be decontaminated before it is sent to the laundry. (xii) Raincoats, overcoats, topcoats, coats, hats, caps, and such street outerwear shall not be kept in the laboratory.

(xiii) Animals and plants not related to the experiment shall not be permitted in the laboratory. (xiv) Vacuum lines shall be protected by filters and liquid traps. (xv) Use of the hypodermic needle and syringe shall be avoided when alternate methods are available. (xvi) If experiments of lesser biohazard potential are to be conducted in the same laboratory concurrently with experiments requiring P3 level physical containment they shall be conducted only in accordance with all P3 level requirements. (xvii) Experiments requiring P3 level physical containment can be conducted in laboratories where the directional air flow and general exhaust air conditions described above cannot be achieved, provided that this work is conducted in accordance with all other requirements listed and is contained in a Biological Safety Cabinet [1] with attached glove ports and gloves. All materials before removal from the Biological Safety Cabinet [1] shall be sterilized or transferred to a non-breakable, sealed container, which is then removed from the cabinet through a chemical decontamination tank, autoclave, ultraviolet air lock, or after the entire cabinet has been decontaminated.

*P4 Level (High)*. Experiments involving recombinant DNA molecules requiring physical containment at the P4 level shall be confined to work areas in a facility of the type designed to contain microorganisms that are extremely hazardous to man or may cause serious epidemic disease. The facility is either a separate building or it is a controlled area, within a building, which is completely isolated from all other areas of the building. Access to the facility is under strict control. A specific facility operations manual is available. Class III Biological Safety Cabinets [1] are available within work areas of the facility.

A P4 facility has engineering features which are designed to prevent the escape of microorganisms to the environment (14, 15, 16, 17). These features include:

(i) Monolithic walls, floods, and ceilings in which all penetrations such as for air ducts, electrical conduits, and utility pipes are sealed to assure the physical isolation of the work area and to facilitate housekeeping and space decontamination; (ii) air locks through which supplies and materials can be brought safely into the facility; (iii) contiguous clothing change and shower rooms through which personnel enter into and exit from the facility; (iv) double-door autoclaves to sterilize and safely remove wastes and other materials from the facility; (v) a biowaste treatment system to sterilize liquid effluents if facility drains are installed; (vi) a separate ventilation system which maintains negative air pressures and directional air flow within the facility; and (vii) a treatment system to decontaminate exhaust air before it is dispersed to the atmosphere. A central vacuum utility system is not encouraged; if one is installed, each branch line leading to a laboratory shall be protected by a high efficiency particulate air filter.

The following practices shall apply to all experiments requiring P4 level physical containment: (i) The universal biohazard sign is required on all facility access doors and all interior doors to individual laboratory rooms where experiments are conducted. Only persons whose entry into the facility or individual laboratory rooms is required on the basis of program or support needs shall be authorized to enter. Such persons shall be advised of the potential biohazards and instructed as to the appropriate safeguards to ensure their safety before entry. Such persons shall comply with the instructions and all other posted entry and exit procedures. Under no condition shall children under 15 years of age be allowed entry. (ii) Personnel shall enter into and exit from the facility only through the clothing change and shower rooms. Personnel shall shower at each exit from the facility. The air locks shall not be used for personnel entry or exit except for emergencies. (iii) Street clothing shall be removed in the outer facility side of the clothing change area and kept there. Complete laboratory clothing including undergarments, pants and shirts or jumpsuits, shoes, head cover, and gloves shall be provided and used by all persons who enter into the facility. Upon exit, this clothing shall be stored in lockers provided for this purpose or discarded into collection hampers before personnel enter into the shower area. (iv) Supplies and materials to be taken into the facility shall be placed in an entry air lock. After the outer door (opening to the corridor outside of facility) has been secured, personnel occupying the facility shall retrieve the supplies and materials by opening the interior air lock door. This door shall be secured after supplies and materials are brought into the facility. (v) Doors to laboratory rooms within the facility shall be kept closed while experiments are in progress. (vi) Experimental procedures requiring P4 level physical containment shall be confined to Class III Biological Safety Cabinets.[1] All materials, before removal from these cabinets, shall be sterilized or transferred to a non-breakable sealed container, which is then removed from the system through a chemical decontaminated tank, autoclave, or after the entire system has been decontaminated.

(vii) No materials shall be removed from the facility unless they have been sterilized or decontaminatel in a manner to prevent the release of agents requiring P4 physical containment. All wastes and other materials and equipment not damaged by high temperautre or steam shall be sterilized in the double-door autoclave. Biological materials to be removed from the facility shall be transferred to a nonbreakable sealed container which is then removed from the facility through a chemical decontamination tank or a chamber designed for gas sterilization. Other materials which may be damaged by temperature or steam shall be sterilized by gaseous or vapor methods in an air lock or chamber designed for this purpose. (viii) Eating, drinking, smoking, and storage of food are not permitted in the facility. Foot-operated water fountains located in the facility corridors are permitted. Separate potable water piping shall be provided for these water fountains. (ix) Facilities to wash hands shall be available within the facility. Persons shall wash hands after experiments. (x) An insect and rodent control program shall be provided. (xi) Animals and plants not related to the experiment shall not be permitted in the facility. (xii) If a central vacuum system is provided, each vacuum outlet shall be protected by a filter and liquid trap in addition to the branch line HEPA filter mentioned above. (xiii) Use of the hypodermic needle and syringe shall be avoided when alternate methods are available. (xiv) If experiments of lesser biohazard potential are to be conducted in the facility concurrently with experiments requiring P4 level containment, they shall be confined in Class I or Class II Biological Safety Cabinets[1] or isolated by other physical containment equipment. Work surfaces of Biological Safety Cabinets[1] and other equipment shall be decontaminated following the completion of the experimental activity contained within them. Mechanical pipetting devices shall be used. All other practices listed above with the exception of (vi) shall apply.

C. *Shipment.* To protect product, personnel, and the environment, all recombinant DNA material will be shipped in containers that meet the requirements issued by the U.S. Public Health Service (Section 72.25 of Part 72, Title 42, Code of Federal Regulations), Department of Transportation (Section 173.387(b) of Part 173, Title 49, Code of Federal Regulations) and the Civil Aeronautics Board (C.A.B. No. 82, Official Air Transport Restricted Articles Tariff No. 6-D) for shipment of etiologic agents. Labeling requirements specified in these Federal regulations and tariffs will apply to all viable recombinant DNA materials in which any portion of the material is derived from an etiologic agent listed in paragraph (c) of 42 CFR 72.25. Additional information on packing and shipping is given in a supplement to the guidelines (Appendix D, part X).

D. *Biological containment levels.* Biological barriers are specific to each host-vector system. Hence the criteria for this mechanism of containment cannot be generalized to the same extent as for physical containment. This is particularly true at the present time when our experience with existing host-vector systems and our predictive knowledge about projected systems are sparse. The classification of experiments with recombinant DNAs that is necessary for the construction of the experimeneal guidelines (Section III) can be accomplished with least confusion if we use the host-vector system as the primary element and the source of the inserted DNA as the secondary element in the classification. It is therefore convenient to specify the nature of the biological containment under host-vector headings such as those given below for *Escherichia coli* K-12.

### III. EXPERIMENTAL GUIDELINES

A general rule that, though obvious, deserves statement is that the level of containment required for any experiment on DNA recombinants shall never be less than that required for the most hazardous component used to construct and clone the recombinant DNA (i.e., vector, host, and inserted DNA). In most cases the level of containment will be greater, particularly when the recombinant DNA is formed from species that ordinarily do not exchange genetic information. Handling the purified DNA will generally require less stringent precautions than will propagating the DNA. However, the DNA itself should be handled at least as carefully as one would handle the most dangerous of the DNAs used to make it.

The above rule by itself effectively precludes certain experiments—namely, those in which one of the components is in Class 5 of the "Classification of Etiologic Agents on the Basis of Hazard" (5), as these are excluded from the United States by law and USDA administrative policy. There are additional experiments which may engender such serious biohazards that they are not to be performed at this time. These are considered prior to presentation of the containment guidelines for permissible experiments.

A. *Experiments that are not to be performed.* We recognize that it can be argued that certain of the recombinants placed in this category could be adequately contained at this time. Nonetheless, our estimates of the possible dangers that may ensue if that containment fails are of such a magnitude that we consider it the wisest policy to at least defer experiments on these recombinant DNAs until there is more information to accurately assess that danger and to allow the construction of more effective biological barriers. In this respect, these guidelines are more stringent than those initially recommended (1).

The following experiments are not to be initiated at the present time: (i) Clon-

[1] See footnotes at end of article.

ing of recombinant DNAs derived from the pathogenic organisms in Classes 3, 4, and 5 of "Classification of Etiologic Agents on the Basis of Hazard" (5), or oncogenic viruses classified by NCI as moderate risk (6), or cells known to be infected with such agents, regardless of the host-vector system used. (ii) Deliberate formation of recombinant DNAs containing genes for the biosynthesis of potent toxins (e.g., botulinum or diphtheria toxins; venoms from insects, snakes, etc.). (iii) Deliberate creation from plant pathogens of recombinant DNAs that are likely to increase virulence and host range. (iv) Deliberate release into the environment of any organism containing a recombinant DNA molecule. (v) Transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture.

In addition, at this time large-scale experiments (e.g., more than 10 liters of culture) with recombinant DNAs known to make harmful products are not to be carried out. We differentiate between small- and large-scale experiments with such DNAs because the probability of escape from containment barriers normally increases with increasing scale. However, specific experiments in this category that are of direct societal benefit may be excepted from this rule if special biological containment precautions and equipment designed for large-scale operations are used, and provided that these experiments are expressly approved by the Recombinant DNA Molecule Program Advisory Committee of NIH.

B. *Containment guidelines for permissible experiments.* It is anticipated that most recombinant DNA experiments initiated before these guidelines are next reviewed (i.e., within the year) will employ *E. coli* K–12 host-vector systems. These are also the systems for which we have the most experience and knowledge regarding the effectiveness of the containment provided by existing hosts and vectors necessary for the construction of more effective biological barriers.

For these reasons, *E. Coli* K–12 appears to be the system of choice at this time, although we have carefully considered arguments that many of the potential dangers are compounded by using an organism as intimately connected with a man as is *E. Coli*. Thus, while proceeding cautiously with *E. Coli*, serious efforts should be made toward developing alternate host-vector systems; this subject is discussed in considerable detail in Appendix A.

We therefore consider DNA recombinants in *E. coli* K–12 before proceeding to other host-vector systems.

1. *Biological containment criteria using E. coli K–12 host-vectors—EK1 host-vectors.* These are host-vector systems that can be estimated to already provide a moderate level of containment, and include most of the presently available systems. The host is always *E. coli* K–12, and the vectors include nonconjugative plasmids [e.g., pSC101, ColE1 or derivatives thereof (19–26)] and variants of bacteriophage λ (27–29).

The *E. coli* K–12 nonconjugative plasmid system is taken as an example to illustrate the approximate level of containment referred to here. The available data from experiments involving the feeding of bacteria to humans and calves (30–32) indicate that *E. coli* K–12 did not usually colonize the *normal* bowel, and exhibited little, if any, multiplication while passing through the alimentary tract even after feeding high doses (i.e., $10^9$ to $10^{10}$ bacteria per human or calf). However, general extrapolation of these results may not be warranted because the implantation of bacteria into the intestinal tract depends on a number of parameters, such as the nature of the intestinal flora present in a given individual and the physiological state of the inoculum. Moreover, since viable *E. coli* K–12 can be found in the feces after humans are fed $10^7$ bacteria in broth (30) or $3\times10^4$ bacteria protected by suspension in milk (31), transductional and conjugational transfer of the plasmid vectors from *E. coli* K–12 to resident bacteria in the fecal matter before and after excretion must also be considered.

The nonconjugative plasmid vectors cannot promote their own transfers, but require the presence of a conjugative plasmid for mobilization and transfer to other bacteria. When present in the same cell with derepressed conjugative plasmids such as F or R1*drd19*, the nonconjugative ColE1, ColE1-*trp* and pSC101 plasmids are transferred to suitable recipient strains under ideal laboratory conditions at frequencies of about 0.5, $10^{-1}$ to $10^{-5}$, and $10^{-6}$ per donor cell, respectively. These frequencies are reduced by another factor of $10^2$ to $10^4$ if the conjugative plasmid employed is repressed with respect to expression of donor fertility.

The experimental transfer system which most closely resembles nonconjugative plasmid transfer in nature is a triparental mating. In such matings, the bacterial cell possessing the nonconjugative plasmid must first acquire a conjugative plasmid from another cell before it can transfer the nonconjugative plasmid to a secondary recipient. With ColE1, the frequencies of transfer are $10^{-2}$ and $10^{-4}$ to $10^{-5}$ when using conjugative plasmid donors possessing derepressed and repressed plasmids, respectively. Mobilization of ColE1-*trp* and pSC101 under similar laboratory conditions is so low as to be usually undetectable (33). Since most conjugative plasmids in nature are repressed for expression of donor fertility, the frequency at which nonconjugative plasmids are mobilized and transferred by this sequence of events *in vivo* is difficult to estimate. However, in calves fed on an antibiotic-supplemented diet, it has been estimated that such triparental nonconjugative R plasmid transfer occurs at frequencies of no more than $10^{-10}$ to $10^{-12}$ per 24 hours per calf (32). In terms of considering other means for plasmid transmission in nature, it should be noted that transduction does operate *in vivo* for *Staphylococcus aureus* (34) and probably for *E. coli* as well. However, no data are available to indicate the frequencies of plasmid transfer *in vivo* by either transduction or transformation.

These observations indicate the low probabilities for possible dissemination of such plasmid vectors by accidental ingestion, which would probably involve only a few hundred or thousand bacteria provided that at least the standard practices (Section II–A above) are followed, particularly the avoidance of mouth pipetting. The possibility of colonization and hence of transfer are increased, however, if the normal flora in the bowel is disrupted by, for example, antibiotic therapy (35). For this reason, persons receiving such therapy must not work with DNA recombinants formed with any *E. coli* K–12 host-vector system during the therapy period and for seven days thereafter; similarly, persons who have achlorhydria or who have had surgical removal of part of the stomach or bowel should avoid such work, as should those who require large doses of antacids.

The observations on the fate of *E. coli* K–12 in the human alimentary tract are also relevant to the containment of recombinant DNA formed with bacteriophage λ variants. Bacteriophage can escape from the laboratory either as mature infectious phage particles or in bacterial host cells in which the phage genome is carried as a plasmid or prophage. The fate of *E. coli* K–12 host cells carrying the phage genome as a plasmid or prophage is similar to that for plasmid-containing host cells as discussed above. The survival of the λ phage genome when released as infectious particles depends on their stability in nature, their infectivity and on the probability of subsequent encounters with naturally occurring λ-sensitive *E. coli* strains. Although the probability of survival of λ and its infection of resident intenstinal *E. coli* in animals and humans has not been measured, it is estimated to be small given the high sensitivity of λ to the low pH of the stomach, the insusceptibility to λ infection of smooth *E. coli* cells (the type that normally resides in the gut), the infrequency of naturally occurring λ-sensitive *E. coli* (36) and the failure to detect infective λ particles in human feces after ingestion of up to $10^{11}$ λ particles (37). Moreover, λ particles are very sensitive to desiccation.

Establishment of λ as a stable lysogen is a frequent event ($10^0$ to $10^{-1}$) for the *att*$^+$ *int*$^+$ *cI*$^+$ phage so that this mode of escape would be the preponderant laboratory hazard; however, most EK1 λ vectors currently in use lack the *att* and *int* functions (27–29) thus reducing the probability of lysogenization to about $10^{-6}$ to $10^{-4}$ (38–40). The frequency for the conversion of λ to a plasmid state for persistence and replication is also only about $10^{-6}$ (41). Moreover, the routine treatment of phage lysates with chloroform (42) should eliminate all surviving bacteria including lysogens and λ plasmid carriers. Lysogenization could also occur

when an infectious λ containing cloned DNA infects a λ-sensitive cell in nature, and recombines with a resident lambdoid prophage. Although λ-sensitive *E. coli* strains seem to be rare, a significant fraction do carry lambdoid prophages (43–44) and thus this route of escape should be considered.

While not exact, the estimates for containment afforded by using these host-vectors are at least as accurate as those for physical containment, and are sufficient to indicate that currently employed plasmid and λ vector systems provide a moderate level of biological containment. Other nonconjugative plasmids and bacteriophages that, in association with *E. coli* K–12 can be estimated to provide the same approximate level of moderate containment are included in the EK1 class.

*EK2 host-vectors.* These are host-vector systems that have been genetically constructed and shown to provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. The genetic modifications of the *E. coli* K–12 host and/or the plasmid or phage vector should not permit survival of a genetic marker carried on the vector, preferably a marker within an inserted DNA fragment, in other than specially designed and carefully regulated laboratory environments at a frequency greater than $10^{-8}$. This measure of biological containment has been selected because it is a measurable entity. Indeed, by testing the contributions of preexisting and newly introduced genetic properties of vectors and hosts, individually or in various combinations, it should be possible to estimate with considerable precision, that the specially designed host-vector system can provide a margin of biological containment in excess of that required. For the time being, no host-vector system will be considered to be a bona fide EK2 host-vector system until it is so certified by the NIH Recombinant DNA Molecule Program Advisory Committee.

For EK2 host-vector systems in which the vector is a plasmid, no more than one in $10^8$ host cells should be able to perpetuate the vector and/or a cloned DNA fragment under non-permissive conditions designed to represent the natural environment either by survival of the original host or as a consequence of transmission of the vector and/or a cloned DNA fragment by transformation, transduction or conjugation to a host with properties common to those in the natural environment.

In terms of potential EK2 plasmid-host systems, the following types of genetic modifications should reduce survival of cloned DNA. *The examples given are for illustrative purposes and should not be construed to encompass all possibilities.* The presence of the non-conjugative plasmids ColE1-*trp* and pS101 in an *E. coli* K–12 strain possessing a mutation eliminating host-controlled restriction and modification (*hsdS*) results in about $10^3$-fold reduction in mobilization to restriction-proficient recipients. The combination of the *dapD8*, *ΔbioH-asd*, *Δgal-chl*$^r$ and *rfb* mutations in *E. coli* K–12 results in no detectable survivors in feces of rats following feeding by stomach tube of $10^{10}$ cells in milk and similarly leads to complete lysis of cells suspended in broth medium lacking diaminopimelic acid. *E. coli* K–12 strains with *ΔthyA* and *deoC* (*dra*) mutations undergo thymineless death in growth medium lacking thymine and give a $10^5$-fold reduced survival during passage through the rat intestine compared to wild-type *thy*$^+$ *E. coli* K–12. (However, the *ΔthyA* mutation alone or in combination with a *deoB*(*drm*) mutation only reduces *in vivo* survival by a factor of $10^2$.) Other host mutations, as yet untested, that might further reduce survival of the plasmid-host system or reduce plasmid transmission are: the combination *polA*(TS) *recA*(TS) *ΔthyA* which might interfere with ColE1 replication and lead to DNA degradation at body temperatures; Con$^-$ mutations that reduce the ability of conjugative plasmids to enter the plasmid-host complex and thus should reduce mobilization of the cloned DNA to other strains; and mutations that confer resistance to known transducing phages. Mutations can also be introduced into the plasmid to cause it to be dependent on a specific host, to make its replication thermosensitive and/or to endow it with a killer capability such that all cells (other than its host) into which it might be transferred will not survive.

In the construction of EK2 plasmid-host systems it is important to use the most stable mutations available, preferably deletions. Obviously, the presence of all mutations contributing to higher degrees of biological containment must be verified periodically by appropriate tests. In testing the level of biological containment afforded by a proposed EK2 plasmid-host system, it is important to design relevant tests to evaluate the survival of the vector and/or a cloned DNA fragment under conditions that are possible in nature and that are also most advantageous for its perpetuation. For example, one might conduct a triparental mating with a primary donor possessing a derepressed F-type or I-type conjugative plasmid, the safer host with *ΔbioH-asd*, *dapD8*, *Δgal-chl*$^r$, *rfb*, *ΔthyA*, *deoC*, *trp* and *hsdS* mutations and a plasmid vector carrying an easily detectable marker such as for ampicillin resistance or an inserted gene such as *trp*$^+$, and a secondary recipient that is Su$^+$ *hsdS trp* (i.e., permissive for the recombinant plasmid). Such matings would be conducted in a medium lacking diaminopimelic acid and thymine and survival of the Ap$^r$ or *trp*$^+$ marker in any of the three strains followed as a function of time. Survival of the vector and/or a cloned marker by transduction could also be evaluated by introducing a known generalized transducing phage into the system. Similar experiments should also be done using a secondary recipient that is restrictive for the plasmid vector as well as with primary donors possessing repressed conjugative plasmids with incompatibility group properties like those commonly found in enteric microorganisms. Since a common route of escape of plasmid-host systems in the laboratory might be by accidental ingestion, it is suggested that the same types of experiments be conducted in suitable animal-model systems. In addition to these tests on survival of the vector and/or a cloned DNA fragment, it would be useful to determine the survival of the host strain under nongrowth conditions such as in water and as a function of drying time after a culture has been spilled on a lab bench.

For EK2 host-vector systems in which the vector is a phage, no more than one in $10^8$ phage particles should be able to perpetuate itself and/or a cloned DNA fragment under non-permissive conditions designed to represent the natural environment either (a) as a prophage or plasmid in the laboratory host used for phage propagation or (b) by surviving in natural environments and transferring itself and/or a cloned DNA fragment to a host (or its resident lamboid prophage) with properties common to those in the natural environment.

In terms of potential EK2 λ-host systems, the following types of genetic modification should reduce survival of cloned DNA. *The examples given are for illustrative purposes and should not be construed to encompass all possibilities.* The probability of establishing λ lysogeny in the normal laboratory host should be reduced by removal of the phage *att* site, the Int function, the repressor gene(s) and adding virulence-enhancing mutations. The frequency of plasmid formation, although normally already less than $10^{-6}$, could be further reduced by defects in the $p_R$-*Q* region, including mutations such as *vir-s*, *cro*(TS), *c*$^{17}$, *ri*$^c$, *O*(TS), *P*(TS), and *nin*. Moreover, chloroform treatment used routinely following cell lysis would reduce the number of surviving cells, including possible lysogens or plasmid carriers, by more than $10^8$. The host may also be modified by deletion of the host λ*att* site and inclusion of one or more of the mutations described above for plasmid-host systems to further reduce the chance of formation and survival of any lysogen or plasmid carrier cell.

The survival of escaping phage and the chance of encountering a sensitive host in nature are very low, as discussed for EK1 systems. The infectivity of the phage particles could be further reduced by introducing mutations (e.g., suppressed ambers) which would make the phage particles extremely unstable except under special laboratory conditions (e.g., high concentrations of salts or putrescine). Another means would be to make the phage itself a two-component system, by eliminating the tail genes and reproducing the phage as heads packed with DNA; when necessary and under specially controlled conditions, these heads could be made infective by adding tail preparations. An additional safety factor in this regimen is the extreme instability of the heads, unless they are stored in 10mM putrescine, a condition easy to obtain in the laboratory but not in nature. The propagation of the es-

caping phage in nature could further be blocked by adding various conditional mutations which would permit growth only under special laboratory conditions or in a special permissive laboratory host with suppressor or *gro*-type (*mop, dnaB, rpoB*) mutations. An additional safety feature would be the use of an $r^-m^-$ (*hsdS*) laboratory host, which produces phage with unmodified DNA which should be restricted in $r^+m^+$ bacteria that are probably prevalent in nature. The likelihood of recombination between the λ vector and lambdoid prophages which are present in some *E. coli* strains might be reduced by elimination of the Red function and the presence of the recombination-reducing Gam function together with mutations contributing to the high lethality of the λ phage. However, these second-order precautions might not be relevant if the stability and infectivity of the escaping λ particles are reduced by special mutations or by propagating the highly unstable heads.

Despite multiple mutations in the phage vectors and laboratory hosts, the yield of phage particles under suitable laboratory conditions should be high ($10^{10}$-$10^{11}$ particles/ml). This permits phage propagation in relatively small volumes and constitutes an additional safety feature.

The phenotypes and genetic stabilities of the mutations and chromosome alterations included in these λ-host systems indicate that containment well in excess of the required $10^{-8}$ or lower survival frequency for the λ vector with or without a cloned DNA fragment should be attained. Obviously the presence of all mutations contributing to this high degree of biological containment must be verified periodically by appropriate tests. Laboratory tests should be performed with the bacterial host to measure all possible routes of escape such as the frequency of lysogen formation, the frequency of plasmid formation and the survival of the lysogen or carrier bacterium. Similarly, the potential for perpetuation of a cloned DNA fragment carried by infectious phage particles can be tested by challenging typical wild-type *E. coli* strains or a λ-sensitive nonpermissive laboratory K–12 strain, especially one lysogenic for a lambdoid phage.

In view of the fact that accurate assessment of the probabilities for escape of infections λ-grown on $r^-$ $m^-$ $Su^+$ hosts is dependent upon the frequencies of $r^+$, $Su^+$, and λ-sensitive strains in nature, investigators need to screen *E. coli* strains for these properties. These data will also be useful in predicting frequencies of successful escape of plasmid cloning vectors harbored in $r^-$ $m^-$ $Su^+$ strains.

When any investigator has obtained data on the level of containment provided by a proposed EK2 system, these should be reported as rapidly as possible to permit general awareness and evaluation of the safety features of the new system. Investigators are also encouraged to make such new safer cloning systems generally available to other scientists. NIH will take appropriate steps to aid in the distribution of these safer vectors and hosts.

*EK3 host-vectors.* These are EK2 systems for which the specified containment shown by laboratory tests has been independently confirmed by appropriate tests in animals, including humans or primates, and in other relevant environments in order to provide additional data to validate the levels of containment afforded by the EK2 host-vector systems. Evaluation of the effects of individual or combinations of mutations contributing to the biological containment should be performed as a means to confirm the degree of safety provided and to further advance the technology of developing even safer vectors and hosts. For the time being, no host-vector system will be considered to be a bona fide EK3 host-vector system, until it is so certified by the NIH Recombinant DNA Molecule Program Advisory Committee.

2. *Classification of experiments using the E. coli K–12 containment systems.* In the following classification of containment criteria for different kinds of recombinant DNAs, the stated levels of physical and biological containment are minimums. Higher levels of biological containment (EK3 > EK2 > EK1) are to be used if they are available and are equally appropriate for the purposes of the experiment.

(a) *Shotgun Experiments.* These experiments involve the production of recombinant DNAs between the vector and the total DNA or (preferably) any partially purified fraction thereof from the specified cellular source.

(i) *Eukaryotic DNA recombinants—Primates.* P3 physical containment + an EK3 host-vector, or P4 physical containment + an EK2 host-vector, except for DNA from uncontaminated embryonic tissue or primary tissue cultures therefrom, and germ-line cells for which P3 physical containment + an EK2 host-vector can be used. The basis for the lower estimated hazard in the case of DNA from the latter tissues (if freed of adult tissue) is their relative freedom from horizontally acquired adventitious viruses.

*Other mammals.* P3 physical containment + an EK2 host-vector.

*Birds.* P3 physical containment + an EK2 host-vector.

*Cold-blooded vertebrates.* P2 physical containment + an EK2 host-vector except for embryonic or germ-line DNA which require P2 physical containment + an EK1 host-vector. If the eukaryote is known to produce a potent toxin, the containment shall be increased to P3 + EK2.

*Other cold-blooded animals and lower eukaryotes.* This large class of eukaryotes is divided into the following two groups:

(1) Species that are known to produce a potent toxin or are known pathogens (i.e., an agent listed in Class 2 of ref. 5 or a plant pathogen) or are known to carry such pathogenic agents must use P3 physical containment + an EK2 host-vector. Any species that has a demonstrated capacity for carrying particular pathogenic agents is included in this group unless it has been shown that those organisms used as the source of DNA do not contain these agents; in this case they may be placed in the second group.

(2) The remainder of the species in this class can use P2 + EK1. However, any insect in this group should have been grown under laboratory conditions for at least 10 generations prior to its use as a source of DNA.

*Plants.* P2 physical containment + an EK1 host-vector. If the plant carries a known pathogenic agent or makes a product known to be dangerous to any species, the containment must be raised to P3 physical containment + an EK2 host-vector.

(ii) *Prokaryotic DNA recombinants—Prokaryotes that exchange genetic information with E. coli.*[3] The level of physical containment is directly determined by the rule of the most dangerous component (see introduction to Section III). Thus P1 conditions can be used for DNAs from those bacteria in Class 1 of ref. 5 ("Agents of no or minimal hazard ***.") which naturally exchange genes with *E. coli;* and P2 conditions should be used for such bacteria if they fall in Class 2 of ref. 5 ("Agents of ordinary potential hazard * * *."), or are plant pathogens or symbionts. EK1 host-vectors can be used for all experiments requiring only P1 physical containment; in fact, experiments in this category can be performed with *E. coli* K-12 vectors exhibiting a lesser containment (e.g., conjugative plasmids) than EK1 vectors. Experiments with DNA from species requiring P2 physical containment which are of low pathogenicity (for example, enteropathogenic *Escherichia coli, Salmonella typhimurium,* and *Klebsiella pneumoniae*) can use EK1 host-vectors, but those of moderate pathogenicity (for example, *Salmonella typhi, Shigella dysenteriae* type I, and *Vibrio cholerae*) must use EK2 host-vectors.[3] A specific example of an experiment with a plant pathogen requiring P2 physical containment + an EK2 host-vector would be cloning the tumor gene of *Agrobacterium tumefaciens.*

*Prokaryotes that do not exchange genetic information with E. coli.* The minimum containment conditions for this class consist of P2 physical containment + an EK2 host-vector or P3 physical containment + an EK1 host-vector, and apply when the risk that the recombinant DNAs will increase the pathogenicity or ecological potential of the host is judged to be minimal. Experiments with DNAs from pathogenic species (Class 2 ref. 5 plus plant pathogens) must use P3 + EK2.

(iii) *Characterized clones of DNA recombinants derived from shotgun experiments.* When a cloned DNA recombinant has been rigorously characterized[4] and there is sufficient evidence that it is free of harmful genes,[4] then experiments involving this recombinant DNA can be carried out under P1 + EK1 conditions if the inserted DNA is from a

See footnotes at end of article.

species that exchanges genes with *E. coli*, and under P2 + EK1 conditions if not.

(b) *Purified cellular DNAs other than plasmids, bacteriophages, and other viruses.* The formation of DNA recombinants from cellular DNAs that have been enriched[6] by physical and chemical techniques (i.e., not by cloning) and which are free of harmful genes can be carried out under lower containment conditions than used for the corresponding shotgun experiment. In general, the containment can be decreased one step in physical containment (P4→P3→P2→P1) while maintaining the biological containment specified for the shotgun experiment, or one step in biological containment (EK3→EK2→EK1) while maintaining the specified physical containment—provided that the new condition is not less than that specified above for characterized clones from shotgun experiments (Section (a)—iii).

(c) *Plasmids, bacteriophages, and other viruses.* Recombinants formed between EK-type vectors and other plasmid or virus DNAs have in common the potential for acting as double vectors because of the replication functions in these DNAs. The containment conditions given below apply only to propagation of the DNA recombinants in *E. coli* K-12 hosts. They do not apply to other hosts where they may be able to replicate as a result of functions provided by the DNA inserted into the EK vectors. These are considered under other host-vector systems.

(i) *Animal viruses.* P4+EK2 or P3EK3 shall be used to isolate DNA recombinants that include *all or part* of the genome of an animal virus. This recommendation applies not only to experiments of the "shotgun" type but also to those involving partially characterized subgenomic segments of viral DNAs (for example, the genome of defective viruses, DNA fragments isolated after treatment of viral genomes with restriction enzymes, etc). When cloned recombinants have been shown by suitable biochemical and biological tests to be free of harmful regions, they can be handled in P3+EK2 conditions. In the case of DNA viruses, harmless regions include the late region of the genome; in the case of DNA copies of RNA viruses, they might include the genes coding for capsid proteins or envelope proteins.

(ii) *Plant viruses.* P3+EK1 or P2+EK2 conditions shall be used to form DNA recombinants that include *all or part* of the genome of a plant virus.

(iii) *Eukaryotic organelle DNAs.* The containment conditions given below apply only when the organelle DNA has been purified[6] from isolated organelles. Mitochondrial DNA from primates: P3+EK1 or P2+EK2. Mitochondrial or chloroplast DNA from other eukaryotes: P2+EK1. Otherwise, the conditions given under shotgun experiments apply.

(iv) *Prokaryotic plasmid and phage DNAs—Plasmids and phage from hosts that exchange genetic information with E. coli.* Experiments with DNA recombinants formed from plasmids or phage genomes that have not been characterized with regard to presence of harmful genes or are known to contribute significantly to the pathogenicity of their normal hosts must use the containment conditions specified for shotgun experiments with DNAs from the respective host. If the DNA recombinants are formed from plasmids or phage that are known not to contain harmful genes, or from purified[6] and characterized plasmid or phage DNA segments known not to contain harmful genes, the experiments can be performed with P1 physical containment + an EK1 host-vector.

*Plasmids and phage from hosts that do not exchange genetic information with E. coli.* The rules for shotgun experiments with DNA from the host apply to their plasmids or phages. The minimum containment conditions for this category (P2+EK2, or P3+EK1) can be used for plasmid and phage, or for purified[6] and characterized segments of plasmid and phage DNAs, when the risk that the recombinant DNAs will increase the pathogenicity or ecological potential of the host is judged to be minimal.

NOTE.—Where applicable, cDNAs( i.e., complementary DNAs) synthesized *in vitro* from cellular or viral RNAs are included within each of the above classifications. For example, cDNAs formed from cellular RNAs that are not purified and characterized are included under (a), shotgun experiments; cDNAs formed from purified and characterized RNAs are included under (b); cDNAs formed from viral RNAs are included under (c); etc.

3. *Experiments with other prokaryotic host-vectors.* Other prokaryotic host-vector systems are at the speculative, planning, or developmental stage, and consequently do not warrant detailed treatment here at this time. However, the containment criteria for different types of DNA recombinants formed with *E. coli* K-12 host-vectors can, with the aid of some general principles given here, serve as a guide for containment conditions with other host-vectors when appropriate adjustment is made for their different habitats and characteristics. The newly developed host-vector systems should offer some distinct advantage over the *E. coli* K-12 host-vectors—for instance, thermophilic organisms or other host-vectors whose major habitats do not include humans and/or economically important animals and plants. In general, the strain of any prokaryotic species used as the host is to conform to the definition of Class 1 etiologic agents given in ref. 5 (i.e., "Agents of no or minimal hazard. * * *.") and the plasmid or phage vector should not make the host more hazardous. Appendix A gives a detailed discussion of the *B. subtilis* system, the most promising alternative to date.

At the initial stage, the host-vector must exhibit at least a moderate level of biological containment comparable to EK1 systems, and should be capable of modification to obtain high levels of containment comparable to EK2 and EK3. The type of confirmation test(s) required to move a host-vector from an EK2-type classification to an EK3-type will clearly depend upon the preponderant habitat of the host-vector. For example, if the unmodified host-vector propagates mostly in, on, or around higher plants, but not appreciably in warm-blooded animals, modification should be designed to reduce the probability that the host-vector can escape to and propagate in, on, or around such plants, or transmit recombinant DNA to other bacterial hosts that are able to occupy these ecological niches, and it is these lower probabilities which must be confirmed. The following principles are to be followed in using the containment criteria given for experiments with *E. coli* K-12 host-vectors as a guide for other prokaryotic systems. Experiments with DNA from prokaryotes (and their plasmids or viruses) are classified according to whether the prokaryote in question exchanges genetic information with the host-vector or not, and the containment conditions given for these two classes with *E. coli* K-12 host-vectors applied. Experiments with recombinants between plasmid or phage vectors and DNA that extends the range of resistance of the recipient species to therapeutically useful drugs must use P3 physical containment + a host-vector comparable to EK1 or P2 physical containment + a host-vector comparable to EK2. Transfer of recombinant DNA to plant pathogens can be made safer by using nonreverting, doubly auxothrophic, non-pathogenic variants. Experiments using a plant pathogen that affects an element of the local flora will require more stringent containment than if carried out in areas where the host plant is not common.

Experiments with DNAs from eukaryotes (and their plasmids or viruses) can also follow the criteria for the corresponding experiments with *E. coli* K-12 vectors if the major habitats of the given host-vector overlap those of *E. coli*. If the host-vector has a major habitat that does not overlap those of *E. coli* (e.g., root nodules in plants), then the containment conditions for some eukaryotic recombinant DNAs need to be increased (for instance, higher plants and their viruses in the preceding example), while others can be reduced.

4. *Experiments with eukaryotic host-vectors—(a) Animal host-vector systems.* Because host cell lines generally have little if any capacity for propagation outside the laboratory, the primary focus for containment is the vector, although cells should also be derived from cultures expected to be of minimal hazard. Given good microbiological practices, the most likely mode escape of recombinant DNAs from a physically contained laboratory is carriage by humans; thus vectors should be chosen that have little or no ability to replicate in human cells. To be used as a vector in a eukaryotic host, a DNA molecule needs to display all of the following properties:

(1) It shall not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture.

(2) Its functional anatomy should be known—that is, there should be a clear

See footnotes at end of article.

idea of the location within the molecule of:

(a) The sites at which DNA synthesis originates and terminates,

(b) The sites that are cleaved by restriction endonucleases,

(c) The template regions for the major gene products.

(3) It should be well studied genetically. It is desirable that mutants be available in adequate number and variety, and that quantitative studies of recombination have been performed.

(4) The recombinant must be defective, that is, its propagation as a virus is dependent upon the presence of a complementing helper genome. This helper should either (a) be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector to that particular cell line) or (b) consist of a defective genome or an appropriate conditional lethal mutant virus (in which case the experiments would be done under nonpermissive conditions), making vector and helper dependent upon each other for propagation. However, if none of these is available, the use of a non-defective genome as helper would be acceptable.

Currently only two viral DNAs can be considered as meeting these reouirements: these are the genomes of polyoma virus and SV40.

Of these, polyoma virus is highly to be preferred. SV40 is known to propagate in human cells, both *in vivo* and *in vitro*, and to infect laboratory personnel, as evidenced by the frequency of their conversion to producing SV40 antibodies. Also, SV40 and related viruses have been found in association with certain human neurological and malignant diseases. SV40 shares many properties, and gives complementation, with the common human papova viruses. By contrast, there is no evidence that polyoma infects humans, nor does it replicate to any significant extent in human cells *in vitro*. However, this system still needs to be studied more extensively. Appendix B gives further details and documentation.

Taking account of all these factors:

(1) *Polyoma Virus.* (*a*) Recombinant DNA molecules consisting of defective polyoma virus genomes plus DNA sequences of any nonpathogenic organism, including Class 1 viruses (5), can be propagated in or used to transform cultured cells. P3 conditions are required. Appropriate helper virus can be used if needed. Whenever there is a choice, it is urged that mouse cells, derived preferably from embryos, be used as the source of eukaryotic DNA. Polyoma virus is a mouse virus and recombinant DNA molecues containing both viral and cellular sequences are already known to be present in virus stocks grown at a high multiplicity. Thus, recombinants formed *in vitro* between polyoma virus DNA and mouse DNA are presumably not novel from an evolutionary point of view.

(*b*) Such experiments are to be done under P4 conditions if the recombinant DNA contains segments of the genomes of Class 2 animal viruses (5). Once it has been shown by suitable biochemical and biological tests that the cloned recombinant contains only harmless regions of the viral genome (see Section IIIB–2–c–i) and that the host range of the polyoma virus vector has not been altered, experiments can be continued under P3 conditions.

(2) *SV40 Virus.*

(*a*) Defective SV40 genomes, with appropriate helper, can be used as a vector for recombinant DNA molecules containing sequences of any non-pathogenic organism or Class I virus (5), (i.e., a shotgun type experiment). P4 conditions are required. Established lines of cultured cells should be used.

(*b*) Such experiments are to be carried out in P3 (or P4) conditions if the non-SV40 DNA segment is (a) a purified [6] segment of prokaryotic DNA lacking toxigenic genes, or (b) a segment of eukaryotic DNA whose function has been established, which does not code for a toxic product, and which has been previously cloned in a prokaryotic host-vector system. It shall be confirmed that the defective virus-helper virus system does not replicate significantly more efficiently in human cells in tissue culture than does SV40, following infection at a multiplicity of infection of one or more helper SV40 viruses per cell.

(*c*) A recombinant DNA molecule consisting of defective SV40 DNA lacking substantial segments of the late region, plus DNA from non-pathogenic organisms or Class I viruses (5), can be propagated as an autonomous cellular element in established lines of cells under P3 conditions provided that there is no exogenous or endogenous helper, and that it is demonstrated that *no* infectious virus particles are being produced. Until this has been demonstrated, the appropriate containment conditions specified in *2. a.* and *2. b.* shall be used.

(*d*) Recombinant DNA molecules consisting of defective SV40 DNA and sequences from non-pathogenic prokaryotic or eukaryotic organisms or Class I viruses (5) can be used to transform established lines of non-permissive cells under P3 conditions. It must be demonstrated that no infectious virus particles are being produced; rescue of SV40 from such transformed cells by co-cultivation or transfection techniques must be carried out in P4 conditions.

(3) Efforts are to be made to ensure that all cell lines are free of virus particles and mycoplasma.

Since SV40 and polyoma are limited in their scope to act as vectors, chiefly because the amount of foreign DNA that the normal virions can carry probably cannot exceed $2\times10^6$ daltons, the development of systems in which recombinants can be cloned and propagated purely in the form of DNA, rather than in the coats of infectious agents is necessary. Plasmid forms of viral genomes or organelle DNA need to be explored as possible cloning vehicles in eukaryotic cells.

(*b*) *Plant host-vector systems.* For cells in tissue cultures, seedlings, or plant parts (e.g. tubers, stems, fruits, and detached leaves) or whole mature plants of small species (e.g., *Arabidopsis*) the P1–P4 containment conditions that we have specified previously are relevant concepts. However, work with most plants poses additional problems. The greenhouse facilities accompanying P2 laboratory physical containment conditions can be provided by: (i) Insect-proof greenhouses, (ii) appropriate sterilization of contaminated plants, pots, soil, and runoff water, and (iii) adoption of the other standard practices for microbiological work. P3 physical containment can be sufficiently approximated by confining the operations with whole plants to growth chambers like those used for work with radioactive isotopes, provided that (i) such chambers are modified to produce a negative pressure environment with the exhaust air appropriately filtered, (ii) that other operations with infectious materials are carried out under the specified P3 conditions, and (iii) to guard against inadvertent insect transmission of recombinant DNA, growth chambers are to be routinely fumigated and only used in insect proof rooms. The P2 and P3 conditions specified earlier are therefore extended to include these cases for work on higher plants.

The host cells for experiments on recombinants DNAs may be cells in culture, in seedling or plant parts. Whole plants or plant parts that cannot be adequately contained shall not be used as hosts for shotgun experiments at this time, and attempts to infect whole plants with recombinant DNA shall not be initiated until the effects on host cells in culture, seedlings or plant parts have been thoroughly studied.

Organelle or plasmid DNAs or DNAs of viruses of restricted host range may be used as vectors. In general, similar criteria for selecting host-vectors to those given in the preceding section on animal systems are to apply to plant systems.

DNA recombinants formed between the initial moderately contained vectors and DNA form cells of species in which the vector DNA can replicate, require P2 physical containment. However, if the source of the DNA is itself pathogenic or known to carry pathogenic agents, or to produce products dangerous to plants, or if the vector is an unmodified virus of unrestricted host range, the experiments shall be carried out under P3 conditions.

Experiments on recombinant DNAs formed between the above vectors and DNAs from other species can also be carried out under P2 if that DNA has been purified [6] and determined not to contain harmful genes. Otherwise, the experiments shall be carried out under P3 conditions if the source of the inserted DNA is not itself a pathogen, or known to carry such pathogenic agents, or to produce harmful products—and under P4 conditions if these conditions are not met.

The development and use of host-vector systems that exhibit a high level of biological containment permit a decrease or one step in the physical con-

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tainment specified above (P4→P3→P2→P1).

(c) *Fungal or similar lower eukaryotic host-vector systems.* The containment criteria for experiments on recombinant DNAs using these host-vectors most closely resemble those for prokaryotes, rather than those for the preceding eukaryotes, in that the host cells usually exhibit a capacity for dissemination outside the laboratory that is similar to that for bacteria. We therefore consider that the containment guidelines given for experiments with *E. coli* K–12 and other prokaryotic host-vectors (Sections IIIB–1 and –2, respectively) provide adequate direction for experiments with these lower eukaryotic host-vectors. This is particularly true at this time since the development of these host-vectors is presently in the speculative stage.

### IV. ROLES AND RESPONSIBILITIES

Safety in research involving recombinant DNA molecules depends upon how the research team applies these guidelines. Motivation and critical judgment are necessary, in addition to specific safety knowledge, to ensure protection of personnel, the public, and the environment.

The guidelines given here are to help the principal investigator determine the nature of the safeguards that should be implemented. These guidelines will be incomplete in some respects because all conceivable experiments with recombinant DNAs cannot now be anticipated. Therefore, they cannot substitute for the investigator's own knowledgeable and discriminating evaluation. Whenever this evaluation calls for an increase in containment over that indicated in the guidelines, the investigator has a responsibility to institute such an increase. In contrast, the containment conditions called for in the guidelines should not be decreased without review and approval at the institutional and NIH levels.

The following roles and responsibilities define an administrative framework in which safety is an essential and integrated function of research involving recombinant DNA molecules.

A. *Principal Investigator.* The principal investigator has the primary responsibility for: (i) Determining the real and potential biohazards of the proposed research, (ii) determining the appropriate level of biological and physical containment, (iii) selecting the microbiological practices and laboratory techniques for handling recombinant DNA materials, (iv) preparing procedures for dealing with accidental spills and overt personnel contamination, (v) determining the applicability of various precautionary medical practices, serological monitoring, and immunization, when available, (vi) securing approval of the proposed research prior to initiation of work, (vii) submitting information on purported EK2 and EK3 systems to the NIH Recombinant DNA Molecule Program Advisory Committee and making the strains available to others, (viii) reporting to the institutional biohazards committee and the NIH Office of Recombinant DNA Activities new information bearing on the guidelines, such as technical information relating to hazards and new safety procedures or innovations, (ix) applying for approval from the NIH Recombinant DNA Molecule Program Advisory Committee for large scale experiments with recombinant DNAs known to make harmful products (i.e., more than 10 liters of culture), and (x) applying to NIH for approval to lower containment levels when a cloned DNA recombinant derived from a shotgun experiment has been rigorously characterized and there is sufficient evidence that it is free of harmful genes.

Before work is begun, the principal investigator is responsible for: (1) Making available to program and support staff copies of those portions of the approved grant application that describe the biohazards and the precautions to be taken, (ii) advising the program and support staff of the nature and assessment of the real and potential biohazards, (iii) instructing and training this staff in the practices and techniques required to ensure safety, and in the procedures for dealing with accidentally created biohazards, and (iv) informing the staff of the reasons and provisions for any advised or requested precautionary medical practices, vaccinations, or serum collection.

During the conduct of the research, the principal investigator is responsible for: (i) Supervising the safety performance of the staff to ensure that the required safety practices and techniques are employed, (ii) investigating and reporting in writing to the NIH Office of Recombinant DNA Activities and the institutional biohazards committee any serious or extended illness of a worker or any accident that results in (a) inoculation of recombinant DNA materials through cutaneous penetration, (b) ingestion of recombinant DNA materials, (c) probable inhalation of recombinant DNA materials following gross aerosolization, or (d) any incident causing serious exposure to personnel or danger of environmental contamination, (iii) investigating and reporting in writing to the NIH Office of Recombinant DNA Activities and the institutional biohazards committee any problems pertaining to operation and implementation of biological and physical containment safety practices and procedures, or equipment or facility failure, (iv) correcting work errors and conditions that may result in the release of recombinant DNA materials, and (v) ensuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., genotypic and phenotypic characteristics, purity, etc.).

B. *Institution.* Since in almost all cases, NIH grants are made to institutions rather than to individuals, all the responsibilities of the principal investigator listed above are the responsibilities of the institution under the grant, fulfilled on its behalf by the principal investigator. In addition, the institution is responsible for establishing an institutional biohazards committee[7] to: (i) Advise the institution on policies, (ii) create and maintain a central reference file and library of catalogs, books, articles, newsletters, and other communications as a source of advice and reference regarding, for example, the availability and quality of the safety equipment, the availability and level of biological containment for various host-vector systems, suitable training of personnel and data on the potential biohazards associated with certain recombinant DNAs, (iii) develop a safety and operations manual for any P4 facility maintained by the institution and used in support of recombinant DNA research, (iv) certify to the NIH on applications for research support and annually thereafter, that facilities, procedures, and practices and the training and expertise of the personnel involved have been reviewed and approved by the institutional biohazards committee.

The biohazards committee must be sufficiently qualified through the experience and expertise of its membership and the diversity of its membership to ensure respect for its advice and counsel. Its membership should include individuals from the institution or consultants, selected so as to provide a diversity of disciplines relevant to recombinant DNA technology, biological safety, and engineering. In addition to possessing the professional competence necessary to assess and review specific activities and facilities, the committee should possess or have available to it, the competence to determine the acceptability of its findings in terms of applicable laws, regulations, standards of practices, community attitudes, and health and environmental considerations. Minutes of the meetings should be kept and made available for public inspection. The institution is responsible for reporting names of and relevant background information on the members of its biohazards committee to the NIH.

C. *NIH Initial Review Groups (Study Sections).* The NIH Study Sections, in addition to reviewing the scientific merit of each grant application involving recombinant DNA molecules, are responsible for: (i) Making an independent evaluation of the real and potential biohazards of the proposed research on the basis of these guidelines, (ii) determining whether the proposed physical containment safeguards certified by the institutional biohazards committee are appropriate for control of these biohazards, (iii) determining whether the proposed biological containment safeguards are appropriate, (iv) referring to the NIH Recombinant DNA Molecule Program Advisory Committee or the NIH Office of Recombinant DNA Activities those problems pertaining to assessment of biohazards or safeguard determination that cannot be resolved by the Study Sections.

The membership of the Study Sections will be selected in the usual manner. Biological safety expertise, however, will be available to the Study Sections for consultation and guidance.

D. *NIH Recombinant DNA Molecule Program Advisory Committee.* The Recombinant DNA Molecule Program Advisory Committee advises the Secretary, Department of Health, Education, and

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Welfare, the Assistant Secretary for Health, Department of Health, Education, and Welfare, and the Director, National Institutes of Health, on a program for the evaluation of potential biological and ecological hazards of recombinant DNAs (molecules resulting from different segments of DNA that have been joined together in cell-free systems, and which have the capacity to infect and replicate in some host cell, either autonomously or as an integrated part of their host's genome), on the development of procedures which are designed to prevent the spread of such molecules within human and other populations, and on guidelines to be followed by investigators working with potentially hazardous recombinants.

The NIH Recombinant DNA Molecule Program Advisory Committee has responsibility for: (i) Revising and updating guidelines to be followed by investigators working with DNA recombinants, (ii) for the time being, receiving information on purported EK2 and EK3 systems and evaluating and certifying that host-vector systems meet EK2 or EK3 criteria, (iii) resolving questions concerning potential biohazard and adequacy of containment capability if NIH staff or NIH Initial Review Group so request, and (iv) reviewing and approving large scale experiments with recombinant DNAs known to make harmful products (e.g., more than 10 liters of culture).

E. *NIH Staff.* NIH Staff has responsibility for: (i) Assuring that no NIH grants or contracts are awarded for DNA recombinant research unless they (a) conform to these guidelines, (b) have been properly reviewed and recommended for approval, and (c) include a properly executed Memorandum of Understanding and Agreement, (ii) reviewing and responding to questions or problems or reports submitted by institutional biohazards committees or principal investigators, and disseminating findings, as appropriate, (iii) receiving and reviewing applications for approval to lower containment levels when a cloned DNA recombinant derived from a shotgun experiment has been rigorously characterized and there is sufficient evidence that it is free of harmful genes, (iv) referring items covered under (ii) and (iii) above to the NIH Recombinant DNA Molecule Program Advisory Committee, as deemed necessary, and (v) performing site inspections of all P4 physical containment facilities, engaged in DNA recombinant research, and of other facilities as deemed necessary.

## V. FOOTNOTES

[1] Biological Safety Cabinets referred to in this section are classified as *Class I, Class II* or *Class III* cabinets. A *Class I* cabinet is a ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air from this cabinet is filtered through a high efficiency or high efficiency particulate air (HEPA) filter before being discharged to the outside atmosphere. This cabinet is used in three operational modes: (1) with an 8 inch high full width open front, (2) with an installed front closure panel (having four eight inch diameter openings) without gloves, and (3) with an installed front closure panel equipped with arm length rubber gloves. The face velocity of the inward flow of air through the full width open front is 75 feet per minute or greater. A *Class II* cabinet is a ventilated cabinet for personnel and product protection having an open front with inward air flow for personnel protection, and HEPA filtered mass recirculated air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full width open front is 75 feet per minute or greater. Design and performance specifications for *Class II* cabinets have been adopted by the National Sanitation Foundation, Ann Arbor, Michigan. A *Class III* cabinet is a closed front ventilated cabinet of gas tight construction which provides the highest level of personnel protection of all Biohazard Safety Cabinets. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm length rubber gloves and is operated under a negative pressure of at least 0.5 inches water gauge. All supply air filtered through HEPA filters. Exhaust air is filtered through HEPA filters or incinerated before being discharged to the outside environment.

[2] Defined as observable under optimal laboratory conditions by transformation, transduction, phage infection and/or conjugation with transfer of phage, plasmid and/or chromosomal genetic information.

[3] The bacteria which constitute Class 2 of ref. 5 ("Agents of ordinary potential hazard * * *.") represent a broad spectrum of etiologic agents which possess different levels of virulence and degrees of communicability. We think it appropriate for our specific purpose to further subdivide the agents of Class 2 into those which we believe to be of relatively low pathogenicity and those which are moderately pathogenic. The several specific examples given may suffice to illustrate the principle.

[4] The terms "characterized" and "free of harmful genes" are unavoidably vague. But, in this instance, before containment conditions lower than the ones used to clone the DNA can be adopted, the investigator must obtain approval from the National Institutes of Health. Such approval would be contingent upon data concerning: (a) the absence of potentially harmful genes (e.g., sequences contained in indigenous tumor viruses or which code for toxic substances), (b) the relation between the recovered and desired segment (e.g., hybridization and restriction endonuclease fragmentation analysis where applicable), and (c) maintenance of the biological properties of the vector.

[5] A DNA preparation is defined as enriched if the desired DNA represents at least 99% (w/w) of the total DNA in the preparation. The reason for lowering the containment level when this degree of enrichment has been obtained is based on the fact that the total number of clones that must be examined to obtain the desired clone is markedly reduced. Thus, the probability of cloning a harmful gene could, for example, be reduced by more that $10^3$-fold when a nonrepetitive gene from mammals was being sought. Furthermore, the level of purity specified here makes it easier to establish that the desired DNA does not contain harmful genes.

[6] The DNA preparation is defined as purified if the desired DNA represents at least 99% (w/w) of the total DNA in the preparation, provided that it was verified by more than one procedure.

[7] In special circumstances, in consultation with the NIH Office of Recombinant DNA Activities, an area biohazards committee may be formed, composed of members from the institution and/or other organizations beyond its own staff, as an alternative when additional expertise outside the institution is needed for the indicated reviews.

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APPENDIX A—STATEMENT ON THE USE OF "BACILLUS SUBTILIS" IN RECOMBINANT MOLECULE TECHNOLOGY

Unquestionably, *Escherichia coli* is the most well characterized unicellular organism. Years of basic research have enabled investigators to develop a well characterized genetic map, to obtain detailed knowledge of virulent and temperate bacteriophages, and to explore the physiology, genetics, and regulation of plasmids. More recently, the development of DNA-mediated transformation has permitted exogenous fragments or molecules of DNA to be incorporated into the genome or to reside as self-replicating units. The discovery of transformation of *Bacillus subtilis* by Spizien (1) stimulated the development of analternative model system. The purpose of this report is to summarize the current status of this genetic system and to describe the actual and potential vectors and vehicles available for recombinant molecule technology.

A. CURRENT KNOWLEDGE OF THE CHROMOSOMAL ARCHITECTURE AND MECHANISMS OF GENETIC EXCHANGE IN B. "SUBTILLS"

Two mechanisms of genetic exchange have been utilized to establish the linkage map of *B. subtilis*, DNA-mediated transformation (capable of transferring approximately 1% of the genome) and transduction with bacteriophage PBSI (capable of transferring 5–8% of the chromosome). Recent detailed genetic studies with PBSI by Lepesant-Kejzlorová *et al.* (2) have resulted in the development of a circular genetic map for this organism. The current edition of the map (3) contains 196 loci. Biophysical analyses have established that the chromosome is circular (4) and replicates bidirectionally (5).

Transformation with purified fragments of DNA is a highly efficient process in *B. subtilis* with frequencies of 1 to 4% usually attained for any auxotrophic or antibiotic resistance markers. Frequencies of approximately 10% transformation can be achieved with DNA prepared from gently lysed L-forms or protoplasts (6). These large fragments of DNA are readily incorporated by the recipient cell. Generalized transduction occurs with bacteriophages SP10 (7), PBS1 (8), and SPP1 (9), while a low frequency of specialized transduction has been reported with bacteriophage $\phi$105 (10).

Although transformation is most efficient in homologous crosses (*B. subtilis* into *B. subtilis*), it has also been possible to exchange DNA among closely related species (11). The most extensively studied members of the *B. subtilis* genospecies include *B. licheniformis*, *B. pumilus*, *B. amyloliquefaciens*, and *B. globigii* (refer to reference 12 for a review and references 13–15 for examples of this heterologous exchange). This exchange occurs even

though there is a surprisingly wide discrepancy between DNA—DNA hybridization among these organisms (16). Even though the frequency of transformation is low in the heterologous cross [e.g., *B. amyloliquefaciens* (donor)/*B subtilis* (recipient)], the newly acquired DNA from *B. amyloliquefaciens* in the *B. subtilis* background can be readily transferred at high efficiencies to other recipient strains of *B. subtilis* (14). Therefore, the extremely high frequency of transformation permits the recognition and selection of rare events.

B. CURRENT AND POTENTIAL VECTORS FOR RECOMBINANT MOLECULE EXPERIMENTS

Lovett and coworkers have recently described crytic plasmids in *B. pumilus* (17) and *B. subtilis* (18). Of these organisms, *B. subtilis* ATCC 7003 appears to be the most useful since it carries one to two copies of a plasmid with a molecular weight of $46 \times 10^6$. This strain is als closely related to *B. subtilis* 168. Another strain of *B. subtilis* (ATCC 15841) contains 16 copies of a plasmid with a molecular weight of $4.6 \times 10^6$. Currently it is not known whether genetic markers can be readily introduced into these plasmids. To date it has not been possible to readily stabilize plasmids derived from *B. pumilus* in *B. subtilis* even with heavy selective pressure (P. Lovett, personal communication).

Two temperate bacteriophages are under development as vectors in *B. subtilis*, Φ3T and SP02. Lysogeny of thymine auxotrophs (strains sarrying *thy*A *thy*B) by bacteriophage Φ3T results in "conversion" to a Thy$^+$ phenotype. The attachment site for this bacteriophage and the bacteriophage gene for thymidylate synthetase (*thy*P) map between the bacterial *thy*A and *thy*B loci in the terminal region of the chromosome of *B. subtilis* (19). The viral genome is readily cleaved by the site-specific endonuclease, Bam 1 (20), to produce 5 fragments (one of which carries the *thy*P gene). The *thy*P carrying gene can be integrated into the bacterial genome in the absence of the intact viral genome. Because deletions are available that include the *thy*P region, it is theoretically possible to introduce *thy*P at many sites on the chromosome. The *thy*P gene can be readily purified for insertion into plasmids or utilized as a scaffold to integrate other heterologous DNA into the chromosome of *B. subtilis*. Alternatively, it is possible to purify fragments of the chromosome by gel electrophoresis (21, 22), for insertion into bacteriophage Φ3T or SP02. At present, unfortunately, only the former carries a selective marker, i.e., the gene for thymidylate synthetase, *thy*P.

C. DEVELOPMENT OF VEHICLES

*B. subtilis* is a Gram-positive sporulating rod that usually inhabits soil. Although it can exist on cutaneous surfaces of man (23) and experimental animals, it rarely produces disease. To develop a suitable vehicle it is imperative to have a host that is asporogenic. The most appropriate deletion mutation is deletion 29 (cit D). In addition to a deficiency in sporulation this mutant rapidly lyses when it has reached the end of its growth cycle. Presumably this is due to the failure to inactivate one of the autolytic enzymes (24). Through the introduction of a D-alanine requirement (34 ug/ml) it is possible to block transport of compounds that are transported by active transport (25, 26). The further introduction of thymine auxotrophy (defects in the *thy*A *thy*B loci) will enable the strain to survive only with a plasmid vector carrying the purified *thy*P gene from bacteriophage Φ3T or a defective bacteriophage Φ3T carrying the *thy*P gene but attached to the chromosome at an alternative site (due to the presence of deletion 29 in the host). We have recently isolated temperature-sensitive *thy*P mutants. If we can isolate a temperature-dependent lysogen that will grow only at 48°C it should be possible to make an unusual vehicle.

D. SITE-SPECIFIC ENDONUCLEASES

Recently two restriction modification systems have been observed between *B. subtilis* 168 and other bacilli. Trautner *et al.* have isolated an effective system that inhibits infection of the R strain of *B. subtilis* by bacteriophage SPP1 propagated on *B. subtilis* 168 (27). The site-specific nuclease recognizes the sequence GGCC. Young, Radnay, and CCGG

Wilson observed a restriction modification system between *B. amyloliquefaciens* and *B. subtilis* 168 (28). The endonuclease from *B. amyloliquefaciens* (20) recognizes the sequence GGATCC (29). More recently, two CCTAGG

additional enzymes have been isolated from *B. globigit* (30). The recognition sequence is not known.

E. ADVANTAGES AND LIABILITIES OF THE *B. "SUBTILIS SYSTEM"*

*a. Advantages*

1. *B. subtilis* is nonpathogenic. Asporogenic deletion mutants are available to preclude the problem of persistence through sporulation.

2. The circular chromosomal map is well defined. At least 196 loci have been positioned.

3. The organism is commercially important in the fermentation industry.

4. Large numbers of organisms can be disposed of readily with minimal environmental impact.

5. Unlike *E. coli*, it lacks endotoxin in the cell wall. Therefore the cells can be used as a single cell protein source.

6. The frequency of transformation is very high, facilitating the detection of rare events.

7. A unique bacteriophage, φ3T, exists that carries a gene that can be readily purified for "scaffolding" experiments.

*b. Disadvantages*

1. The knowledge of genetics and physiology of plasmids and viruses is primitive compared with *E. coli*.

2. High-frequency, specialized transduction is not available as a means of gene enrichment.

Based on its promise, it seems appropriate, and not chauvinistic, to urge development of this system.

Prepared by: Dr. Fank Young, University of Rochester.

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APPENDIX B.—POLYOMA AND SV40 VIRUS

Polyoma virus is a virus of mice, and infection of wild mouse populations is a common event, for the virus has often been isolated from a high proportion of healthy adult animals, both wild and laboratory bred, of many colonies (Gross, L., Proc. Soc. Exp. Biol. *88*, 362–368, 1955; Rowe, W. P., Bact. Rev. *25* 18–31, 1961). As far as is known the virus almost never causes a disease in these animals. However, when large quantities of the virus are inoculated into newborn or suckling mice or hamsters, a variety of solid tumors is induced (Gross, L., Oncogenic Viruses, Second Edition, Pergamon Press, NY).

Polyoma virus grows lytically in mouse cells in tissue culture. Thus mouse cells in culture are probably transformed only by virus particles that contain certain kinds of defective genomes. Cells of other rodent species, however, can be transformed by polyoma virus particles that contain complete genomes (Folk, W., J. Virol., *11*, 424–431, 1973). The virus does not replicate to a significant extent in human cells in tissue culture (Eddy, B. E., Virol. Monogr., *7*, 1–114, 1969; Pollack, R. E. Salas, J., Wang, R., Kusano, T., and Green, H., J. Cell Physiol. *77*, 117–120, 1971). The resistance of the cells seems to be a consequence of the failure of the virus to absorb or uncoat. However even when naked viral DNA is introduced into the cells only an abortive cycle of replication ensues; early viral proteins are made, there is induction of cellular DNA synthesis, but no expression of late viral proteins is detectable (Gruen, R., Grassmann, M. and Grassmann, A., Virology, *58*, 290–293, 1974).

There is no evidence that polyoma virus can infect humans (Hartley, J., Huebner, R., Parker, J. and Rowe, W. P., unpublished data). Thus no antibodies to the virus have been detected in people living in buildings that are infested with virus-infected mice, nor in laboratory workers who have been exposed to the virus for a number of years.

At most, a small segment of polyoma virus DNA shows weak homology with a portion of the late region of SV40 DNA (Ferguson, J. and Davis, R. W., J. Bol. Biol., *94*, 135–150, 1975). However, there appears to be no genetic interaction between the two viruses and there is no immunological cross-reaction between the gene products of the two viruses.

SV40 causes persistent but apparently harmless infections of the kidneys of virtually all adult rhesus monkeys (Hsiung, G. D., Bact. Revs. *32*, 185–205, 1968), it causes tumors when injected into newborn hamsters (Girardi, A. J., Sweet, B. H., Slotnick, V. B. and Hillemann, M. R., Proc. Soc. Exp. Biol. Med., *105*, 420–427, 1964) and transforms cells of several mammalian species (including human). SV40 is able to infect human since antibodies to the virus are found in a small proportion of the human population (Shah, K. V., Goverdhan, M. K. and Ozer, H. L., Am. J. Epid. *93*, 291–298, 1970) and serum conversions have been noted in many laboratory personnel who have been exposed to the virus (Horvath, L. B., Acta Microbiol. Acta Sci. Hung. *12*, 201–206, 1965).

Isolations of SV40 have been reported from humans, twice from patients suffering from the rare demyelinating disease, progressive multifocal leukoencephalopathy (Weiner, L., Herndon, R., Narayon, O., Johnson, R. T., Shah, K., Rubinstein, L. G., Prezozisi, T. J. and Conley, F. K., New England J. Med. *286*, 385–390, 1972) and apparently from a tumor of a person with metastatic melanoma (Soriano, F., Shelburne, C. E. and Gokcen, M., Nature, *249*, 421–424, 1974). In other studies a non-structural antigen characteristic of papovaviruses, T antigen, has been detected in the nuclei of cells cultured from 2 meningiomas, while another SV40-specific antigen, U antigen, has been found in the cells of a third tumor of the same type (Weiss, A. F., Portman, R., Fisher, H., Simon, J. and Zang, K. D., Proc. Nat. Acad. Sci. USA 72, 609–613, 1975). Furthermore new papovaviruses have been isolated from the brains of patients with PML (JC virus—Padgett, B. L., Walker, D. L., zuRhein, G. M., Eckroade, R. I. and Dessel, B. H., Lancet *1*, 1257–1260, 1971), from the urine of a patient carrying a renal allograft (BK virus—Gardner, S. D., Field, A. M., Coleman, D. V. and Hulme, B. Lancet *1*, 1253–1257, 1971) and from a reticulum cell sarcoma and the urine of patients with the sex-linked recessive disorder, Wiscott-Aldrich syndrome (Takemoto, K. K., Rabson, A. S., Mullarkey, M. F., Blaese, R. M. Garon, C. F. and Nelson, D. J., Nat. Cancer Inst., *53*, 1205–1207, 1974). All of these viruses which are distributed widely throughout human populations share antigenic and biological properties with SV40; the virus particles are identical in size and architecture (Madeley, C. R., In Virus Morphology, Churchill-Livingstone, London, 134–135, 1972); the non-structural intracellular T antigen, which appears to be coded by the A gene of SV40 cross reacts extensively with antigens found in cells infected or transformed by BK or JC viruses; both JC or BK viruses induce tumors in newborn hamsters (Walter, D. L., Padgett, B. L. zuRhein, B. M., Albert, A. E. and Marsh, R. F., Science *181*, 674–676, 1973; Shah, K. V., Daniel, R. W. and Strandberg, J., J. Nat. Cancer Inst. *54*, 945–950, 1975); BK virus causes transformation of hamster cells in culture (Major, E. D., and DiMayorca, G., Proc. Nat. Acad. Sci. US, *70*, 3210–3212, 1973; Portolani, M., Barbanti, A., Brodano, G. and LaPlaca, M. J., Virol. *15*, 420–422, 1975) and is able to complement the growth of certain temperature-sensitive mutants of SV40 (Mason, D. H. and Takemoto, K. K., submitted for publication).

FURTHER WORK

At present, a potential eukaryotic vector of choice is polyoma virus. And while available information indicates that it fulfills all the necessary criteria, we recommend that the following subjects be further investigated:

1. The molecular mechanism of resistance of human cells to the virus.

2. The extent of homology between polyoma virus DNA and the DNAs of human papovaviruses.

3. The ability of human papovaviruses to complement defective polyoma virus genomes.

Report of a working group consisting of: Dr. Bernard Fields, Harvard University School of Medicine; Dr. Thomas J. Kelly, Jr., Johns Hopkins University School of Medicine; Dr. Andrew Lewis, National Institute of Allergy and Infectious Diseases; Dr. Malcolm Martin, National Institute of Allergy and Infectious Diseases; Dr. Robert Martin, National Institute of Arthritis, Metabolism, and Digestive Diseases; Dr. Elmer Pfefferkorn, Dartmouth Medical School; Dr. Wallace P. Rowe, National Institute of Allergy and Infectious Diseases; Dr. Aaron Shatkin, Roche Institute of Molecular Biology; Dr. Maxine Singer, National Cancer Institute. Rapporteur: Dr. Joe Sambrook, Cold Spring Harbor Laboratory.

APPENDIX C.—SUMMARY OF THE WORKSHOP ON THE DESIGN AND TESTING OF SAFER PROKARYOTIC VEHICLES AND BACTERIAL HOSTS FOR RESEARCH ON RECOMBINANT DNA MOLECULES

TORREY PINES INN, LA JOLLA, CALIFORNIA

The development of techniques for the cloning of DNA from both prokaryotic and eukaryotic organisms in bacteria has had great impact on research in biology and medicine and promises extraordinary social benefits. The biohazards involved in the use of this technology in many instances are very difficult to assess. For this reason codes of practice are being formulated in the United States and other countries for the conduct of those experiments that present a potential biohazard. One of the requirements for conducting certain cloning experiments is the use of safer vector (bacteriophage or plasmid) -host systems, i.e., vector-bacterium systems that have restricted capacity to survive outside of controlled conditions in the laboratory. Approximately sixty scientists from the United States and several foreign countries participated in a workshop on the Design and Testing of Safer Prokaryotic Vehicles and Bacterial Hosts for Research on Recombinant DNA Molecules at La Jolla, California, on 1 to 3 December, 1975. The workshop was sponsored by the Research Resources Branch of the National Institute of Allergy and Infectious Diseases. The purposes of the meeting were the exchange of recent data on the development of safer prokaryotic host-vector systems, devising methods of testing the level of containment provided by these systems and exploring the various directions that future research should take in the construction of safer bacterial systems for the cloning of foreign DNA.

The first session of the workshop, chaired by W. Szybalski (University of Wisconsin), was devoted to bacteriophage vectors. Szybalski outlined the main safety features of the two-component, phage-bacterial system, in which the host bacteria offer the safety feature of not carrying the cloned DNA, and the phage vectors cannot be propagated in the absence of an appropriate host. There are two primary escape routes for the clones of foreign DNA carried by the phage vector: (1) establishment of a stable prophage or plasmid in the laboratory host used for phage propagation, and subsequent escape of this self replicating lysogen or carrier system, and (2) escape of the phage vector which carries the cloned DNA and its subsequent productive encounter with a suitable host in the natural environment. The general consensus was that to ensure safety, both routes should be blocked by appropriate genetic modifications. For phage λ, route (1) can be blocked by phage mutations that interfere with lysogenization (*att*⁻, *int*⁻, cI⁻, cIII⁻, *vir*) *and plasmid formation* (*N*⁻, *nin*R, *vS*, *ri*⁻, c17, Ots, crots), and by mutations on the *Escherichia coli* host that affect these processes (*att*B⁻, *dnc*Ats) and host survival. Route (2), [which is of low probability since λ phages do not survive well in natural environments (no λcI phage was recovered after ingestion of $10^8$–$10^{11}$ particles), are killed by desiccation, and have a low chance to encounter a naturally sensitive host] can be blocked further by the following phage modifications: (a) mutations which result in extreme instability of the infectious phage particles under all conditions other than those specially designed for phage propagation in the laboratory (e.g., high concentrations of putrescine or some other compound), or (b) employing phage vectors in which the tail genes are deleted and which permit propagation of only the DNA-packed heads; only under laboratory conditions could such heads be made transiently infec-

tious by rejoining them with separately prepared tails. The high instability of the phage would minimize the possibility of transfer of the cloned genes into receptive bacteria found in nature. Moreover, the propagation of the phage can be blocked by many conditional mutations, which would be designed to block any secondary route of escape, mainly depending on transfer of the cloned DNA into another phage or bacterial host. It was recommended further that the vector be designed in such a manner as to permit easy insertion and monitoring of the foreign DNA and rapid assay of the safety features and give a high yield of cloned DNA (not less than $10^{11}$ molecules per ml). There also was general agreement that host-phage systems other than *E. coli* should be considered, especially those restricted to very rare and unusual environments. Also, plasmids derived from phage vectors and which give very high DNA yields while exhibiting safety features, e.g., λdv*crots*, should be considered as vehicles for cloned DNA.

Szybalski and S. Brenner (Cambridge University) stressed that research on recombinant DNA molecules may lend itself to very simple and inexpensive mechanical containment, e.g., a small sealed glove box, since all the vectors that carry such recombinant molecules possibly can be both created and destroyed in such a box, while development of special methods might permit study of many properties of the recombinant DNA, without ever removing it from the box.

These safety features were reflected in the subsequent presentations. F. Blattner and W. Williams (University of Wisconsin) described four specially constructed λ–φ80 phages which incorporate many of these safety features, and which they named Charon phages, for the mythical boatman of the river Styx. Some of these highly contained phages give yields of over $10^{11}$ particles/ml. R. Davis, J. Cameron and K. Struhl (Stanford University) found that λ phages that carry foreign DNA never grow as well as the parental vector, which would select against their survival in nature. They also reported that some eukaryotic genes could be expressed in *E. coli*, partially compensating for deficiencies in the histidine pathway or in *polA* or *lig* functions. These investigators surveyed over 1000 strains of *E. coli* isolated in the natural environment and did not find a single strain that could support propagation of the λ*vir* vector.

V. Bode (Kansas State University) discussed the possibility of growing tail-free λ heads. Such heads, which are packed with DNA, are very fragile, unless stored in 0.01 M putrescine buffer. Head yields close to $10^{11}$/ml could easily be attained and, when required, heads could be quantitatively rejoined with separately supplied tails under special laboratory conditions. W. Arber, D. Scandella and J. Elliott (University of Basel) described bacterial host mutants that permit efficient infection only by phages with a full complement of DNA. This permits selecting for vectors that carry long fragments of foreign DNA.

K. Matsubara, T. Mukai and Y. Takagi (University of Osaka and Kyushu University), and G. Hobom and P. Phillippsen (University of Freiburg and Stanford University) described various defective λ plasmids (λdv) that could be used as efficient vectors. Matsubara has shown that temperature-sensitive *cro* mutations permit obtaining between 1000 and 3000 cloned molecules per cell and at the same time result in killing of the carrier cells at body temperature. The mutations *Ots* and *Pts* were also evaluated as safety features. Phillippsen described many new λdv plasmids created by cutting λ DNA with *Hind*III and *Bam*I restriction endonucleases followed by ligation. The final talk by F. Young, G. Wilson and M. Williams (University of Rochester) summarized the progress on the development of safer *Bacillus subtilis* host mutants and phages, especially φ3, as vectors. New restriction nucleases, Bgl–1 and Bgl–2, were also described.

The morning session on bacteriophage vectors was followed by a session on plasmid vectors that was chaired by D. Helinski (University of California, San Diego). Helinski presented the following properties as highly desirable characteristics of a safer plasmid vehicle: (a) non-conjugative; (b) non-mobilizable or poorly mobilizable by a conjugative plasmid; (c) possesses little or no extraneous genetic information; (d) poorly recombines or does not recombine with the chromosome of the host cell; (e) provides no selective advantage to the host cell or the selective property is conditional; and (f) possesses mutations that restrict its maintenance to a specific host, prevent replication at mammalian body temperature and/or provide the plasmid with the capability of killing any cell to which it might be transmitted other than the host cell. V. Hershfield (University of California, San Diego) described the properties of a variety of derivatives of the ColE1 plasmid and the broad-host range, P-type plasmid, RK2. One of the ColE1 derivatives, ColE1–*trp*, constructed in collaboration with C. Yanofsky and N. Franklin (Stanford University) provides the means to use the tryptophan genes of *E. coli* as a selective marker in transformation with recombinant DNA in situations where it is desirable to avoid antibiotic resistance genes. In addition, Hershfield described collaborative work with H. Boyer that resulted in the development of a mini-ColE1 plasmid and derivatives of this plasmid (mini-ColE1-*kan* and mini-ColE1-*trp*) as cloning vehicles. Finally, she described the temperature-sensitility properties of *trp* and *kan* derivatives of a temperature sensitive replication mutant of ColE1 isolated by J. Collins (Molecular biology Institute, Stockheim) and hybrid ColE1 plasmids carrying the *Eco*RI generated Cts fragment of bacteriophage λ-trp61.

J. Carbon (University of California, Santa Barbara) described a replica plating method that greatly facilitates the detection of *E. coli* clones bearing ColE1 plasmids. The procedure, which utilizes the F, plasmid to promote the transfer of a hybrid ColE1 plasmid to a suitable auxotrophic recipient, was successful in identifying clones bearing hybrid plasmids carrying a number of different regions of the *E. coli* chromosome. The contributions of A. J. Clark and collaborators (University of California, Berkeley) were relevant to the problem of the mobilization and subsequent transfer of non-conjugative plasmids carrying foreign DNA of a potentially hazardous nature. Clark described the variations in transmission frequencies between the nonconjugative plasmids pSC101, pML31, pSC138 and a number of pSC101 hybrids containing various *Eco*RI fragments of F when the conjugal transfer of these plasmids was promoted by several different conjugative plasmids.

I. C. Gunsalus and collaborators (University of Illinois) and A. Chakrabarty (General Electric Research and Development Center) described the properties of a variety of plasmids isolated from *Pseudomonas putida*. These contributions were followed by a discussion on the merits of developing plasmid-host systems involving *Pseudomonas strains* that naturally exhibit unusual growth requirements. Similar studies with plasmids isolated from *Bacillus megaterium* by B. Carlton (University of Georgia) from *B. subtilis* by P. Lovett (University of Maryland) and other naturally occurring *Bacillus* species by W. Goebel and K. Bernhard (Microbiology Institute, Wurzburg) were discussed and their further development as plasmid-host cloning systems was explored. It was clear from these presentations that considerable progress has been made recently in the identification and characterization of a variety of plasmid elements that occur naturally in *Pseudomonas* and *Bacillus* species. Several of the plasmids described show considerable promise as plasmid cloning systems involving a host other than *E. coli*.

A third session on the ecology and epidemiology of vector-host systems was chaired by S. Falkow (University of Washington). This workshop emerged, in part, from expressed fears that microorganisms containing cloned fragments of foreign DNA potentially pose a threat to health or disrupt the normal ecological chain in some manner. Consequently, this session was devoted to a review of currently available information on the ecology and epidemiology of *E. coli* and related bacterial species since it was recognized that *E. coli* K–12 would be the prokaryotic host most commonly employed in the cloning of DNA molecules in the immediate future. F. Orskov (Escherichia Reference Center, Copenhagen) reviewed the state of *E. coli* serotyping and what has been learned about the distribtuion of *E. coli* types in health and disease. Only certain *E. coli* types are generally recognized as good colonizers of the human gut and such strains come from a handful of the 160 well defined O (lipopolysaccharide) antigen types and invariably posses K (acidic polysaccharide capsule) antigens. Some serotypes apparently have become disseminated worldwide and possibly represent the proliferation of a bacterial clone because of, as yet unkown, selective pressures. In contrast, *E. coli* K–12 has no detectable O or K antigens and is considered to be rough. This may account, at least in part, for its demonstrable poor ability to colonize the human or animal gut. However, R. Freter (University of Michigan) point out that we still remain largely ignorant of the factors which control intestinal *E. coli* populations. Freter also noted that while adherence to the mucosal surface of the small intestine is important in the pathogenesis of *E. coli* diarrheal disease, the "normal" long-lasting symbiotic relationship between a mammalian host and bacterium is established in the cecum and colon. It is in these locations that factors come into play to determine whether an *E. coli* strain passing through the intestine will become successfully implanted or whether it will be quickly eliminated in the feces.

The factors controlling implantation include competition for substrates, inhibitors and the physiological state of the organism when it reaches the large bowel. For example, ingested *E. coli* previously grown under usual laboratory conditions fare poorly while cells of the same strain "pre-adapted" in Eh, pH, etc., often colonize well. Freter has developed a continuous flow culture model which may be useful in studying the mechanisms of implantation. Falkow reviewed the pathogenicity of *E. coli*. *E. coli* causes diarrheal disease either by direct invasion of the bowel epithelium or by elaboration of enterotoxin(s). While invasive *E. coli* appear to owe their pathogenicity to a constellation of at least five unlinked chromosomal gene clusters, toxigenic *E. coli* species generally owe their pathogenicity to the possession of two species, Ent and K. The introduction of Ent and K plasmids may be sufficient to convert a normal wild-type *E. coli* into a strain now capable of causing overt clinical disease. However, the introduction of these plasmids into *E. coli* K–12 sublines had no discernible effect on their ability to cause disease, although the K–12 strains could now better colonize calves. Despite the observation that

*E. coli* K-12 did not appear to offer a significant hazard as a potential enteric pathogen even when it possessed well-defined determinants of pathogenicity it was emphasized by Orskov, Freter and Falkow that *E. coli* K-12 strains carrying recombinant DNA molecules could still act as effective genetic donors *in vivo* and still posed a significant problem requiring control. E. Geldreich (U.S. Environmental Protection Agency, Cincinnati, Ohio) discussed the possible outcomes of the release of *E. coli* containing recombinant DNA molecules into the aquatic environment and concluded that total reliance cannot be placed on sewage treatment and the natural self-purification capacity of receiving waters to limit potential hazards. While these are realistic barriers to the dissemination of *E. coli* and associated fecal organisms via the water route, they are not infallible because of technological limitations, improper operational practices and system overloading. Finally, M. Starr University of California, Davis) described the numerous genera of gram-negative bacteria found naturally occurring in the soil and on plants. He stated that most of these organisms do not appear to be a reasonable alternative to *E. coli* K-12 as a host for recombinant DNA molecules. Indeed, Starr pointed out that since such genera as *Erwinia, Rhizobium* and *Agrobacterium* are known to conjugate with *E. coli*, the potential dissemination of recombinant DNA molecule includes a greater spectrum of microorganisms than just enteric species.

The fourth session of the workshop, chaired by R. Curtiss III (University of Alabama), was concerned with the construction of safer bacterial hosts for DNA cloning. The goals in constructing safer host strains enumerated at the beginning of the session included introduction of mutations that would: (a) preclude colonization in normal ecological niches; (b) preclude cell wall biosynthesis except in specially defined media; (c) cause degradation of genetic information in normal ecological niches; (d) cause vectors to be host-dependent; (e) minimize transmission of recombinant DNA to other strains in normal ecological niches; (f) increase usefulness for recombinant DNA molecule research; and (g) permit monitoring.

Most of the progress in developing safer hosts has been achieved with *E. coli* K-12, although F. Young described a *B. subtilis* strain with a deletion for sporulation genes which readily undergoes autolysis. The strain also has defects in genes for purine and TTP biosynthesis and a mutation conferring a D-alanine requirement can be introduced to cause cell wall biosynthesis to be defective. This strain may be defective in transformation, however, and therefore might be useful only with a phage vector which has yet to be developed and/or discovered.

A. I. Bukhari (Cold Spring Harbor Laboratory) described the use of the *dapD8* mutation in *E. coli* K-12 to block cell wall biosynthesis and another non-reverting mutation which causes sensitivity to bile salts and detergents. The *dapD8* allele is the most stable *dap* point mutation known, although it does revert at frequencies of $10^{-8}$ to $10^{-9}$. The mutation conferring bile salts sensitivity was obtained after Mu-1 infection of an Hfr strain and, although exhibiting the theoretically useful properties of ease of DNA isolation and inability to survive in the intestinal tract, might be due to Mu insertion which would compromise its use for safe strain construction.

Curtiss reported on the work performed by him and his coworkers in constructing and testing numerous strains with different mutations. Survival of strains *in vivo* was tested by feeding rats $10^{10}$ cells in milk by stomach tube. △*pur* mutations did not reduce strain titers in feces whereas △*thyA*; △*thyA drm*; and △*thyA dra* mutations gave $10^2$-fold, $10^3$-fold and $10^5$-fold reductions, respectively, in strain titers in feces. Strains with △*thyA* mutations also exhibited thymineless death in *in vitro* tests. Since strains with the *dapD8* allele can revert to Dap+ strains were constructed with both the *dapDs and* △*bioH-asd mutations*. These strains have not been observed to revert to Dap+ but can survive passage through the rat intestine and in growth media lacking diaminopimelic acid but containing NaCl and 0.5% usable carbon sources. This survival was due to the production of the mucopolysaccharide, colanic acid, which permits many of the cells to grow and survive as spheroplasts. A △*gal-chl*$^r$ mutation (also deletes λ*att*, *bio* and *uvrB* genes) was introduced which blocks colanic acid biosynthesis and leads to no detectable survivors in media lacking diaminopimelic acid or following passage through the rat intestine. The *dapD8* △*bioH-asd* △*gal-chl*$^r$ strains are more readily lysed, transform at higher frequencies and are conjugation-defective in matings with donors possessing conjugative plasmids in the P, W and O incompatibility groups but Con+ as recipients for F, I and T group plasmids when compared to the dap+ *gal*+ parent strain. Strains with *endA mutations* were also observed to exhibit increased transformation frequencies. Attempts to introduce temperature-sensitive *polA* alleles into strains to block replication of ColE1 cloning vectors at elevated temperatures and to cause DNA degradation at elevated temperatures in the presence of *recA* and △*thyA* alleles often do not have the same properties in the constructed strains as in the strains in which the allele was originally induced. Many mutations causing a Con- phenotype have been investigated, but many of these revert or do not exhibit a Con- phenotype in matings with donors possessing conjugative plasmids of the incompatibility groups commonly found in enteric microorganisms. Some Con- mutants exhibit increased sensitivity to bile salts; thus, the mutant described by Bukhari may also exhibit a Con- phenotype. All of the strains constructed by the Curtiss group are SuII+ and most have mutations abolishing restriction alone or both restriction and modification. Thus, sufficient information is now known to construct a usable safer *E. coli* K-12 host. Curtiss and collaborators are now introducing the △*thyA* and *dna* mutations into their *dapD8* △*bio-asd* △*gal-chl*$^r$*-uvrB hsr nalA*$^r$ (for ase in monitoring) Su+ λ$^r$ Φ80$^r$ strain to accomplish this objective.

The final session involved a general discussion of some of the major points raised previously in the workshop. There was general agreement at this session that both plasmid-host and phage-host systems have been developed that should meet the criteria of an EK2 system specified by the National Institutes of Health guidelines for research on recombinant DNA molecules. Additional testing is required to confirm the EK2 properties of these available systems, but it is anticipated that these vector-host systems will meet these tests.

Dr. Donald R. Helinski, University of California, San Diego.

Dr. Stanley Falkow, University of Washington.

Dr. Roy Curtiss III, University of Alabama.

Dr. Waclaw Szybalski, University of Wisconsin.

## Appendix D.—Supplementary Information on Physical Containment

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### I. BIOLOGICAL SAFETY CABINETS

Biological Safety Cabinets suitable for confining operations involving recombinant DNA molecules are described below:

1. *Class I.* A ventilated cabinet for personnel protection only, with an unrecirculated inward flow of air away from the operator. The exhaust air from this cabinet may be filtered through a high-efficiency or high-efficiency particulate air (HEPA) filter before being discharged to the outside atmosphere. This cabinet is suitable for research work with the Center for Disease Control (CDC) classes of etiologic agents 1, 2 and 3 where no product protection is required. This cabinet may be used in three operational modes: (i) with an eight-inch high, full-width open front; (ii) with an installed front closure panel (having four, eight-inch diameter openings) without gloves; and (iii) with an installed front closure panel equipped with arm length rubber gloves. See Table I for ventilation requirements, agent use limitations, and minimum performance requirements.

2. *Class II.* A ventilated cabinet for personnel and product protection having an

open front with inward air flow for personnel protection, and HEPA-filtered recirculated mass air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. Two models of this cabinet are available, Type 1 and Type 2.

(i) *Type 1.* The Type 1 recirculates approximately 70% of the air. The exhaust air from this cabinet may discharge into the laboratory or be diverted out of the laboratory. This cabinet is suitable for CDC classes of etiologic agents 1, 2, and 3. Vapors or gases which are hazardous from a toxic, radioactive, or flammability standpoint should not be used in this cabinet because of the high quantity of recirculated air.

(ii) *Type 2.* The Type 2 cabinet recirculates approximately 30% of the air. The exhaust air from this cabinet is normally ducted out of the laboratory through a HEPA filter and, occasionally, an activated charcoal filter depending on the operation. The cabinet may be used with gases or vapors that are hazardous from a toxic, radioactive, or flammability standpoint. However, any consideration of use of such materials should be evaluated carefully from the standpoint of build-up to dangerous levels and problems of decontamination of the cabinet. See Table I for ventilation requirements, agent use limitations, and minimum performance requirements.

3. *Class III.* A closed front ventilated cabinet of gas-tight construction providing total protection for personnel and product from contaminants exterior to the cabinet. The cabinet is operated under a negative pressure of at least 0.5 inches water gauge. All supply air is HEPA-filtered. Exhaust air is HEPA-filtered or incinerated to protect the environment. This cabinet, fitted with arm length rubber gloves, provides the highest containment of these three classes of cabinets and is utilized for all activities involving high risk agents (i.e., CDC etiologic agents, class 4). See Table I for ventilation requirements, agent use limitations, and minimum performance requirements.

The integrity of any cabinet depends on initial and periodic evaluation to meet established performance tests. Table I outlines the minimum performance required to assure that the cabinets will provide protection of personnel and the environment.

TABLE I.—*Biological safety cabinets, safety performance requirements, and specifications, June 1976*

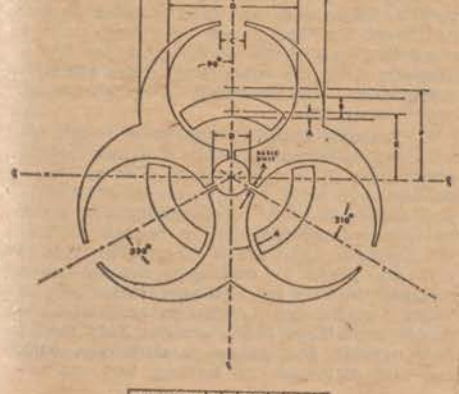
| Cabinet | Use classification | | Performance requirements | | | | Exhaust filter efficiency (percent) |
|---|---|---|---|---|---|---|---|
| | | | Face velocity | Exhaust air (cubic feet per minute) | | Leak tightness | |
| | DNA [1] | CDC [2] | (linear feet per minute) | 4-ft hood | 6-ft hood | | |
| Class I | P1-P3 | 1-3 | 75 | 200 | 300 | Not applicable | 99.97 |
| Class II, type 1 | P1-P3 | 1-3 | 75 | 260 | 400 | Gas tight; leak rate <1 by $10^{-6}$ cm³/s 2-in water gage pressure. | 99.97 |
| Class II, type 2 | P1-P3 | 1-3 | 100 | 250 | 360 | Pressure tight; no air/soap bubble at 2-in water gage pressure. | 99.97 |
| Class III | P4 | 4 | [3] | [4] | [4] | Gas tight; leak rate <1 by $10^{-6}$ cm³/s at 3-in water gage pressure. | 99.97 |

[1] For work with recombinant DNA molecules.
[2] Center for Disease Control (U.S. Public Health Service).
[3] Not applicable.
[4] Based on 1 vol. of air change each 3 min, in the absence of unusual heat or moisture that would require more air changes.

II. UNIVERSAL BIOHAZARD WARNING SYMBOL (1)

The biological hazard warning symbol (biohazard symbol) specified herein shall be used to signify the actual or potential presence of a biohazard and to identify equipment, containers, rooms, materials, experimental animals or combinations thereof which contain or are contaminated with viable hazardous agents.

The biohazard symbol shall be designed and proportioned as illustrated here:



| DIMENSION | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| UNITS | 7 | 3½ | 4 | 4 | 11 | 13 | 21 | 30 |

The symbol shall be as prominent as practical, and of a size consistent with the size of the equipment or material to which it is affixed, provided the proportions shown above are maintained, and, in any case, that the symbol can be easily seen from as many directions as possible.

Except when circumstances do not permit, the symbol shall be oriented with one of the three open circles pointed up and the other two forming a base.

The symbol color shall be a fluorescent orange or orange-red color.* Background color is optional as long as there is sufficient contrast for the symbol to be clearly defined.




Revised 9-3-66
*Day-Glo® Fire Orange of the Switzer Brothers, Inc. is cited as an example, not an endorsement.

The biohazard symbol shall be used or displayed only to signify the actual or potential presence of biological hazard.

Appropriate wording may be used in association with the symbol to indicate the nature or identity of the hazard, name of individual responsible for its control, precautionary information, etc., but never should this information be superimposed on the symbol.





ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

Hazard identity: _____

Responsible investigator: _____

In case of emergency call:

Daytime phone _____ Home phone _____

Authorization for entrance must be obtained from the Responsible investigator named above.

III. LABORATORY TECHNIQUES FOR BIOHAZARD CONTROL

*A. Pipetting*

1. No infectious or toxic materials should be pipetted by mouth (2, 3, 4).

2. No infectious mixtures should be prepared by bubbling expiratory air through a liquid with a pipette (2, 3, 4).

3. No infectious material should be blown out of pipettes (2, 3, 4).

4. Pipettes used for the pipetting of infectious or toxic materials should be plugged with cotton (2, 3, 4).

5. Contaminated pipettes should be placed horizontally in a pan containing enough suitable disinfectant to allow complete immersion (2, 4, 4). They should not be placed vertically in a cylinder.

6. The pan and pipettes should be autoclaved as a unit and replaced by a clean pan with fresh disinfectant (2, 3, 4).

7. Infectious material should not be mixed by alternate suction and expulsion through a pipette (2, 3, 4).

8. Mark-to-mark pipettes are preferable to other types, as they do not require expulsion of the last drop (5).

9. Discharge should be as close as possible to the fluid or agar level, or the contents should be allowed to run down the wall of the tube or bottle whenever possible—not dropped from a height (5).

10. A disinfectant-wetted towel over the immediate work surface is useful in some cases to minimize the splash from accidental droppage (9).

*B. Syringes and Needles* (9)

1. To lessen the chance of accidental injection, aerosol production or spills, avoid unnecessary use of the syringe and needle. For instance:

(i) Use the needle for parenteral injections but use a blunt needle or a cannula on the syringe for oral or intranasal inoculations.

(ii) Do not use a syringe and needle as a substitute for a pipette in making dilutions of dangerous fluids.

2. Use the syringe and needle in a Biological Safety Cabinet only and avoid quick and unnecessary movements of the hand holding the syringe.

3. Examine glass syringes for chips and cracks, and needles for barbs and plugs.

Note: This should be done prior to sterilization before use.

4. Use needle-locking (Luer-Lok® type) syringes only, and be sure that the needle is locked securely into the barrel. A disposable syringe-needle unit (where the needle is an integral part of the unit) is preferred.

5. Wear surgical or other type rubber gloves for all manipulations with needles and syringes.

6. Fill the syringe carefully to minimize air bubbles and frothing of the inoculum.

7. Expel excess air, liquid and bubbles from a syringe vertically into a cotton pledget moistened with the proper disinfectant, or into a small bottle of sterile cotton.

8. Do not use the syringe to expel forcefully a stream of infectious fluid into an open vial or tube for the purpose of mixing. Mixing with a syringe is condoned only if the tip of the needle is held below the surface of the fluid in the tube.

9. If syringes are filled from test tubes, take care not to contaminate the hub of the needle, as this may result in transfer of infectious material to the fingers.

10. When removing a syringe and needle from a rubber-stoppered bottle, wrap the needle and stopper in a cotton pledget moistened with the proper disinfectant. If there is danger of the disinfectant contaminating sensitive experiments, a sterile dry pledget may be used and discarded immediately into disinfectant solution.

11. Inoculate animals with the hand "behind" the needle to avoid punctures.

12. Be sure the animal is properly restrained prior to the inoculation, and be on the alert for any unexpected movements of the animal.

13. Before and after injection of an animal, swab the site of injection with a disinfectant.

14. Discard syringes into a pan of disinfectant without removing the needle. The syringe first may be filled with disinfectant by immersing the needle and slowly withdrawing the plunger, and finally removing the plunger and placing it separately into the disinfectant. The filling action clears the needle and dilutes the contents of the syringe. Autoclave syringes and needles in the pan of disinfectant.

15. Use separate pans of disinfectant for disposable and nondisposable syringes and needles to eliminate a sorting problem in the service area.

16. Do not discard syringes and needles into pans containing pipettes or other glassware that must be sorted out from the syringes and needles.

*C. Opening Culture Plates, Tubes, Bottles, and Ampoules*

1. Plates, tubes and bottles of fungi may release spores in large numbers when opened. Such cultures should be manipulated in a Biological Safety Cabinet (6, 15).

2. In the absence of definite accidents or obvious spillage, it is not certain that opening of plates, tubes and bottles of other microorganisms has caused laboratory infection. However, it is probable that among the highly infective agents, some infections have occurred by this means and are represented in the 80% for which no known act or accident is ascribable (3).

3. Water of syneresis in petri dish cultures is usually infected and forms a film between the rim and lid of the inverted plate. Aerosols are dispersed when this film is broken by opening the plate. Vented plastic petri dishes where the lid touches the rim at only three points are less likely to offer this hazard (8, 19).

4. The risk may also be minimized by using properly dried plates, but even these (when incubated anaerobically) are likely to be wet after removal from an anaerobic jar. Filter papers fitted into the lids reduce, but do not prevent, dispersal. If plates are obviously wet they should be opened in the Biological Safety Cabinet (8).

5. Less obvious is the release of aerosols when screw-capped bottles or plugged tubes are opened. This happens when a film of infected liquid which may collect between the rim and the liner is broken during removal of the closure (8).

6. Dried, infected culture material may also collect at or near the rim or neck of culture tubes and may be dispersed into the air when disturbed (18). Containers of dry powdered hazardous materials (e.g., Class 3 fungal agents in the spore phase of growth) should be opened only in a Biological Safety Cabinet (6, 14).

7. When the neck of an ampoule containing liquid is broken after nicking with a file, the snapping action creates aerosols. The following methods have been recommended:

(i) After nicking the ampoule with a file, wrap the ampoule in disinfectant-wetted cotton before breaking. Wear gloves (2).

(ii) The bottom of the ampoule should be held in several layers of tissue paper to protect the hands, and a file mark made at the neck. A hot glass rod should be carefully applied to the mark. The glass will crack, allowing air to enter the ampoule and equalize the pressures. After a few seconds the ampoule should be wrapped in a few layers of tissue and broken along the crack. The tissues and ampoule neck can then be discarded into disinfectant, and the contents of the ampoule removed with a syringe. If the ampoule contains dried cultures, about 0.5 $cm^3$ of broth should be added slowly to avoid blowing dried material out. The contents may then be mixed without bubbling and withdrawn into a culture tube (8).

(iii) The researcher uses an intense, but tiny, gas-oxygen flame and heats the tip of the hard glass ampoule until the expanding internal air pressure blows a bubble. After allowing this to cool, he breaks the bubble while holding it in a large low temperature flame; this immediately incinerates any infectious dust which may come from the ampoule when the glass is broken (16). Preliminary practice with a simulant ampoule of the same type actually in use is necessary to develop a technique that will not cause explosion of the ampoule.

(iv) A simple device has been recommended consisting of a sleeve of rubber tubing into which the ampoule is inserted before it is broken (17, 18).

*D. Centrifuging*

1. A safety centrifuge cabinet or safety centrifuge cup (3, 7, 8, 14, 22) may be used to house or safeguard all centrifuging of infectious substances. When bench type centrifuges are used in a Biological Safety Cabinet, the glove panel should be in place with the glove ports covered. The centrifuge operation creates air currents that may cause escape of agent from an open cabinet (2, 3, 4, 13).

2. In some situations, in the absence of O-ring cap sealed trunnion cups, specimens can be enclosed in sealed plastic bags before centrifugation (12).

3. Before centrifuging, inspect tubes for cracks, inspect the inside of the trunnion cup for rough walls caused by erosion or adhering matter, and carefully remove bits of glass from the rubber cushion (4, 10).

4. A germicidal solution should be added between the tube and trunnion cup to disinfect the materials in case of accidential breakage. This practice also provides an excellent cushion against shocks that might otherwise break the tube (4, 10).

5. Avoid decanting centrifuge tubes. If you must do so, afterwards wipe off the outer rim with a disinfectant; otherwise the infectious fluid will spin off as an aerosol (4, 10).

6. Avoid filling the tube to the point that the rim, cap or cotton plug ever becomes wet with culture (4, 10).

7. Screw caps, or caps which fit over the rim outside the centrifuge tube are safer than plug-in closures. Some fluid usually collects between a plug-in closure and the rim of the tube. Even screw-capped bottles are not without risk, however; if the rim is soiled some fluid will escape down the outside of the tube. Screw-capped bottles may jam in the bucket, and removing them is hazardous. Propping such bottles higher in the bucket with additional rubber buffers is mechanically unsound (8).

8. Kitchen foil is often used to cap centrifuge tubes. This creates more risk than the screw cap. Foil caps often become detached in handling and centrifuging (8).

9. The balancing of buckets is often mismaanged. Care must be taken to ensure that matched sets of trunnions, buckets and plastic inserts do not become mixed. If the components are not inscribed with their weights by the manufacturer, colored stains can be applied to avoid confusion. When the tubes are balanced, the buckets, trunnions and inserts should be included in the procedure; and care must be taken to ensure that the centers of gravity of the tubes are equidistant from the axis of rotation. To illustrate the importance of this, two identical tubes containing 20 g of mercury and 20 g of water respectively will balance perfectly on the scales; but their performance in motion is totally different, leading to violent vibration with all its attendant hazards (5).

10. Fill and open centrifuge tubes or trunnion cups in a Biological Safety Cabinet (10).

*E. High-Speed Centrifuges (22)*

1. In high-speed centrifuges the bowl is connected to a vacuum pump. If there is a breakage or accidental dispersion of infected particles the pump and the oil in it will become contaminated. A high efficiency filter should be placed between the centrifuge and the pump (8).

2. High speed rotor heads are prone to metal fatigue, and where there is a chance that they may be used on more than one machine each rotor should be accompanied by its own log book indicating the number of hours run at top or de-rated speeds. Failure to observe this precaution can result in dangerous and expensive disintegration. Frequent inspection, cleaning and drying are important to ensure absence of corrosion or other traumata which may lead to creeping cracks. Rubber O-rings and tube closures must be examined for deterioration and be kept lubricated with the material recommended by the makers. Where tubes of different materials are provided (e.g., celluloid, polypropylene, stainless steel), care must be taken that the tube closures designed specifically for the type of tube in use are employed. These caps are often similar in appearance, but are prone to leakage if applied to tubes of the wrong material. When properly designed tubes and rotors are well maintained and handled, leaking should never occur (5).

3. Cleaning and disinfection of tubes, rotors and other components requires considerable care. It is unfortunate that no single process is suitable for all items, and the various manufacturers' recommendations must be followed meticulously if fatigue, distortion and corrosion are to be avoided. This is not the place to catalogue recommended methods, but one less well appreciated fact is worthy of mention. Celluloid (cellulose nitrate) centrifuge tubes are not only highly inflammable and prone to shrinkage with age and distortion on boiling, but can be-

have as high explosive in an autoclave (5). Large-scale zonal centrifugation requires special attention (11).

*F. Blenders, Ultrasonic Disintegrators, Colloid Mills, Ball Mills, Jet Mills, Grinders, Mortar and Pestle.*

All these devices release considerable aerosols during their operation. For maximum protection to the operator during the blending of infectious materials, the following practices should be observed:

1. Operate blending and cell-disruption and grinding equipment in a Biological Safety Cabinet (9).

2. Use safety blenders designed to prevent leakage from the rotor bearing at the bottom of the bowl (9).

3. In the absence of a leak-proof rotor, inspect the rotor bearing at the bottom of the blender bowl for leakage prior to operation. Test it in a preliminary run with sterile saline or methylene blue solution prior to use with infected material (9).

4. Sterilize the device and residual infectious contents promptly after use. Use a towel moistened with disinfectant over the top of the blender (9).

5. Glass blender bowls are undesirable for use with infectious material because of potential breakage. If used, they should be covered with a polypropylene jar to prevent dispersal of glass (8).

6. A new machine, the Colworth Stomacker (England), in which material is homogenized in a plastic bag in a closed container, would appear to be safer than some of the other blenders (8).

7. A heat-sealed flexible plastic film enclosure for a grinder or blender can be used, but it must be opened in a Biological Safety Cabinet (7).

8. Blender bowls sometimes require supplemental cooling to prevent destruction of the bearings and to minimize thermal efforts on the product (7).

9. Before opening the safety blender bowl, permit the blender to rest for at least one minute to allow settling of the aerosol cloud.

10. Clinical or other laboratories handling human blood should be aware of the aerosols produced by the microhaematocrit centrifuge, the autoanalyzer stirrer, and the microtonometer, inasmuch as it seems that airborne transmission of infectious hepatitis may occur in the laboratory (20).

*G. Miscellaneous Precautions and Recommendations*

1. Water baths and Warburg baths used to inactive, incubate, or test infectious substances should contain a disinfectant. For cold water baths, 70% propylene glycol is recommended (4, 10).

2. Deepfreeze, liquid nitrogen, and dry ice chests and refrigerators should be checked and cleaned out periodically to remove any broken ampoules, tubes, etc., containing infectious material, and decontaminated. Use rubber gloves and respiratory protection during this cleaning. All infectious or toxic material stored in refrigerators or deepfreezes should be properly labelled. Security measures should be commensurate with the hazards (4, 10, 21).

3. Freeze-dried culture ampoules should always be opened in a Biological Safety Cabinet. The ampoule should be wrapped in a disinfectant-soaked swab before breaking it open to minimize the risk of cutting the hands, and to a lesser extent of releasing aerosol of dried material. Whenever possible, ampoules should be filled with dry nitrogen after freeze-drying, thus avoiding implosion that may occur during the sealing as well as opening of evacuated ampoules. The whole process of freeze-drying itself should be performed in a Biological Safety Cabinet. Filtration of the effluent air from the vacuum pump is desirable either up (preferably), or down stream of the pump (5).

4. Ensure that all virulent fluid cultures or viable powdered infectious materials in glass vessels are transported, incubated, and stored in easily handled, nonbreakable leakproof containers that are large enough to contain all the fluid or powder in case of leakage or breakage of the glass vessel (4, 10).

5. All inoculated petri plates or other inoculated solid media should be transported and incubated in leak-proof pans or leakproof containers (4, 10).

6. Care must be exercised in the use of membrane filters to obtain sterile filtrates of infectious materials. Because of the fragility of the membrane and other factors, such filtrates cannot be handled as noninfectious until culture or other tests have proved their sterility (4, 10).

7. Shaking machines should be examined carefully for potential breakage of flasks or other containers being shaken. Screw capped durable plastic or heavy walled glass flasks should be used. These should be securely fastened to the shaker platform. An additional precaution would be to enclose the flask in a plastic bag with or without an absorbent material.

8. No person should work alone on an extremely hazardous operation (4, 10).

IV. PERSONAL HYGIENE, HABITS, AND PRACTICES

Personal hygienic practices in the laboratory are directed, in most part, toward the prevention of occupationally acquired physical injury or disease. To a less obvious extent, they can raise the quality of the laboratory work by reducing the possibilities for contamination of experimental materials. The reasons for many of the recommended precautions and practices are obvious, but, in some instances, amplification will permit a better review of the applicability to any one specific laboratory.

Consequently, what might be forbidden in one laboratory might be only discouraged in another, and be permissible in a third. Nevertheless, adherence to safe practices that become habitual, even when seemingly not essential, provides a margin of safety in situations where the hazard is unrecognized. The history of occupational injury is replete with examples of hazards unrecognized until too late. The following guidelines, recommendations, and comments are presented with this in mind:

1. Food, candy, gum, and beverages for human consumption will be stored and consumed only outside the laboratory (5, 10).

2. Foot-operated drinking fountains should be the sole source of water for drinking by human occupants of the laboratory (27).

3. Smoking is not permitted in the laboratory or animal quarters. Cigarettes, pipes, and tobacco will be kept only in clean areas (5, 10, 26).

4. Shaving and brushing of teeth are not permitted in the laboratory. Razors, toothbrushes, toiletry supplies, and cosmetics are permissible only in clean change rooms or other clean areas, and should never be used until after showering or thorough washing of the face and hands (27).

5. A beard may be undesirable in the laboratory in the presence of actual or potential airborne contamination, because it retains particulate contamination more persistently than clean-shaven skin. A clean-shaven face is essential to the adequate facial fit of a face mask or respirator when the work requires respiratory protection (10, 27, 31).

6. Develop the habit of keeping hands away from mouth, nose, eyes, face, and hair. This may prevent self-inoculation (10, 27).

7. For product protection, persons with long hair should wear a suitable hair net or head cover that can be decontaminated. This has long been a requirements in hospital operating rooms and in the manufacture of biological pharmaceutical products. A head cover also will protect the hair from fluid splashes, from swinging into Bunsen flames and petri dishes, and will reduce facial contamination caused by habitual repetitive manual adjustment of the hair (5).

8. Long-flowing hair and loose-flapping clothing are dangerous in the presence of open flame or moving machinery. Rings and wrist watches also are a mechanical hazard during operation of some types of machines (5, 10).

9. Contact lenses do not provide eye protection. The capillary space between the contact lenses and the cornea may trap any material present on the surface of the eye. Caustic chemicals trapped in this space cannot be washed off the surface of the cornea. If the material in the eye is painful or the contact lens is displaced, muscle spasms will make it very difficult, if not impossible, to remove the lens. For this reason, contact lenses must not be worn by persons exposed to caustic chemicals unless safety glasses with side shields, goggles, or plastic face masks are also worn to provide full protection. It is the responsibility of supervisors to identify employees who wear contact lenses (25, 26).

10. Personal items, such as coats, hats, storm rubbers or overshoes, umbrellas, purses, etc., do not belong in the laboratory. These articles should be kept elsewhere (25).

11. Plants, cut flowers, an aquarium, and pets of any kind are undesirable sources of yeast, molds, and other potential microbial contaminants of biological experimental materials (25).

12. Books and journals returnable to the institutional library should be used only in the clean areas as much as possible (10, 27).

13. When change rooms with showers are provided, the employer should furnish skin lotion (27).

14. When employees are subject to potential occupational infection, the shower and/or face/hand-washing facilities should be provided with germicidal soap (8, 27).

15. Personal cloth handkerchiefs should not be used in the laboratory. Cleansing tissue should be available instead.

16. Hand washing for personal protection:

(i) This should be done promptly after removing protective gloves. Tests show it is not unusual for microbial or chemical contamination to be present despite use of gloves, due to unrecognized small holes, abrasions, tears, or entry at the wrist.

(ii) Throughout the day, at intervals dictated by the nature of the work, the hands should be washed. Presence of a wrist watch discourages adequate washing of the wrist (10, 25).

(iii) Hands should be washed after removing soiled protective clothing, before leaving laboratory area, before eating, and before smoking. The provision of hand cream by the employer encourages these practices (5, 8, 10).

(iv) A disinfectant wash or dip may be desirable in some cases, but its use must not be carried to the point of causing roughening, desiccation or sensitization of the skin.

17. Anyone with a fresh or healing cut, abrasion, or skin lesion should not work with infective material unless the injured area is completely protected (8, 25).

18. Persons vaccinated for smallpox may be shedders of vaccinia virus during the phase of cutaneous reaction. Therefore, vaccination requires permission of the appropriate supervisor, because two weeks' absence may be necessary before returning to work with

normal cell cultures or with susceptible animals, especially the normal mouse colony (25).

19. The surgeon's mask of gauze or filter paper is of little value for personal respiratory protection (29). It is designed to prevent escape of droplets from the nose or mouth (23G). If biohazards demand respiratory protection, then nothing but a full face respirator or ventilated hood will suffice. A half-mask respirator does not protect the eyes, which are an unevaluated avenue of infection through the conjunctiva and the nasolacrimal duct (5, 8).

20. Nonspecific contamination by environmental organisms from humans, animals, equipment, containers for specimens or supplies, and outside air is a complication that may affect or invalidate the results of an experiment. The human sources of this contamination are evaluated as follows:

(i) Sneezing, coughing and talking (23A, 24A). Sneezing, variously reported to generate as many 32,000 or 1,000,000 droplets below 100 microns in diameter; coughing, which produces fewer and larger droplets; and talking, which has been reported to average only 250 droplets when speaking 100 words, show great differences between persons in regard to the number of microorganisms aerosolized. As a general rule, it may be said that these actions by normal healthy persons may play a less important role in transmission or airborne infection to humans or experimental materials than does liberation of microorganisms from human skin.

(ii) Dispersal of bacteria from human skin. There is a tremendous variation in the number of bacteria shed from the skin by a clothed subject. For instance, in one study, the number varied from 6,000 to 60,000 per minute (23C). These bacteria were released on skin scales which were of a size that could penetrate the coarse fabric used for the laboratory and surgical clothing in the test (23D). Dispersal of skin bacteria was several times greater from below the waist than from upper parts of the body (24D). Effective reduction is accomplished by use of closely-woven or impervious clothing fitted tightly at the neck, wrists, and ankles to prevent the clothing from acting as a bellows that disperses air carrying skin scales laden with bacteria (23B). Such clothing sometimes is too warm to work in. It was found that a significant reduction in dispersal of bacteria occurred with the wearing of close-fitting and closely-woven underpants beneath the usual laboratory clothing (23D). The purpose of this summary is to alert laboratory personnel to the existence of this source of contamination (9).

(iii) Prolific dispersal of bacteria occurs from infected abrasions, small pustles, boils, and skin disease (23F, 24B). Washing the lesions with germicidal soap will greatly decrease the number of organisms on the skin and dispersal into the air. Healthy nasal carriers who generate aerosolized staphylococci usually can be identified by the presence of heavy contamination of their fingers, face, and hair (23E). This point may be useful in investigating the source of staphylococcal contamination of cell lines.

(iv) Footwear. In moderate and high risk situations, shoes reserved for only laboratory use have been recommended as a precaution against transporting spilled infectious agents outside the laboratory. However, in experiments during which reduction of potential contamination of experimental materials is important, laboratory-only shoes can reduce the microbial load brought into the laboratory each day by street shoes. Shoes are efficient transporters. In one study, there were 4 to 850 times as many bacteria per square centimeter on the laboratory footwear as on the floor itself (30).

## V. CARE AND USE OF LABORATORY ANIMALS (10,32–37)

### *A. Care and Handling*

1. Special attention must be given to the humane treatment of all laboratory animals in accordance with the Animal Welfare Act of 1970. The implementing rules and regulations appear in the Code of Federal Regulations (CFR) Title 9, Chapter 1, Subchapter A, parts 1, 2, 3. Recommended provisions and practices that meet the requirements of the Act have been published by the U.S. Public Health Service (32).

2. There are specific minimum requirements (33) concerning the caging, feeding, watering, and sanitation for dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. To meet these requirements, the animal room supervisor must have a copy of 9 CFR Chapter 1, Subchapter A, Parts 1, 2, 3.

3. Each laboratory should establish procedures to ensure the use of animals that are free of disease prejudicial to the proposed experiments and free from carriers of disease or vectors, such as ectoparasites, which endanger other experimental animals or personnel (10).

### *B. Cages Housing Infected Animals* (10)

1. Careful handling procedures should be employed to minimize the dissemination of dust from cage refuse and animals.

2. Cages should be sterilized by autoclaving. Refuse, bowls and watering devices should remain in the cage during sterilization.

3. All watering devices should be of the "non-drip" type.

4. Cages should be examined each morning and at each feeding time so that dead animals can be removed.

5. Heavy gloves should be worn when feeding, watering, handling, or removing infected animals. Bare hands should NEVER be placed in the cage to move any object therein.

6. When animals are to be injected with biohazardous material, the animal caretaker should wear protective gloves and the laboratory workers should wear surgeons gloves. Animals should be properly restrained to avoid accidents that might result in disseminating biohazardous material, as well as to prevent injury to the animal and to personnel.

7. Animals exposed to biohazardous aerosols should be housed in ventilated cages, in gas-tight cabinet systems, or in rooms designed for protection of personnel by use of ventilated suits.

8. Animals inoculated by means other than by aerosols should be housed in equipment suitable for the level of risk involved.

9. Infected animals to be transferred between buildings should be placed in ventilated cages or other aerosol-proof containers.

10. The oversize canine teeth of large monkeys present a particular biting hazard; these are important in the potential transmission of naturally-occurring, and very dangerous, monkey virus infections. Such teeth should be blunted or surgically removed by a veterinarian.

11. Presently available epidemiologic evidence indicates that infectious hepatitis may be transmitted from nonhuman primates (typically chimpanzees) to man. Newly imported animals may be naturally infected with this disease, and persons in close contact with such animals may become infected. After six months residence in this country, chimpanzees apparently no longer transmit the disease. A record should be maintained for each newly imported animal. A sign should be posted at rooms housing these animals to warn that the animals are potentially infectious.

### *C. General Guidelines that Apply to Animal Room Maintenance (10)*

1. Doors to animal rooms should be kept closed at all times except for necessary entrance and exit.

2. Unauthorized persons should not be permitted to enter animal rooms.

3. A container of disinfectant should be kept in each animal room for disinfecting gloves and hands, and for general decontamination, even though no infectious animals are present. Hands, floors, walls, and cage racks should be washed with an approved disinfectant at the recommended strength as frequently as the supervisor directs.

4. Floor drains in animal rooms, as well as floor drains throughout the building should be flooded with water or dininfectant periodically to prevent backup of sewer gases.

5. Shavings or other refuse on floors should not be washed down the floor drain because such refuse clogs the sewer lines.

6. An insect and rodent control program should be maintained in all animal rooms and in animal food storage areas.

7. Special care should be taken to prevent live animals, especially mice, from finding their way into disposable trash.

### *D. Necropsy Rules for Infected Animals (10)*

1. Necropsy of infected animals should be carried out by trained personnel in Biological Safety Cabinets with the hinged glass panel down. The glove port panel with or without attached gloves, and a respirator should be used at the discretion of the supervisor.

2. Surgeons gowns should be worn over laboratory clothing during necropsies.

3. Rubber gloves should be worn when performing necropsies.

4. The fur of the animal should be wetted with a suitable disinfectant.

5. Small animals should be pinned down or fastened on wood or metal in a metal tray.

6. Upon completion of necropsy, all potentially biohazardous material should be placed in suitable containers and sterilized immediately.

7. Contaminated instruments should be placed in a horizontal bath containing a suitable disinfectant.

8. The inside of the Biological Safety Cabinets and other potentially contaminated surfaces should be disinfected with a suitable germicide.

9. Grossly contaminated rubber gloves should be cleaned in disinfectant before removal from the hands, preparatory to sterilization.

10. Dead animals should be placed in proper leak-proof containers, autoclaved and properly tagged before being placed outside for removal and incineration.

## VI. DECONTAMINATION AND DISPOSAL (7, 10, 38–42)

### *A. Introduction*

Available date on the efficacy of various decontaminants for etiologic agents indicate that no major surprises will be forthcoming regarding the susceptibility of organisms containing recombinant DNA molecules. In the absence of adequate information, tests to determine the efficacy of candidate decontaminants should be conducted with the specific agent of interest. The goal of decontamination is not only the protection of personnel and the environment from exposure to infectious agents, but also the prevention of contamination of experimental materials by a variable, persistent, and unwanted background of microorganisms. This additional factor should be considered in selecting decontamination materials and methods.

*B. Decontamination Methods*

Physical and chemical means of decontamination fall into four main categories: Heat; Liquid Decontaminants; Vapors and Gases; and UV Radiation.

1. *Heat.* The application or heat, either moist or dry, is recommended as the most effective method of sterilization. Steam at 121 C under pressure in the autoclave is the most convenient method of rapidly achieving sterility. Dry heat at 160 to 170 C for periods to 2 to 4 hours is suitable for destruction of viable agents on impermeable nonorganic material such as glass, but is not reliable in even shallow layers of organic or inorganic material that can act as insulation. Incineration is another use of heat in the decontamination of microorganisms and also serves as an efficient means for disposal.

2. *Liquid Decontaminants.* In general, the liquid decotaminants find their most practical use in surface decontamination and, at sufficient concentration, as decontaminants of liquid wastes for final disposal in sanitary sewer systems.

There are many misconceptions concerning the use of liquid decontaminants. This is due largely to a characteristic capacity of such liquids to perform dramatically in the test tube and to fail miserably in a practical situation. Such failures often occur because proper consideration was not given to such factors as temperature, time of contact, pH, concentration, and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application. Small variations in the above factors may make large differences in effectiveness of decontamination. For this reason, even when used under highly favorable conditions, complete reliance should not be placed on liquid decontanimants when the end result must be sterility.

There are many liquid decontaminants available under a wide variety of trade names. In general, these can be categorized as halogens, acids or alkalies, heavy metal salts, quaternary ammonium compounds, phenolic compounds, aldehydes, ketons, alcohols and amines. Unfortunately, the more active the decontaminant the more likely it is that the decontaminant will possess undesirable characteristics, such as the possession of corrosive propertie. None is equally useful or effective under all conditions.

3. *Vapors and Gases.* A variety of vapors and gases possess decontamination properties. The most useful of these are formaldehyde and ethylene oxide. When these can be employed in closed systems and under controlled conditions of temperature and humidity, excellent decontamination can result. Vapor and gas decontaminants are primarily useful in decontaminating: (i) Biological Safety Cabinets and associated effluent air-handling systems and air filters; (ii) bulky or stationary equipment that resists penetration by liquid surface decontaminants; (iii) instruments and optics that might be damaged by other decontamination methods; and (iv) rooms and buildings and associated airhandling systems.

4. *Radiation.* The usefulness of ultraviolet (UV) irradiation as a decontaminant is limited by its low penetrating power. No information is available regarding the effectiveness of UV irradiation for decontaminating microorganisms containing recombinant DNA molecules. Dependence on UV must be based on the results of experiments imitating particular anticipated environmental conditions and applications. Ultraviolet light is generally of limited application and is primarily useful in air locks and animal holding areas for controlling low levels of airborne contaminants.

No one procedure or material will solve all decontamination problems. The only method of assuring the efficacy of selected methodologies is to critically examine the results obtained in practical tests with the microorganism(s) of interest.

*C. Laboratory Spills*

A troublesome problem that may occur in the laboratory is the decontamination of an overt biological spill. The occurence of a spill poses less of a problem if it occurs in a Biological Safety Cabinet provided splattering to the outside of the cabinet does not occur. Direct application of concentrated liquid decontaminant and a thorough wipe down of the internal surfaces of such cabinetry will usually be effective for decontaminating the work ozne but gaseous decontaminants would be required to rid the interior sections of the cabinet of contaminants. Each researcher must realize that in the event of an overt accident, research materials such as tissue cultures, media, and animals within such cabinets may well be lost to the experiment.

The greater problem arises if the incident occurs in the open laboratory. All laboratory protocols should be designed to prevent such occurrences. The first action in the event of an overt laboratory spill is evacuation of the affected area to minimize the exposure of personnel involved. Next, the spill area must be isolated to prevent exposure of personnel and experimental materials beyond those involved in the immediate area of the spill. The procedures adopted must be rapidly effective and must not create additional aerosol or foster mechanical transfer of materials to unaffected areas. Personnel carrying out the procedures must be provided with protective clothing and equipment, including respiratory protection. Consideration must be given to the safe disposal of all materials and liquids resulting from cleanup procedures. Reentry of personnel to the area should be avoided until it can be reasonably established that the area has been effectively decontaminated. Further specific details are provided in Section VIII.

*D. Disposal*

Decontamination and disposal in infectious disease laboratories are closely interrelated acts in which decontamination constitutes the introductory phase of disposal. All materials and equipment used in research on recombinant DNA molecules will ultimately be disposed of; however, in the sense of daily use, only a portion of these will require actual removal from the laboratory complex or on-site destruction. The remainder will be recycled for use either within the same laboratory or in other laboratories that may or may not engage in DNA recombinant research. Examples of the latter that immediately come to mind are: reusable laboratory glassware, instruments used in necropsy of infected animals, and laboratory clothing. Disposal should therefore be interpreted in the broadest sense of the word, rather than in the restrictive sense of dealing solely with a destructive process.

The principal questions to be answered prior to disposal of any objects or materials from laboratories dealing with potentially infectious microorganisms or animal tissues are:

1. Have the objects or materials been effectively decontaminated by an approved procedure?

2. If not, have the objects or materials been packaged in an approved manner for immediate on-site incineration or transfer to another laboratory?

3. Does disposal of the decontaminated objects or materials involve any additional potential hazards, biological or otherwise, to personnel either:

(i) Those carrying out the immediate disposal procedures or

(ii) Those who might come into contact with the objects or materials outside the laboratory complex?

Laboratory materials requiring disposal will normally occur as liquid, solid, and animal room wastes. The volume of these can become a major problem when there is the requirement that all wastes be decontaminated prior to disposal. It is most evident that a significant portion of this problem can be eliminated if the kinds of materials initially entering the laboratory are reduced. In any case, and wherever possible, materials not essential to the research should be retained in the nonresearch areas for disposal by conventional methods. Examples are the packaging materials in which goods are delivered, disposable carton-cages for transport of animals, and large carboys or tanks of fluids which can be left outside and drawn from as required. Reduction of this bulk will free autoclaves and other decontamination and disposal processes within the laboratory for the more rapid and efficient handling of materials known to be contaminated.

Inevitably, disposal of materials raises the question, "How can we be sure that the materials have been treated adequately to assure that their disposal does not constitute a hazard?" In the small laboratory, the problem is often solved by requiring that each investigator decontaminate all contaminated materials not of immediate use at the end of each day and place them in suitable containers for routine disposal. In larger laboratories where the mass of materials for disposal becomes much greater and sterilization and decontamination bottlenecks occur, materials handling and disposal will likely be the chore of personnel not engaged in the actual research. In either situation, a case can be made for establishing a positive method of designating the state of materials to be disposed of. This may consist of a tagging system stating that the materials are either sterile or contaminated.

Disposal of materials from the laboratory and animal holding areas will be required for research projects ranging in size from an individual researcher to those involving large numbers of researchers of many disciplines. Procedures and facilities to accomplish this will range from the simplest to the most elaborate. The primary consideration in any of these is to dispel the notion that laboratory wastes can be disposed of in the same manner and with as little thought as household wastes. Selection and enforcement of safe procedures for disposal of laboratory materials are of no less importance than the consideration given to any other methodology for the accomplishment of research objectives.

Materials of dissimilar nature will be common in laboratories studying recombinant DNA molecules. Examples are combinations of common flammable solvents, chemical carcinogens, radioactive isotopes, and concentrated viruses or nucleic acids. These may require input from a number of disciplines in arriving at the most practical approach for their decontamination.

*E. Characteristics of Chemical Decontaminants in Common Use in Laboratory Operations*

Every person actively working with viable microorganisms, no matter how remote the field of specialization, will, from time to time, find it necessary to decontaminate by chemical methods work areas and materials, equipment, and specialized instruments. Chemical decontamination is necessary because the use of pressurized steam, the most rapid and reliable method of sterilization, is not normally feasible for decontaminating large spaces, surfaces, and stationary equipment. Moreover, high temperatures and moisture often damage delicate instruments,

particularly those having complex optical and electronic components.

Chemicals with decontaminant properties are, for the most part, available as powders, crystals, and liquid concentrates. These may be added to tap water for application as surface decontaminants, and some, when added in sufficient quantity, find use as decontaminants of bulk liquid wastes. Chemical decontaminants that are gaseous at room temperatures are useful as space-penetrating decontaminants. Others become gases at reasonably elevated temperatures and can act as either aqueous surface or gaseous space-penetrating decontaminants.

Inactivation of microorganisms by chemical decontaminants may occur in one or more of the following ways:

1. Coagulation and denaturation of protein.
2. Lysis.
3. Binding to enzymes, or inactivation of an essential enzyme by either oxidation, binding, or destruction of enzyme substrate.

The relative resistance to the action of chemical decontaminants can be substantially altered by such factors as: concentration of active ingredient, duration of contact, pH, temperature, humidity, and presence of extrinsic organic matter. Depending upon how these factors are manipulated, the degree of success achieved with chemical decontaminants may range from minimal inactivation of target microorganisms to an indicated sterility within the limits of sensitivity of the assay systems employed.

There are dozens of decontaminants available under a wide variety of trade names. In general, these decontaminants can be classified as halogens, acids or alkalies, heavy metal salts, quaternary ammonium compounds, phenolic compounds, aldehydes, ketones, alcohols, and amines. Unfortunately, the more active the decontaminant the more likely it will possess undesirable characteristics. For example, peracetic acid is a fast-acting, universal decontaminant. However, in the concentrated state it is a hazardous compound that can readily decompose with explosive violence. When diluted for use, it has a short half-life, produces strong, pungent, irritating odors, and is extremely corrosive to metals. Nevertheless, it is such an outstanding decontaminant that it is commonly used in germ-free animal studies despite these undesirable characteristics.

The halogens are probably the second most active group of decontaminants. Chlorine, iodine, bromine, and fluorine will rapidly kill bacterial spores, viruses, rickettsiae, and fungi. These decontaminants are effective over a wide range of temperatures. In fact, chlorine has been shown to be effective at −40 F. (On the other hand, phenols and formaldehyde have high temperature coefficients). The halogens have several undesirable features. They readily combine with protein, so that an excess of the halogen must be used if proteins are present. Also, the halogens are relatively unstable so that fresh solutions must be prepared at frequent intervals. Finally, the halogens corrode metals. A number of manufacturers of decontaminants have treated the halogens to remove some of the undesirable features. For example, sodium hypochlorite reacts with p-toluenesulfonamide to form Chloramine T, and iodine reacts with certain surface-active agents to form the popular iodophors. These "tamed" halogens are stable, non-toxic, odorless, and relatively noncorrosive to metals. However, the halogens are highly reactive elements, and, because they are reactive they are good germicides. When a halogen acts as a decontaminant, free halogen is the effective agent. Rising the pH or combining the halogen with other compounds to decrease the corrosive effect will also decrease the germicidal power. A trade-off situation occurs.

Ineffectiveness of a decontaminant is due primarily to the failure of the decontaminant to contact the microorganisms rather than failure of the decontaminant to act. If one places an item in a liquid decontaminant, one can see that the item is covered with tiny bubbles. Of course, the area under the bubbles is dry, and microorganisms in these dry areas will not be affected by the decontaminant. Also, if there are spots of grease, rust or dirt on the object, microorganisms under these protective coatings will not be contacted by the decontaminant. Scrubbing an item when immersed in a decontaminant is helpful, and a decontaminant should have, and most do have, incorporated surface-active agents.

*F. Properties of Some Common Decontaminants*

1. *Alcohol.* Ethyl or isopropyl alcohol in a concentration of 70–85% by weight is often used. Alcohols denature proteins and are somewhat slow in their germicidal action. However, they are effective decontaminants against lipid-containing viruses.

2. *Ether and Chloroform.* These compounds are not ordinarily used as decontaminants, but they do demonstrate the fact that lipid-containing viruses are inactivated by these organic solvents, whereas non-lipid-containing viruses are quite resistant.

3. *Formaldehyde.* Formaldehyde for use as a decontaminant is usually marketed as a solution of about 37% concentration referred to as formalin or as a solid polymerized compound called paraformaldehyde. Formaldehyde in a concentration of 5% active ingredient is an effective liquid decontaminant. It loses considerable activity at refrigeration temperatures and the pungent, irritating odors make formaldehyde solutions difficult to use in the laboratory. Formaldehyde vapor generated from formaldehyde solution is an effective space decontaminant for decontaminating rooms or buildings, but in the vapor state with water it tends to polymerize out on surfaces to form paraformaldehyde, which is persistent and unpleasant. Formaldehyde gas can be liberated by heating paraformaldehyde to depolymerize it. In the absence of high moisture content in the air, formaldehyde released in the gaseous state forms less polymerized residues on surfaces and less time is required to clear treated areas of fumes than formaldehyde released in the vapor state.

4. *Phenol.* Phenol itself is not often used as a decontaminant. The odor is somewhat unpleasant and a sticky, gummy residue remains on treated surfaces. This is especially true during steam sterilization. Although phenol itself may not be in widespread use, phenol homologs and phenolic compounds are basic to a number of popular decontaminants. The phenolic compounds are effective decontaminants against some viruses, rickettsiae, fungi and vegetative bacteria. The phenolics are not effective in ordinary usage against bacterial spores.

5. *Quaternary Ammonium Compounds or Quats.* After 30 years of testing and use, there is still a considerable controversy about the efficacy of the Quats as decontaminants. These cationic detergents are strongly surface-active and are effective against lipid-containing viruses. The Quats will attach to protein so that dilute solutions of Quats will quickly lose effectiveness in the presence of proteins. The Quats tend to clump microorganisms and are neutralized by anionic detergents, such as soap. The Quats have the advantages of being nontoxic, odorless, nonstaining, noncorrosive to metals, stable, and inexpensive.

6. *Chlorine.* This halogen is a universal decontaminant active against all microorganisms, including bacterial spores. Chlorine combines with protein and rapidly decreases in concentration in its presence. Free, available chlorine is an active element. It is a strong oxidizing agent, corrosive to metals. Chlorine solutions will gradually lose strength so that fresh solutions must be prepared frequently. Sodium hypochlorite is usually used as a base for chlorine decontaminants. An excellent decontaminant can be prepared from household or laundry bleach. These bleaches usually contain 5.25 percent available chlorine or 52,500 ppm. If one dilutes them to 1 to 100, the solution will contain 525 ppm of available chlorine, and, if a nonionic detergent such as Naccanol is added in a concentration of about 0.7 percent, a very good decontaminant is created.

7. *Iodine.* The characteristics of chlorine and iodine are similar. One of the most popular groups of decontaminants used in the laboratory is the iodophors, and Wescodyne is perhaps the most popular. The range of dilution of Wescodyne recommended by the manufacturer is 1 oz. in 5 gal. of water giving 25 ppm of available iodine to 3 oz. in 5 gal. giving 775 ppm. At 75 ppm, the concentration of free iodine is .0075 percent. This small amount can be rapidly taken up by any extraneous protein present. Clean surfaces or clear water can be effectively treated by 75 ppm available iodine, but difficulties may be experienced if any appreciable amount of protein is present. For bacterial spores, a dilution of 1 to 40 giving 750 ppm is recommended by the manufacturer. For washing the hands, it is recommended that Wescodyne be diluted 1 to 10 or 10% in 50% ethyl alcohol (a reasonably good decontaminant itself) which will give 1,600 ppm of available iodine, at which concentration relatively rapid inactivation of any and all microorganisms will occur.

*G. Vapors and Gases*

The use of formaldehyde as a vapor or gas has already been discussed. Other chemical decontaminants which have been used this way included ethylene oxide, peracetic acid, beta-propiolactone (BPL), methyl bromide, and ethylene amine. When these can be used in closed systems and under controlled conditions of temperature and humidity, excellent decontamination can be obtained. Residues from ethylene oxide must be removed by aeration; but otherwise it is convenient to use, versatile, and noncorrosive. Peracetic acid is corrosive for metals and rubber. BPL in the vapor form acts rapidly against bacteria, rickettsiae, and viruses. It has a half-life of 3.5 hours when mixed with water, is easily neutralized with water, and lends itself to removal by aeration. The National Institutes of Health does not recommend BPL as a decontaminant because it has been identified as a suspect carcinogen.

*H. Residual Action of Decontaminants*

As noted in the preceding discussion of decontaminant properties, many of the chemical decontaminants often have residual properties that may be considered a desirable feature in terms of aiding in the control of background contamination. One is cautioned, however, to consider residual properties carefully. Ethylene oxide used to sterilize laboratory shoes can leave residues which cause skin irritation. Animal cell cultures, as well as viruses of interest, are also inhibited or inactivated by the decontaminants persisting after routine cleaning procedures. Therefore, reusable items that are routinely held in liquid decontaminant prior to autoclaving and cleaning should receive particular attention in rinse cycles. Similarly, during general area decontamination with gases or vapors, it may be necessary to protect new and used clean items by removing them from the area or by enclosing

them in gastight bags or by insuring adequate aeration following decontamination.

*I. Selecting Chemical Decontaminants for Research on Recombinant DNA Molecules*

No single chemical decontaminant or method will be effective or practical for all situations in which decontamination is required. Selection of chemical decontaminants and procedures must be preceded by practical consideration of the purposes for the decontamination and the interacting factors that will ultimately determine how that purpose is to be achieved. Selection of any given procedure will be influenced by the information derived from answers to the following questions:

1. What is the target microorganism(s)?
2. What decontaminants in what form are known to, or can be expected to, inactivate the target microorganisms(s)?
3. What degree of inactivation is required?
4. In what menstruum is the microorganism suspended; i.e., simple or complex, on solid or porous surfaces, and/or airborne?
5. What is the highest concentration of cells anticipated to be encountered?
6. Can the decontaminant either as an aqueous solution, a vapor, or a gas reasonably be expected to contact the microorganisms, and can effective duration of contact be maintained?
7. What restrictions apply with respect to compatibility of materials?
8. Does the anticipated use situation require immediate availability of an effective concentration of the decontaminant or will sufficient time be available for preparation of the working concentration shortly before its anticipated use?

The primary target of decontamination in the infectious disease laboratory is the microorganism under active investigation. Laboratory preparations or infectious agents usually have titers grossly in excess of those normally observed in nature. The decontamination of these high-titer materials presents certain problems. Maintenance systems for bacteria or viruses are specifically selected to preserve viability of the agent. Agar, proteinaceous nutrients, and cellular materials can be extremely effective in physically retarding or chemically binding active moieties of chemical decontaminants. Such interferences with the desired action of decontaminants may require the use of decontaminant concentrations and contact times in excess of those shown to be effective in the test tube. Similarly, a major portion of decontaminant contact time required to achieve a given level of agent inactivation may be expended in inactivating a relatively small number of the more resistant members of the population. The current state of the art provides little information on which to predict the probable virulence of these survivors. These problems are, however, common to all potentially pathogenic agents and must always be considered in selecting decontaminants and procedures for their use.

Microorganisms exhibit a range of resistance to chemical decontaminants. In terms of practical decontamination, most vegetative bacteria, fungi and lipid-containing viruses, are relatively susceptible to chemical decontamination. The non-lipid-containing viruses and bacteria with a waxy coating such as tubercle bacillus occupy a mid-range of resistance. Spore forms are the most resistant.

A decontaminant selected on the basis of its effectiveness against microorganisms on any range of the resistance scale will be effective against microorganisms lower on the scale. Therefore, if decontaminants that effectively control spore forms are selected for routine laboratory decontamination, it can be assumed that any other microorganisms generated by laboratory operations, even in high concentrations, would also be inactivated.

An additional area that must be considered and for which there is little definitive information available is the "inactivation" of nucleic acid. Nucleic acids often have better survival characteristics under adverse conditions than do the intact virions and cells from which they were derived. Strong oxidizers, strong acids and bases, and either gaseous or aqueous formaldehyde should react readily with nucleic acids. Their ability to destroy the nucleic acid being studied, however, should be confirmed in the experimenter's laboratory. Because of innate differences in the chemistry of RNA and DNA the effectiveness of a decontaminant for one cannot be extrapolated to the other. For example, RNA molecules are susceptible to mild alkaline hydrolysis by virtue of the free hydroxyl group in the 2' position, whereas DNA molecules are not susceptible to mild alkaline hydrolysis.

Table II summarizes pertinent characteristics and potential applications for several categories of chemical decontaminants most likely to be used in the biological laboratory. Practical concentrations and contact times that may differ markedly from the recommendations of manufacturers of proprietary products are suggested. It has been assumed that microorganisms will be afforded a high degree of potential protection by organic menstruums. It has not been assumed that a sterile state will result from application of the indicated concentrations and contact times. It should be emphasized that these data are only indicative of efficacy under artificial test conditions. The efficacy of any of the decontaminants should be conclusively determined by individual investigators. It is readily evident that each of the decontaminants has a range of advantages and disadvantages as well as a range of potential for inactivation of a diverse microflora. Equally evident is the need for compromise as an alternative to maintaining a veritable "drug store" of decontaminants.

APPENDIX B

TABLE II

SUMMARY OF PRACTICAL DECONTAMINANTS FOR USE IN THE LABORATORY

| DECONTAMINANTS | | PRACTICAL REQUIREMENTS | | | | | INACTIVATES | | | | IMPORTANT CHARACTERISTICS | | | | | | | | | | | | POTENTIAL APPLICATION | | | | | | | | | | | PROPRIETARY DECONTAMINANTS SUPPLIER |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TYPE | CATEGORY | CONCENTRATION ACTIVE INGREDIENT | CONTACT TIME (Minutes) LIPO VIRUS ONLY | CONTACT TIME (Minutes) BROAD SPECTRUM | TEMP. °C | REL. HUMID. % | VEG. BACT. | LIPO VIRUS | HYDROPHILIC VIRUS | BACT. SPORES | EFFECTIVE SHELF LIFE > 1 YEAR | CORROSIVE | FLAMMABLE | EXPLOSION POTENTIAL | RESIDUE | INACTIVATED BY ORGANIC MATTER | LEAG COMPATIBLE | ELECTRONICS LABORATORY COMPATIBLE | SKIN IRRITANT | EYE IRRITANT | RESPIRATORY IRRITANT | TOXIC | WORK SURFACES | DIRTY GLASSWARE | LARGE AREA DECON. | AIR HANDLING SYSTEMS | PORTABLE EQUIP. SURFACE DECON. | PORTABLE EQUIP. PENETRATING DECON. | STATIONARY EQUIP. SURFACE DECON. | STATIONARY EQUIP. PENETRATING DECON. | LENSES & ELECTRONIC INSTRUMENTS | LIQUIDS FOR BIOLOGICAL DISCARD | BASES, PAPERS | |
| LIQUID | Quat. Ammon. CPDS | 1% | 10 | N.E. | | | • | • | | | • | | | | | • | • | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Phenolic CPDS | 1% | 10 | N.E. | | | • | • | 1 | | • | • | | | • | • | | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Chlorine CPDS | 1% | 10 | 30 | | | • | • | • | • | | • | | | • | • | | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | ✓ | |
| | Iodophor | 1% | 10 | 30 | | | • | • | • | • | • | • | | | • | • | | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Alcohol, Ethyl | 85% | 10 | N.E. | | | • | • | 1 | | • | | • | | | | | | | • | | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Alcohol, Isopropyl | 85% | 10 | N.E. | | | • | • | 1 | | • | | • | | | | | | | • | | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Formaldehyde | 8% | 10 | 30 | | | • | • | • | • | • | | | | • | | | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| | Glutaraldehyde | 2% | 10 | 30 | | | • | • | • | • | • | | | | • | | • | | | • | • | • | ✓ | ✓ | | | ✓ | | ✓ | | | | | |
| GAS | Ethylene Oxide | 450g/l | 60 | 60 | 37 | 30 | • | • | • | • | N.A. | | • [2] | • [3] | | | | • | • | • | • | • | | | | | | ✓ | | | ✓ | | ✓ | |
| | Paraformaldehyde | 2g/ft³ | 60 | 60 | > 23 | > 60 | • | • | • | • | N.A. | | • [2] | • [3] | | | | • | • | • | • | • | | | | ✓ | ✓ | | ✓ | | ✓ | ✓ | | | |

N.A. = Not applicable • N.E. = Not effective

1. Variable results dependent on virus.
2. Reaches flammable or explosive in 90% $CO_2$ as fluorinate hydrocarbon use farm.
3. At concentrations of 3 to 5% by volume in air, solid-exposure to open flame.
4. Protected from light and air.
5. By skin or mouth or both - refer to manufacturer's literature and/or merck index.
6. Space limitations preclude listing all products available. Individual listings for omissions do not imply endorsement or rejection of any product by the NIH.
7. Refers to microscope and camera lenses.

VII. HOUSEKEEPING

*A. Introduction*

Well-defined housekeeping procedures and schedules are essential in reducing the risks of working with etiologic agents and in protecting the integrity of the research program. This is particularly true in the biological laboratory operating under less than total containment concepts and in all areas used for the housing of animals, whether or not they have been intentionally infected. A well-conceived and well-executed housekeeping program limits physical clutter that could distract the attention and interfere with the activities of laboratory personnel at a critical moment in a potentially hazardous procedure, provides a work area that will not in itself be a source of physical injury or contamination, and provides an area that promotes the efficient use of decontaminants in the event of the inadvertent release of a harmful agent. Less immediately evident are the benefits of establishing, among personnel of widely varying levels of education, an appreciation of the nature and sources of biological contamination.

Housekeeping is an omnibus term that can be interpreted as broadly or as narrowly as one chooses. It can be seen that many of the

procedures found under special headings, such as decontamination, disposal, and animal care, are, in reality, specific instructions for safely accomplishing otherwise routine housekeeping chores. In these safety suggestions for research on recombinant DNA molecules, it has been elected to address specifically only tasks of a janitorial nature under the subject of housekeeping.

The objectives of housekeeping in the biological laboratory are to:

1. Provide an orderly work area conducive to the accomplishment of the research program.

2. Provide work areas devoid of physical hazards.

3. Provide a clean work area with background contamination ideally held to a zero level but more realistically to a level such that extraordinary measures in sterile techniques are not required to maintain integrity of the biological systems being researched.

4. Prevent the accumulation of materials from current and past experiments that constitute a hazard to laboratory personnel.

5. Prevent the creation of aerosols of hazardous materials as a result of the housekeeping procedures used.

Procedures developed in the area of housekeeping should be based on the highest level of risk to which the personnel and integrity of the experiments will be subject. Such an approach avoids the confusion of multiple practices and retraining of personnel. The primary function, then, of routine housekeeping procedures is to prevent the accumulation of organic debris that (i) may harbor microorganisms that are a potential threat to the integrity of the biological systems under investigation, (ii) may enhance the survival of microorganisms inadvertently released in experimental procedures, (iii) may retard penetration of decontaminants, (iv) may be transferable from one area to another on clothing and shoes, (v) may, with sufficent buildup, become a biohazard as a consequence of secondary aerosolization by personnel and air movement, and (vi) may cause allergenic sensitization of personnel, e.g., to animal danders.

Housekeeping in animal care units has the same primary function as that stated for the laboratory and should, in addition, be as meticulously carried out in quarantine and conditioning areas as in areas used to house experimentally infected animals. No other areas in the laboratory have the constant potential for creation of significant quantities of contaminated organic debris than do animal care facilities.

In all laboratories, efforts to achieve total decontamination and to conduct a major cleanup of the biological complex are normally undertaken at relatively long time intervals. Routine housekeeping must be relied on to provide a work area free of significant sources of background contamination. The provision of such a work area is not simply a matter of indicating in a general way what has to be done, who will do it, and how often. The supervisor must view each task critically in terms of the potential biohazard involved, decide on a detailed procedure for its accomplishment, and provide instructions to laboratory personnel in a manner that minimizes the opportunity for misunderstanding.

The following checklist outlines a portion of the items requiring critical review by the laboratory supervisor. It is not intended to be complete but is presented as an example of the detailed manner in which housekeeping in the biological laboratory complex must be viewed.

Administration Areas
Aisles
Animal Food Storage
Animal Bedding Storage
Biological Safety Cabinets
Bench Tops and Other Work Surfaces
Ceilings
Change Rooms
Cleaning Solution Disposal
Cages and Cage Racks
Dry Ice Chests
Deep Freeze Chests
Entry and Exit Ways
Equipment Storage
Floors
Glassware
General Laboratory Equipment Cleanup
Hallways
Incubators
Instruments
Insect and Rodent Control
Light Fixtures
Mechanical Equipment Areas
Mops
Pipes—Wall and Ceiling Hung
Refrigerators
Showers
Supply Storage
UV Lamps
Vacuum Cleaners
Waste Accumulations
Waste Water Disposal
Others

Housekeeping in the laboratory is one of the avenues that leads to accomplishing the research program safely. It is important that housekeeping tasks be assigned to personnel who are knowledgeable of the research program and special hazards of the research environment. The recommended approach to housekeeping is the assignment of housekeeping tasks to the research teams on an individual basis for their immediate work areas and on a cooperative basis for areas of common usage. Similarly, animal caretaker personnel should be responsible for housekeeping in animal care areas. The laboratory supervisor must determine the frequency with which the individual and cooperative housekeeping chores need be accomplished. He should provide schedules and perform frequent inspection to assure compliance. This approach assures that research work flow patterns will not be interrupted by an alien cleanup crew, delicate laboratory equipment will be handled only by those most knowledgeable of its particular requirements, and the location of concentrated biological preparations and contaminated equipment used in their preparation and application will be known.

*B. Floor Care*

Avoidance of dry sweeping and dusting will reduce the formation of nonspecific environmental aerosols. Wet mopping or vacuum cleaning with a high-efficiency particulate air (HEPA) filter on the exhaust is recommended.

Careful consideration must be given to design and quality in the selection of cleaning equipment and materials and in their use to prevent the substitution of one hazard for another.

In the absence of overt hazardous spills, the cleaning process commonly will consist of an initial vacuuming to remove all gross particulate matter and a follow-up wet mopping with a solution of chemical decontaminant containing a detergent. Depending on the nature of the surfaces to be cleaned and availability of floor drains, removal of residual cleaning solutions can be accomplished by a number of methods. Among these are: pickup with a partially dry mop, pickup with a wet vacuum that has an adequately filtered exhaust, or removal to a convenient floor drain by use of a floor squeegee.

After cleaning up a spill of infected material, the residual solution should not be discharged to a sanitary sewer until it has been autoclaved or given further chemical treatment, such as by the addition of sodium hypochlorite sufficient to provide a final concentration of 500 ppm chlorine. Most household bleaches are marketed with a chlorine content of 5.25%. These in a final dilution of 1:100, yield 525 ppm of available chlorine. After allowing a contact time of 15 minutes, these solutions may be flushed down any available drain. Chlorine solutions in these high concentrations may be too corrosive for general application to floors and equipment. In any event, if solutions are used in this way, after the contact time the area should be rinsed with water.

*C. Dry Sweeping*

While it is recommended that dry sweeping be minimized, this may be the only method available or practicable under certain circumstances. In such cases, sweeping compounds used with push brooms and dry-dust mop heads treated to suppress aerosolization of dust should be used.

Sweeping compounds available from the usual janitorial supply firms fall in three categories:

Wax-based compounds used on vinyl floors and waxed floor coverings.

Oil-based compounds for concrete floors.

Oil-based compounds with abrasives (such as sand) to achieve a dry scouring action where much soil is present.

Dry-dust mop heads can be purchased as treated disposable units or as reusable, washable heads that must be treated with appropriate sprays or by other means to improve their dust-capturing property.

*D. Vacuum Cleaning*

In the absence of a HEPA filter on the exhaust, the usual wet and dry industrial-type vacuum cleaner is a potent aerosol generator. The HEPA-filtered exhaust used in conjunction with a well-sealed vacuum unit, however, can negate this factor because of its ability to pass large volumes of exhaust air while retaining particles with a minimum efficiency of 99.97%. Wet and dry units incorporating a HEPA filter on the exhaust are available from a number of manufacturers.

There are no particular requirements with respect to the manner in which the dry vacuuming is accomplished other than to emphasize that the objective is to remove all debris and particulate matter. The manufacturer's directions adequately detail the frequency of bag changes, filter changes, and mechanical adjustments.

Dry material vacuum-collected during these floor-cleaning activities is potentially contaminated, but the nature of the risk is probably greater to the experiment than to the experimenter. It is wise to effect bag and filter changes and to clean out collection tanks in a manner that will avoid or minimize aerosolizing the contents of the vacuum cleaner.

A vacuum machine that collects debris in a disposable bag is preferable to machines that collect the major debris in a tank and on an exposed primary filter. Even though it may serve as a primary filter, the disposable bag must be removed with caution. A bellows effect may pump dust out of the bag if its intake opening is not sealed before moving it to a plastic bag for transfer out of the area. In any event, the outer surface of the disposable bag will probably bear some dust contamination, which also may occur on inner surfaces of the machine.

To avoid contaminating experimental materials, the emptying of vacuum collection tanks and changing of bags and filters are best done away from the immediate laboratory area, for example, in a small area that can be easily cleaned afterwards. The use of heavy rubber gloves is recommended when

removing wastes from tanks in case broken glass is present. After making the filter changes, all external surfaces of the immediate work area and the equipment should be wiped with a cloth moistened in decontaminant. The operator might plan for a change of laboratory clothing afterwards so as to minimize carrying contamination into other areas of the laboratory.

Avoid use of dry vacuum cleaning equipment in work with high risk agents in the open laboratory. Should it be necessary to use it, it is recommended that gaseous sterilization be used to minimize aerosolization of microorganisms before waste is emptied from the vacuum container. Because complete penetration of sterilizing gases into the collected dry dust may be a problem, all wastes should be placed in a plastic bag, which then is tightly closed and incinerated or disposed of in an approved manner.

When dry vacuum cleaning equipment has been used within a gastight safety cabinet system, it can be treated in an attached double-door carboxyclave (an autoclave equipped with an ethylene oxide gas sterilization system) to allow for removal and emptying of the collection tank.

If a wet vacuum is to be used for pickup of the detergent-germicide solution from the floor, the manufacturer's recommendations on filter life should be followed. In addition, the operation of the vacuum should be closely observed for evidence of operating changing indicating restricted airflow or, conversely, increased flow indicating filter failure. Liquids collected in the vacuum cleaner after floor mopping will contain decontaminant material. These liquids may be poured down a convenient floor drain, except in the case of cleanup wastes from an overt spill. The collected liquid should then be autoclaved or treated with chlorine solution before disposal.

Provisions should be made for regular decontamination of the entire vacuum cleaner with formaldehyde gas or vapor, or ethylene oxide. This should be done after use if the vacuum is used in any manner for cleanup of overt spills of infectious material.

*E. Selection of a Cleaning Solution*

The selection of a detergent-decontaminant combination for routine cleaning of the laboratory complex should be based on the requirements of the area of greatest potential for contamination by the widest spectrum of microorganisms. With rare exception, this will be identified as the animal holding area and the expected microorganisms. With rare exception, this will be identified as the animal holding area and the expected microorganisms may well include fungi, viruses, and the vegetative and spore forms of bacteria. A decontaminating solution for such a range of microorganisms would, however, be expensive and excessively corrosive for routine use. Except in those rare instances where it can be assumed that pathogenic spores are being shed by laboratory animals, the risks from the spores are more likely to affect the experiments than the personnel. The spores tend to be associated with organic debris from bedding and food, thus offering potential for removal or at least a large initial reduction in their numbers by vacuum cleaning. A wide range of cleaning solutions that are mildly sporicidal, reasonably residual, and are not destructive to the physical plant are available. Phenol derivatives in combination with a detergent have these characteristics and have been selected for routine use in a number of research facilities. There are numerous detergent-phenolic combinations available on the market. The phenols are one type of a broad spectrum of biocidal substances that includes the mercurials, quaternary ammonium compounds, chloride compounds, iodophores, alcohols, formaldehyde, glutaraldehyde, and combinations of alcohol with either iodine or formaldehyde. These have been discussed in Section VI.

The laboratory supervisor should make a selection from those types most readily available which meet the general criteria of effectiveness, residual properties, and low corrosiveness.

*F. Wet Mopping—Two-Bucket Method*

Wet mopping of floors in laboratory and animal care areas is, from a safety standpoint, most conveniently and efficiently accomplished using a two-bucket system. The principal feature of such a system is that fresh detergent-decontaminant solution is always applied to the floor from one bucket, while all spent cleaning solution wrung from the mop is collected in the second bucket. Compact dolly-mounted double-bucket units with foot-operated wringers are available from most janitorial supply houses. A freshly laundered mop head of the cotton string type should be used daily. This requires that a mop with removable head be provided as opposed to a fixed-head type. In practice, the mop is saturated with fresh solution, very lightly wrung into the second bucket and applied to the floor using a figure eight motion of the mop head. After every four or five strokes, the mop head is turned over and the process continued until an area of approximately 100 $ft^2$ has been covered. After allowing a contact time of five minutes, the solution is removed with either a wet vacuum cleaner with HEPA-filtered exhaust or with the wrung-out mop. The mopping is continued in 100 $ft^2$ increments until the total floor area has been covered. Floor-cleaning procedures are most effectively completed after the majority of the work force has departed and should progress from areas of least potential contamination to those of greatest potential. Before a mop head is sent to a laundry, it should be autoclaved. Spent cleaning fluids are disposed of by flushing down the drain.

If the cleanup follows an overt spill of infectious material, the spent cleaning solution, after removal from the floor, should be autoclaved or treated with chlorine solution. Chlorine (as household bleach) should be added to give 500 ppm and held for a contact time of 15 minutes before dumping in the sanitary sewer.

*G. Alternative Floor Cleaning Method for Animal Care Areas and Areas with Monolithic Floors*

The absence of permanently placed laboratory benches and fixed equipment, coupled with the mobility of modern cage racks, makes possible alternate floor-cleaning procedures in animal care facilities. As in all considerations of methodologies in biomedical laboratory facilities, it is necessary to assess the compatibility of procedures and facilities from the hazard point of view. The alternative floor-cleaning procedure to be discussed requires that floors are completely sealed or of monolithic construction so that liquid leakage to adjacent areas does not occur and that floor drains or wet vacuum cleaners are available.

Subsequent to the removal of all debris by dry vacuum, move the cage racks to one side of the room. Cover the floor of the remaining cleared portion of the room with detergent-decontaminant solution applied at a rate of approximately one gallon per 144 $ft^2$ from a one-gallon tank sprayer, using a setting of the nozzle which will cause the solution to flow on and not create a spray. The nozzle is placed close to the floor. Allow a fifteen-minute contact period; then push the cleaning solution to the floor drain with a large floor squeegee or pick it up with a wet vacuum. Allow the flow to air dry; move the cage racks into the cleaned area, and repeat the process for the remaining floor area. Floor drains in these areas should be rim-flush, at least six inches in diameter, and fitted with a screen or porous trap bucket to catch large debris that escapes the initial dry cleaning. Such screens and baskets should be emptied after treatment with a decontaminant. If space utilization does not require frequent floor washdown, pour a half-gallon of detergent-decontaminant solution into the drain each week to keep the trap in the waste line filled against backup of sewer gases.

## VIII. CLEAN-UP OF BIOHAZARDOUS SPILLS (8, 9, 10)

*A. Biohazards Spill in a Biological Safety Cabinet*

Chemical decontamination procedures should be initiated at once while the cabinet continues to operate to prevent escape of contaminants from the cabinet.

1. Spray or wipe walls, work surfaces, and equipment with a 2% solution of an iodophor-decontaminant (Wescodyne or equivalent). A decontaminant detergent has the advantage of detergent activity, which is important because extraneous organic substances frequently interfere with the reaction between the microorganisms and the active agent of the decontaminant. Operator should wear gloves during this procedure.

2. Flood the top work surface tray, and, if a Class II cabinet, the drain pans and catch basins below the work surface, with a decontaminant and allow to stand 10–15 minutes.

3. Remove excess decontaminant from the tray by wiping with a sponge or cloth soaked in a decontaminant. For Class II cabinets, drain the tray into the cabinet base, lift out tray and removable exhaust grille work, and wipe off top and bottom (underside) surfaces with a sponge or cloth soaked in a decontamiant. Then replace in position and drain decontaminant from cabinet base into appropriate container and autoclave according to standard procedures. Gloves, cloth or sponge should be discarded in an autoclave pan and autoclaved.

*B. Biohazard Spill Outside a Biological Safety Cabinet*

1. Hold your breath, leave the room immediately, and close the door.

2. Warn others not to enter the contaminated area.

3. Remove and put into a container contaminated garments for autoclaving and thoroughly wash hands and face.

4. Wait 30 minutes to allow dissipation of aerosols created by the spill.

5. Put on a long-sleeve gown, mask, and rubber gloves before reentering the room. For a high risk agent, a jumpsuit with tight-fitting wrists and use of a respirator should be considered).

6. Pour a decontaminant solution (5% iodophor or 5% hypochlorite are recommended) around the spill and allow to flow into the spill. Paper towels soaked with the decontaminant may be used to cover the area. To minimize aerosolization, avoid pouring the decontaminant solution directly onto the spill.

7. Let stand 20 minutes to allow an adequate contact time.

8. Using an autoclavable dust pan and squeegee, transfer all contaminated materials (paper towels, glass, liquid, gloves, etc.) into a deep autoclave pan. Cover the pan with aluminum foil or other suitable cover and autoclave according to standard directions.

9. The dust pan and squeegee should be placed in an autoclavable bag and autoclaved according to standard directions. Contact of reusable items with non autoclavable plastic bags should be avoided—separation of the plastic after autoclaving can be very difficult.

*C. Radioactive Biohazard Spill Outside a Biological Safety Cabinet*

In the event that a biohazardous spill also involves a radiation hazard, the clean-up procedure may have to be modified, depending on an evaluation of the risk assessment of relative biological and radiological hazard.

Laboratories handling radioactive substances must have the services of a designated radiation protection officer available for consultation.

The following procedure indicates suggested variations from the biohazard spill procedure (above) that should be considered when a radioactive biohazard spill occurs outside a Biological Safety Cabinet.*

1. Holding your breath, leave the room immediately and close the door.

2. Warn others not to enter the contaminated area.

3. Remove and put in a container contaminated garments for autoclaving and thoroughly wash hands and face.

4. Wait thirty minutes to allow dissipation of aerosols created by the spill.

**Before clean-up procedures begin, a radiation protection officer should survey the spill for external radiation hazard to determine the relative degree of risk.*

5. Put on a long-sleeve gown, mask, and rubber gloves before reentering the room. (For a high risk agent, a jumpsuit with tight-fitting sleeves and a respirator should be considered).

6. Pour a decontaminant solution (5% iodophor or 5% hypochlorite are recommended) around the spill and allow to flow into the spill. Paper towels soaked with the decontaminant may be used to cover the area. To minimize aerosolization, avoid pouring the decontaminant solution directly onto the spill.

7. Let stand 20 minutes to allow adequate disinfectant contact time.

8. **In most cases, the spill will involve $^{14}C$ or $^{3}H$, which present no external hazard. However, if more energetic beta or gamma emitters are involved, care must be taken to prevent hand and body radiation exposure. The radiation protection officer must make this determination before the clean-up operation is begun.*

If the radiation protection officer approves, the biohazard-handling procedure may begin: Using an autoclavable dust pan and squeegee, transfer all contaminated materials (paper towels, glass, liquid, gloves, etc.) into a deep autoclave pan. Cover the pan with aluminum foil or other suitable cover and autoclave according to standard directions.

**If the radiation protection officer determines that radioactive vapors may be released and thereby contaminate the autoclave, the material must not be autoclaved. In that case, sufficient decontaminant solution to immerse the contents should be added to the waste container. The cover should be sealed with waterproof tape, and the container stored and handled for disposal as radioactive waste. Radioactive and biohazard warning symbols should be affixed to the waste container. As a general rule, autoclaving should be avoided.*

9. If autoclaving has been approved, the dust pan and squeegee should be placed in an autoclavable bag and autoclaved according to standard directions. Contact of reusable items with plastic bags should be avoided—separation of the plastic after autoclaving can be very difficult.

**A final radioactive survey should be made of the spill area, dust pan, and squeegee with a Geiger counter, or a smear should be taken and counted in a liquid scintillation counter.*

IX. A SECONDARY RESERVOIR AND FILTRATION APPARATUS FOR VACUUM SYSTEMS

The aspiration of tissue culture media from monolayer cultures and of supernatants from centrifuged samples into collection vessels or reservoirs is a common procedure in many laboratories. To prevent the accidental contamination by aerosols or fluids of house vacuum systems or laboratory pumps, some investigators have installed side arm flasks containing cotton, sulfuric acid or decontaminant between the reservoir and the vacuum line. Cotton is not completely effective as a filtering agent, sulfuric acid will corrode pipes, and decontaminants may lose their inactivating ability upon standing. The introduction of a cartridge-type filter that is moisture resistant and has a rated capacity to remove particles 350 nm (0.35u) or larger in size provides an effective barrier to virus aerosols.

The secondary reservoir and filtration apparatus can be assembled from readily available units as shown in Figure 1. A length of plastic tubing ¼ inch I.D. $\times \frac{1}{16}$ inch wall is attached at one end of the reservoir and at the other end to the lower arm of a filtration and media storage flask. These flasks vary in capacity from 250 to 4000 ml, the choice of flask depending on available space and amount of fluid that could be accidentally aspirated. A second tube of the same dimensions is attached from the upper arm of the flask to the inlet port of the disposable filter assembly. The third tube is attached from the filter assembly to a vacuum source. The tubes are securely held to the filter by fittings supplied with the filter and the other tubing connections can be secured by worm drive hose clamps.

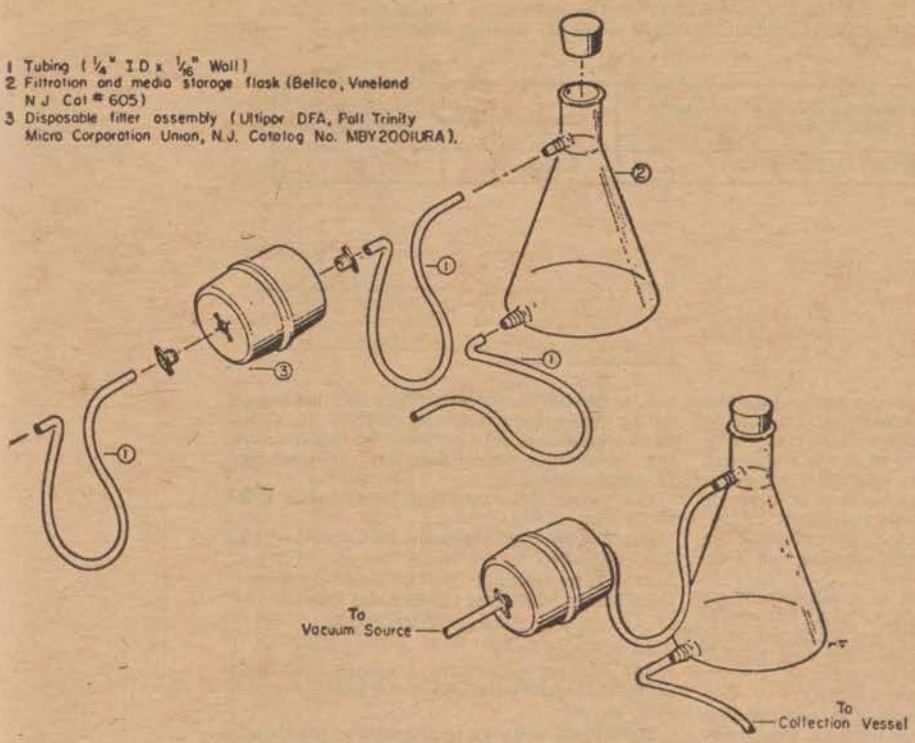
Ideally the flask should be placed higher than the reservoir of collection vessel. If fluid is accidentally drawn into the flask, the liquid can drain back into the reservoir by gravity if the connection at the vacuum line is broken. This prevents the loss of fluid which the investigator needs to retain.

Should the flask be used only for the recovery and storage of waste fluids, then the addition of a few grams of Dow Corning Antifoam A to the flask will reduce violent foaming of fluids aspirated into it. Such fluids can be decontaminated by introducing into the reservoir a final 5% concentration of an iodophor or other appropriate decontaminant, holding for 30 minutes and draining as above.

If the filter becomes contaminated or requires changing, the filter and flask can be safely removed by clamping the line between filter and vacuum source. The filter and flask should be autoclaved before the filter is discarded. A new filter can then be installed and the assembly replaced.

*Changes in procedures have been starred and underlined.

Figure 1
A SECONDARY RESERVOIR AND FILTRATION APPARATUS




X. PACKAGING AND SHIPPING

*A. Introduction*

Federal regulations and carrier tariffs have been promulgated to ensure the safe transport of hazardous biological materials. The NIH Guidelines specify that all DNA recombinant materials will be packaged and shipped in containers that meet the requirements of these regulations and carrier tariffs. In addition when any portion of the recombinant DNA material is derived from an etiologic agent listed in paragraph (c) of 42 CFR 72.25 (which is included at the end of this section, page D-85) the labeling requirements in these regulations and carrier tariffs shall apply.

*B. Packaging of Recombinant DNA Materials*

1. Volume less than 50 ml.

Material shall be placed in a securely closed, watertight container [primary container (test tube, vial, etc.)] which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

If dry ice is used as a refrigerant, it must be placed outside the secondary container(s).

Descriptions of this packaging method are given in Table III.

2. Volumes of 50 ml. or Greater.

Material shall be placed in a securely closed, watertight container (primary container) which shall be enclosed in a second, durable watertight container (secondary container). Single primary containers shall not contain more than 500 ml. of material. However, two or more primary containers whose combined volumes do not exceed 500 ml. may be placed in a single secondary container. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient non-particulate absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength. A shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Not more than eight secondary shipping containers may be enclosed in a single outer shipping container. (The maximum amount of materials which may be enclosed within a single outer shipping container should not exceed 4,000 ml.).

If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

Descriptions of packages which comply with the regulations of the Department of Transportation (DOT) are given in Table IV.

*C. Labeling of Packages Containing Recombinant DNA Materials*

1. Materials which do not contain any portion of an etiologic agent listed in paragraph (c) of 42 CFR 72.25.

Material data forms, letters, and other information identifying or describing the material should be placed around the outside of the secondary container. Place only the address label on the outer shipping container. DO NOT USE THE LABEL FOR ETIOLOGIC AGENTS/BIOMEDICAL MATERIAL.

2. Materials which contain any portion of an etiologic agent listed in paragraph (c) of 42 CFR 72.25.

Material data forms, letters, and other information identifying or describing the material should be placed around the *outside* of the secondary container. In addition to the address label, the label for Etiologic Agents/Biomedical Material must be affixed to the outer shipping container. This label is described in paragraph (c)(4) of 42 CFR 72.25.

3. Materials which contain any portion of a plant pest (plant pathogens) which are so defined by the Department of Agriculture (USDA).

Material data forms, letters, and other information identifying or describing the material should be placed around the *outside* of the secondary container. In addition to the address label, the shipping labels furnished by the USDA as part of the General, Courtesy, or Special Permits required for research with and shipment of such agents shall be affixed to the outer shipping container.

*D. Additional Shipping Requirements and Limitations for Recombinant DNA Materials*

1. Domestic Transportation.

Civil Aeronautics Board Rule No. 82 (Air Transport Association Restricted Articles Tariff 6-D) requires that a Shipper's Certificate, depicted below, be completed and affixed to all shipments which bear the ETIOLOGIC AGENT/BIOMEDICAL MATERIALS label required under the provisions of the Interstate Quarantine regulations [42 CFR Section 72.25(c)]. The Certificate must be completed in duplicate and affixed to the outer shipping container.

This is to certify that the contents of this consignment are properly classified, described by proper shipping name and are packed, marked and labelled and are in proper condition for carriage by air according to all applicable carrier and government regulations. (For international shipments add "and to the IATA Restricted Articles Regulations".) This consignment is within the limitations prescribed for: PASSENGER AIRCRAFT/CARGO ONLY (cross out nonapplicable).

| Number of Packages | Specify Each Article Separately (Proper Shipping Name) | Classification | Net Quantity per Package |
|---|---|---|---|
| | ETIOLOGIC AGENT, n.o.s. | ETIO. AG. | |

Shipper:

Date _____

_____
(Signature of Shipper)

Shipments of recombinant DNA Materials exceeding 50 ml in volume and containing any portion of an etiologic agent listed in paragraph (c) of 42 CFR 72.25 are restricted, by DOT regulations, to transport by cargo only aircraft. When the volume of a single primary container exceeds the 50 ml limitation, this restriction must be indicated on the Shipper's Certificate by crossing out "Passenger Aircraft".

When dry ice is used as a refrigerant an "ORA-Group A–DRY ICE LABEL" should be affixed to the outer shipping container. The amount of dry ice used and the date packed should be designated on the label.

2. International Transportation.

In addition to the packaging and labeling requirements of the regulations previously cited, international shipments of recombinant DNA materials in which any portion of the material is derived from an etiologic agent listed in paragraph (c) of 42 CFR 72.25 must have one or more of the following documents—depending on the country of destination:

(1) Parcel Post Customs Declaration (PS 2966) tag.

(2) Parcel Post Customs Declaration (PS 2966–A) label.

(3) International Parcel Post—Instructions Given by Sender (POD 2922) label.

(4) Dispatch note (POD 2972) tag.

(5) "Violet Label".

(6) Shipper's Certificate specified in the current International Air Transport Association Tariff.

Individual country requirements are listed in "International Postage Rates and Fees" (USPO Publication 51).

TABLE III.—*Description of packages for material in volume less than 50 ml.*

| Volume (milliliter) | Primary container | Packing | Secondary container | Packing | Outer shipping container [1] |
|---|---|---|---|---|---|
| 15 maximum | Sealed vial(s) or small glass test tube, screw cap or stopper, taped.[3] | Nonparticulate absorbent material at top, bottom, and sides that will completely absorb contents of the primary container(s). | Metal can 1-in diameter by 7-in outside dimensions metal screw cap. | None required | Fiberbody; metal screw cap, top and bottom; 1½-in diameter by 7-to 7½-in outside dimensions. |
| 50 or less | One 20 by 150 mm test tube, taped stopper or multiple small vials.[3] | do | Metal can 2½-in diameter by 6½-in high outside dimensions screw cap. | do | Fiberbody; metal screw cap, top and bottom; 3¼-in diameter by 7-to 7½ in outside dimensions. |
| Do | Plastic screw cap bottle or Pyrex glass with skirt rubber stopper.[2] | do | do | do | Do. |
| Do | Multiple watertight vials or tubes, taped stoppers.[3] | do | 1 or more friction-seal tin cans 306 by 400 or larger.[3] | None required, but with the 306 by 400 cans or larger cans use sufficient nonparticulate shock-absorbent material to prevent rattling. | Fiberboard box. |

[1] If materials are to be refrigerated, it is recommended that an overpack be used to contain the refrigerant and the secured (original) outer shipping container. A leakproof outer container must be used for water ice. If dry ice is used the outer container must permit release of carbon dioxide. Interior supports must be provided to hold the container(s) in the original position(s) after wet or dry ice has dissipated.

[2] The flexibility of the plastic bottle requires that a stopper or screw cap be secured in place by adhesive tape. The usual equivalent-size glass flat-sided prescription bottle is too fragile for use. For air transport, all stoppers, corks, and caps on primary containers must be secured in place with wire, tape, or other means, and all screw-capped containers of unfrozen liquid must be placed in 5- or 6-mil polyvinyl tubing, heat sealed at both ends to prevent atmospheric decompression that may result in leakage past the screw cap.

[3] 610 by 708 and 804 by 908 are trade designations for outside dimensions of 6 19/16-in diameter by 7 9/16-in height, and 8 1/16-in by 9 9/16-in.

TABLE IV.—*Description of packages for material in volumes of 50 ml or greater*

| Volume (milliliter) | Primary container | Packing | Secondary container | Packing | | Outer shipping container | |
|---|---|---|---|---|---|---|---|
| | | | | With refrigerant | Without refrigerant | With refrigerant | Without refrigerant |
| 51 to 100 | Plastic or Pyrex glass screw cap bottle; rubber or skirt rubber stopper, taped.[1] | Nonparticulate absorbent material at top, bottom, and sides that will completely absorb contents of the primary container(s). | Consists of metal container and outer container specified in table III. | Styrofoam box shock-absorbent insulation. | Shock absorbent material, in volume at least equal to that between the primary and secondary container(s), at the top, bottom, and sides between the secondary container and the outer shipping container. The shock absorbent material shall be so placed that the secondary container(s) does not become loose inside the outer shipping container as the water ice or dry ice is dissipated. | Fiberboard box closely fitting the styrofoam box, taped shut. | Corrugated fiberboard or cardboard box, taped shut. |
| 100 maximum | 1 100-ml plastic screw cap narrow neck bottle or Pyrex glass, taped.[1] | do | No. 3 crimp seal tin can 404 by 700 or a 1-gal friction-seal tin can, 610 by 708, top soldered or clipped at 4 points.[2] | do | do | do | V3C cardboard box PS3 type, 9 3/16 in by 9 3/16 in by 11 1/4 in high outside dimensions, taped shut with 3 in type PS3 tape. |
| 200 maximum | 2 100-ml plastic screw cap bottles or Pyrex glass, taped.[1] | do | do[2] | do | do | do | Do. |
| 250 maximum | 1 250-ml plastic narrow mouth screw cap bottle or Pyrex glass skirted rubber stopper, taped.[1] | do | do[2] | do | do | do | Do. |
| 500 maximum | 2 250-ml plastic screw cap bottles or Pyrex glass bottles, taped.[1] | do | 2-gal friction-seal tin can, 804 by 908, top soldered or clipped at 4 points.[2] | do | do | do | V3C cardboard box 12 1/4 in by 12 1/4 in by 10 3/16 in high outside dimensions, taped shut with 3-in wide PS3 tape. |
| Do | 500-ml Pyrex glass bottle, rubber-skirt stopper, taped, or 500-ml plastic bottle, narrow or wide mouth, screw cap, taped.[1] | do | No. 12 crimp seal tin can 603 by 810 2-gal friction-seal tin can, 804 by 908, top soldered or clipped at 4 points.[2] | do | do | do | V3C cardboard box 12 1/4 in by 12 1/4 in by 10 3/16 in high outside dimensions, taped shut with 3 in wide PS3 tape. For the No. 12 can a cardboard box is OK taped shut. |

[1] The flexibility of the plastic bottle requires that a stopper or screw cap be secured in place by adhesive tape. The usual equivalent-size glass flat-sided prescription bottle is too fragile for use. For air transport, all stoppers, corks, and caps on primary containers must be secured in place with wire, tape, or other means, and all screw-capped containers of unfrozen liquid must be placed in 5 or 6 mil polyvinyl tubing heat-sealed at both ends to prevent atmospheric decompression that may result in leakage past the screw cap.

[2] 610 by 708 and 804 by 908 are trade designations for outside dimensions of 6 19/64-in diameter by 7 5/16 in height, and 8 5/16 in by 9 5/16 in.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; PUBLIC HEALTH SERVICE; CENTER FOR DISEASE CONTROL; ATLANTA, GEORGIA 30333; TELEPHONE: (404) 633-3311, EXT. 3883

TITLE 42—PUBLIC HEALTH; CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING; PART 72—INTERSTATE QUARANTINE; SUBPART C—SHIPMENT OF CERTAIN THINGS

Section 72.25 of Part 72, Title 42, Code of Federal Regulations, is amended to read as follows:

§ 72.25 *Etiologic agents.*[1]

(a) *Definitions.* As used in this section:

(1) An "etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease.

(2) "diagnostic specimen" means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

(3) A "biological product" means a biological product prepared and manufactured in accordance with the provisions of 9 CFR Part 10, Licensed Veterinary Biological Products, 42 CFR Part 73, Licensed Human Biological Products, 21 CFR 130.3, *New drugs for investigational use in humans*, 9 CFR Part 103, Biological Products for Experimental Treatment of Animals, or 21 CFR 130.3(a), *New drugs for investigational use in animals*, and which, in accordance with such provisions may be shipped in interstate traffic.

(b) *Transportation; etiologic agent minimum packaging requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material, including but not limited to, diagnostic specimens and biological products, containing, or reasonably believed by such person to contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

(c) *Transportation; etiologic agents subject to additional requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material, other than diagnostic specimens and biological products, containing, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged in accordance with the requirements specified in paragraph (b) of this section, and unless, in addition, such material is packaged and shipped in accordance with the requirements specified in subparagraphs (1)–(6) of this paragraph:

[1] The requirements of this section are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

BACTERIAL AGENTS

*Actinobacillus*—all species.
*Arizona hinshawii*—all serotypes.
*Bacillus anthracis.*
*Bartonella*—all species.
*Bordetella*—all species.
*Borrelia recurrentis, B. vincenti.*
*Brucella*—all species.
*Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.*
*Corynebacterium diphtheriae C, equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.*
*Diplococcus (Streptococcus) pneumoniae.*
*Erysipelothrix insidiosa.*
*Escherichia coli*, all enteropathogenic serotypes.
*Francisella (Pasteurella) tularensis.*
*Haemophilus ducreyi, H. influenzae.*
*Herellea vaginicola.*
*Klebsiella*—all species and all serotypes.
*Leptospira interrogans*—all serotypes.
*Listeria*—all species.
*Mima polymorpha.*
*Moraxella*—all species.
*Mycobacterium*—all species.
*Mycoplasma*—all species.
*Neisseria gonorrhoeae, N. menihgitidis.*
*Pasteurella*—all species.
*Pseudomonas pseudomallei.*
*Salmonella*—all species and all serotypes.
*Shigella*—all species and all serotypes.
*Sphaerophorus necrophorus.*
*Staphylococcus aureus.*
*Streptobacillus moniliformis.*
*Streptococcus pyogenes.*
*Treponema careteum, T. pallidum, and T. pertenue.*
*Vibrio fetus, V. comma*, including biotype El Tor, and *V. parahemolyticus.*
*Yersenia (Pasteurella)* pestis.

FUNGAL AGENTS

*Actinomycetes* (including *Nocardia species, Actinomyces* species and *Arachnia propionica*).
*Blastomyces dermatitidis.*
*Coccidioides immitis.*
*Cryptococcus neoformans.*
*Histoplasma capsulatum.*
*Paracoccidioides brasiliensis.*

VIRAL, RICKETTSIAL, AND CHLAMYDIAL AGENTS

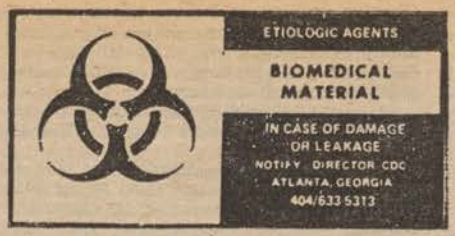
*Adenoviruses*—human—all types.
*Arboviruses.*
*Coxiella burnetii.*
*Coxsackie A and B viruses*—all types.
*Cytomegaloviruses.*
*Dengue virus.*
*Echoviruses*—all types.
*Encephalomyocarditis virus.*
*Hemorrhagic fever agents*, including *Crimean hemorrhagic fever (Congo), Junin*, and *Machupo viruses*, and others as yet undefined.
*Hepatitis-associated antigen.*
*Herpesvirus*—all members.
*Infectious bronchitis-like virus.*
*Influenza viruses*—all types.
*Lassa virus.*
*Lymphocytic choriomeningitis virus.*
*Marburg virus.*
*Measles virus.*
*Mumps virus.*
*Parainfluenza viruses*—all types.
*Polioviruses*—all types.
*Poxviruses*—all members.
*Psittacosis-Ornithosis-Trachoma-Lymphogranuloma* group of agents.
*Rabies virus*—all strains.
*Reoviruses*—all types.
*Respiratory syncytial virus.*
*Rhinoviruses*—all types.
*Rickettsia*—all species.
*Rubella virus.*
*Simian viruses*—all types.
*Tick-borne encephalitis virus* complex, including *Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever*, and *Central European encephalitis viruses.*
*Vaccinia virus.*
*Varicella virus.*
*Variola major* and *Variola minor viruses.*
*Vesicular stomatis virus.*
*Yellow fever virus.*

(1) *Volume less than 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed or corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

(2) *Volume 50 ml. or greater.* Packaging of material in volumes of 50 ml. or more shall include, in addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 500 ml. of material. However, two or more primary containers whose combined volumes do not exceed 500 ml. may be placed in a single, secondary container. Not more than eight secondary shipping containers may be enclosed in a single outer shipping container. (The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.)

(3) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be so placed that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) *Labels.* The label for Etiologic Agents/Biomedical Material, except for size and color, must be shown:




(i) The color of material on which the label is printed must be white and the symbol and printing in red.

(ii) The label must be a rectangle measuring 51 mm. (2 inches) high by 102.5 mm. (4 inches) long.

(iii) The red symbol measuring 38 mm. (1½ inches) in diameter must be centered in a white square measuring 51 mm. (2 inches) on each side.

(iv) Type size of the letters of label shall be as follows:

| | |
|---|---|
| ETIOLOGIC AGENT | 10 pt. rev. |
| BIOMEDICAL MATERIAL | 14 pt. |
| IN CASE OF DAMAGE OR LEAKAGE | 10 pt. rev. |
| NOTIFY DIRECTOR CDC ATLANTA, GA | 8 pt. rev. |
| 404 633 5313 | 10 pt. rev. |

(5) *Damaged packages.* Carriers shall promptly, upon discovery of damage to the package that indicates damage to the primary container, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road NE., Atlanta, GA 30333 (telephone (404) 633–5313), and the sender.

(6) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification to the shipper immediately upon delivery:

*Actinobacillus mallei.*
*Coccidioides immitis.*
*Francisella (Pasteurella) tularensis.*
*Hemorrhagic fever agents,* including, but not limited to, *Crimean hemorrhagic fever (Congo), Junin, Machupo viruses.*
*Herpesvirus simiae* (B virus).
*Histoplasma capsulatum.*
*Lassia virus.*
*Marburg virus.*
*Pseudomonas pseudomallei.*
*Tick-borne encephalitis virus* complex. Including, but not limited to, *Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever,* and *Central European encephalitis viruses, Variola minor* and *Variola major.*
*Yersenia (Pasteurella) pestis.*

(d) *Notice of delivery; failure to receive.* When notice of delivery of agents containing, or suspected of containing, etiologic agents listed in paragraph (c) (6) of this section is not received by the sender within 5 days following anticipated delivery of the package, the shipper shall notify the Director, Center for Disease Control, 1600 Clifton Road NE., Atlanta, GA 30333 (telephone (404) 633–5313).

(e) *Requirements; variations.* The Administrator may approve variations from the requirements of this section if, upon review and evaluation, he finds that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and makes such findings a matter of official record.

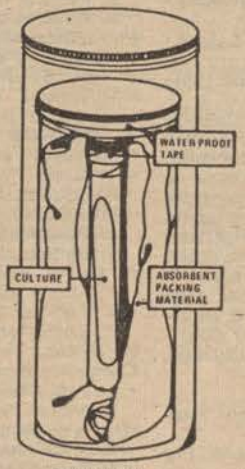
(Sec. 361, 58 Stat. 703; 42 U.S.C. 264)

[FR Doc.72-9887 Filed 6-29-72;8:45 am]

Effective July 30, 1972




## PACKAGING AND LABELING OF ETIOLOGIC AGENTS




CROSS SECTION OF PROPER PACKING

The Interstate Quarantine Regulations 142 CFR, Part 72.25 Etiologic Agents) was revised July 31, 1972 to provide for packaging and labeling requirements for etiologic agents and certain other materials shipped in interstate traffic.

Figures 1 and 2 diagram the packaging and labeling of etiologic agents in volumes of less than 50 ml. in accordance with the provisions of subparagraph (C) (1) of the cited regulation. Figure 3 illustrates the color and size of the label, described in subparagraph (C) (4) of the regulations, which shall be affixed to all shipments of etiologic agents.

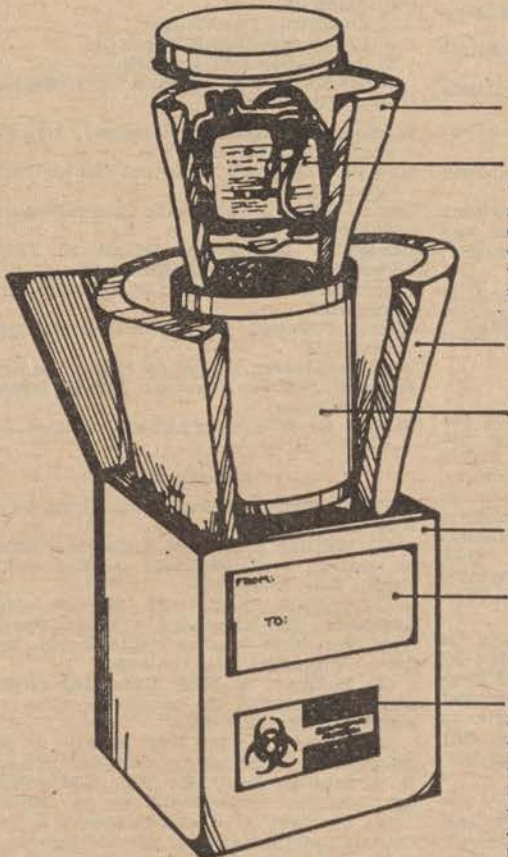
For further information on any provision of the regulation contact:

Center for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road
Atlanta, Georgia 30333
Telephone: 404 633 3311

FIGURE 3




## PACKAGING AND LABELING OF ETIOLOGIC AGENTS




*NOTE: Single primary containers may not exceed 500 ml. of material. Two or more primary containers whose combined volumes do not exceed 500 ml. may be enclosed in a single, secondary container. The maximum volume of etiologic agent which may be enclosed in a single outer shipping container shall not exceed 4000 ml.

The Interstate Quarantine Regulations (42 CFR, Part 72.25, Etiologic Agents) was revised July 31, 1972, to provide for packaging and labeling requirements for etiologic agents and certain other materials shipped in interstate traffic. The illustration shows acceptable packaging and labeling of etiologic agents in accordance with subparagraphs (c) (2) and (4) of the cited regulation.

For further information on any provision of this regulation contact:

Center for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road
Atlanta, Georgia 30333

Telephone: 404-633-3311

XI. TRAINING AIDS, MATERIALS AND COURSES

*A. Slide-Tape Cassettes*

1. Assessment of Risk in the Cancer Virus Laboratory ($10).

2. Effective Use of The Laminar Flow Biological Safety Cabinet ($10).

3. Formaldehyde Decontamination of Laminar Flow Biological Safety Cabinets ($10).

4. Certification of Class II (Laminar Flow) Biological Safety Cabinets ($13).

5. Hazard Control in the Animal Laboratory ($10).

6. Basic Principles of Contamination Control (In preparation).

7. Selection of a Biological Safety Cabinet (In preparation). These slide tape cassettes are available for purchase from the National Audiovisual Center. The price for each is given above after the title. Send your order prepaid with a check or money order made payable to National Archives Trust Fund and mail to: Sales Branch, National Audiovisual Center (GSA), Washington, D.C. 20409.

8. Research Laboratory Safety. This slide tape cassette, stock number 176.79, is available for $75 from the National Safety Council, 425 North Michigan Avenue, Chicago, Illinois 60611.

*B. Films*

1. Air Sampling for Microbiological Particulates (M-926).

2. Handling the Laboratory Guinea Pig (T2618-X).

3. Handling the Laboratory Mouse (T2617-X).

4. Infectious Hazards of Bacteriological Techniques (M-382).

5. Laboratory Design for Microbiological Safety (M-1091).

6. Plastic Isolators: New Tools for Medical Research (M-599).

7. Safe Handling of Laboratory Animals (M-455).

8. Surface Sampling for Microorganisms (Rodac Method) (M-924).

9. Surface Sampling for Microorganisms (Swab Method) (M-925).

These films are available on loan without charge from: Media Resources Branch, National Medical Audiovisual Center (Annex), Station K, Atlanta, Georgia 30324.

The same films (except 2 and 3) can be rented or bought from: National Audiovisual Center (GSA) (Rental Branch) = (Sales Branch), Washington, D.C. 20409.

*C. Courses*

1. Biohazard and Injury Control in the Biomedical Laboratory. Presented by the University of Minnesota, School of Public Health and the National Cancer Institute, Office of Research Safety. Direct inquiries to Dr. Donald Vesley, University of Minnesota, School of Public Health, 1325 Mayo Memorial Building, Minneapolis, Minnesota 55455. June 22–24, 1976, Los Angeles, CA; October 26–28, 1976, Boston, MA; December 7–9, 1976, Bethesda, MD.

2. Biohazard Containment and Control for Recombinant DNA Molecules. Presented by the University of Minnesota, School of Public Health and the National Cancer Institute, Office of Research Safety. Direct inquiries as above. September 8–9, 1976, Stanford, CA: September 21–11, 1976; Cold Spring Harbor, NY.

3. Safety in Laboratory. Presented by National Institute of Occupational Safety and Health, Division of Training and Manpower Development, by special arrangement. Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

4. Laboratory Safety Management. Presented by the Laboratory and Training Division, Bureau of Laboratories, Center for Disease Control, Atlanta, Georgia. September 14–16, 1976, September 13–15, 1977.

XII. OUTLINE OF A SAFETY AND OPERATION MANUEL FOR A P4 FACILITY

*A. Purpose*

*B. Policy*

*C. Responsibility and Authority*

1. Management.
2. Supervisor.
3. Each Employee.
4. Facility Safety Officer.
5. Biohazard Safety Committee.

*D. Facility Assignment Procedures*

*E. Reporting of Major and Minor Accidents and Injuries, Exposure to Toxic or Infectious Materials, Unsafe Conditions and Property Damages, and Rendering First-Aid*

*F. General Laboratory Safety*

1. Fire.
2. Equipment.
3. Physical.
4. Chemical.
5. Radiological.

*G. Safety Procedures Associated with Biohazard Activities of the Laboratory*

1. Personnel Practices.
2. Operational Practices.

*H. Medical Surveillance*

*I. Facility Operations*

1. Personnel Access Procedures.
2. Access Procedures for Equipment Materials and Supplies.
3. Maintenance and Support.
4. Zone Classification.
5. Facility Monitoring Procedures.
6. Housekeeping.

*J. Others*

1. Packaging and Shipment of Biohazardous Materials.
2. Emergency Procedures.
3. Insect and Rodent Control.
4. Orientation and Training.

Appendix D was prepared by a Working Group Consisting of:

W. Emmett Barkley (Chairman), National Cancer Institute, NIH.
Manuel S. Barbeito, National Cancer Institute, NIH.
Everett Hanel, Jr., Frederick Cancer Research Center.
George S. Michaelsen, School of Public Health, University of Minnesota.
Vinson R. Oviatt, Division of Research Services, NIH.
Warren V. Powell, Division of Research Services, NIH.
John Richardson, Center for Disease Control.
James F. Sullivan, National Animal Disease Laboratories.
Arnold G. Wedum, Frederick Cancer Research Center.

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[FR Doc.76–19151 Filed 7–6–76;8:45 am]

federal register

WEDNESDAY, JULY 7, 1976




PART III:

# OFFICE OF MANAGEMENT AND BUDGET

■

# OFFICE OF DRUG ABUSE POLICY

## Proposed Rescission

## OFFICE OF MANAGEMENT AND BUDGET

### OFFICE OF DRUG ABUSE POLICY

#### Proposed Rescission

TO THE CONGRESS OF THE UNITED STATES:

In accordance with the Impoundment Control Act of 1974, I herewith propose rescission of $250,000 provided in the Second Supplemental Appropriations Act, 1976, for establishment of the Office of Drug Abuse Policy (ODAP) in the Executive Office of the President. When I signed into law P.L. 94–237, the "Drug Abuse Office and Treatment Act Amendments of 1976" which extended necessary appropriation authorizations for Federal drug abuse prevention and treatment programs, I expressed by opposition to establishing ODAP. I stated that "I thoroughly agree with the position of the Congress on the importance of a well coordinated Federal drug abuse program. I have consistently held, however, that such coordination can best be carried out by existing departments and agencies, without an additional agency for that purpose." Accordingly, I am recommending to the Congress that it rescind the $250,000 appropriated for ODAP.

This new Office is a relatively minor item in terms of dollars and staff size. The Director of ODAP is to "make recommendations to the President with respect to . . . drug abuse functions and . . . (to) coordinate the performance of such functions by Federal departments and agencies." ODAP represents an unnecessary expense for the taxpayer and adds to the Federal bureaucracy. Furthermore, I believe the establishment of this Office is an encroachment on my responsibilities as Chief Executive to organize the Executive Office of the President to carry out, as effectively as possible, the programs and laws which are established by Congress.

Since I have taken office, it has been my consistent objective to place the responsibility for governmental action with the Cabinet officers and their respective agencies. The Office of Drug Abuse Policy flies in the face of this objective, and adds to the bureaucracy a redundant layer that will have no direct management responsibilities. The drug abuse area—including treatment, enforcement, and international narcotics control—already has the necessary coordinating mechanisms and resources to accomplish its objectives. Likewise, I already have Cabinet officers, agency heads, and others to provide me advice on drug abuse matters. I do not need another Office with two officials with salaries of $42,000 (ODAP Director) and $39,900 (ODAP Deputy Director) to duplicate their work. Lastly, the annual preparation of the budget provides an effective process for identification and resolution of Executive Branch policy issues.

The attached chart displays the following coordinating mechanisms that already exist for Federal drug abuse treatment, law enforcement, and international activities:

—Domestic Council
—Drug Abuse Cabinet Committees
—National Security Council
—Office of Management and Budget

The Cabinet Committees will assure that various Federal agencies' efforts are integrated into an effective overall program but will keep responsibility for specific program management with the appropriate agencies. The Congressional committees can call upon the heads of the Cabinet Committees or agencies with drug abuse responsibilities to testify concerning my Administration's policies whenever there is a need. I see no need for one more drug abuse spokesperson.

*Administration Drug Abuse Initiatives to Date.* During my Administration, the following initiatives have been taken demonstrating the priority I have placed on drug abuse:

—I launched a complete review of Federal drug abuse policies, and then endorsed the resultant *White Paper on Drug Abuse.*

—I have requested funding for fiscal year 1977 totaling over $780 million for Federal drug abuse programs to maintain existing programs and to implement the major recommendations of the *White Paper*, e.g., additional community treatment capacity and better targeting of law enforcement efforts at high level traffickers.

—I have met with the heads of the governments of Turkey, Mexico and Colombia to strengthen and improve our international drug abuse efforts.

—I transmitted a drug abuse message to the Congress on April 27, 1976, which included, among others, proposals for strengthening law enforcement efforts.

—The Cabinet officers have placed priority attention on strengthening their drug abuse organizations.

*Future Actions.* My Administration plans to strengthen its efforts against the drug abuse problem.

—The Cabinet Committee for Drug Law Enforcement has held its first meeting and the Cabinet Committee on Drug Abuse Prevention, Treatment, and Rehabilitation will be fully operational within a month. The Office of Management and Budget and the agencies involved will provide the necessary support to the Cabinet Committees.

—Over the next month, Cabinet officers will contact the Congressional committees with drug abuse responsibilities to discuss the agenda from the Cabinet Committees.

—The agencies affected by the recommendations of the *White Paper* will provide me with a full status report when they submit their budget requests for fiscal year 1978 this September.

In summary, the Office of Drug Abuse Policy is an example of unnecessary growth in the Federal bureaucracy, and should not be established. It is the responsibility of public officials to guard against the unwarranted or inefficient use of public funds. I am, therefore, asking that the Congress rescind the funds for the Office of Drug Abuse Policy.

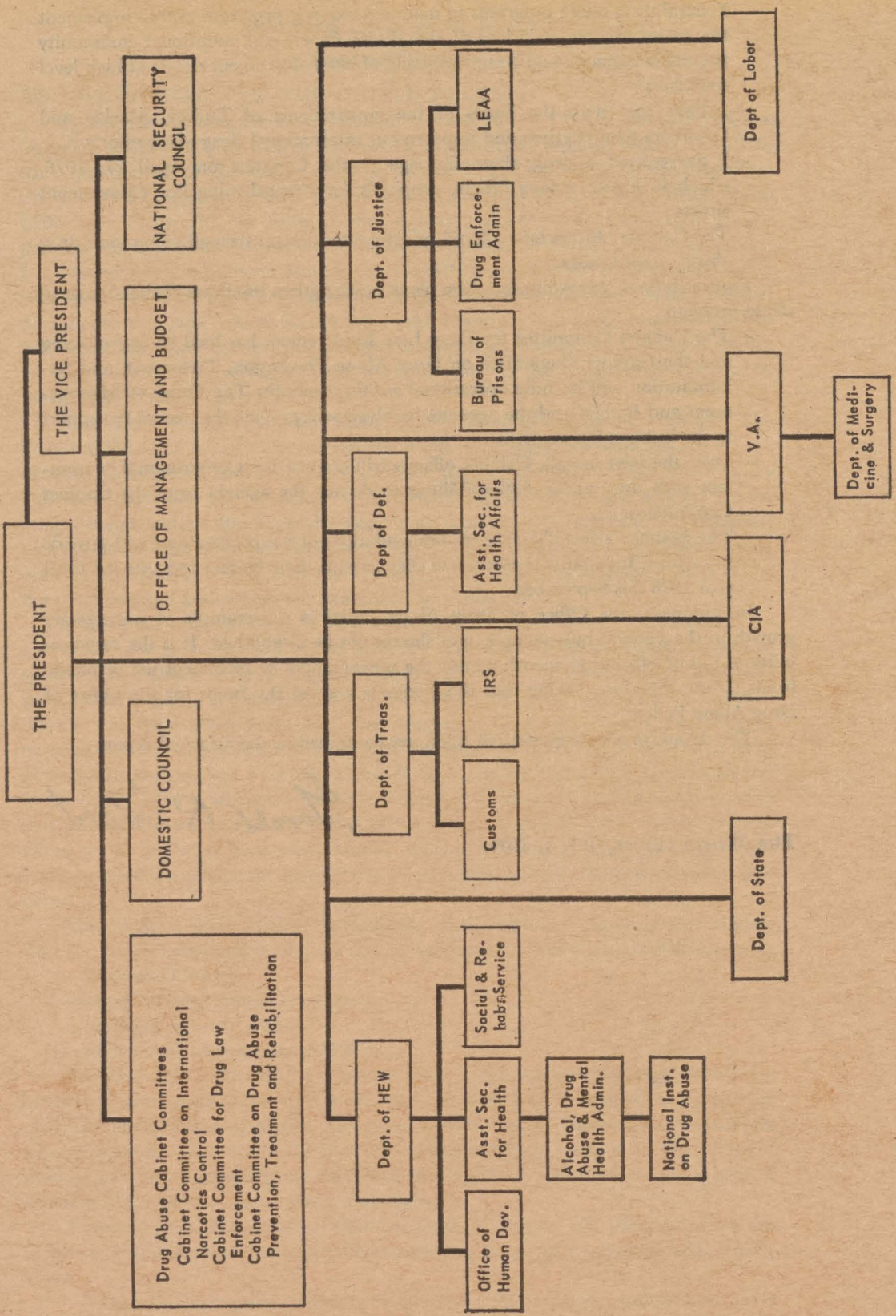
The details of the proposed rescission are contained in the attached report.

Gerald R. Ford

THE WHITE HOUSE, July 1, 1976.

Attachment

# Organization of Federal Agencies with Major Drug Abuse Coordination and Program Responsibilities



CONTENTS OF SPECIAL MESSAGE
(in thousands of dollars)

| Rescission # | Item | Budget Authority |
|---|---|---|
| | Executive Office of the President | |
| R76-45 | Office of Drug Abuse Policy | 250 |

* * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *

Summary of Special Messages
for FY 1976

(Amounts in thousands of dollars)

| | Rescissions | Deferrals |
|---|---|---|
| Sixteenth special message: | | |
| New item | 250 | --- |
| Changes to amounts previously submitted | --- | --- |
| Effect of the sixteenth special message | 250 | --- |
| Previous special messages | 3,328,714 | 9,017,337 |
| Adjustments to eliminate double counting | --- | -242,023 |
| Total amount proposed in special messages | 3,328,964 (in 45 rescission proposals) | 8,775,314 (in 111 deferrals) |

NOTE: All amounts listed represent budget authority except for $125,565,331 consisting of two general revenue sharing deferrals (of outlays only). A supplementary report (D76-25E) was included in the fourteenth special message for one of these deferrals. The other deferral (D76-67) was reported in the seventh 1976 special message.

Rescission Proposal No: R76-45

## PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 93-344

| | |
|---|---|
| Agency: EXECUTIVE OFFICE OF THE PRESIDENT<br>Bureau: Office of Drug Abuse Policy<br>Appropriation title & symbol:<br>Salaries and Expenses<br>1161451 | New budget authority (P.L. 94-303 ) $ 250,000<br>Other budgetary resources —<br>Total budgetary resources 250,000<br>Amount proposed for rescission $ 250,000 |
| OMB identification code: 03-45-1451-0-1-802<br>Grant program ☐ Yes ☒ No | Legal authority (in addition to sec. 1012): ☒ Antideficiency Act ☐ Other |
| Type of account or fund: ☒ Annual ☐ Multiple-year (expiration date) ☐ No-year | Type of budget authority: ☒ Appropriation ☐ Contract authority ☐ Other |

Justification:

The $250,000 proposed for rescission would provide for the establishment within the Executive Office of the President of a new Office of Drug Abuse Policy (ODAP) authorized by P.L. 94-237, the "Drug Abuse Office and Treatment Act Amendments of 1976." The rescission is proposed because the funds are not required to carry out the objectives for which they were provided. The establishment of the Office would duplicate existing drug abuse coordinating and policy formulation mechanisms, e.g., Cabinet committees composed of Cabinet officers and agency heads with Federal drug abuse responsibilities, the Domestic Council, and the budget process. The objectives of ODAP, i.e., drug abuse policy recommendations and coordination among the various drug abuse program components, can be best accomplished through these existing means. Another layer of Federal bureaucracy is unnecessary. The Cabinet committees will assure that various Federal agencies' efforts are integrated into an effective overall program.

The establishment of ODAP is an encroachment on the President's prerogative to organize the Executive Office of the President as he deems appropriate. The President has sought to place primary responsibility of governmental action in the drug abuse area with the Cabinet Secretaries and their respective agencies. ODAP would hinder this effort and merely add a redundant layer for policy development while having no program responsibility.

The Cabinet officers, agencies heads, and their staffs--with drug abuse program responsibilities--are capable of providing advice on drug abuse policies. A Director of ODAP at an annual salary of $42,000 and a Deputy Director of ODAP at

an annual salary of $39,900 are not needed to duplicate their work. The congressional committees can call up heads of the drug abuse Cabinet committees or agencies with drug abuse program responsibilities whenever there is need. One more drug abuse spokesperson is not needed.

The taxpayers should not be asked to support this unnecessary expense. If established, this Office would also necessitate up to $2 million annually starting next fiscal year.

Estimated Effects:

The proposed rescission would prevent unnecessary duplication of functions and would thus facilitate the effective and efficient operation of drug abuse policy and coordination activities.

Outlay Effect:

Comparison with the President's 1976 Budget:

| | |
|---|---|
| 1. Budget outlay estimate for 1976 | -0- |
| 2. Outlay savings, if any, included in the budget outlay estimate | -0- |

Current Outlay Estimates for 1976:

| | |
|---|---|
| 3. Without rescission | -0- |
| 4. With rescission | -0- |
| 5. Current outlay savings (line 3 - line 4) | -0- |

| | |
|---|---|
| Outlay Savings for the Transition Quarter | $200,000 |
| Outlay Savings for 1977 | $ 50,000 |
| Outlay Savings for 1978 | -0- |

R76-45

EXECUTIVE OFFICE OF THE PRESIDENT

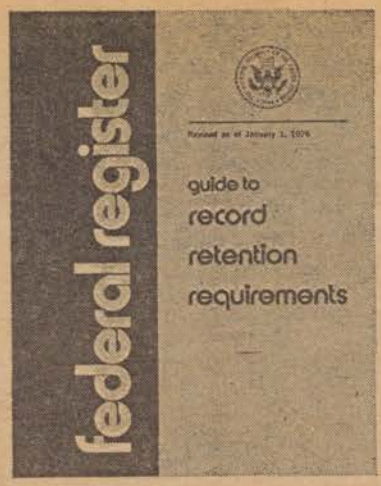
Office of Drug Abuse Policy

Salaries and Expenses

Appropriations provided under this head in the Second Supplemental Appropriations Act, 1976, are rescinded in the amount of $250,000 for the fiscal year ending June 30, 1976.

[FR Doc.76-19534 Filed 7-1-76;3:21 pm]

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# Guide to Record Retention Requirements

[Revised as of January 1, 1976]

This useful reference tool, compiled from agency regulations and U.S. Statutes, is designed to assist industry and the public with their recordkeeping obligations.

The various digests in the 96-page "Guide" tell the user (1) what records must be kept, (2) who must keep them, and (3) how long they must be kept. Each digest also carries a reference to the full text of the basic law or regulation providing for such retention.

The booklet's index lists for ready reference the categories of persons, groups, and products affected by Federal record retention requirements.

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