(g) A separate bond shall be required for each area. An operator's bond in the same amount may be substituted at any time for the lessee's bond.

(h) Where, upon a default, the surety makes a payment to the United States of an obligation incurred under a lease, the face amount of the surety bond and the surety's liability thereunder shall be reduced by the amount of such payment.

(i) After default, the principal shall, within 6 months after notice or within such shorter period as may be fixed by the Director, either post a new bond or increase the existing bond to the amount previously held. In lieu thereof, the principle may, within that time, file separate or substitute bonds for each lease. Failure to meet these requirements may result in a suspension of operations including production on leases covered by such bonds.

(j) The Director shall not consent to termination of the period of liability of any bond unless an acceptable alternative bond has been filed or until all the terms and conditions of the lease covered by the bond have been met.

§ 282.41 Method of royalty calculation.

In the event that the provisions of royalty management regulations do not apply to the specific commodities produced under regulations in this part, the lessee shall comply with procedures specified in the leasing notice.

§ 282.42 Payments.

Rentals, royalties, and other payments due the Federal Government on leases for OCS minerals shall be paid and reports submitted by the payor for a lease in accordance with § 281.26 of this title.

Subpart E—Appeals

§ 282.50 Appeals.

Orders or decisions issued under the regulations in this part may be appealed in accordance with the provisions of Part 290 of this title. The filing of an appeal with the Director shall not suspend the requirement for compliance with an order or decision other than the payment of a civil penalty.

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August 18, 1988

Part IV

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Update of Ambulatory Surgical Center Payment Rates; Notice of Proposed Rates

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BERC-460-PN]

Medicare Program; Update of Ambulatory Surgical Center Payment Rates

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of proposed rates.

SUMMARY: This proposed notice sets forth the updated payment rates for ambulatory surgical center services. As required by section 1833(i)(2)(A) of the Social Security Act, these revised rates would be effective July 1, 1988.

We are proposing to refine the methodology used to determine the payment rates and base the rates on the most recent survey data collected from ambulatory surgical centers. In addition, we would compute the payment rates using the HCFA hospital wage index. We are also proposing to incorporate the payment for intraocular lens implanted during cataract surgery into the facility rate as required by section 4063(b) of the Omnibus Budget Reconciliation Act of 1987, which was enacted on December 22, 1987. Finally, we are proposing changes regarding the payment policy for surgical procedures that are terminated due to medical complications that increase the surgical risk to the patient.

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on October 17, 1988.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-460-PN, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-460-PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Vivian Braxton, (301) 966-4571.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that, under Part B of Medicare (Supplementary Medical Insurance), benefits include services furnished in connection with those surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by the Secretary and that are performed in an ambulatory surgical center (ASC). As defined in 42 CFR 416.2, an ASC is any distinct entity that—

- Operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization;
- Has an agreement with HCFA to participate in the Medicare program as an ASC; and
- Meets specified conditions for coverage set forth in Subpart B of 42 CFR Part 416.

Generally, there are two elements in the total charge for a surgical procedure—a charge for the physician's professional services for performing the procedure, and a charge for the facility's services (such as use of an operating room). Before the enactment of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203), if the physician agreed to accept assignment, the physician's professional services furnished in connection with these surgical procedures when performed in an ambulatory setting were paid at 100 percent of the reasonable charge (or 100 percent of the reasonable cost in the case of a health maintenance organization reimbursed under section 1876 of the Act) (42 CFR 416.110). If the physician did not accept assignment for these services, payment was made at 80 percent of the reasonable charge. The changes made to this policy by Pub. L. 100-203 are discussed below.

Section 1833(i)(2)(A) of the Act authorizes the Secretary to pay ASCs a prospectively determined rate for facility services associated with covered surgical procedures meeting the criteria specified under section 1833(i)(l)(A) of the Act. Facility services furnished after June 30, 1987 are subject to the usual Medicare Part B 20 percent coinsurance and deductible requirements. Therefore, participating ASCs are paid 80 percent of the prospectively determined rate. The rate is intended to represent the Secretary's estimate of a fair fee that takes into account the cost of facility services provided in conjuction with a procedure. Currently, the rate is a standard overhead amount that does not include physicians' fees and other medical items and services (for example, prosthetic devices) for which separate payment may be authorized under other provisions of the Medicare program.

The Report of the Senate Committee on Finance accompanying section 934 of Pub. L. 96-499 (the legislation that added the ASC benefit to the Medicare program) states, "The overhead factor is expected to be calculated on a prospective basis * * * utilizing sample survey and similar techniques to develop reasonable estimated overhead allowances for each of the listed procedures * * *." (See S. Rep. 471, 96th Cong., 1st Sess. 35 (1979).) Section 416.140 of the regulations provides that a survey will be conducted periodically. In addition, section 1833(i)(2)(A)(ii) of the Act requires that the ASC facility payment rate must result in substantially less Medicare expenditure than would have been paid if the same procedure was performed on an inpatient basis.

Currently, all covered ASC surgical procedures are classified into four separate payment groups for which four separate ASC payment rates apply. When two or more procedures are performed in the same operation, payment to the ASC is at the full rate for the procedure classified in the highest payment group and 50 percent of the rate for each of the other procedures (§ 416.120(c)(2)), subject to deductible and coinsurance amounts. Freestanding facilities and hospital-operated ASCs electing to participate under the ASC benefit are paid at the same rate.

On August 5, 1982, we issued two documents in the **Federal Register** to implement the ASC benefit. The first was a final rule to add to the benefits available under Part B of Medicare the services associated with certain surgical procedures provided in an ASC setting. (See 47 FR 34082.) In the second document, which was a final notice, the Secretary, after consulting with appropriate medical organizations, specified a list of surgical procedures that may be performed safely on an ambulatory basis in an ASC. (See 47 FR 34099.) Subsequently, we have revised the list of covered ASC procedures in an April 21, 1987 final notice (52 FR 13176), and proposed further revision to that list in an August 11, 1987 proposed notice (52 FR 29729). Corrections to the latter notice were published on September 15, 1987 (52 FR 34848).

In March 1983, we issued implementing instructions at sections

2266.3 and 5243.3 of the Medicare Carriers Manual (HCFA Pub. 14-3). Section 2266.3 restates the list of covered procedures published in the August 5, 1982 final notice using the specific procedure codes from the Physicians' Current Procedural Terminology, Fourth Edition (commonly referred to as CPT-4). Since the list of approximately 100 procedure codes published in the August 5, 1982 final notice generally represented two or more distinct procedures, the list as restated in specific CPT-4 codes included more than 400 procedure codes. In June 1987, the list of CPT-4 codes in the Medicare Carriers Manual was revised to include the revisions set forth in the April 21, 1987 final notice. The list now includes 1535 procedure codes.

Section 5243.3 defines the criteria for payment of multiple covered procedures performed in the same operative session. With one exception, all of the covered procedures listed in section 2266.3 and designated by a single CPT-4 code are considered single procedures. The exception, insertion of intraocular lens prosthesis with cataract extraction (initially coded as procedure code 66980 and subsequently recoded as procedure codes 66983 and 66984 to distinguish an intracapsular cataract extraction from an extracapsular extraction, respectively), is treated as two separate procedures. The manual instructs the carriers to pay this procedure at one and one-half times the applicable Group 4 payment rate.

II. Notice of Updated Payment Rates Effective July 1, 1987

A. Introduction

In a June 1, 1987 notice with comment period (52 FR 20466), we updated the ASC facility payment rates for the first time since they were first published in the August 5, 1982 final rule. The updated rates were based on the projected increase (18.7 percent) in the consumer price index for all urban consumers (CPI-U) from September 1982 (the effective date of the initial ASC payment rates) to January 1988 (the midpoint of the 12-month period beginning July 1, 1987). We used Data Resources, Incorporated (DRI) forecasts for the fourth quarter calendar year 1987 and the first quarter calendar year 1988 index levels to project the January 1988 index level.

The ASC facility services payment rates that were effective July 1, 1987 are as follows:

Group 1—$274
Group 2—$326
Group 3—$351
Group 4—$399

B. Discussion of Comments

In response to the notice, we received 75 items of correspondence. The majority of the comments were submitted by individuals who owned or operated ASCs. All of the comments dealt with two general issues, as discussed below.

Comment: A number of commenters objected to the use of an economic index to update the facility payment rates because they believed that the original rates were inadequate and were based on limited and obsolete data. They stated that the update should have been based on the ASC survey data collected in 1986.

Response: We acknowledge the limitations of our original data base and agree that it would have been preferable to update the facility rates based on the new survey data rather than on an economic index. However, as explained in the June 1987 notice (52 FR 20467), we were unable to complete our analysis of the survey data in time to meet the statutory deadline of July 1, 1987 because of delays beyond our control in completing audits of 97 sample facilities. (Section 1833(i)(2)(A) of the Act requires that the payment rates be updated not later than July 1, 1987, and annually thereafter.) Due to discrepancies observed in the unaudited data, it was imperative that the audits be completed before the results were incorporated into an updated methodology.

Comment: Commenters argued that the hospital market basket index rather than the CPI-U should have been used to account for inflation when updating the facility payment rates for July 1, 1987. They believed that the hospital market basket index is more appropriate because of the similarity between costs incurred for surgical services offered by ASCs on an outpatient basis and costs incurred for surgery performed by hospitals on an inpatient basis.

Response: After carefully considering all alternatives, we updated the payment rates using the CPI-U because it is a generalized index that reflects increases in the prices paid for a representative market basket of goods and services. Congress has mandated the use of the CPI-U for the Medicare clinical diagnostic laboratory fee schedule, and it has also been used to limit increases in allowable charges for nonphysician services.

The hospital market basket index is a specialized index specifically related to goods and services commonly associated with hospital inpatient costs. Notwithstanding similarities in surgical costs incurred by ASCs and hospitals, the mix of goods and services differ substantially. Because of this difference, we believe that use of the hospital market basket index would have distorted the ASC payment rates.

III. New Legislation

On December 22, 1987, the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203) was enacted. This new legislation includes the following provisions that affect payment for ASC services:

- Section 4084 of Pub. L. 100-203 amended section 1833(1) of the Act to add ASCs to the list of entities that can bill and be paid separately for the services of certified registered nurse anesthetists (CRNAs) who are either employed by the ASC or who have entered into a contractual arrangement to perform services for the ASC. This change applies to services furnished on or after January 1, 1989. We intend to implement this provision in a separate rulemaking document. For purposes of this proposed notice, we note our intention to continue the current practice of incorporating the costs associated with CRNA services furnished by CRNAs who are either employed directly by the ASC or who have a contractual arrangement with the ASC into the facility payment rate.
- Section 4054 of Pub. L. 100-203 limited section 1833(1) of the Act to repeal, in effect, the waiver of Medicare Part B coinsurance and deductible requirements for physicians' services furnished in connection with an ASC covered procedure effective April 1, 1988. As of that date, physicians' services are paid at 80 percent of reasonable charges and beneficiaries are responsible for a 20 percent coinsurance and the Medicare Part B deductible.
- Section 4063(b) of Pub. L. 100-203 amended section 1833(i)(2)(A) of the Act to mandate that payment for an intraocular lens (IOL) implant performed in an ASC in conjunction with cataract surgery be included in the facility payment rate effective with services furnished on or after July 1, 1988. It further requires that the payment amount for the IOL be reasonable and related to the cost of acquiring certain types of lenses.

IV. Provisions of the Proposed Notice

A. Methodology for Ratesetting

The payment methodology published in the August 5, 1982 final rule established four facility payment rate groups based on 1979 and 1980 cost and charge information obtained from approximately 40 ASCs. Using these

data, we first developed an indexing method for ranking each covered procedure based on a facility's charge for an individual procedure as compared to its average charge for all procedures offered. By indexing procedures, we were able to determine the value a particular facility places on a covered procedure in relation to other procedures it offers.

We calculated the average of the index numbers across all facilities for each procedure and then arrayed the procedures by this national average index. After determining the national average index value for each procedure, we classified the covered procedures into four groups by that value. We used interval points to establish group breaking points as follows:

Group 1—index less than .90
Group 2—index between .90 and 1.00
Group 3—index between 1.01 and 1.10
Group 4—index greater than 1.10

The index value was used exclusively for classification purposes. For determining the actual payment rate of a group, we used actual charge and cost information reported by the facilities. To establish the payment rates for each of the four groups, we used a five-step procedure, as described below.

Step 1—To remove the effects of area wage differences, we adjusted (that is, deflated) the actual charges for each procedure using the hospital wage index published on June 30, 1981 (46 FR 33641). Based on our analysis of submitted financial reports, we determined that, on the average, the labor portion is approximately one-third of the charge for each procedure. Assuming facilities' charges to be similarly related to costs, we adjusted one-third of the charge for each procedure by the wage index.

Step 2—We then calculated the average charge-per-procedure for each covered procedure by summing the wage-adjusted charge for all facilities in our data base that furnished a given procedure and dividing that result by the number of ASCs performing the same procedure.

Step 3—The procedures within each payment group were arrayed by the average charge. We identified the 60th percentile of average charges within the four payment groups.

Step 4—Based on a review of financial statements submitted by ASCs, we determiend a cost-to-charge ratio of 0.9. In order to make Medicare payments to ASCs cost-related as required under section 1833(i)(2) of the Act, we multiplied the average charge at the 60th percentile by 0.9.

Step 5—We further adjusted the average charge at the 60th percentile of each payment group to account for inflation occurring between 1980 and the effective date of the rates (September 7, 1982). The four payment group rates were set at the inflation-adjusted amounts.

As stated, above, we applied an across-the-board inflation factor to update the 1982 payment rates for services furnished on or after July 1, 1987.

For purposes of computing the ASC payment rates for services furnished on or after July 1, 1988, we are proposing to change our ratesetting methodology as described below.

1. Use of the Latest Survey Data

The payment rates proposed in this notice were developed based on the most recent survey data available on facility overhead expenses and procedure-specific charges. The data contained in our new data base were gathered through a survey of the industry conducted between May and August 1986. The survey instrument, the Ambulatory Surgical Center Payment Rate Survey (Form HCFA–452), was mailed in May 1986 to all ASCs (approximately 500) that were identified as participating facilities during March 1986. Facilities were required to complete Form HCFA–452 by July 10, 1986. Due to difficulties encountered by a large number of facilities in complying with the deadline, the due date was extended for at least 30 days upon request.

Of the approximately 500 facilities included in our mailing, about 470 of the ASCs completed Form HCFA–452. This statistic excludes 12 ASCs that had terminated their participation prior to receipt of the survey form.

The survey gathered information specific to total charges (Medicare and non-Medicare) on each procedure performed and the total number of times the procedure was performed as well as aggregate charges and cost data for each ASC's most recently completed fiscal year. The survey also obtained information on the number of Medicare patients and total patients treated by the ASC.

In preparing the 470 survey forms for data extraction, we identified forms from 333 ASCs that could potentially be used to develop the proposed rates included in this notice. We excluded those forms from ASCs that—

- Had been in operaton for less than six months;
- Could not separate operation of the ASC from operation of other entities; or
- Were unable to capture charge data from their recordkeeping systems in the manner requested.

The ASCs represented in our data base are located largely in urban areas (87 percent) and are overwhelmingly freestanding facilities (98 percent). Summary data on the national ASC survey are available upon request of HCFA.

These survey data represent a significantly broader data base than the one used in setting the current ASC rates. The new survey data base includes data from calendar years 1984, 1985, and 1986. In addition, this data base contains charge information on more than 1200 of the 1535 covered procedures.

Our initial analysis of the survey data indicated that there were flaws in the data, which we have attributed to ASCs' unfamiliarity with the new survey form and inconsistencies among ASCs in their recordkeeping systems. Preliminary review of the survey form responses indicated several problem areas (for example, underreporting of aggregate charges and commingling of receipts from a physician's private practice with the ASC operation) that prompted us to conduct a nationwide audit of a sample of ASCs for the purpose of validating the survey responses and developing from the audited data statistical measures such as the cost-to-charge ratio needed to make payments cost-related.

2. Sample Design and Audit

a. *Sample Design.* As discussed above, we conducted national audits of a sample of the survey data. To determine the appropriate sample size required to apply the audit findings to the survey responses obtained from a total population of 333 ASCs, we approximated the variance of audited costs, the variance of audited charges, and the correlation between audited costs and audited charges for a randomly selected sample of 50 unaudited Form HCFA–452s. Reported revenues were used as a proxy for charges and reported total expenses were used for costs. After reviewing a variety of precision levels with a given sampling error percentage, we determined that a random sample of 100 facilities would be appropriate to estimate audit results with adequate precision for ratesetting purposes.

To draw the sample, we identified the 333 ASCs solely by their six-digit Medicare provider number. These numbers were listed in numerical sequence. Sample ASCs were then randomly selected using appropriate statistical procedures. Of the 100 ASCs selected for audit only 97 ASCs were actually audited because 3 incorrect

provider numbers were included in the sample drawing. However, we used data from only 90 facilities because, of the 97 audited ASCs, 3 ASCs failed to report their charges correctly and 4 ASCs failed to report their Medicare and total patient statistics properly. Of the 97 ASCs actually audited, 20 percent were located in California, 9 percent in Texas, 8 percent in Arizona, and 5 percent in Florida.

b. *Audit Results.* The nationwide audit was conducted from November 1986 through March 1987 by the Medicare fiscal intermediates. Although ASCs are serviced by Medicare carriers, we had fiscal intermediaries conduct the audits because we believe their audit capabilities are better suited to conduct this type of activity. The home offices of ASC chains included in the sample were audited by the Office of the Inspector General (OIG). We instructed the auditors to determine reasonable costs of the audited facilities in accordance with Medicare principles of reimbursement.

Audits resulted in net adjustments that reduced reported costs by 9.1 percent and increased reported aggregated charges by 6.1 percent. The audit adjustments brought aggregate charges more in line with total revenue. The major cost reductions occurred in plant and property, equipment, laboratory, and other or miscellaneous costs such as travel, education, and malpractice insurance premiums. Prostheses and durable medical equipment (DME) costs were adjusted upward by nearly 13 percent while salary and supply costs were increased 1.5 and 0.8 percent, respectively.

After the audits were completed, we made the following adjustments to the audited data:

• As mentioned above, we eliminated three facilities from the aduit sample because their charges were reported improperly. We eliminated four other facilities because they either had no Medicare patients or incorrectly reported their patient statistics. Inclusion of these ASCs would have distorted the computed cost-to-charge ratio.

• We eliminated any excessive compensation paid to an administrator or to a medical director based on our audited analysis of administrative staff expenses and owner's compensation. Our analysis showed that the average salary for one full-time administrator or medical director in an ASC is $40,000. Therefore, we adjusted owner's compensation for nine audited facilities where the amount paid was in excess of $40,000 and was not related to duties performed.

• We determined that charges were not reported for prostheses and DME furnished by the ASCs even though expenses associated with these items were reflected in the cost data. Under the ASC benefit, payment for prostheses and DME is separate from the facility payment rate. Therefore, when computing the cost-to-charge ratio, we excluded those audited costs.

After completing these adjustments, we then performed the following calculations on the audited data:

• We summed each facility's salary and fringe benefits costs including owner's compensation and contractual personnel costs in order to derive the total labor-related costs for the sample.

• We summed each facility's net total costs.

• We then divided the total labor-related costs by the net total costs to derive the average labor-related percentage. The results were used to apportion the per procedure charges for the total population into their labor-related (34.45 percent) and nonlabor-related (65.55 percent) components prior to adjusting for geographic wage differences.

• We multiplied the net total costs for the facility by its ratio of Medicare patients to total patients to determine the portion of its costs attributable to Medicare patients. Similarly, we multiplied each facility's aggregate charges by its ratio of Medicare patients to total patients to determine the portion of its charges attributable to Medicare patients. We then summed each facility's Medicare costs and divided by the sum of the Medicare aggregate charges. We arrayed the resulting ratios in descending order and calculated the median Medicare cost-to-charge ratio for the sample (0.776). We then used the cost-to-charge ratio to relate each per procedure charge to cost as described below. Because the median is unaffected by extreme variations in individual facility costs and charges, we believe that use of a median rather than a mean cost-to-charge ratio is a distinct improvement over the current methodology.

3. Use of an Inflation Adjustment

The initial ASC rates that were determined in 1982 were adjusted for inflation. In addition, when we updated the rates for services furnished on or after July 1, 1987, we used the CPI–U and DRI forecasts to adjust the four basic group rates to account for inflation. This adjustment resulted in an across-the-board rate of increase and we used this approach solely to establish revised rates in the absence of a new data base. As a refinement to our ratesetting methodology, we are proposing to continue to use the CPI–U and DRI forecasts to construct inflation factors to adjust for the effects of changing price levels on ASC costs. The annual rates of increase used to derive the proposed inflation factors are shown in Table I below.

In the absence of an ASC-specific market basket, we believe that use of the CPI–U, a generalized index, is appropriate to reflect the impact of actual and projected changes in wages and prices on ASC costs occurring between the periods represented in our data base and the period covered by the revised rates. Unlike our initial data base which consisted almost entirely of data from 1980, our new data base contains survey data that are based on several calendar years of data (that is, 1984, 1985, and 1986). We are proposing this approach to ensure that the rates based on these reporting years include reasonably fair estimates of inflation that has occurred since the period covered by the survey.

We would apply the inflation adjustment on a facility by facility basis to the per procedure charge extracted from the survey forms to account for historical and projected price changes occurring between the midpoints of the periods included in our data base and the midpoint of the 12-month period to which the new rates would apply (December 31, 1988).

The annual percentage increases that were used to compute the proposed ASC rates are as follows:

TABLE I

	Percent increase[1] in the CPI–U
Calendar year:	
1984	4.3
1985	3.6
1986	1.9
1987	3.8
1988	4.6

[1] DRI fourth quarter 1987 update.

4. Deflation by Wage Index

After adjusting charges for inflation, we separated each ASC's per procedure charge into its labor-related and nonlabor-related portions. The labor-related portion (34.45 percent) was determined by calculating the average percentage of audited labor-related costs for the sample of 90 facilities. We defined labor-related costs to include salary, fringe benefits, contractual personnel expenses and owner's

compensation. We then divided the labor-related component of the per procedure charge by the wage index applicable to the ASC's location to derive a standardized labor-related portion of the charge. (The wage index is set forth in Addendum C to this proposed rule.) The effect of this calculation is to remove any variation in ASC per procedure charges that may be due solely to geographical differences in wages. We would then add the adjusted labor-related portion of the charge to the nonlabor-related portion prior to arraying and determining the weighted median charges.

5. Wage Index

Since the initial publication of the ASC facility payment rates in the August 5, 1982 final rule, we have used the 1981 Bureau of Labor Statistics' (BLS) wage index to adjust the payment rates for area wage variation. This wage index was published initially in the **Federal Register** on June 30, 1981 (46 FR 33637) and subsequently republished on November 26, 1984 (49 FR 46495). The wage index was constructed from 1979 hospital wage and employment data obtained from the BLS ES 202 Employment, Wages, and Contributions file for hospital workers, a standard reporting category. The BLS ES 202 system compiles information on employment and total wages for workers covered by unemployment insurance.

Since initial use of the BLS wage index, we have been aware of certain limitations in the BLS data, especially with regard to the lack of information on hours of employment or full-time equivalents. The BLS data provide information only on the number of workers employed at a hospital and their aggregate salaries. As a result, area wage indexes produced from these data do not distinguish between part-time and full time employees. Although we recognized these shortcomings, we used the BLS wage index in calculating the ASC facility payment rates because we believed that the advantage of using the best national data available outweighed any disadvantages.

It is important to note that when the ASC rates were established in 1982, data were not available to construct an ASC-specific wage index. Fewer than 100 ASCs were operational at that time. Therefore, we adopted the BLS hospital wage index as the best available proxy for adjusting area wage levels. While the 1986 ASC survey instrument (Form HCFA–452) included limited information on salaries and employment, such information was not presented in sufficient detail to permit the construction of an ASC industry-specific wage index from only these survey data. In addition, a significant proportion of ASCs failed to report or erroneously reported either the salary or full-time equivalent data or both.

Since we are unable to construct an ASC industry-specific wage index at this time, we are proposing to adopt the HCFA hospital wage index for use in calculating ASC payment rates. The HCFA hospital wage index was constructed in an effort to overcome the limitations of the BLS data with regard to full-time and part-time employment. We conducted a survey in 1944 that provided for the extraction of specific hospital salary and fringe benefit data from the Medicare cost report, and for the extraction from hospital records of data on paid hours worked. A complete description of the survey, as well as the survey results, can be found in the following **Federal Register** documents:

- The proposed rule published on July 3, 1984 (49 FR 27439).
- The final rule published on August 31, 1984 (49 FR 34764).
- The June 10, 1985 proposed rule (50 FR 24375).
- The September 3, 1985 final rule (50 FR 35661).

The HCFA wage index, which is currently used to set the inpatient hospital prospective payment system rates, the skilled nursing facility (SNF) cost limits, and the home health agency (HHA) cost limits, overcomes the limitations inherent in the BLS index with respect to part-time employment. The HCFA index, which is based on gross salaries and wages, measures the relative difference from area to area in gross average hourly hospital wages, that is, the wages paid to all hospital employees. Because the index is based on the average hourly wage paid in each urban or rural area, it accounts for regional differences in part-time employment.

We are proposing to adopt the HCFA wage index that was published in the September 1, 1987 hospital prospective payment final rule (52 FR 33095) (set forth as Addendum C of this document) for use in calculating the ASC facility payment rates that will be effective July 1, 1988. We believe that the use of this index would result in ASC facility payment rates that reflect more accurately the prevailing economic environment in which ASCs are located.

6. Urban and Rural Classifications

We currently use Standard Metropolitan Statistical Areas (SMSAs and non-SMSAs) and, in New England, New England County Metropolitan Areas (NECMAs and non-NECMAs) to classify urban and rural locations for purposes of applying the wage index adjustment to ASC facility payment rates. With few exceptions, urban locales consist of those counties that comprise either an SMSA or NECMA as defined in 1981 by the Executive Office of Management and Budget (EOMB). Rural areas consist of those counties within a State that lie outside an SMSA or NECMA. However, on June 30, 1983, EOMB began using Metropolitan Statistical Areas (MSAs) in lieu of SMSAs. Therefore, we are proposing to use the MSA designations for ASC ratesetting purposes for the following reasons:

- It is the classification system currently used by EOMB.
- It is the classification system applied to hospitals subject to the prospective payment system and to SNFs and HHAs for determining payments as well as in calculating their wage indexes.
- It reflects 1980 census changes in urban and rural areas.

MSAs are designated and defined following a set of standards prepared by the Federal Committee on MSAs, which advises EOMB on metropolitan area definitions. Under these standards, an area qualifies for recognition as an MSA if—

- A city of at least 50,000 population is located in the area; or
- It is an urbanized area of at least 50,000 population with a total metropolitan population of at least 100,000.

In addition to a county containing a main city, an MSA may also include additional counties that have close economic and social ties to the central county. MSAs are defined in terms of constituent counties or county equivalents, except in the six New England States. In most cases, there is little difference between the SMSA designations and the MSA designations. The MSA designations are shown in Addendum C of this document with their applicable wage index values.

Further, the HCFA wage index presented in Addendum C incorporates exceptions to the MSA classification system for certain New England counties. These exceptions, authorized under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21), require that any hospital located in New England be classified as being in an urban area if the hospital was classified as being in an urban area under the classification system in effect in 1979. This provision is intended to ensure equitable treatment under the hospital prospective payment system.

Under this authority, the following counties have been deemed to be urban areas:

• Litchfield County, CT in the Hartford-New Britain-Middleton-Bristol, CT MSA.

• York County, ME and Sagadahoc County, ME in the Portland, ME MSA.

• Merrimack County, NH in the Manchester-Nashua, NH MSA.

• Newport County, RI in the Providence-Pawtucket-Woonsocket, RI MSA.

In addition, in the September 3, 1986 hospital prospective payment final rule, we provided an exception to the urban/rural classification system for hospitals in redesignated rural counties that are primarily surrounded on all sides by urban counties (51 FR 31469). We currently consider Shiawassee County, Michigan, which meets the exceptions criteria, as an urban area (in the Flint, Michigan MSA) in computing both the wage index and the payment amounts under the prospective payment system.

We propose to adopt these urban exceptions for the purpose of applying the HCFA wage index to the ASC facility payment rates. Since the ASC rates are applied also to hospital outpatient departments performing ASC covered procedures, we believe that adoption of the urban exceptions would provide for greater consistency among Medicare facilities in applying the HCFA wage index. That is, if these urban exceptions are not adopted, it would mean, for example, that a hospital located in Litchfield County, Connecticut that furnishes ASC-approved procedures in its outpatient department would be assigned two different wage index values: (1) An urban wage index value to calculate payment for the inpatient services, and (2) a rural wage index value to calculate payment for the ASC procedures. Classification of the same hospital as urban under one payment system and rural under another system and the assignment of two different wage index values is inconsistent and could be confusing, possibly resulting in payment error.

Section 4005 of Pub. L. 100-203 provides for further exceptions to the urban/rural classification system effective October 1, 1988. However, because the ASC rates proposed in this notice would be effective July 1, 1988, we do not believe it appropriate to incorporate the October 1, 1988 exceptions at this time.

7. Use of Weighted Median

In addition to collecting information on each facility's charge for a given procedure, the ASC survey collected information on the number of times the procedure was furnished in the facility during the period covered by the survey. As explained above, we are proposing to make several adjustments to each facility's charge before determining the charge for the procedure across all facilities. We are proposing to use the median charge for the procedure, weighted by the number of times the procedure was performed on Medicare patients, to determine the charge for the procedure across all facilities. The number of times the procedure was performed on Medicare patients was determined by multiplying the total number of times the procedure was performed in the facility by the ratio of the number of Medicare patients treated by the facility to the total number of patients treated by the facility. The weighted median represents the charge at or below which the procedure was furnished 50 percent of the time to Medicare patients.

We believe the use of the Medicare weighted median is a distinct improvement over the previous methodology, which used an unweighted average. Previously, each facility carried the same weight regardless of whether it performed a procedure 5 times or 100 times. Weighting by the number of times the procedure was performed on Medicare patients gives recognition to the relative importance of each facility in furnishing procedures covered by the Medicare program. In addition, the use of the median as opposed to the mean eliminates the effect any extreme variations in individual facility charges might have on the charge for the procedure across facilities.

8. Cost-to-Charge Adjustment

Section 1833(i)(2)(A) of the Act requires that Medicare payments to ASCs be cost-related. To comply with this requirement, we are proposing to use a cost-to-charge ratio of 0.776. This ratio was calculated based on Medicare costs and charges derived from the 90 ASCs in the audited sample. The Medicare costs and charges were determined by multiplying each facility's total costs and charges by its ratio of Medicare patients to total patients. We are proposing to multiply the weighted median charge of each procedure by 0.776.

9. Revised Classification System

Industry representatives have suggested that the number of payment groups should be increased in view of the large number of procedures now approved for coverage and advances in medical technology. We indicated in our April 21, 1987 notice (52 FR 13176) that we would consider changes to our current system if warranted by the new data. In this notice, we are proposing to eliminate the indexing method we currently use and develop a classification system based on fixed dollar intervals. We would expand the number of payment groups from four to six.

Additionally, because of the unique character of cataract procedures in ASCs, we solicit the advisability of classifying all cataract procedures within their own payment group. Cataract procedures account for approximately 53 percent of Medicare volume of ASC services and generate approximately 66 percent of all Medicare revenues in ASCs.

Currently, we use a four group classification system under which all procedures within the same group are paid the same rate. To develop that classification system, we used an indexing method for ranking each procedure based on a facility's charge for an individual procedure as compared to its average charge for all procedures offered. Since data were not available to permit the indexing of about 1200 new procedures added by the April 21, 1987 notice, we relied upon the medical expertise of our staff physicians to classify these procedures into the appropriate payment groups. The indexing method was intended to overcome facility bias in charging patterns related to cost and efficiency differences. Although it successfully compared a facility's charge for a given procedure to its average charge for all procedures, it did not provide a method to standardize the facility's average charge to permit comparison across facilities.

Our analysis of the per procedure charge data indicates that there are no common procedures that are offered by all facilities in our data base. Many centers perform specialty operations, for example, specializing in eye procedures only. While cataract extractions with IOL implantation tend to be the overall high volume procedure, a significant number of facilities do not perform this type of surgery. An eye specialty center performing a cataract extraction with insertion of an IOL generally would have a lower index value for that procedure than a multipurpose facility whose procedure volume is primarily associated with carpal tunnel surgery. One result was that there was a wide distribution in the costs of the procedures included in the same payment grouping. As discussed in detail, above, the data base we are using for this proposed notice is

comprised of data from the new survey form as reported in 1986 by 333 ASCs. The data base includes charge data on approximately 1200 of the more than 1500 covered procedure codes. Hence, the number of covered procedures is now four times as many as those initially subject to the indexing method.

Because of the wide variation found in types of procedures offered by ASCs represented in our data and the lack of a common procedure furnished by all ASCs, the indexing method is no longer effective in constructing a classification system. Rather, we believe that the following classification system based on $75 intervals of the weighted median per procedure cost is more appropriate. This method would classify procedures with similar costs into the same payment group.

Payment Groups: Weighted Median Per Procedure Cost

Group 1—Less than $275
Group 2—$275 through $349
Group 3—$350 through $424
Group 4—$425 through $499
Group 5—$500 through $574
Group 6—$575 and above

10. Classifying Services with Limited Data

There are a number of services that we could not classify based on the cost data derived under the rate development methodology. Although the survey was conducted in 1986, it was designed to gather charge data on procedures that we anticipated would be approved for coverage in 1987. However, such data were not furnished for 316 procedures. The majority of these surgical procedures were among those added to the list of covered procedures effective May 21, 1987. Also, another 346 procedures involved reporting by fewer than three facilities. Since the pricing patterns of these procedures were based on a small universe of ASCs, we eliminated these costs from our data base to avoid a statistically unreliable impact on the rates.

We are proposing to assign these 662 procedures to the appropriate payment groups based on the medical expertise of our staff physicians. This practice is consistent with that used in 1987 when the list of procedures was expanded and our data base did not contain sufficient charge data to classify the added procedures.

In addition, we encountered some aberrant per procedure costs in our data base that we believe are largely due to low utilization and, in part, to errors in reporting that are a result of the ASCs lack of familiarity with the new survey form. These abnormal costs affect the classification of 259 procedure codes. Of this number, 170 involve cost data reported by more than 2 facilities but fewer than 10 facilities. Analysis of these abnormal costs indicates that, in most cases, less costly procedures had higher per procedure costs than more complex ones.

For example, procedure code 26205 pertains to the removal of bone cyst or benign tumor of the metacarpal with autogenous graft that includes obtaining the graft. Procedure code 26215 is basically the same procedure but involves the proximal, middle, or distant phalanx. These two procedures are similar in terms of complexity and should be assigned to the same payment group. However, if we use reported costs to assign these procedures to the appropriate payment groups, 26205 would be assigned to payment Group 2 and 26215 would be assigned to Group 4. In this case, costs were reported by fewer than 10 ASCs.

In another instance, procedure code 11600 involves the removal of a malignant skin lesion that is less than 0.6 centimeters in diameter. Procedure code 11606 pertains to the removal of a malignant skin lesion over 4.0 centimeters in diameter. Although the latter procedure code is considered the more complex of the two, use of the new cost data would result in assignment of 11600 to a higher payment group (2) than 11606 (1). In this case, the number of facilities reporting costs for each procedure is in excess of 30. Therefore, we believe that the aberrant costs in this instance are attributable to reporting errors. Because of the number of similar procedures relating to the excision of skin lesions, we believe that reporting facilities may have failed to discriminate properly between them and may have instead combined codes when reporting.

Since these abnormal costs tend to create inconsistencies among the classification of similar procedures, we propose to eliminate costs associated with the 259 procedures from our data base. Our analysis indicates that elimination of these procedures would not affect calculation of the group rates since they are generally low-volume procedures. We propose to assign these surgical procedures to the appropriate payment groups based on the clinical judgment of our staff physicians. These proposed classifications are detailed in Addendum B to this proposed notice.

We have carefully considered the following alternatives to eliminating the anomalous per procedure costs:

a. *Not eliminate any abnormal costs.* While this approach would reduce the number of procedures that are subject to clinical judgment, we believe that it would result in classifications being determined based on costs that are not representative of the industry experience and would produce payment rates that are clinically inconsistent.

b. *Group similar procedures and aggregate associated costs.* This option would tend to overcome inconsistencies in the pricing of like procedures; however, it would require uniformity of treatment across all procedures and would require extensive clinical judgments concerning which procedures should be grouped together.

c. *Eliminate the costs for all procedures if the number of facilities performing a given service is fewer than 10.* This approach may ensure that the data base is not biased by the pricing patterns of a small universe of facilities. However, we rejected this approach for two reasons. First our review indicated that the cost data for a number of procedures reported by fewer than 10 facilities appear reasonable and result in an appropriate payment grouping. We do not believe these data should be arbitrarily excluded. Unilateral elimination of procedures reported by fewer than 10 facilities would result in an additional 216 procedures that would be classified by clinical judgment only. In addition, even if we did eliminate these procedures, we would still need to address the issue of those procedures with aberant costs that were reported by 10 or more facilities.

We invite public comment on our approach as well as cost information that would support changing any of the payment classifications we have made based on clinical judgment.

11. ASC Facility Payment Rates

To establish the payment rate for each of the six payment groups, we used a six-step procedure, as described below. We used per procedure charge data from 94 audited facilities and 239 unaudited facilities, or a total of 333 facilities. We excluded procedures that had charges reported by fewer than 3 facilities. Of the 1535 procedures, 316 procedures had no charge data and an additional 346 procedures had data reported by fewer than three facilities.

Step 1—We applied an inflation adjustment based on the CPI-U to the actual per procedure charge extracted from the survey data for each facility in order to account for historical and projected price changes occurring between the midpont of the facility's fiscal period represented in our data base and the midpoint of the 12-month period to which the new rates would apply (December 31, 1988).

Step 2—To remove the effects of area wage differences, we standardized the charge for each procedure using the HCFA hospital wage index set forth in Addendum C to this proposed notice. Based on our analysis of the audited survey data, we determined that on the average, the labor-related portion is approximately 34.45 percent. We then divided 34.45 percent of the inflated charge for each procedure by the wage index applicable to the ASC's location.

Step 3—After adding the wage adjusted labor-related portion back to the nonlabor-related portion, we calculated the median charge, weighted by the Medicare frequency, for the facilities reporting charge data for the procedure.

Step 4—We related the weighted median charge per procedure to cost as required by section 1833(i)(2) of the Act. To make this adjustment, we multiplied the weighted median charge for each procedure by 0.776.

Step 5—We arrayed procedures in descending order of median weighted cost values. We then classified the covered procedures into six payment groups based on a classification system that was developed using $75 intervals of the weighted median per procedure wage-adjusted costs.

Step 6—We then reviewed the cost for each procedure and its payment group to verify the clinical consistency in the classification of similar procedures and we identified 173 procedures with aberrant costs. We removed these procedures from the data base and assigned them to the appropriate payment group based on the clinical judgment of our staff physicians. After removing the 173 procedures, we set the payment rate at the weighted median cost of the procedures in each payment group, rounded to the nearest ten dollars.

The resulting ASC facility payment rates, as set forth below, would be effective July 1, 1988.

Group 1—$250
Group 2—$310
Group 3—$380
Group 4—$460
Group 5—$500
Group 6—$620

Addendum A to this proposed notice lists each CPT procedure code and the payment group under which we propose it would be paid, as well as the current group under which it is paid.

The proposed rates result in an estimated average increase of 5.5 percent. We are proposing these rates because they are based on the best data currently available to us, and we are required to review and update the rates by July 1, 1988.

We believe that the survey data have certain limitations that we have addressed through our rate development methodology and use of the audited sample. For example, the survey did not capture the Medicare frequency data that would allow a direct determination of a facility's Medicare costs on a procedure-specific basis. Therefore, in order to take Medicare's experience into account in establishing the payment rates, we are proposing to determine the necessary Medicare statistics by multiplying the data for all patients by the ratio of Medicare patients to total patients. Other limitations are the reliability of the reported data and their currency in view of the rapid growth in ASC services furnished to Medicare patients. For purposes of future updates, we intend to intiate a regular data collection effort that would obtain current Medicare cost information on a procedure-specific basis.

In lieu of using the survey data to establish the rates that are effective July 1, 1988, we considered updating the current rates by the increase in the CPI–U and postponing any refinements in our methodology until we obtain more complete and, presumably, more reliable information from ASCs. We considered updating the current rates by the increase in the CPI–U because of clear evidence that the current rates are adequate to ensure that Medicare beneficiaries have access to ASC services. For example, the number of ASCs participating in the Medicare program has grown from 254 in 1984 to over 900. In 1984, only 56 percent of all ASCs were Medicare-participating whereas more than 90 percent are currently participating in Medicare. In Federal fiscal year (FY) 1984, Medicare expenditures for ASCs totaled $34 million; expenditures for the first three quarters of FY 1987 (that is, the period before the July 1, 1987 update of the rates) were $150 million and exceeded total FY 1986 expenditures. Although we have concluded that the survey represents an improvement over the data base used to establish the current rates and should be used to establish the rates to be effective on July 1, 1988, we invite public comment concerning whether it would be more appropriate to update the current rates using the CPI–U increase. Use of this method for updating would result in a 4.6 percent increase in the payment rates.

12. Calculation of an Individual ASC's Payment Rates

The following is an example of how the payment would be determined for a procedure in Group 4 ($460) performed in an ASC located in Baltimore, Maryland. The appropriate HCFA wage index value is 1.0178.

Adjusted rate
= [($460 × .3445) × 1.0178] + ($460 × .6555)
= [$158.47 × 1.0178] + $301.53
= $161.29 + $301.53
= $462.82

B. Other Proposed Changes

1. Payment for Intraocular Lens Implant Procedures

Currently, when an IOL is implanted during cataract surgery performed in an ASC, separate payment for the lens is made under Medicare Part B at 80 percent of the reasonable charge. Either the ASC or the physician may bill and be paid for the prosthesis. Section 4063(b) of Pub. L. 100–203 amended section 1833(i)(2)(A) of the Act to mandate that, effective July 1, 1988, payment for ASC facility services must include a payment for the IOL that is reasonable and related to the acquisition cost of the class of lens involved.

To implement the provisions of section 4063(b) of Pub. L. 100–203, we are proposing to adopt a $200 add-on per lens to the appropriate payment group rate in which the specific cataract procedure that would require insertion of an IOL is classified. The add-on would be applicable to only the following covered procedures:

CPT–4 code	Proposed group
66983	6
66984	6
66985	4

While the amendment made by section 4063 of Pub. L. 100–203 to section 1833(i)(2)(A) of the Act requires that payment for IOLs be related to the cost of acquiring the class of lens implanted, we are proposing a single payment rate for IOLs at this time and invite public comment on the extent to which distinctions based on class are appropriate. We are doing this because our preliminary evidence is insufficient to allow for meaningful distinction in IOL pricing. We are soliciting scientific evidence that shows that one type of IOL is medically more beneficial than another to Medicare beneficiaries in order to make this distinction, if appropriate. As the choice of lens is made, generally, by the physician, it would be unreasonable to pay more for one type of lens than another unless the more expensive lens were medically

more beneficial to Medicare patients. We are interested in both information on the differences in lenses and scientific evidence regarding the medical benefits and medical reasons why some patients should require more complex and expensive lenses.

Based on information received from one industry component, eighty percent of the lenses currently used are multipiece, the basic styles being the J loop, the modifed J loop, and the wide loop. Among other types, these include plano, biconvex, ridge, and aspheric optics and may be found with holes, without holes (or tabs), or with an ultraviolet absorber. About 19 percent of the IOLs are one piece and these also come in a large selection of styles with a variety of optics. Small incision, silicone, and hydrosel lenses are used in about one percent of current implants. Some industry representations have suggested that we adopt a three-tier classification system for payment of IOLs based on whether the IOL is a multipiece, one piece, or small incision lens. We invite comments on whether such distinctions are appropriate and particularly solicit scientific studies that might support such a position.

To determine an allowance for IOLs, we analyzed the data obtained from the Medicare participating ASCs on the 1986 ASC survey form. These data represented IOLs furnished by ASCs between June 1, 1985 and December 31, 1985. The net cost of a lens was defined as the total cost of lenses minus discounts, rebates, and refunds divided by those used, less any that were returned. In the survey, we defined two classes of lens: (1) Differentiated lenses including those with an ultraviolet filter, laser-safe optic, PMMA optics, or other special features and (2) generic lenses, which were all other types. The reported net cost of differentiated lenses by 123 ASCs ranged from $126 to $463. The net cost of generic lenses ranged from $106 to $402. Difference in lens style was not consistently related to net cost.

The survey results also reveal inconsistencies in the reporting of data. Some ASCs purchased highly specialized lenses for less than other facilities paid for generic types. Further, some ASCs failed to report any revenue or expenses associated with the IOLs.

Because of these factors, we asked the Office of the Inspector General (OIG) to review a sample of the ASCs that had participated in our survey. The OIG found that lens companies regularly offer significant discounts, rebates, and other incentives as inducements to purchase their product, but that generally these savings were not passed on to the Medicare program. In view of the widespread availability of discounts and other price reductions, we believe it is appropriate in determining the reasonable payment rate for IOLs to consider only the cost incurred by ASCs that have been prudent purchasers and negotiated prices with the lens manufacturers.

Among the sample facilities visited, the OIG determined that 11 had negotiated prices with an average lens price of $200. Another four had negotiated discounts, but it was not possible to determine the discount amount because, for example, the value of credits for supplies and equipment was not reflected on the IOL invoices or in the ASC records. Because this on-site inspection examined ASC invoices for IOLs and industry marketing practices, we believe that payment for lenses based on these results would be more appropriate than basing payment on the 1986 survey data that revealed significant inconsistencies in reporting net IOL costs. (Copies of this OIG final report entitled "Medicare Certified Ambulatory Surgical Centers, Cataract Surgery Costs and Related Issues," (OAI–09–88–00490 issued in March 1988) can be obtained by writing to the Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201.)

In its report, the OIG also recommended a handling fee allowance. We have not accepted this recommendation because the proposed ASC facility Group 6 payment rate of $620 is already intended to fully compensate the ASC for all of its direct and indirect costs. All costs incurred in obtaining, handling and storing the lenses have been considered in setting the rate.

We invite coments on all of these studies and solicit any other information that can be provided on the reasonable acquisition cost of IOLs.

2. Payment for Terminated Surgical Procedures

We have received a number of requests for policy clarification regarding the appropriate ASC payment rate for a scheduled surgical procedure that is terminated due to medical complications that increase the surgical risk to the patient. Elevated blood pressure or eye pressure and cardiac or respiratory arrest are some of the common medical indicators that would trigger termination of a surgical procedure. We believe that termination of surgical procedures in the ASC setting should be an infrequent occurrence given the facilities' preoperative screening capabilities and the diagnostic testing that is required to ensure that patients are good candidates for outpatient surgery.

It is our policy that a denial is appropriate when an ASC submits a claim for a procedure that is terminated either for nonmedical or medical reasons before the ASC has expended substantial resources (for example, the patient on intake complains of cold or flu). We beleive that the carriers have had little trouble in making payment decisions in situations such as these. However, they have had difficulty in determining whether, or to what extent, payment should be made when surgery is terminated after the procedure has begun, for example, after anesthesia is induced.

Because we believe that ASCs incur some costs in connection with surgery that is terminated due to a sudden onset of medical complications, we are proposing that carriers pay ASCs 50 percent of the facility payment rate if the surgical procedure is terminated due to the onset of medical complications that occur after the patient has been prepped for surgery and taken to the operating room but before anesthesia has been induced (for example, the patient develops an allergic reaction to a drug administered by the ASC prior to surgery). (This, however, would not preclude the carrier from paying a different percentage of the rates if, in the individual case, documentation would support such action.)

However, if a medical complication arises after the inducement of the anesthetic agent, the carrier would pay the full applicable rate. In these cases, we believe that resources of the facility are consumed in essentially the same manner and to the same extent as they would have been had the surgery been completed as scheduled. In order for the carriers to pay ASCs a claim for terminated surgery, we are proposing that the facility be required to submit an operative report with each claim. Also, the carriers would be required to report all claims for terminated surgery to the appropriate peer review organization for quality of care review.

3. Elimination of Exception for Cataract Extraction with Insertion of Intraocular Lens

Since May 1983, Medicare payment policy has, with one exception, treated each of the ASC covered procedures designated by a single CPT–4 procedure code as a single procedure. The exception has been the insertion of an IOL prosthesis with cataract extraction (procedure codes 66983 and 66984). This cataract procedure has been paid at one

and one-half times the applicable Group 4 rate as if it were two procedures.

We instituted this exception in response to industry comments that the Group 4 rate did not take into account the additional costs associated with implanting the IOL in the same operative session in which the cataract is extracted. Then the procedure code (66980) did not distinguish between the various techniques (for example, intracapsular versus extracapsular) used in cataract surgery. Some industry representatives believed that the added costs of the IOL could vary significantly in relation to a particular technique. Because we did not have sufficient data available in 1982 that would have permitted us to determine a fair estimate of the added costs associated with these types of cataract surgery, we adopted this special exception in order to avoid penalizing ASCs for legitimate facility costs.

However, we now believe that adequate data are available that would permit us to determine a payment rate for such surgery. Therefore, we believe that an exception is no longer warranted. Cataract surgery accounts for about 53 percent of the Medicare procedure volume in our new data base. This volume represents reporting by more than one-third of the facilities.

We have compared the facilities' pricing for surgery by various techniques both with and without insertion of the IOL. Our analysis indicates that there are significant pricing differences between the extraction of a cataract and the implantation of an IOL in the same operation as compared to a procedure in which only an extraction or implant is done. Therefore, we believe that rates based on the reported per procedure charges for procedure codes 66983 and 66984 should reflect an appropriate cost level associated with performing these procedures. Under the proposed payment methodology, we also note that these cataract procedures are classified in Group 6 with procedures that have comparable costs and, because of their relatively high volume, the cataract procedures heavily influence the payment rate for the group. Under the previous methodology, these cataract procedures were classified with procedures that had a wider range of costs and, since there was no weighting, the cataract procedures had no more influence than any other procedure on the payment rate for the group. Thus, we believe a special exception for these procedures is no longer warranted and we are proposing to eliminate the payment policy exception applicable to procedure codes 66983 and 66984. We would pay for each of these procedure codes as a single procedure at the proposed Group 6 rate.

V. Regulatory Impact Analysis

A. Introduction

Executive Order 12291 (E. O. 12291) requires us to prepare and publish an initial regulatory impact analysis for any proposed notice such as this one that meets one of the E. O. criteria for a "major rule"; that is, that would be likely to result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or in the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that the proposed notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we treat all ASCs and hospitals as small entities.

Also, section 1102(b) of the Social Security Act requires the Secretary to prepare an initial regulatory impact analysis for any proposed notice such as this one that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area or a New England County Metropolitan Area.

The following discussion, in combination with the rest of this proposed notice, constitutes a combined regulatory impact analysis and regulatory flexibility analysis.

B. Program Costs

1. Payment to ASCs

As a direct result of increasing payment rates for procedures performed in ASCs, we would expect an average increase in payments per case to ASCs of approximately 5.5 percent for the period July 1, 1988 to June 30, 1989. Individual facilities, however, may experience significant variations in total revenues as a result of several factors influencing local demand for ASC services. These factors may include—

- The concentration of ASCs in a market region;
- The number of hospital outpatient departments competing in the same market; and
- The number of Medicare beneficiaries in the market region.

The impact of the proposed rates on individual facilities would also greatly depend on a facility's case mix. Although an ASC with a typical case mix may expect the average payment per case to increase by about 5.5 percent, payments for cases falling into proposed Group 1, for example, would decrease 9 percent compared to the current payment levels for Group 1. This contrasts with proposed increases of nearly 8 percent and 15 percent in the ASC rates for cases falling into proposed Groups 3 and 4, respectively, compared to the rates for the current Groups 3 and 4. Thus, ASCs that serve a larger than average number of cases that would be classified into Groups 3 or 4 could expect to receive a larger than average increase in Medicare payments while ASCs that serve a larger than average number of cases categorized into Group 1 could expect a smaller than average increase and possibly a decrease.

It should be noted, however, that because of the proposed revision to the grouping methodology, the four current payment Groups cannot be compared directly to proposed Groups 1, 2, 3, and 4. For example, cases that are classified into Group 1 under the present payment system may fall into either Groups 1 or 2 under the proposed payment system. Thus, the only valid method of comparison would be to compare rates under the two systems for each procedure.

For the most frequently performed procedure (that is, the one-stage removal of a cataract and insertion of an intraocular lens, which would be assigned to proposed Group 6), the change in payment rate would be an increase of about 3.5 percent. The survey data indicate that cataract procedures account for about 53 percent of the Medicare volume of ASC services, and under our proposed rates, they should generate about 66 percent of all Medicare revenues.

Another factor that would affect ASC payments is the proposed replacement of the BLS wage index with the HCFA wage index that was published in the September 1, 1987 hospital prospective payment final rule for computing the ASC rates and payment amounts. Because the HCFA wage index is based

on gross hourly wages paid to hospital employees rather than on the average salary per hospital employee (which serves as the basis for the 1981 BLS wage index), application of the HCFA wage index would produce different index values for each rural and urban locality from those values in effect now. Thus, depending on an ASC's location, the effect of using the HCFA wage index in place of the BLS wage index, both in computing the ASC rates and in determining payments to ASCs, would be to slightly increase or decrease payments from the amount an ASC would receive using the 1981 BLS wage index.

Table I, below, displays the projected effects of the proposed rates over the next five fiscal years, beginning with FY 1989.

TABLE I.—PROJECTED MEDICARE COSTS AS A RESULT OF PROPOSED ASC RATES*

FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
$0	$5	$5	$5	$5

*Rounded to the nearest $5 million.

Since we are rounding our projected cost estimates to the nearest $5 million, we point out that the value entered for FY1989 signifies increased Medicare outlays of less than $2.5 million rather than no increase.

It is significant to note that the number of ASCs participating in Medicare has grown from 87 in 1983 to 838 by the end of 1987. The rapid increase in the number of ASCs, especially among proprietary facilities, indicates that few barriers to market entry exist and that most facilities have been financially successful. The only serious barriers to market entry appear to be State laws restricting licensure of ASCs or Certificate of Need restrictions on the building of ASCs. Where construction or operations of ASCs are permitted by State laws, we anticipate that the proposed rate changes would further stimulate the expansion of ASCs.

It is not clear, however, whether the rapid development of ASCs is entirely the result of the level of facility payments. Prior to April 1, 1988, physicians providing approved services in an ASC received payments equal to 100 percent of their reasonable charges if they accepted assignment. In addition, many physicians have financial interests in ASCs. The combined incentives of higher Medicare payments to physicians and physicians' proprietary interests may also have played a significant role in the rapid growth of ASCs.

Effective April 1, 1988, section 4054 of Pub. L. 100–203 required us to reduce payments to physicians accepting Medicare assignment from 100 percent of their reasonable charges for services performed in an ASC to 80 percent (leaving the Medicare beneficiary responsible for the 20 percent copayment). We are unable to determine what effects this change in physician payments, in combination with the proposed payment rates to ASCs, will have on ASC utilization or the continued growth of ASCs in Medicare participation. On the one hand, the reduction of payments from 100 percent to 80 percent of physicians' reasonable charges will reduce direct payments to physicians. On the other hand, the higher ASC rates would directly benefit ASCs and may indirectly benefit those physicians who have proprietary interests in ASCs.

We believe that the incentives created by higher ASC facility payments would stimulate physicians with proprietary interests in ASCs to provide services in an ASC setting whenever possible. To the extent that physicians would seek to shift services from either the hospital inpatient or outpatient setting to the ASC, this should result in some program savings and savings to beneficiaries in the form of lower copayments.

2. Payments for ASC Covered Procedures Performed in Hospitals on an Outpatient Basis

a. *Payment Methodology.* Section 9343(a) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) amended section 1833(a)(4) of the Act and added section 1833(i)(3) to the Act to provide that, for hospital cost reporting periods beginning on or after October 1, 1987, payment for services approved to be performed in ASCs, but performed in hospitals on an outpatient basis is to be based, in the aggregate, on a comparison between two amounts. The payment is to be the lesser of the following:

- The amount for the services that would be paid to the hospital under section 1833(a)(2)(B) of the Act (that is, the lower of the hospital's reasonable costs or customary charges for the services, reduced by deductibles and coinsurance).
- An amount based on a blend of—

—The amount that would be paid to the hospital for the services under section 1833(a)(2)(B) of the Act reduced by deductibles and coinsurance (called the hospital-specific amount); and

—The amount that would be paid to a freestanding ASC for the same procedure in the same geographic area in accordance with section 1833(i)(2)(A) of the Act, which is equal to 80 percent of the standard overhead amount net of deductibles (the ASC amount).

Section 1833(i)(3)(B) of the Act further specifies that for cost reporting periods beginning on or after October 1, 1987 but before October 1, 1988, the blended amount is to be determined by using 75 percent of the hospital-specific amount and 25 percent of the ASC payment amount attributable to the procedure. For cost reporting periods beginning on or after October 1, 1988, the blended payment amount is to be based on 50 percent of the ASC payment amount. This provision of the law was implemented through a final rule published on October 1, 1987 (52 FR 36765) and is set forth in regulations at § 413.118.

b. *Impact of Proposed ASC Rates on Payments for Hospital Outpatient Services.* It should be noted that although payments for IOLs provided in connection with cataract procedures performed in a hospital outpatient setting must be incorporated into the ASC portion of the hospital's blended payment (in compliance with section 4063(b) of Pub. L. 100–203), our study of hospital payments for cataract procedures does not examine the effects the proposed IOL payment of $200 would have on hospital payments. Instead we relied on data derived from several sources to arrive at an overall average payment for IOLs and compared this amount to the proposed $200 amount (See section B.3 of this impact analysis for more information.)

Our analysis did not specifically address the impact of the statutory change in the blend from the current 25 percent ASC amount and 75 percent hospital-specific amount to a 50 percent blend of each amount because this change is mandated by statute rather than by this proposed notice. To control for the effects of the statutory change in the blend, we compared current payments under current rates based on a blend of 50 percent ASC rates and 50 percent hospital-specific amounts with payments under the proposed rates and the same blend of ASC and hospital-specific amounts. Also, our results reflect only proposed changes to the ASC rates and do not reflect any changes in behavior that hospitals or physicians may adopt in response to the rate changes.

It should be noted that although our proposed rates would result in higher payments to hospitals for performing ASC-approved procedures on an outpatient basis than what they would

have received, overall payments have declined (and will continue to decline) as a result of section 1833(i)(3)(A) of the Act, which requires us to pay hospitals for these services at the lower of the hospitals aggregate cost or charges, or a blend of the hospital's cost or charges and the applicable ASC amount (whichever is less). Thus, the increase in payments being proposed must be viewed in the context of an overall reduction in payments that became effective for cost reporting periods beginning on or after October 1, 1987.

Prior to October 1, 1987, hospitals submitted claims for outpatient services using the International Classification of Diseases 9th edition, Clinical modification (ICD-9-CM). Since October 1, 1987, hospitals have been required to use the HCPCS coding system on claims for outpatient services, which is the same coding system as is used by ASCs. In order to estimate the impact of the proposed rates on payments to hospitals, we reviewed outpatient bills received from October 1, 1987 through April 1988 using the HCPCS coding system. We used the seven months of billing data to analyze the costs and payment rates for high volume ASC procedures performed in hospital outpatient departments. Based on this analysis we estimate that the proposed ASC payment rates would result in an approximate one percent increase in payments to hospitals for ASC procedures performed in hospital outpatient settings. Consequently, we believe that this notice will not have a significant impact on hospitals and on rural hospitals. For FY 1988, we project that the proposed ASC rates will produce a rise in Medicare hospital outpatient services payments in the range of $0-5 million. Over the next five fiscal years, beginning in FY 1989, we project a $140 million increase in Medicare expenditures.

Table II below shows the projected impact of the proposed rates on Medicare program expenditures over the next five fiscal years beginning with FY 1989. In arriving at these estimates, present payments under existing ASC rates, computed on the basis of the 50 percent payment blend that will become effective for hospital cost reporting periods beginning on or after October 1, 1988, were compared with proposed payments and rates computed on the basis of the same 50 percent blend. The estimates assume these payment conditions will remain in effect over the next five fiscal years. In addition, the average year-to-year increase in payments was weighted to reflect the distribution of cases falling into the six payment groups and the variation in payment increases among the proposed payment groups compared to the current payment rates and categories.

TABLE II.—ESTIMATED RANGE OF MEDICARE PROGRAM COSTS FOR HOSPITAL OUTPATIENT SERVICES RESULTING FROM PROPOSED ASC PAYMENT RATES

(in millions)

FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
$0-20	$0-20	$0-30	$0-30	$0-40

3. Impact of Changes in Payments for IOLs

In addition to proposing changes in the way we determine payment rates for ASCs and increases in those rates, we also propose to establish a single payment amount for an IOL provided to a Medicare patient in connection with the performing of a cataract procedure in an ASC (in accordance with section 4063(b) of Pub. L. 100-203 which amended section 1833(i)(2)(A) of the Act). The amount we propose to pay is $200 per IOL. (See section IV.B.1. of this notice for a full explanation of how we determined this amount.)

Under section 1833(i)(3)(A) of the Act, we are required to determine payment to a hospital that performs an ASC approved procedure in an outpatient setting on the basis of the applicable standard ASC rate (as determined under section 1833(i)(2)(A) of the Act) that would be paid to an ASC in the same geographic area when the hospital's cost or charges exceed the appropriate blend of the applicable wage adjusted ASC rate and the hospital-specific payment amount. For periods between July 1, 1988 and the hospital's next cost reporting period that begins in FY 1989, the blend is comprised of 25 percent of the wage adjusted ASC rate and 75 percent of the hospital-specific amount. For hospital cost reports that begin on or after October 1, 1988, the blend is comprised of 50 percent of the wage adjusted ASC payment rate and 50 percent of the hospital specific amount.

Since section 4063(b) of Pub. L. 100-203 amended section 1833(i)(2)(A) of the Act to include a standard payment amount of IOLs furnished in an ASC, we propose to base payments to hospitals for the furnishing of an IOL in connection with a cataract procedure on the same amount we are proposing to pay an IOL furnished in an ASC. That is, we would pay a hospital for an IOL supplied in connection with a cataract procedure a blend comprised of 25 percent of the standard IOL amount and 75 percent of the hospital's acquisition cost during the period of July 1, 1988 to the hospital's next cost reporting period that begins in FY 1989. For hospital cost reporting period beginning on or after October 1, 1988, we would pay the hospital a blend comprised of 50 percent of the standard IOL amount and 50 percent of the hospital's IOL acquisition cost.

Data derived from several sources, discussed in section IV.B.1. of this notice, indicate that the average amount we now pay both ASCs and hospitals is $350 per IOL. By setting the payment amount per IOL at $200, the Medicare program would be able to save about $50 million in FY 1989 and about $300 million over the next five fiscal years.

For the typical ASC, the combined effect of the increase in the standard payment for a cataract procedure involving the implantation of an IOL and the decrease in the payment amount for the IOL itself would result in an overall reduction of about 14 percent compared to the combined amount we now pay. For the typical hospital, the combined impact of the proposed ASC rate change and IOL payment amount would result in a five percent reduction for hospital cost reporting periods beginning in FY 1989. Here again, to control for the statutory change in the blend, we compared present payments based on a 50 percent blend of ASC and hospital-specific amounts with proposed payment using the same blend.

Table III, below, shows the annual savings to the Medicare program for the next five fiscal years, beginning with FY 1989, that would result from the proposal to establish payments for IOLs at $200 per lens.

TABLE III.—MEDICARE PROGRAM SAVINGS RESULTING FROM THE PROPOSAL TO PAY $200 PER IOL SUPPLIED IN ASCS AND IN HOSPITAL OUTPATIENT SETTINGS *

FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
−$50	−$60	−$60	−$60	−$70

* Rounded to the nearest $10 million.

C. Conclusion

In general terms, we believe the payment reduction necessitated by the statutory blend change, in combination with the increase in payments made directly to ASCs, and the incentives for doctors to take a proprietary interest in ASCs, would have the effect of shifting the furnishing of ASC-approved procedures from the hospital outpatient

setting to the ASC setting. For those ASC procedures that will continue to be performed in hospital outpatient settings, the proposed ASC rate would significantly lessen the reductions in payment for these services mandated by statute.

VI. Other Required Information

A. Paperwork Reduction Act

This proposed notice would not impose information collection requirements. Consequently, it need not be reviewed by EOMB under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

B. Effective Date of the Revised Payment Rates

Section 1833(i)(2)(A) of the Act requires that the ASC payment rates be reviewed and updated not later than July 1, 1988. However, we are first publishing the revised rates in proposed form to allow full public participation and comment before publication of the final rates. In addition, in accordance with the provisions of section 1871(b)(1) of the Act, we are allowing a 60-day period for public comment. Since we did not publish the final rates before the statutorily required effective date of July 1, 1988, we issued a program instruction to our Medicare contractors describing the interim payment procedures for ASCs for facility services and intraocular lenses effective July 1, 1988. As of that date, Medicare payments for intraocular lenses will no longer be made to physicians.

We plan to issue the notice of final rates as soon as possible following the end of the comment period and our evaluation and consideration of the comments we receive. When we do publish the final payment rates, they will be retroactively applied to all services furnished on or after July 1, 1988.

C. Comments

Because of the large number of items of correspondence we normally receive on a proposed notice, we are not able to acknowledge or respond to them individually. However, in preparing the final notice, we will consider all comments that we receive by the date and time specified in the "Date" section of this preamble and respond to those comments in the preamble to that notice.

(Sections 1832(a) and 1833(i) of the Social Security Act (42 U.S.C. 1395k(a) and 1395l(i); 42 CFR 416.120)

(Catalog of Federal Domestic Assistance Program No. 13.774, Medicare—Supplemental Medical Insurance)

Dated: August 4, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: August 8, 1988.

Otis R. Bowen,

Secretary.

Addenda

Addendum A—List of Covered Surgical Procedures.—Addendum

Note:

• Procedure codes preceded by an asterisk indicate that the procedure has been covered since August 5, 1982.

• Procedure codes without an asterisk indicate additions to the list of surgical procedures which are covered effective May 21, 1987. The covered procedures, listed by body system and payment, together with applicable CPT–4 codes, are as follows:

	Payment groups		
	Old	New	
			Integumentary system
			Skin, Subcutaneous and Areolar Tissues
Incision			
10141	2	2	Incision and drainage of hematoma; complicated.
Excision debridement			
11042	1	2	Debridement; skin, and subcutaneous tissue.
11043	1	2	Debridement; skin, subcutaneous tissue, and muscle.
11044	1	2	Debridement; skin, subcutaneous tissue, muscle, and bone.
Excision-benign lesions			
*11200	1	2	Excision, skin tags, multiple fibrocutaneous tags, any area; up to 15.
*11201	1	1	Each additional ten lesions.
*11401	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), trunk, arms or legs; lesion diameter 0.6 to 1.0 cm.
*11402	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), trunk, arms or legs; lesion diameter 1.1 to 2.0 cm.
*11403	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), trunk, arms or legs; lesion diameter 2.1 to 3.0 cm.
*11404	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), trunk, arms or legs; lesion diameter 3.1 to 4.0 cm.
*11406	1	2	Excision, benign lesion, except skin tag (unless listed elsewhere), trunk, arms or legs; lesion diameter over 4.0 cm.
*11421	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm.
*11422	1	2	Excision, benign lesion, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm.
*11423	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; lesion diameter 2.1 to 3.0 cm.
*11424	1	1	Excision, benign lesion, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm.
*11426	1	2	Excision, benign lesion, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm.
*11441	1	1	Excision, other benign lesion (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm.
*11442	1	1	Excision, other benign lesion (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm.
*11443	1	1	Excision, other benign lesion (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 2.1 to 3.0 cm.
*11444	1	1	Excision, other benign lesion (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 3.1 to 4.0 cm.
*11446	1	2	Excision, other benign lesion (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 4.0 cm.
11471	2	2	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with other closure.
Excision—Malignant lesions			

	Payment groups		
	Old	New	
*11600	1	1	Excision, malignant lesion, trunk, arms, or legs; lesion diameter 0.5 cm or less.
*11601	1	1	Excision, malignant lesion, trunk, arms, or legs; lesion diameter 0.6 to 1.0 cm.
*11602	1	1	Excision, malignant lesion, trunk, arms, or legs; lesion diameter 1.1 to 2.0 cm.
*11603	1	1	Excision, malignant lesion, trunk, arms, or legs; lesion diameter 2.1 to 3.0 cm.
*11604	1	1	Excision, malignant lesion, trunk, arms, or legs; lesion diameter 3.1 to 4.0 cm.
*11606	2	2	Excision, malignant lesion, trunk, arms, or legs; lesion diameter over 4.0 cm.
*11620	1	1	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less.
*11621	1	1	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm.
*11622	1	1	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm.
*11623	1	1	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 2.1 to 3.0 cm.
*11624	1	1	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm.
*11626	2	2	Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm.
*11640	1	1	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 0.5 cm or less.
*11641	1	1	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 0.6 to 1.0 cm.
*11642	1	1	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 1.1 to 2.0 cm.
*11643	1	1	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 2.1 to 3.0 cm.
*11644	1	1	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 3.1 to 4.0 cm.
*11646	2	2	Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter over 4.0 cm.
			Nails
*11750	1	1	Excision of nail and nail matrix, partial or complete, (e.g., ingrown or deformed nail) for permanent removal.
			Miscellaneous
*11770	3	3	Excision of pilonidal cyst or sinus; simple.
*11771	3	3	Excision of pilonidal cyst or sinus; extensive.
*11772	3	3	Excision of pilonidal cyst or sinus; complicated.
Repair-simple			
12006	2	2	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 20.1 cm to 30.0 cm.
12007	2	2	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); over 30.0 cm.
12017	2	2	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm.
12018	2	2	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm.
Repair-intermediate			
12036	2	2	Layer closure of wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 20.1 cm to 30.0 cm.
12037	2	2	Layer closure of wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); over 30.0 cm.
12046	2	2	Layer closure of wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm.
12047	2	2	Layer closure of wounds of neck, hands, feet and/or external genitalia; over 30.0 cm.
12056	2	2	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm.
12057	2	2	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm.
Repair-complex			
13101	1	2	Repair, complex, trunk; 2.6 cm to 7.5 cm.
13121	1	3	Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm.
13132	2	3	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm.
13152	3	3	Repair, complex, eyelids, nose, ears, and/or lips; 2.6 cm to 7.5 cm.
13300	3	4	Repair, unusual, complicated, over 7.5 cm, any area.
Adjacent tissue transfer or rearrangement			
14001	3	3	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm.
14020	3	3	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10 sq cm or less.
14021	3	3	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10.1 sq cm to 30.0 sq cm.
14041	3	3	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm.
14060	3	3	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less.
14061	3	3	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10.1 sq cm to 30.0 sq cm.
14300	3	4	Adjacent tissue transfer or rearrangement, more than 30 sq cm, unusual or complicated, any area.
14350	3	3	Filleted finger or toe flap, including preparation of recipient site.
Free skin grafts			
*15000	3	2	Excisional preparation or creation of recipient site by excision of essentially intact skin (including subcutaneous tissues), scar, or other lesion prior to repair with free skin graft (list as separate service in addition to skin graft).
*15050	3	2	Pinch graft, single or multiple, to cover small ulcer, tip of digit, or other minimal open area (except on face), up to defect size 2 cm diameter.
*15100	3	2	Split graft, trunk, scalp, arms, legs, hands, and/or feet (except multiple digits); 100 sq cm or less, or each one percent of body area of infants and children (except 15050).
*15101	3	3	Split graft, trunk, scalp, arms, legs, hands, and/or feet (except multiple digits); each additional 100 sq cm, or each one percent body area of infants and children, or part thereof.
15200	3	3	Full thickness graft, free, includng direct closure of donor site, trunk; 20 sq cm or less.
15201	3	2	Full thickness graft, free, including direct closure of donor site, trunk; each additional 20 sq cm.
15220	3	2	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; 20 sq cm or less.
15221	3	2	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; each additional 20 sq cm.
15240	3	3	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 20 sq cm or less.
15241	3	3	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 20 sq cm.
15260	3	2	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less.
15261	3	2	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips, each additional 20 sq cm.
15350	3	2	Application of allograft (homograft), skin.
15410	3	2	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; 100 sq cm or less.
15412	3	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; between 101 and 160 sq cm.

	Payment groups		
	Old	New	
15414	3	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; between 161 and 230 sq cm.
15416	3	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; over 230 sq cm.
Repair			
Pedicle flaps (skin and deep tissues)			
15500	4	3	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on trunk.
15505	4	3	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on scalp, arms, or legs.
15510	4	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on forehead, cheeks, chin, mouth, neck, axillae genitalia, hands, or feet.
15515	4	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on eyelids, nose, ears, or lips.
15540	4	1	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to trunk.
15545	4	2	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to scalp, arms, or legs.
15550	4	2	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to forehead, cheeks, chin, mouth, neck, axillae, genitalia, or hands, feet.
15555	4	3	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to eyelids, nose, ears or lips.
15580	4	3	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; cross finger pedicle flap, including free graft to donor site.
15600	4	3	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at trunk.
15610	4	3	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at scalp, arms, or legs.
15620	4	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at forehead, cheeks, chin, neck, axillae, genitalia, hands (except 15625), or feet.
15625	4	3	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; section pedicle of cross finger flap.
15630	4	3	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at eyelids, nose, ears, or lips.
15650	4	5	Transfer, intermediate, of any pedicle flap (e.g., abdomen to wrist, Walking tube), any location.
15700	4	1	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; trunk.
15710	4	2	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; scalp, arms, or legs.
15720	4	2	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands, or feet.
15730	4	3	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; eyelids, nose, ears, or lips.
Other grafts			
15740	3	2	Graft; island pedicle flap.
15745	4	2	Graft; myocutaneous flap.
15750	4	2	Graft; neurovascular pedicle flap.
15755	4	3	Graft; free flap (microvascular transfer).
15760	3	2	Graft; composite (full thickness of external ear or nasal ala); including primary closure, donor area.
15770	3	3	Graft; derma-fat-fascia.
Miscellaneous procedures			
15840	4	4	Graft for facial nerve paralysis; free fascia graft (including obtaining fascia).
15841	4	4	Graft for facial nerve paralysis; free muscle graft (including obtaining graft).
15842	4	4	Graft for facial nerve paralysis; free muscle graft by microsurgical technique.
15845	4	4	Graft for facial nerve paralysis; regional muscle transfer.
Pressure ulcers (decubitus ulcers)			
15920	3	3	Excision, coccygeal pressure ulcer, with coccygectomy; with primary suture.
15922	3	4	Excision, coccygeal pressure ulcer, with coccygectomy; with local or regional skin flap closure.
15931	3	3	Excision, sacral pressure ulcer, with primary suture.
15933	3	3	Excision, sacral pressure ulcer, with primary suture; with ostectomy.
15941	3	3	Excision, ischial pressure ulcer, with primary suture; with ostectomy (ischiectomy).
15944	3	3	Excision, ischial pressure ulcer, with local or regional skin flap closure.
15945	3	4	Excision, ischial pressure ulcer, with local or regional or regional skin flap closure; with ostectomy.
15946	3	4	Excision, ischial pressure ulcer, with ostectomy, with muscle flap or myocutaneous flap closure.
15950	3	3	Excision, trochanteric pressure ulcer with primary suture.
15951	3	4	Excision, trochanteric pressure ulcer, with primary suture; with ostectomy.
15952	3	3	Excision, trochanteric pressure ulcer, with local rotation skin flap closure.
15953	3	4	Excision, trochanteric pressure ulcer, with local rotation skin flap closure; with ostectomy.
15954	3	3	Excision, trochanteric pressure ulcer, with bipedicle flap closure.
15955	3	4	Excision, trochanteric pressure ulcer, with bipedicle flap closure; with ostectomy.
15956	3	3	Excision, trochanteric pressure ulcer, with muscle or myocutaneous flap closure.
15958	3	4	Excision, trochanteric pressure ulcer, with muscle or myocutaneous flap closure; with ostectomy.
15960	3	2	Excision, heel pressure ulcer, with primary suture.
15961	3	4	Excision, heel pressure ulcer, with primary suture; with ostectomy.
15964	3	3	Excision, heel pressure ulcer, with skin flap closure.
15965	3	4	Excision, heel pressure ulcer, with skin flap closure; with ostectomy.
15966	3	4	Excision, heel pressure ulcer, with other flap closure.
15967	3	4	Excision, heel pressure ulcer, with other flap closure; with ostectomy.
15970	3	2	Excision, leg pressure ulcer, with primary suture.
15971	3	4	Excision, leg pressure ulcer, with ostectomy.
15972	3	3	Excision, leg pressure ulcer, with local skin flap(s).
15973	3	4	Excision, leg pressure ulcer, with local skin flap(s); with ostectomy.
15974	3	4	Excision, leg pressure ulcer, with muscle or myocutaneous flap closure.
15975	3	4	Excision, leg pressure ulcer, with muscle or myocutaneous flap closure; with ostectomy.
15980	3	3	Excision, knee pressure ulcer with local skin flap closure.
15981	3	4	Excision, knee pressure ulcer, with local skin flap closure; with ostectomy.
15982	3	3	Excision, knee pressure ulcer, with other flap closure.
15983	3	4	Excision, knee pressure ulcer, with other flap closure; with ostectomy.

	Payment groups		
	Old	New	
Burns, local treatment			
16015	1	2	Dressing and/or debridement, initial or subsequent; under anesthesia, medium or large, or with major debridement.
			Breast
Incision			
19020	1	2	Mastotomy with exploration or drainage of abscess, deep.
Excision			
*19101	3	3	Biopsy of breast; incisional.
*19120	3	3	Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion or nipple lesion (except 19140), male or female, on or more lesions.
*19140	4	4	Mastectomy for gynecomastia through circumareolar or other incision.
19160	4	3	Mastectomy, partial.
19180	4	4	Mastectomy, simple, complete.
19182	4	4	Mastectomy, subcutaneous.
			Musculoskeletal system
			General
Incision			
20005	1	2	Incision of soft tissue abscess (e.g., secondary to osteomyelitis); deep or complicated.
Excision			
20205	1	3	Biopsy, muscle; deep.
20225	3	2	Biopsy, bone, trocar or needle; deep (vertebral body, femur).
20240	2	2	Biopsy, excisional; superficial (e.g., ilium, sternum, spinous process, ribs, trochanter of femur).
20245	3	3	Biopsy, excisional, deep (e.g., humerus, ischium, femur).
20250	4	3	Biopsy, vertebral body, open; thoracic.
20251	4	3	Biopsy, vertebral body, open; lumbar or cervical.
Introduction or removal			
20525	2	3	Removal of foreign body in muscle; deep or complicated.
20650	2	3	Insertion of wire or pin with application of skeletal traction, including removal (separate procedure).
20660	2	2	Application of tongs or caliper, including removal (separate procedure).
20661	2	3	Application of halo; including removal cranial.
20662	2	3	Application of halo; pelvic.
20663	2	3	Application of halo; femoral.
20665	2	1	Removal of tongs or halo applied by another physician.
20680	3	3	Removal of implant; deep (e.g., buried wire, pin, screw, metal band, nail, rod or plate).
Grafts (oroimplants)			
20900	3	3	Bone graft, any donor area; minor or small (e.g., dowel or button).
20902	4	4	Bone graft, any donor area; major or large.
20912	4	4	Cartilage graft; nasal septum.
20920	4	4	Fascia lata graft; by stripper.
20922	4	3	Fascia lata graft; by incision and area exposure, complex or sheet.
20926	4	4	Tissue grafts, other (e.g., paratenon, fat, dermis, etc.).
Miscellaneous			
20955	4	4	Bone graft with microvascular anastomosis; fibula.
20960	4	4	Bone graft with microvascular anastomosis; rib.
20962	4	4	Bone graft with microvascular anastomosis; other bone graft (specify).
20969	4	4	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, rib, metatarsal, or great toe.
20970	4	4	Free osteocutaneous flap with microvascular anastomosis; iliac crest.
20971	4	4	Free osteocutaneous flap with microvascular anastomosis; rib.
20972	4	4	Free osteocutaneous flap with microvascular anastomosis; metatarsal.
20973	4	4	Free osteocutaneous flap with microvascular anastomosis; great toe with web space.
20975	2	2	Electrical stimulation to aid bone healing; invasive (operative).
			Head
Incision			
21010	3	2	Arthrotomy, temporomandibular joint; unilateral.
21011	3	3	Arthrotomy, temporomandibular joint; bilateral.
			General
Excision			
21034	4	3	Excision of malignant tumor of facial bone other than mandible.
*21040	3	2	Excision of benign cyst or tumor of mandible; simple.
21044	4	2	Excision of malignant tumor of mandible.
21050	4	3	Arthrectomy, temporomandibular joint; unilateral.
21060	4	2	Meniscectomy, temporomandibular joint; unilateral.
21061	4	2	Meniscectomy, temporomandibular joint; bilateral.
Introduction or removal			
21100	4	2	Application of halo type appliance for maxillofacial fixation, includes removal (separate procedure).
Fracture and/or dislocation			
*21310	1	2	Treatment of closed or open nasal fracture without manipulation.
*21315	1	2	Manipulative treatment, nasal bone fracture; without stabilization.
21320	1	2	Manipulative treatment, nasal bone fracture; with stabilization.
21325	3	4	Open treatment of nasal fracture; uncomplicated.
21330	4	5	Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation.
21335	4	6	Open treatment of nasal fracture; with concomitant open treatment of fractured septum.
21338	4	4	Open treatment of nasoethmoid fracture; without external fixation.
21340	4	4	Treatment of closed or open nasoethmoid complex fracture, with splint, wire or headcap fixation, including repair of canthal ligaments and/or the nasolacrimal apparatus.
*21355	2	3	Manipulative treatment of closed or open fracture or malar area, including zygomatic arch and malar tripod, towel clip technique.
*21360	2	4	Open treatment of closed or open depressed malar fracture, including zygomatic arch and malar tripod.
21365	4	5	Open treatment of closed or open complicated (e.g. multiple fractures), of malar area, including zygomatic arch and malar tripod, with internal skeletal fixation and multiple surgical approaches.

	Payment groups		
	Old	New	
21450	4	3	Treatment of closed or open mandibular fracture; without manipulation.
21451	4	4	Treatment of closed or open mandibular fracture; with manipulation, may include external fixation.
21452	4	2	Treatment of open mandibular fracture; without manipulation.
21453	4	3	Treatment of open mandibular fracture; with manipulation.
21480	2	1	Uncomplicated treatment of temporomandibular dislocation, initial or subsequent.
21485	3	2	Complicated manipulative treatment of temporomandibular dislocation, initial or subsequent.
21490	4	3	Open treatment of temporomandibular dislocation.
21494	3	4	Treatment of closed or open hyoid fracture; with manipulation.
21495	4	4	Open treatment of closed or open hyoid fracture.
			Neck (soft tissues) and thorax
Incision			
21501	1	2	Incision and drainage, deep abscess or hematoma.
21502	3	2	Incision and drainage, deep abscess or hematoma; with partial rib ostectomy.
21510	3	3	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
21555	1	2	Excision, benign tumor; subcutaneous.
Excision			
21556	2	2	Excision, benign tumor; deep, subfascial, intramuscular.
21600	3	2	Excision of rib, partial.
21610	3	2	Costotransversectomy (separate procedure).
			Abdomen
Excision			
22900	2	4	Excision, abdominal wall tumor, subfascial (e.g., desmoid).
			Shoulder
Incision			
23000	3	2	Removal of subdeltoid (or intratendinous) calcareous deposits.
23020	3	2	Capsular contracture release (Sever type procedure) for Erb's palsy.
23030	1	1	Incision and drainage; deep abscess or hematoma.
23035	2	3	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
23040	4	3	Arthrotomy, glenohumeral joint, for infection, with exploration, drainage or removal of foreign body.
23044	4	4	Arthrotomy with exploration, drainage or removal of foreign body, acromicoclavicular, sternoclavicular joint.
Excision			
23066	1	2	Biopsy, soft tissues, deep.
23076	1	2	Excision, benign tumor; deep, subfascial or intramuscular.
23100	4	2	Arthrotomy for biopsy, glenohumeral joint.
23101	4	6	Arthrotomy for biopsy or for excision of torn cartilage, acromioclavicular, sternoclavicular joint.
23130	4	5	Acromionectomy, partial or total.
23140	4	4	Excision or curettage of bone cyst or benign tumor of clavicle or scapula.
23150	4	4	Excision or curettage of bone cyst or benign tumor of proximal humerus.
*23170	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), clavicle.
*23172	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), scapula.
*23174	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), humeral head to surgical neck.
23180	3	4	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), clavicle.
23182	3	4	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), scapula.
23184	3	4	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), proximal humerus.
23190	3	4	Ostectomy of scapula, partial (e.g., superior medial angle).
23195	3	5	Resection humeral head.
Introduction or removal			
23331	2	1	Removal of foreign body; deep (e.g., Neer prosthesis removal).
Repair, revision or reconstruction			
23405	3	2	Tenomyotomy; single.
23406	3	2	Tenomyotomy; multiple through same incision.
Fracture and/or dislocation			
23505	2	1	Treatment of closed clavicular fracture; with manipulation.
23515	4	3	Open treatment of closed or open clavicular fracture, with or without internal or external skeletal fixation.
23605	2	2	Treatment of closed humeral (surgical or anatomical neck) fracture; with manipulation.
23610	4	3	Treatment of open humeral (surgical or anatomical neck) fracture; with uncomplicated soft tissue closure.
23625	2	2	Treatment of closed greater tuberosity fracture; with manipulation.
23630	4	5	Open treatment of closed or open greater tuberosity fracture, with or without internal or external skeletal fixation.
23655	1	1	Treatment of closed shoulder dislocation, with manipulation; requiring anesthesia.
23658	4	3	Treatment of open shoulder dislocation, with uncomplicated soft tissue closure.
23660	4	3	Open treatment of closed or open shoulder dislocation.
23665	2	2	Treatment of closed shoulder dislocation, with fracture of greater tuberosity, with manipulation.
23670	4	3	Open treatment of closed or open shoulder dislocation, with fracture of greater tuberosity.
23675	2	2	Treatment of closed shoulder dislocation, with surgical or anatomical neck fracture, with manipulation.
23680	4	3	Open treatment of closed or open shoulder dislocation, with surgical or anatomical neck fracture.
Manipulation			
23700	2	1	Manipulation under anesthesia, including application of fixation apparatus (dislocation excluded).
			Humerus (Upper Arm) and Elbow
Incision			
23930	1	1	Incision and drainage; deep abscess or hematoma.
23935	2	2	Incision, deep, with opening of (e.g., cortex for osteomyelitis or bone abscess).
24000	2	4	Arthrotomy, elbow, for infection, with exploration, drainage or removal of foreign body.
Excision			
24075	2	2	Excision, benign tumor; subcutaneous.
24076	2	2	Excision, benign tumor; deep, subfascial or intramuscular.
24100	4	1	Arthrotomy, elbow; for synovial biopsy only.
24101	4	4	Arthrotomy, elbow; with joint exploration, with or without biopsy, with or without removal of foreign body.
*24105	3	3	Excision, olecranon bursa.
24110	3	2	Excision, or curettage of bone cyst or benign tumor, humerus.

	Payment groups		
	Old	New	
24115	4	3	Excision or curettage of bone cyst or benign tumor, humerus; with primary autogenous graft (includes obtaining graft).
24116	4	3	Excision or curettage of bone cyst or benign tumor, humerus; with homogenous or other nonautogenous graft.
24120	3	3	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process.
24125	4	3	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with primary autogenous graft (includes obtaining graft).
24126	4	3	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with homogenous or other nonautogenous graft.
24130	3	3	Excision, radial head.
*24134	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), shaft or distal humerus.
*24136	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), radial head or neck.
*24138	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess), olecranon process.
24140	2	3	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis), humerus.
24145	2	3	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis), radial head or neck.
24147	2	2	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis), olecranon process.
24155	4	3	Resection of elbow joint (arthrectomy).
Introduction or removal			
24160	2	2	Implant removal; elbow joint.
24164	2	3	Implant removal; radial head.
24201	1	2	Removal of foreign body; deep.
Repair revision and reconstruction			
24301	3	4	Muscle or tendon transfer, any type, single (excluding 2430-24331).
24310	3	3	Tenotomy, open, elbow to shoulder, single, each.
*24320	4	3	Tenoplasty, with muscle transfer, with or without free graft, elbow to shoulder, single (Seddon-Brookes type procedure).
24330	4	3	Flexor-plasty, elbow, (e.g., Steindler type advancement).
24331	4	3	Flexor-plasty, elbow, (e.g., Steindler type advancement); with extensor advancement.
24340	4	3	Tenodesis for rupture of biceps tendon at elbow.
24342	4	3	Reinsertion of ruptured biceps tendon, distal, with or without tendon graft (includes obtaining graft).
*24350	4	3	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis).
*24351	4	3	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis); with extensor origin detachment.
*24352	4	3	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis); with annular ligament resection.
*24354	4	3	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis); with stripping.
24356	4	3	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis); with partial ostectomy.
24420	4	3	Osteoplasty, humerus (e.g., shortening or lengthening) (excluding 64876).
24470	4	3	Hemiepiphyseal arrest (e.g., for cubitus varus or valgus, distal humerus).
24495	3	2	Decompression fasciotomy, forearm, with brachial artery exploration.
Fracture and/or dislocation			
24505	1	1	Treatment of closed humeral shaft fracture; with manipulation.
24506	2	3	Treatment of closed humeral shaft fracture; percutaneous insertion of pin or rod.
24510	3	3	Treatment of open humeral shaft fracture, with uncomplicated soft tissue closure.
24515	4	4	Open treatment of closed or open humeral shaft fracture, with or without internal or external skeletal fixation.
24530	1	1	Treatment of closed supracondylar or transcondylar fracture, without manipulation.
24531	2	2	Treatment of closed supracondylar or transcondylar fracture, without manipulation; with traction (pin or skin).
24535	1	1	Treatment of closed supracondylar or transcondylar fracture, with manipulation.
24536	2	2	Treatment of closed supracondylar or transcondylar fracture, with manipulation; with traction (pin or skin).
24538	2	2	Treatment of closed supracondylar or transcondylar fracture, with manipulation; with percutaneous skeletal fixation.
24540	4	3	Treatment of open supracondylar or transcondylar fracture, with uncomplicated soft tissue closure.
24542	4	3	Treatment of open supracondylar or transcondylar fracture, with uncomplicated soft tissue closure; with traction (pin or skin).
24545	4	4	Open treatment of closed or open supracondylar or transcondylar fracture, with or without internal or external skeletal fixation.
24565	1	2	Treatment of closed epicondylar fracture, medical or lateral; with manipulation.
24570	3	2	Treatment of open epicondylar fracture, medial or lateral, with uncomplicated soft tissue closure.
24575	4	3	Open treatment of closed or open epicondylar fracture, medial or lateral, with or without internal or external skeletal fixation.
24577	1	1	Treatment of closed condylar fracture, medial or lateral; with manipulation.
24578	3	2	Treatment of open condylar fracture, medial or lateral, with uncomplicated soft tissue closure.
24579	4	3	Open treatment of closed or open condylar fracture, medial or lateral, with or without internal or external skeletal fixation.
24580	1	2	Treatment of closed comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), treatment with traction (pin or skin); without manipulation.
24581	1	1	Treatment of closed comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), treatment with traction (pin or skin); with manipulation.
24583	4	3	Treatment of open comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), with uncomplicated soft tissue closure.
24585	4	4	Open treatment of closed or open comminuted elbow fracture (fracture distal humerus and/or proximal ulna/radius), with or without internal or external skeletal fixation.
24586	4	4	Open treatment of closed or open comminuted elbow fracture (fracture distal humerus and/or proximal ulna/radius), with or without internal or external skeletal fixation; with elbow resection.
24605	1	2	Treatment of closed elbow dislocation; requiring anesthesia.
24610	3	3	Treatment of open elbow dislocation, with uncomplicated soft tissue closure.
24615	3	3	Open treatment of closed or open elbow dislocation.
24620	2	2	Treatment of closed Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head).
24625	4	3	Treatment of open Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head), with uncomplicated soft tissue closure.
24635	4	3	Open treatment of closed or open Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head), with or without internal or external skeletal fixation.
24655	1	1	Treatment of closed radial head or neck fracture; with manipulation with complicated soft tissue closure.
24665	4	4	Open treatment of closed or open radial head or neck fracture with or without internal fixation or radial head excision.

	Payment groups		
	Old	New	
24666	4	4	Open treatment of closed or open radial head or neck fracture, with or without internal fixation or radial head excision; with implant.
24675	1	1	Treatment of closed ulnar fracture, proximal end (olecranon process); with manipulation.
24680	3	2	Treatment of open ulnar fracture, proximal end (olecranon process), with uncomplicated soft tissue closure.
24685	4	3	Open treatment of closed or open ulnar fracture proximal end (olecranon process), with or without internal or external skeletal fixation.
			Forearm and Wrist
Incision			
*25000	2	3	Tendon sheath incision; at radial styloid for deQuervain's disease.
25005	2	3	Tendon sheath incision; at wrist for other stenosing tenosynovitis.
*25020	4	3	Decompression fasciotomy, flexor and/or extensor compartment.
*25023	4	3	Decompression fasciotomy, flexor and/or extensor compartment; with debridement of nonviable muscle and/or nerve.
25028	1	1	Incision and drainage, deep abscess or hematoma.
25035	2	2	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
25040	2	4	Arthrotomy radiocarpal or mediocarpal joint, for infection, with exploration, drainage, or removal of loose or foreign body.
Excision			
25066	1	4	Biopsy, soft tissues; deep.
25076	1	3	Excision, benign tumor, deep, subfascial or intramuscular.
25085	3	3	Capsulotomy, wrist (e.g., for contracture).
25100	2	2	Arthrotomy, wrist joint, for biopsy.
25101	3	3	Arthrotomy, wrist joint, with joint exploration, with or without biopsy, with or without removal of foreign body.
25107	3	3	Arthrotomy distal radioulnar joint for repair of triangular cartilage complex.
25110	3	3	Excision, lesion of tendon sheath.
*25111	3	3	Excision, of ganglion, wrist (dorsal or volar); primary.
*25112	3	4	Excision of ganglion, wrist (dorsal or volar); recurrent.
25120	3	3	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process).
25125	4	3	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with primary autogenous graft (including obtaining graft).
25126	4	3	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of redius and olecranon process); with homogenous or other nonautogenous graft.
25130	3	3	Excision or curettage of bone cyst or benign tumor of carpal bones.
25135	3	3	Excision or curettage of bone cyst or benign tumor of carpal bones; with primary autogenous graft (includes obtaining graft).
25136	4	3	Excision or curettage of bone cyst or benign tumor of carpal bones; with homogenous or other monautogenous graft.
25145	2	2	Sequestrectomy (e.g. for osteomyelitis or bone abscess).
25150	2	2	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis); ulna.
25151	2	2	Partial excision (craterizaton, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis); radius.
25210	3	3	Carpectomy; one bone.
25215	3	4	Carpectomy; all bones of promimal row.
25230	3	4	Radial styloidectomy (separate procedure).
25240	3	4	Excision distal ulna (Darrach type procedure).
25248	2	2	Exploration for removal of deep foreign body.
Repair, revision or reconstruction			
*25260	3	4	Repair, tendon or muscle, flexor; primary, single, each tendon or muscle.
*25263	3	2	Repair, tendon or muscle, flexor; secondary, single, each tendon or muscle.
*25265	4	3	Repair tendon or muscle, flexor; secondary, with free graft (includes obtaining graft), each tendon or muscle.
*25270	3	4	Repair, tendon or muscle, extensor; primary, single, each tendon or muscle.
*25272	3	3	Repair, tendon or muscle, extensor; secondary, single, each tendon or muscle.
25274	4	4	Repair, tendon or muscle, extensor, secondary, with tendon graft (includes obtaining graft), each tendon.
25280	3	4	Lengthening or shortening of flexor or extensor tendon, single, each tendon.
25290	3	3	Tenotomy, open, single, flexor or extensor tendon, each tendon.
25295	3	3	Tenolysis, single flexor or extensor tendon, each tendon.
25300	3	3	Tenodesis at wrist; flexors of fingers.
25301	3	3	Tenodesis at wrist; extensors of fingers.
*25310	4	3	Tendon transplantation or transfer, flexor or extensor, single; each tendon.
*25312	4	4	Tendon transplantation or transfer, flexor or extensor, single; with tendon graft(s) (includes obtaining graft), each tendon.
25315	3	3	Flexor origin slide for cerebral palsy.
25316	3	3	Flexor origin slide for cerebral palsy; with tendon(s) transfer.
25317	3	3	Flexor origin slide for Volkmann contracture.
25318	3	3	Flexor origin slide for Volkmann contracture; with tendon(s) transfer.
25320	4	3	Capsulorrhaphy or reconstruction, capsulectomy, wrist (includes synovectomy, resection of capsule, tendon insertions).
25390	4	3	Osteoplasty radius OR ulna; shortening.
25391	4	4	Osteoplasty, radius OR ulna; lengthening with autogenous bone graft.
25392	4	3	Osteoplasty, radius AND ulna; shortening (excluding 64876).
25393	4	4	Osteoplastry, radius AND ulna; lengthening with autogenous bone graft.
25450	4	3	Epiphyseal arrest by epiphysiodesis or stapling; distal radius OR ulna.
25455	4	3	Epiphyseal arrest by epiphysiodesis or stapling; distal radius AND ulna.
Fracture and/or dislocation			
25505	1	1	Treatment of closed radial shaft fracture; with manipulation.
25510	3	2	Treatment of open radial shaft fracture, with uncomplicated soft tissue closure.
25515	4	3	Open treatment of closed or open radial shaft fracture, with or without internal or external skeletal fixation.
25535	1	1	Treatment of closed ulnar shaft fracture; with manipulation.
25540	3	2	Treatment of open ulnar shaft fracture, with uncomplicated soft tissue closure.
25545	4	3	Open treatment of closed or open ulnar shaft fracture, with or without internal or external skeletal fixation.
25565	1	2	Treatment of closed radial and ulnar shaft fractures; with manipulation.
25570	3	3	Treatment of open radial and ulnar shaft fractures, with uncomplicated soft tissue closure.
25575	4	3	Open treatment of closed or open radial and ulnar shaft fractures, with or without internal or external skeletal fixation.

	Payment groups		
	Old	New	
25605	1	3	Treatment of closed distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid; with manipulation.
25610	2	3	Treatment of closed, complex, distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, requiring manipulation; without external skeletal fixation or percutaneous pinning.
25611	2	3	Treatment of closed, complex, distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, requiring manipulation; percutaneous pinning or pins and plaster technique.
25615	3	4	Treatment of open distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, with uncomplicated soft tissue closure.
25620	4	5	Open treatment of closed or open distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, with or without internal or external skeletal fixation.
25626	3	2	Treatment of open carpal scaphoid (navicular) fracture, with uncomplicated soft tissue closure.
25628	4	3	Open treatment of closed or open carpal scaphoid (navicular) fracture, with or without skeletal fixation.
25635	1	1	Treatment of closed carpal bone fracture (excluding carpal scaphoid (navicular)); with manipulation, each bone.
25640	4	2	Treatment of open carpal bone fracture (excluding carpal scaphoid (navicular)), with uncomplicated soft tissue closure, each bone.
25645	4	3	Open treatment of closed or open carpal bone fractaure (excluding carpal scaphoid (navicular)), each bone.
25660	1	1	Treatment of closed radiocarpal or intercarpal dislocation, one or more bones, with manipulation.
25665	3	3	Treatment of open radiocarpal or intercarpal dislocation, one or more bones, with uncomplicated soft tissue closure.
25670	4	3	Open treatment of closed or open radiocarpal or intercarpal dislocation, one or more bones.
25675	1	1	Treatment of closed distal radioulnar dislocation with manipulation.
25676	3	2	Open treatment of closed or open distal radioulnar dislocation, acute or chronic.
25680	1	2	Treatment of closed trans-scaphoperilunar type of fracture dislocation, with manipulation.
25685	3	3	Open treatment of closed or open trans-scaphoperilunar type of fracture dislocation.
25690	1	1	Treatment of lunate dislocation, with manipulation.
25695	3	2	Open treatment of lunate dislocation.
			Hands and Fingers
Incision			
26011	1	1	Drainage of finger abscess; complicated (e.g., felon, etc).
26020	1	2	Drainage of tendon sheath, one digit and/or palm.
26025	1	1	Drainage of palmar bursa; single, ulnar or radial.
26030	1	2	Drainage of palmar bursa; multiple or complicated.
26034	2	2	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
26035	2	4	Decompression fingers and/or hand, injection injury (e.g., grease gun, etc.).
*26040	4	4	Fasciotomy, palmar, for Dupuytren's contracture; closed (subcutaneous).
*26045	4	3	Faciotomy, palmar, for Dupuytren's contracture; open, partial.
*26055	1	3	Tendon sheath incision for trigger finger.
*26060	1	2	Tenotomy, subcutaneous, single, each digit.
26070	2	2	Arthrotomy, for infection, with exploration, drainage or removal of loose or foreign body; carpometacarpal joint.
26075	2	4	Arthrotomy with exploration, drainage or removal of loose or foreign body; metacarpophalangeal joint.
26080	2	4	Arthrotomy with exploration, drainage or removal of loose or foreign body; interphalangeal joint, each.
Excision			
26100	3	2	Arthrotomy for synovial biopsy; carpometacarpal joint.
26105	3	1	Arthrotomy for synovial biopsy; metacarpophalangeal joint.
26110	3	1	Arthrotomy for synovial biopsy; interphalangeal joint, each.
26115	3	2	Excision of benign tumor; subcutaneous.
26116	3	2	Excision of benign tumor; deep, subfascial, intramuscular.
*26120	4	4	Fasciectomy, palmar, simple, for Dupuytren's contracture; partial excision.
*26122	4	3	Fasciectomy, palmar, simple, for Dupuytren's contracture; up to one-half palmar fascia, with single digit involvement, with or without Z-plasty or other local tissue rearrangement.
26124	4	4	Fasciectomy, palmar, complicated, requiring skin grafting (includes obtaining graft); with single digit involvement.
26126	4	3	Fasciectomy, palmar, complicated, requiring skin grafting (includes obtaining graft); each additional digit.
*26128	4	4	Fasciectomy, palmar, complicated, requiring skin grafting (includes obtaining graft); each finger joint release.
26135	4	4	Synovectomy, metacarpophalangeal joint including intrinsic release and extensor hood reconstruction, each digit.
*26140	4	2	Synovectomy, proximal interphalangeal joint, including extensor reconstruction, each interphalangeal joint.
*26145	4	3	Synovectomy tendon sheath, radicial (tenosynovectomy), flexor, palm or finger, single , each digit.
26160	3	3	Excision of lesion of tendon sheath or capsule (e.g., cyst or ganglion).
26170	3	3	Excision of tendon, palm, flexor, single (separate procedure), each.
26180	3	3	Excision of tendon, finger, flexor (separate procedure).
26200	3	2	Excision or curettage of bone cyst or benign tumor of metacarpal.
26205	3	3	Excision or curettage of bone cyst or benign tumor of metacarpal; with autogenous graft (includes obtaining graft).
26210	3	2	Excision or curettage of bone cyst or benign tumor or proximal, middle or distal phalanx.
26215	3	3	Excision or curettage of bone cyst or benign tumor of proximal, middle or distal phalanx; with autogenous graft (includes obtaining graft).
26230	3	2	Partial excision (craterization saucerization, or diaphysectormy) of bone (e.g., for osteomyelitis); metacarpal.
26235	3	3	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis); proximal or middle phalanx.
26250	4	3	Radical resection (ostectomy) for tumor, metacapal.
26225	4	3	Radical resection (ostectomy) for tumor, metacarpal; with autogenous graft (includes obtaining graft).
26261	4	3	Radical resection (ostectomy) for tumor, proximal or middle phalanx; with autogenous graft (includes obtaining graft).
Repair, revision or reconstruction			
*26350	3	1	Flexor tendon repair or advancement, single, not in "no man's land"; primary or secondary without free graft, each tendon.
*26352	4	3	Flexor tendon repair or advancement, single, not in "no man's land"; secondary with free graft (includes obtaining graft), each tendon.
*26356	3	4	Flexor tendon repair or advancement, single, in "no man's land"; primary, each tendon.
*26358	4	4	Flexor tendon repair or advancement, single, in "no man's land"; secondary with free graft (includes obtaining graft), each tendon.
*26370	3	4	Profundus tendon repair or advancement, with intact sublimis; primary.
*26372	4	4	Profundus tendon repair or advancement, with intact sublimis; secondary with free graft (includes obtaining graft).
*26373	3	3	Profundus tendon repair or advancement, with intact sublimis; secondary without free graft.

	Payment groups		
	Old	New	
*26390	3	4	Flexor tendon excision, implantation of plastic tube or rod for delayed tendon graft.
*26392	4	3	Removal of tube or rod and insertion of tendon graft (includes obtaining graft).
*26410	3	3	Extensor tendon repair, dorsum of hand, single, primary or secondary; without free graft, each tendon.
*26412	4	3	Extensor tendon repair, dorsum of hand, single, primary or secondary; with free graft (includes obtaining graft) each tendon.
*26418	3	3	Extensor tendon repair, dorsum of finger, single, primary or secondary; without free graft, each tendon.
*26420	4	4	Extensor tendon repair, dorsum of finger, single, primary or secondary; with free graft (includes obtaining graft), each tendon.
*26426	4	3	Extensor tendon repair, central slip repair, secondary (boutonniere deformity); using local tissues.
*26428	4	3	Extensor tendon repair, central slip repair, secondary (boutonniere deformity); with free graft (includes obtaining graft).
*26432	4	3	Extensor tendon repair, distal insertion ("mallet finger"), closed, splinting with or without percutaneous pinning.
*26433	3	3	Extensor tendon repair, open, primary or secondary repair; without graft.
*26434	4	3	Extensor tendon repair, open, primary or secondary repair; with free graft (includes obtaining graft).
26440	3	3	Tenolysis, simple, flexor tendon; palm OR finger, single, each tendon.
26442	3	3	Tenolysis, simple, flexor tendon; palm AND finger, each tendon.
26445	3	3	Tenolysis, extensor tendon, dorsum of hand or finger; each tendon.
26449	4	3	Tenolysis, complex, extensor tendon, dorsum of hand or finger, including hand and forearm.
*26450	1	3	Tenotomy, flexor, single, palm, open, each.
*26455	1	3	Tenotomy, flexor, single finger, open, each.
*26460	1	3	Tenotomy, extensor, hand or finger, single, open, each.
26471	2	2	Tenodesis; for proximal interphalangeal joint stabilization.
26474	2	2	Tenodesis; for distal joint stabilization.
26476	3	1	Tendon lengthening, extensor, single, each.
26477	3	1	Tendon shortening, extensor, single, each.
*26480	4	3	Tendon transfer or transplant, carpometacarpal area.
*26483	4	3	Tendon transfer or transplant, carpometacarpal area.
*26485	4	2	Tendon transfer or transplant, palmar, single, each tendon; without free tendon graft.
*26489	4	3	Tendon transfer or transplant, palmar, single, each tendon; with free tendon graft (includes obtaining graft), each tendon.
26490	4	3	Opponens plasty; sublimis tendon transfer type.
26492	4	3	Opponens plasty; tendon transfer with graft (includes obtaining graft).
26494	4	3	Opponens plasty; hypothenar muscle transfer.
26496	4	3	Opponens plasty; other methods.
26497	4	3	Tendon transfer to restore intrinsic function; ring and small finger.
26498	4	4	Tendon transfer to restore intrinsic function; all four fingers.
26499	4	3	Correction claw finger; other methods.
26500	4	4	Tendon pulley reconstruction; with local tissues (separate procedure).
26502	4	4	Tendon pulley reconstruction; with tendon or facial graft (includes obtaining graft) (separate procedure).
26508	4	3	Thenar muscle release for thumb contracture.
26510	4	3	Cross intrinsic transfer.
26516	2	1	Capsulodesis for M-P joint stabilization; single digit.
26517	2	3	Capsulodesis for M-P joint stabilization; two digits.
26518	3	3	Capsulodesis for M-P joint stabilization; three or four digits.
*26520	3	3	Capsulectomy for contracture; metacarpophalangeal joint, single, each.
*26525	3	3	Capsulectomy for contracture; interphalangeal joint, single, each.
*26530	4	3	Arthroplasty, metacarpophalangeal joint; single, each.
*26531	4	6	Arthroplasty, metacarpophalangeal joint; with prosthetic implant, single, each.
*26535	4	4	Arthroplasty interphalangeal joint; single, each.
*26536	4	5	Arthroplasty interphalangeal joint; with prosthetic implant, single, each.
*26540	4	4	Primary repair of collateral ligament, metacarpophalangeal joint.
*26541	4	6	Reconstruction, collateral ligament, metacarpophalangeal joint; with tendon or facial graft (includes obtaining graft).
26542	4	4	Primary repair of collateral ligament, metacarpophalangeal joint; with local tissue.
*26545	4	4	Reconstruction, collateral ligament, interphalangeal joint, single, including graft, each joint.
26552	4	4	Reconstruction thumb with toe.
26555	4	3	Positional change of other finger.
26557	4	3	Toe to finger transfer; first stage.
26558	4	2	Toe to finger transfer; each delay.
26559	4	2	Toe to finger transfer; second stage.
*26567	4	4	Osteotomy for correction of deformity; phalanx.
26568	4	3	Osteoplasty for lengthening of metacarpal or phalanx.
26570	4	2	Bone graft, (includes obtaining graft); metacarpal.
26574	4	2	Bone graft, (includes obtaining graft); phalanx.
Fractures and/or dislocations			
26605	1	2	Treatment of closed metacarpal fracture, single; with manipulation, each bone.
26607	2	2	Treatment of closed metacarpal fracture, single, with manipulation, with skeletal fixation, each bone.
26610	2	4	Treatment of open metacarpal fracture, single, with uncomplicated soft tissue closure, each bone.
26645	1	1	Treatment of closed carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation.
26650	2	2	Treatment of closed carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation; with skeletal fixation.
26655	3	3	Treatment of open carpometacarpal fracture dislocation, thumb (Bennett fracture), with uncomplicated soft tissue closure.
26660	3	3	Treatment of open carpometacarpal fracture dislocation, thumb (Bennett fracture), with uncomplicated soft tissue closure; with skeletal fixation.
26665	3	4	Open treatment of closed or open carpometacarpal fracture dislocation, thumb (Bennett fracture), with or without internal or external skeletal fixation.
26675	1	2	Treatment of closed carpometacarpal dislocation, other than Bennett fracture, single, with manipulation; requiring anesthesia.
26676	2	2	Treatment of closed carpometacarpal dislocation, other than Bennett fracture, single, with manipulation; with percutaneous pinning.
26680	2	2	Treatment of open carpometacarpal dislocation, other than Bennett fracture, single, with uncomplicated soft closure.

	Payment groups		
	Old	New	
26685	3	3	Open treatment of closed or open carpometacarpal dislocation, other than Bennett fracture; single, with or without internal or external skeletal fixation.
26686	3	3	Open treatment of closed or open carpometacarpal dislocation, other than Bennett fracture; complex, multiple or delayed reduction.
26705	1	2	Treatment of closed metacarpophalangeal dislocation, single, with manipulation; requiring anesthesia.
26706	2	2	Treatment of closed metacarpophalangeal dislocation, single, with manipulation; with percutaneous pinning.
26710	2	2	Treatment of open metacarpophalangeal dislocation, single, with uncomplicated soft tissue closure.
26715	3	4	Open treatment of closed or open metacarpophalangeal dislocation, single, with or without internal or external skeletal fixation.
26727	2	6	Treatment of unstable phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with manipulation, requiring traction or fixation, each.
26730	2	2	Treatment of open phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with uncomplicated soft tissue closure, each.
26735	3	4	Open treatment of closed or open phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with or without internal or external skeletal fixation, each.
26744	2	2	Treatment of open articular fracture, involving metacarpophalangeal or proximal interphalangeal joint; with uncomplicated soft tissue closure, each.
26746	3	5	Open treatment of closed or open articular fracture, involving metacarpophalangeal or proximal interphalangeal joint, each.
26765	3	4	Open treatment of closed or open distal phalangeal fracture, finger or thumb, each.
26780	2	2	Treatment of open interphalangeal joint dislocation, single, with uncomplicated soft tissue closure.
26785	3	2	Open treatment of closed or open interphalangeal joint dislocation, single.
Arthrodesis			
*26820	4	5	Fusion in opposition, thumb, with antogenous graft (includes obtaining graft).
*26841	4	4	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation.
*26842	4	4	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation; with autogenous graft (includes obtaining graft).
*26843	4	3	Arthrodesis, carpometacarpal joint, digits, other than thumb.
*26844	4	3	Arthrodesis, carpometacarpal joint, digits, other than thumb; with autogenous graft (includes obtaining graft).
*26860	4	3	Arthrodesis, interphalangeal joint, with or without internal fixation.
*26861	4	2	Arthrodesis, interphalangeal joint, with or without internal fixation; each additional interphalangeal joint.
*26862	4	4	Arthrodesis, interphalangeal joint, with or without internal fixation; with autogenous graft (includes obtaining graft).
*26863	4	3	Arthrodesis, interphalangeal joint, with or without internal fixation; with autogenous graft (includes obtaining graft), each additional joint.
Amputation			
*26910	2	3	Amputation, metacarpal, with finger or thumb (ray amputation), single, with or without interosseus transfer.
*26951	2	2	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with direct closure.
*26952	4	4	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with local advancement flaps (V-Y, hood).
			Pelvis and Hip Joint
Incision			
26990	2	1	Incision and drainage; deep abscess or hematoma.
26991	2	1	Incision and drainage; infected bursa.
26992	2	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
27000	3	2	Tenotomy, adductor, subcutaneous, closed (separate procedure).
27001	4	2	Tenotomy, adductor, subcutaneous, open; unilateral.
27002	4	2	Tenotomy, adductor, subcutaneous, open; bilateral.
27003	4	3	Tenotomy, adductor, subcutaneous, open, with obturator neurectomy; unilateral.
27004	4	3	Tenotomy, adductor, subcutaneous, open, with obturator neurectomy; bilateral.
27030	4	3	Arthrotomy, hip, for infection, with drainage.
27033	4	3	Arthotomy, hip, for exploration or removal of loose or foreign body.
27035	4	4	Hip joint denervation, intrapelvic or extrapelvic intra- articular branches of sciatic, femoral or obturator nerves.
Excision			
27040	4	2	Biopsy, soft tissues; superficial.
27041	4	2	Biopsy, soft tissues; deep.
27047	4	2	Excision, benign tumor; subcutaneous.
20748	4	3	Excision, benign tumor; deep, subfascial, intramuscular.
27052	4	3	Arthrotomy for biopsy; hip joint.
27065	4	4	Excision of bone cyst or benign tumor; superficial (wing of ilium, symphysis pubis, or greater trochanter of femur) with or without autogenous bone graft.
27066	4	5	Excision of bone cyst or benign tumor; deep, with or without bone graft.
27080	4	2	Coccygectomy, primary.
Introduction and/or removal			
27087	2	3	Removal of foreign body; deep.
27095	1	1	Injection procedure for hip arthrography; with anesthesia.
Fractures and/or dislocations			
27201	4	2	Treatment of open coccygeal fracture.
27202	4	2	Open treatment of closed or open coccygeal fracture.
Manipulation			
27275	2	2	Manipulation, hip joint, requiring general anesthesia.
			Femur (Thigh Region) and Knee Joint
Incision			
27301	2	3	Incision and drainage of deep abscess, infected bursa, or hematoma.
27303	2	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
*27305	4	2	Fasciotomy, illiotibial (tenotomy), open.
*27306	1	3	Tenotomy, subcutaneous, closed, adductor or hamstring, (separate procedure); single.
*27307	1	3	Tenotomy, subcutaneous, closed, adductor or hamstring, (separate procedure); multiple.
27310	4	4	Arthrotomy, knee, for infection, with exploration, drainage or removal of foreign body.

	Payment groups		
	Old	New	
*27315	4	2	Neurectomy, hamstring muscle.
*27320	4	2	Neurectomy, popliteal (gastrocnemius).
Excision			
27324	2	1	Biopsy, soft tissues; deep.
27327	1	2	Excision, benign tumor; subcutaneous.
27328	2	3	Excision, benign tumor; deep, subfascial, or intramuscular.
27330	4	4	Arthrotomy, knee; for synovial biopsy only.
27345	4	4	Excision of synovial cyst of popliteal space (Baker's cyst).
27350	4	4	Patellectomy or hemipatellectomy.
27355	4	3	Excision or curettage of bone cyst or benign tumor of femur.
27360	4	5	Partial excision (craterization, saucerization or diaphysectomy) of bone, (e.g., for osteomyelitis), femur, proximal tibia and/or fibula.
Introduction and/or removal			
27372	3	6	Removal foreign body, deep.
Repair, revision or reconstruction			
27390	4	1	Tenotomy, open, hamstring, knee to hip; single.
27391	4	2	Tenotomy, open, hamstring, knee to hip; multiple, one leg.
27392	4	3	Tenotomy, open, hamstring, knee to hip; multiple, bilateral.
27393	4	2	Lengthening of hamstring, tendon; single.
27394	4	3	Lengthening of hamstring, tendon; multiple, one leg.
27395	4	3	Lengthening of hamstring, tendon; multiple, bilateral.
27396	4	3	Transplant, hamstring tendon to patella; single.
27397	4	3	Transplant, hamstring tendon to patella; multiple.
27400	4	3	Tendon or muscle transfer, hamstrings to femur (Eggers type procedure).
27420	4	3	Reconstruction for recurrent dislocating patella; (Hauser type procedure).
27422	4	6	Reconstruction for recurrent dislocating patella; with extensor realignment and/or muscle advancement or release (Campbell, Goldwaite, etc., type procedure).
27424	4	3	Reconstruction for recurrent dislocating patella; with patellectomy.
27425	4	6	Lateral retinacular release (any method).
27430	4	4	Quadriceps plasty (Bennett or Thompson type).
27435	4	4	Capsulotomy, knee, posterior capsular release.
Fractures and/or dislocations			
27522	3	3	Treatment of open pateller fracture, with uncomplicated soft tissue closure.
27524	4	3	Open treatment of closed or open patellar fracture, with repair and/or excision.
Excision			
27532	1	1	Treatment of closed tibial fracture, proximal (plateau); with manipulation.
Fractures and/or dislocations			
27534	3	2	Treatment of open tibial fracture, proximal (plateau), with uncomplicated soft tissue closure.
Excision			
27552	1	1	Treatment of closed knee dislocation; requiring anesthesia.
27562	1	1	Treatment of closed patellar dislocation; requiring anesthesia.
Fractures and/or dislocations			
27564	4	2	Treatment of open patellar dislocation, with uncomplicated soft tissue closure.
27566	4	2	Open treatment of closed or open patellar dislocation, with or without partial or total patellectomy.
Manipulation			
27570	2	1	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices).
			Leg (tibia and fibula) and ankle joint
Incision			
27603	2	2	Incision and drainage; deep abscess or hematoma.
*27605	1	1	Tenotomy, Achilles tendon, subcutaneous (separate procedure); local anesthesia.
*27606	1	1	Tenotomy, Achilles tendon, subcutaneous (separate procedure); general anesthesia.
27607	2	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
27610	2	2	Arthrotomy, ankle, with exploration, drainage or removal of loose or foreign body.
27612	4	3	Arthrotomy, ankle, posterior capsular release, with or without archilles tendon lengthening.
Excision			
27620	3	4	Arthrotomy, ankle, for biopsy.
27630	3	3	Excision of lesion of tendon sheath or capsule (e.g., cyst or ganglion).
27635	3	3	Excision or curettage of bone cyst or benign tumor, tibia or fibula.
27637	4	3	Excison or curettage of bone cyst, or benign tumor, tibia or fibula; with primary autogenous graft (includes obtaining graft).
27638	4	3	Excision or curettage of bone cyst, or benign tumor, tibia or fibula; with primary homogenous graft.
27640	4	2	Partial excision (craterization, saucerization, or diaphysectomy) of bone, (e.g., for osteomyelitis); tibia.
27641	4	2	Partial excision (craterization, saucerization, or diaphysectomy) of bone, (e.g., for osteomyelitis); fibula.
Repair, revision or reconstruction			
*27650	3	3	Repair, primary, open or percutaneous, ruptured Achilles tendon.
*27652	4	3	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft).
*27654	4	3	Suture, secondary, ruptured Achilles tendon, with our without graft.
*27656	3	2	Repair, fascial defect of leg.
*27658	3	1	Repair or suture of flexor tendon of leg; primary, without free graft, single, each.
*27659	4	2	Repair or suture of flexor tendon of leg; secondary with or without free graft, single tendon, each.
*27664	3	2	Repair or suture of extensor tendon of leg; primary, without free graft, single, each.
*27665	4	2	Repair or suture of extensor tendon of leg; secondary with or without free graft, single tendon, each.
*27675	4	2	Repair for dislocating peroneal tendons; without fibular osteotomy.
*27676	4	3	Repair for dislocating peroneal tendons; with fibular osteotomy.
27680	3	3	Tenolysis, including tibia, fibula and ankle flexor; single.
27681	4	2	Tenolysis, including tibia,fibula and ankle flexor; multiple (through same incision), each.
27685	3	3	Lengthening or shortening of tendon; single (separate procedure).
27686	4	3	Lengthening or shortening of tendon; multiple (through same incision), each.

	Payment groups		
	Old	New	
27690	4	4	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (e.g., anterior tibial extensors into midfoot).
27691	4	4	Transfer or transplant of single tendon (with muscle redirection or rerouting); anterior tibial or posterior tibial through interosseous space.
27692	4	3	Transfer or transplant of single tendon (with muscle redirection or rerouting); each additional tendon.
Fractures and/or dislocations			
27756	4	3	Open treatment of closed or open tibial shaft fracture, with internal skeletal fixation; simple.
27758	4	4	Open treatment of closed or open tibial shaft fracture, with internal or external skeletal fixation; complicated.
27764	3	2	Treatment of open distal tibial fracture (medial malleolus), with uncomplicated soft tissue closure.
27766	3	3	Open treatment of closed or open distal tibial fracture (medial malleolus), with fixation.
27781	1	1	Treatment of closed proximal fibula or shaft fracture; with manipulation.
27782	3	2	Treatment of open proximal fibula or shaft fracture, with uncomplicated soft tissue closure.
27784	4	3	Open treatment of closed or open proximal fibula or shaft fracture, with or without internal or external skeletal fixation.
27790	3	3	Treatment of open distal fibular fracture (lateral malleolus), with uncomplicated soft tissue closure.
27792	4	3	Open treatment of closed or open distal fibular fracture (lateral malleolus), with fixation.
27802	1	1	Treatment of closed tibia and fibula fractures, shafts; with manipulation.
27804	3	3	Treatment of open tibia and fibula fractures, shafts, with uncomplicated soft tissue closure (e.g., "pins above and below").
27842	1	1	Treatment of ankle dislocation; requiring anesthesia.
27844	3	2	Treatment of open ankle dislocation, with uncomplicated soft tissue closure.
27846	4	3	Open treatment of closed or open ankle dislocation.
27848	4	3	Open treatment of closed or open ankle dislocation; with fixation.
Manipulation			
27860	1	1	Manipulation of ankle under general anesthesia (includes application of traction or other fixation apparatus).
			Foot
Incision			
28002	2	3	Deep infection, below fascia, requiring deep dissection, with or without tendon sheath involvement; single bursal space, specify.
28003	2	3	Deep infection, below fascia, requiring deep dissection, with or without tendon sheath involvement; multiple areas.
28005	2	3	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
*28008	4	3	Fasciotomy, plantar and/or toe, subcutaneous.
*28010	1	2	Tenotomy, subcutaneous, toe; single.
*28011	1	2	Tenotomy, subcutaneous, toe; multiple.
*28030	4	4	Neurectomy of intrinsic musculature of foot.
28035	4	4	Tarsal tunnel release (posterior tibial nerve decompression).
Excision			
28045	2	3	Excision, benign tumor; deep, subfascial, intramuscular.
28050	3	2	Arthrotomy for synovial biopsy; intertarsal or tarsometatarsal joint.
28062	4	3	Fasciectomy, excision of plantar fascia; radical (separate procedure).
*28072	4	3	Synovectomy; metatarsophalangeal joint, each.
*28080	3	3	Excision of Morton neuroma, single, each.
*28086	4	2	Synovectomy, tendon sheath; flexor.
*28088	4	2	Synovectomy, tendon sheath; extensor.
*28090	4	3	Excision of lesion of tendon or fibrous sheath or capsule (including synovectomy) (cyst or ganglion); foot.
*28092	4	3	Excision of lesion of tendon or fibrous sheath or capsule (including synovectomy) (cyst or ganglion); toes.
28102	4	3	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autogenous bone graft (includes obtaining graft).
28103	4	3	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with homogenous bone graft.
28107	3	3	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal bones, except talus or calcaneus; with homogenous bone graft.
*28110	3	3	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure).
*28111	3	3	Ostectomy complete excision; first metatarsal head.
*28112	3	3	Ostectomy; complete excision other metatarsal head (second, third, or fourth).
*28113	3	3	Ostectomy; complete excision fifth metatarsal head.
*28114	3	3	Ostectomy; complete excision all metatarsal heads, with proximal phalangectomy, excluding first metatarsal (Clayton type procedure).
28118	3	4	Ostectomy, calcaneus; partial.
28120	3	3	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) of bone (e.g., for osteomyelitis), talus or calcaneus.
28122	3	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for ostemyelitis), tarsal or metatarsal bone, except talus or calcaneus.
28140	3	3	Metatarsectomy.
28171	3	3	Radical resection for tumor; tarsal (except talus or calcaneus).
28173	3	3	Radical resection for tumor; metatarsal.
28175	3	3	Radical resection for tumor; phalanx.
Introduction and/or removal			
28193	2	4	Remove foreign body; complicated.
Repair revision or Reconstruction			
*28200	3	3	Repair or suture of tendon, foot, flexor, single; primary or secondary, without free graft, each tendon.
*28202	4	3	Repair or suture of tendon, foot, flexor, single; secondary with free graft, each tendon (includes obtaining graft).
*28208	3	3	Repair or suture of tendon, foot, extensor, single; primary or secondary, each tendon.
*28210	4	3	Repair or suture of tendon, foot, extensor, single; secondary with free graft, each tendon, (including obtaining graft).
*28222	3	1	Tenolysis, flexor; multiple (through same incision).
*28225	3	1	Tenolysis, extensor; single.
*28226	3	1	Tenolysis, extensor; multiple (through same incision).
*28230	1	1	Tenotomy, open, flexor; foot, single or multiple (separate procedure).
*28232	1	4	Tenotomy, open, flexor; toe, single (separate procedure).
*28234	1	3	Tenotomy, open, extensor, foot or toe.

	Payment groups		
	Old	New	
*28240	1	3	Tenotomy or release, abductor hallucis muscle.
28250	2	3	Division of plantar fascia and muscle ("Steindler stripping") (separate procedure).
28260	3	3	Capsulotomy, midfoot; medial release only (separate procedure).
28261	3	3	Capsulotomy, midfoot; with tendon lengthening.
*28264	3	1	Capsulotomy, midtarsal (Heyman type procedure).
*28270	3	2	Capsulotomy for contracture; metatarsophalangeal joint, with or without tenorrhaphy, single, each joint (separate procedure).
*28272	3	3	Capsulotomy for contracture; interphalangeal joint, single, each joint (separate procedure).
*28285	4	3	Hammertoe operation; one toe (e.g., interphalangeal fusion, filleting, phalangectomy) (separate procedure).
*28286	4	4	Hammertoe operation; for cock-up fifth toe with plastic skin closure, (Ruiz-Mora type procedure).
*28290	4	4	Hallux valgus (bunion) correction, with or without sesamoidectomy; simple exostectomy (Silver type procedure).
*28292	4	4	Hallux valgus (bunion) correction, with or without sesamoidectomy; Keller, McBride or Mayo type procedure.
*28293	4	5	Hallux valgus (bunion) correction, with or without sesamoidectomy; resection of joint with implant.
*28294	4	6	Hallux valgus (bunion) correction, with or without sesamoidectomy; with tendon transplants (Joplin type procedure).
*28296	4	5	Hallux valgus (bunion) correction, with or without sesamoidectomy; with metatarsal osteotomy (e.g., Mitchell, Chevron, or concentric type procedures).
28297	4	3	Hallux valgus (bunion) correction, with or without sesamoidectomy; Lapidus type procedure.
*28298	4	3	Hallux valgus (bunion) correction, with or without sesamoidectomy; by phalanx osteotomy.
*28299	4	5	Hallux valgus (bunion) correction, with or without sesamoidectomy; by other methods (e.g., double osteotomy).
*28306	4	4	Osteotomy, metatarsal, base or shaft, single, for shortening or angular correction; first metatarsal.
*28308	4	2	Osteotomy, metatarsal, base or shaft, single, for shortening or angular correction; other than first metatarsal.
*28310	4	3	Osteotomy for shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure).
*28312	4	3	Osteotomy for shortening, angular or rotational correction; other phalanges, any toe.
28315	3	4	Sesamoidectomy, first toe (separate procedure).
28320	4	4	Repair of nonunion or malunion; tarsal bones (calcaneus, talus, etc).
28322	4	4	Repair of nonunion or malunion; metatarsal, with or without bone graft (includes obtaining graft).
Fracture and/or dislocation			
28405	1	2	Treatment of closed calcaneal fracture; with manipulation including Cotton or Bohler type reductions.
28406	2	2	Treatment of closed calcaneal fracture; with manipulation and skeletal fixation.
28420	4	4	Open treatment of closed or open calcaneal fracture, with or without internal or external skeletal fixation; with primary iliac or other autogenous bone graft (includes obtaining graft).
28435	1	2	Treatment of closed talus fracture; with manipulation.
28436	2	2	Treatment of closed talus fracture; with manipulation and percutaneous pinning.
28465	4	3	Open treatment of closed or open tarsal bone fracture (except talus and calcaneus), with or without internal or external skeletal fixation, each.
28485	4	4	Open treatment of closed or open metatarsal fracture, with or without internal or external skeletal fixation, each.
28500	3	3	Treatment of open fracture great toe, phalanx or phalanges, with uncomplicated soft tissue closure.
28505	3	3	Open treatment of closed or open fracture great toe, phalanx or phalanges, with or without internal or external skeletal fixation.
28520	2	3	Treatment of open fracture, phalanx or phalanges, other than great toe, with uncomplicated soft tissue closure, each.
28525	3	3	Open treatment of closed or open fracture, phalanx or phalanges, other than great toe, with or without internal or external skeletal fixation, each.
28545	1	1	Treatment of closed tarsal bone dislocation; requiring anesthesia.
28546	2	2	Treatment of closed tarsal bone dislocation, with percutaneous skeletal fixation.
28555	4	2	Open treatment of closed or open tarsal bone dislocation, with or without internal or external skeletal fixation.
28575	1	1	Treatment of closed talotarsal joint dislocation; requiring anesthesia.
28585	4	3	Open treatment of closed or open talotarsal joint dislocation, with or without internal or external skeletal fixation.
28605	1	1	Treatment of closed tarsometatarsal joint dislocation; requiring anesthesia.
28606	2	2	Treatment of closed tarsometatarsal joint dislocation, with percutaneous skeletal fixation.
28615	4	3	Open treatment of closed or open tarsometatarsal joint dislocation, with or without internal or external skeletal fixation.
28645	4	3	Open treatment of closed or open metatarsophalangeal joint dislocation.
28670	3	3	Treatment of open interphalangeal joint dislocation, with uncomplicated soft tissue closure.
28675	4	3	Open treatment of closed or open interphalangeal joint dislocation.
Arthrodesis			
*28750	4	4	Arthrodesis, great toe; metatarsophalangeal joint.
*28755	4	4	Arthrodesis, great toe; interphalangeal joint.
*28760	4	4	Arthrodesis, great toe, interphalangeal joint, with extensor hallucis longus transfer to first metatarsal neck (Jones type procedure).
Amputation			
*28810	2	2	Amputation, metatarsal, with toe, single.
*28820	2	2	Amputation, toe; metatar sophalangeal joint.
*28825	2	2	Amputation, toe; interphalanged joint.
Arthroscopy			
29870	4	2	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure).
29874	4	3	Arthroscopy, knee, surgical; for removal of loose body or foreign body (e.g., osteochondritis dissecans fragmentation, chondral fragmentation).
29875	4	3	Arthroscopy, knee, surgical; synovectomy, limited (e.g., plica or shelf resection).
29876	4	3	Synovectomy, major, two or more compartments (e.g., medial or lateral).
29877	4	3	Debridement/shaving of articular cartilage (chondroplasty).
29881	4	3	Arthroscopy, knee, surgical; with meniscectomy (medial or lateral including any meniscal shaving).
29887	4	3	Drilling for intact osteochondritis dissecans lesion with internal fixation.
			Respiratory system
			Nose
Excision			
*30115	2	2	Excision, nasal polyp(s), extensive; unilateral.
30116	2	2	Excision, nasal polyp(s), extensive; bilateral.
30117	2	3	Excision, intranasal lesion; internal approach.
30118	2	2	Excision, intransal lesion; external approach (lateral rhinotomy).

	Payment groups		
	Old	New	
30125	3	2	Excision dermoid cyst, nose; complex, under bone or cartilage.
*30130	1	3	Excision turbinate, partial or complete.
*30140	4	3	Submucous resection turbinate, partial or complete.
30150	4	3	Rhinectomy; partial.
30160	4	4	Rhinectomy; total.
Removal foreign body			
30310	1	1	Removal of foreign body, intranasal; requiring general anesthesia.
30320	2	2	Removal foreign body; by lateral rhinotomy.
Repair			
30400	4	4	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip.
30410	4	4	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip.
30420	4	5	Rhinoplasty, primary; including major septal repair.
30430	4	3	Rhinoplasty, secondary; minor revision (small amount of nasal tip work).
30435	4	5	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies).
30450	4	6	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies).
30520	4	4	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft.
30580	4	4	Repair fistula; oromaxillary (combine with 31030 if antrotomy is included).
30600	4	4	Repair fistula; oronasal.
*30620	4	6	Reconstruction, functional, internal nose (septal or other intranasal dermatoplasty) (does not include obtaining graft).
*30630	4	6	Repair nasal septal perforations.
Other procedures			
30915	4	1	Ligation arteries; ethmoidal.
30920	4	2	Ligation arteries; internal maxillary artery, transantral.
			Accessory sinuses
Incision			
*31020	2	3	Sinusotomy, maxillary (antrotomy); intranasal, unilateral.
*31021	2	3	Sinusotomy, maxillary (antrotomy); intranasal, bilateral.
*31030	2	3	Sinusotomy, maxillary (antrotomy); radical, unilateral (Caldwell-Luc) without removal of antrochoanal polyps.
*31031	2	3	Sinusotomy, masillary (antrotomy); radical, bilateral (Caldwell-Luc) without removal of antrochoanal polyps.
31032	4	4	Sinusotomy, maxillary (antrotomy); radical unilateral (Caldwell-Luc) with removal antrochoanal polyps.
31033	4	4	Sinusotomy, maxillary (antrotomy); radical, bilateral (Caldwell-Luc) with removal antrochoanal polyps.
31070	2	2	Sinusotomy frontal; external, simple (trephine operation).
Excision			
*31200	3	2	Ethmoidectomy; intranasal, anterior.
*31201	3	5	Ethmoidectomy; intranasal, total.
*31205	3	3	Ethmoidectomy; extranasal, total.
			Larynx
Endoscopy			
*31505	1	2	Laryngoscopy, indirect (separate procedure); diagnostic.
*31510	1	2	Laryngoscopy, indirect (separate procedure); with biopsy.
*31511	1	2	Laryngoscopy, indirect (separate procedure); with removal of foreign body.
*31512	1	2	Laryngoscopy, indirect (separate procedure); with removal of lesion.
31513	2	2	Laryngoscopy, indirect (separate procedure); with vocal cord injection.
*31515	1	1	Laryngoscopy direct; for aspiration.
*31525	1	1	Laryngoscopy, direct; diagnostic, except newborn.
*31526	1	2	Laryngoscopy, indirect; diagnostic, with operating microscope.
31527	2	1	Laryngoscopy, direct; with insertion of obturator.
*31530	1	2	Laryngoscopy, direct, operative, with foreign body removal.
*31531	1	3	Laryngoscopy, direct, operative, with foreign body removal; with operating microscope.
*31535	1	2	Laryngoscopy, direct, operative, with biopsy.
*31536	1	3	Laryngoscopy, direct, operative, with biopsy; with operating microscope.
*31540	1	3	Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis.
*31541	1	4	Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis; with operating microscope.
*31560	1	1	Laryngoscopy, direct, operative, with arytenoidectomy.
*31561	1	2	Laryngoscopy, direct, operative, with arytenoidectomy; with operating microscope.
*31570	1	2	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic.
*31571	1	2	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope.
31576	1	2	Laryngoscopy, flexible fiberscopic; with biopsy.
31577	1	2	Laryngoscopy, flexible fiberscopic; with removal of foreign body.
31578	1	2	Laryngoscopy, flexible fiberscopic; with removal of lesion.
			Trachea and bronchi
Incision			
31600	2	2	Tracheostomy, planned (separate procedure).
31612	1	1	Tracheal puncture, percutaneous for aspiration of mucus (transtracheal aspiration).
31613	2	2	Tracheostoma revision; simple, without flap rotation.
31614	2	2	Tracheostoma revision; complex, with flap rotation.
Endoscopy			
31615	1	1	Tracheobronchoscopy through established tracheostomy incision.
31622	1	1	Bronchoscopy; diagnostic, (flexible original), with or without cell washing or brushing.
*31625	1	2	Bronchoscopy; with biopsy.
31628	1	2	Bronchoscopy; with transbronchial lung biopsy, with or without fluoroscopic guidance.
*31630	1	2	Bronchoscopy; with tracheal or bronchial dilation or closed reduction of fracture.
31631	1	2	Bronchoscopy; with tracheal dilation and placement of tracheal stent.
*31635	1	2	Bronchoscopy; with removal of foreign body.

	Payment groups		
	Old	New	
*31640	1	2	Bronchoscopy; with excision of tumor.
31641	1	2	Bronchoscopy; with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser).
*31645	1	1	Bronchoscopy; with therapeutic aspiration of tracheobronchial tree, initial (e.g., drainage of lung abscess).
31646	1	1	Bropnchoscopy; with therapeutic aspiration of tracheobronchial tree, subsequent.
31656	1	1	Bronchoscopy; with injection of contrast material for segmental bronchography (fiberscope only).
31659	1	1	Bronchoscopy; with other bronchoscopic procedures.
Introduction			
31700	1	1	Catheterization, transglottic (separate procedure).
31708	1	1	Instillation of contrast material for laryngography or bronchography, without catheterization.
31710	1	1	Catheterization for bronchography, with or without instillation of contrast material.
31715	1	1	Transtracheal injection for bronchography.
31717	1	1	Catheterization with bronchial brush biopsy.
31719	1	1	Transtracheal (percutaneous) introduction of indwelling tube for therapy (tickle tube).
31720	1	1	Catheter aspiration (separate procedure); nasotracheobronchial.
			Cardiovascular system
Repair, ligation and other procedures			
37609	1	2	Ligation or biopsy, temporal artery.
*37700	4	2	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions, unilateral.
*37701	4	3	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions, unilateral; bilateral.
*37720	4	3	Ligation and division and complete stripping of long or short saphenous veins; unilateral.
*37721	4	3	Ligation and division and complete stripping of long or short saphenous veins; bilateral.
*37730	4	3	Ligation and division and complete stripping of long and short saphenous veins; unilateral.
*37731	4	3	Ligation and division and complete stripping of long and short saphenous veins; bilateral.
37735	4	3	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia; unilateral.
37737	4	3	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep facia; bilateral.
37760	4	3	Ligation and perforators, subfascial, radical (Linton Type), with or without skin graft.
*37780	4	3	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure); unilateral.
*37781	4	3	Bilateral. Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure).
37785	3	3	Ligation, division and/or excision of secondary varicose veins (clusters) of leg; unilateral.
37787	3	3	Ligation, division and/or excision of secondary varicose veins (clusters) of leg; bilateral.
			Hemic and lymphatic system
			Lymph nodes and lymphatic channels
Incision			
38305	1	2	Drainage of lymph node abscess or lymphadenitis; extensive.
38308	1	2	Lymphagiotomy or other operations on lymphatic channels.
Excision			
*38500	2	2	Biopsy or excision of lymph node(s); superficial (separate procedure).
*38510	2	2	Biopsy or excision of lymph node(s); deep, cervical node(s).
*38520	2	2	Biopsy or excision of lymph node(s); deep cervical node(s) with excision scalene fat pad.
38530	3	2	Biopsy or excision of lymph node(s); internal mammary node(s) (separate procedure).
38542	3	2	Dissection; deep jugular node(s).
38550	3	3	Excision of cystic hygroma, axillary or cervical, without deep neurovascular dissection; simple.
38555	4	3	Excision of cystic hygroma, axillary or cervical, without deep neurovascular dissection; complex.
Radical lymphadenectomy (radical resection of lymph nodes)			
38700	4	2	Suprahyoid lymphadenectomy; unilateral.
38701	4	3	Suprahyoid lymphadenectomy; bilateral.
38740	3	2	Axillary lymphadenectomy; superficial.
38745	3	4	Axillary lymphadenectomy; complete.
38760	3	2	Inquinofemoral lymphadenectomy, superficial, including Cloquet's node (separate procedure); unilateral
38761	3	3	Inquinofemoral lymphadenectomy, superficial, including Cloquet's node (separate procedure); bilateral.
Introduction			
38790	1	1	Injection procedure for lymphangiography; unilateral.
38791	1	1	Injection procedure for lymphangiography; bilateral.
			Digestive system
			Lips
Excision			
*40500	2	2	Vermilionectomy (lip shave), with mucosal advancement.
*40510	3	2	Excision of lip; transverse wedge excision with primary closure.
*40520	3	2	Excision lip; V-excision with primary direct linear closure.
40525	3	2	Excision lip; full thickness, reconstruction with local flap (Estlander or fan).
40527	3	2	Excision lip; full thickness, reconstruction with cross lip flap (Abbe-Estlander).
40530	3	2	Resection of lip, more than one-fourth, without reconstruction.
Repair (cheiloplasty)			
40650	3	3	Repair lip, full thickness; vermilion only.
40654	4	3	Repair lip, full thickness; over one half vertical height, or complex.
			Vestibule of mouth
Incision			
40801	1	2	Drainage of abscess, cyst, hematoma, vestibule of mouth; complicated.
40805	1	2	Removal of embedded foreign body; complicated.
Excision, destructive			
40814	2	2	Excision of lesion of mucosa and submucosa, with complex repair.
40816	2	2	Excision of lesion of mucosa and submucosa; complex with excision of underlying muscle.

	Payment groups		
	Old	New	
40818	2	1	Excision of mucosa as donor graft.
Repair			
40831	2	1	Closure of laceration; over 2.6 cm or complex.
40840	2	2	Vestibuloplasty; anterior.
40842	2	3	Vestibuloplasty; posterior, unilateral.
40843	2	3	Vestibuloplasty; posterior, bilateral.
40844	3	5	Vestibuloplasty; entire arch.
40845	4	5	Vestibuloplasty; complex.
			Tongue, floor of mouth
Incision			
*41000	1	1	Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; lingual.
*41005	1	1	Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; sublingual, superficial.
Excision			
*41100	1	2	Biopsy of tongue; anterior two-thirds.
*41105	1	2	Biopsy of tongue; posterior one-third.
41114	2	2	Excision of lesion of tongue with closure; with local tongue flap.
41115	1	1	Excision of lingual frenum (frenectomy)
41116	1	1	Excision lesion of floor of mouth.
41120	3	5	Glossectomy; less than one-half tongue.
Repair			
41251	3	2	Repair laceration up to 2 cm; posterior one-third of tongue.
			Dentoalveolar structures
Incision			
41806	2	1	Removal embedded foreign body; from bone.
Excision, destruction			
41826	2	2	Excision of lesion or tumor (except listed above); with simple repair.
41827	3	2	Excision of lesion or tumor (except listed above); with complex repair.
			Palate, uvula
Incision			
*42000	1	2	Drainage of abscess of palate, uvula.
Excision, destruction			
42104	1	2	Excision, lesion of palate, uvula; without closure.
42106	1	2	Excision, lesion of palate, uvula; with simple primary closure.
42107	1	2	Excision, lesion of palate, uvula; with local flap closure.
42120	2	4	Resection of palate or extensive resection of lesion.
42140	2	2	Uvulectomy, excision of uvula.
Repair			
42182	1	2	Repair laceration of palate; over 2 cm or complex.
			Salivary gland and ducts
Incision			
42305	1	2	Drainage of abscess; parotid, complicated.
42320	1	1	Drainage of abscess; submaxillary external.
42325	2	2	Fistulization of sublingual salivary cyst (ranula).
42335	2	2	Sialolithotomy; submandibular (submaxillary), complicated, intraoral.
42340	2	2	Sialolithotomy; parotid, extraoral or complicated intraoral.
Excision			
42408	2	3	Excision of sublingual salivary cyst (ranula).
42410	4	3	Excision of parotid tumor or parotid gland; lateral lobe, without nerve dissection.
42440	4	2	Excision of submandibular (submaxillary) gland.
42450	4	2	Excision of sublingual gland.
Repair			
42500	3	3	Plastic repair of salivary duct, sialodochoplasty; primary or simple.
42505	4	4	Plastic repair salivary duct, sialodochoplasty; secondary or complicated.
42507	4	2	Parotid duct diversion, bilateral (Wilke type procedure).
42508	4	3	Parotid duct diversion, bilateral (Wilke type procedure); with excision of one submandibular gland.
42509	4	3	Parotid duct diversion, bilateral (Wilke type procedure); with excision of both submandibular glands.
Other procedures			
42600	1	1	Closure salivary fistula.
42665	1	1	Ligation salivary duct, intraoral.
			Pharynx, adenoids, and tonsils
Incision			
42720	1	1	Incision and drainage abscess; retropharyngeal or parapharyngeal, intraoral approach.
42725	1	2	Incision and drainage abscess; retropharyngeal or parapharyngeal, external approach.
Excision			
42806	2	2	Biopsy; nasopharynx, survey for unknown primary lesion.
42808	1	2	Excision of lesion of pharynx.
*42810	2	3	Excision branchial cleft cyst or vestige; confined to skin and subcutaneous tissues.
*42815	2	5	Excision branchial cleft cyst or vestige; extending beneath subcutaneous tissues.
42860	2	3	Excision of tonsil tags.
42870	2	3	Excision lingual tonsil (separate procedure).
42880	2	5	Excision nasopharyngeal lesion (e.g., fibroma).
Repair			

	Payment groups		
	Old	New	
42900	2	1	Suture pharnyx for wound or injury.
42950	4	2	Pharyngoplasty (plastic or reconstructive operation on pharnyx).
Other procedures			
42955	2	2	Pharyngostomy (fistulization of pharynx, external for feeding).
			Esophagus
Endoscopy			
*43200	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); diagnostic procedure.
*43202	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for biopsy and/or collection of specimen by brushing or washing.
43204	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for injection sclerosis of esophageal varices.
*43215	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for removal of foreign body.
*43217	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for removal of polypoid lesion(s).
43219	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for insertion of plastic tube or stent.
43220	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for dilation, direct.
43226	1	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for insertion of wire to guide dilation.
43227	1	2	Esophagoscopy, rigid or flexible fiberoptic (specify); for control of hemorrhage (e.g., electrocoagulation laser photocoagulation).
43228	1	2	Esophagoscopy, rigid or flexible fiberoptic (specify); for ablation of tumor or mucosal lesion.
43235	1	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; complex diagnostic.
43239	1	2	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for biopsy and/or collection of specimen by brushing or washing.
43247	1	2	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of foreign body.
43251	1	2	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of polypoid lesion(s).
43255	1	2	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
43258	1	2	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for ablation of tumor or mucosal lesion (e.g., electrocoagulation, with laser photocoagulation).
43260	2	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection.
43262	2	2	Endoscopic retrograde cholangiopancreatography (ERCP) with or without specimen collection; for sphincterotomy/papillotomy.
43263	2	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection; for pressure measurement of sphincter of Oddi.
43264	2	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection; for removal of stone(s) from biliary and/or pancreatic ducts.
Manipulation			
43450	1	1	Dilation of esophagus, by unguided sound or bougie single or multiple passes; initial session.
43451	1	1	Dilation of esophagus, by unguided sound or bougie single or multiple passes; subsequent session.
43453	1	1	Dilation of esophagus, over guide wire or string.
43455	1	2	Dilation of esophagus, by balloon or Stark dilator.
43456	1	2	Dilation of esophagus, by balloon or Stark dilator; retrograde.
			Intestines (except rectum)
Enterostomy—external fistulization of intestines (separate procedure)			
*44340	3	3	Revision of colostomy; simple (release of superficial scar).
44345	4	4	Revision of colostomy; complicated reconstruction in depth.
44346	4	4	Revision of colostomy; with repair of paracolostomy Lernia.
Endoscopy, small bowel and stomal			
44360	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; diagnostic.
44361	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for biopsy and/or collection of specimen by brushing or washing.
44363	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for removal of foreign body.
44364	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for removal of polypoid lesion(s).
44366	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
44369	1	2	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for ablation of tumor or mucosal lesion (e.g., laser).
44380	1	1	Fiberoptic ileoscopy through stoma.
44382	1	1	Fiberoptic ileoscopy through stoma; with biopsy and/or collection of specimen by brushing or washing.
44388	1	1	Fiberoptic colonoscopy through colostomy.
44389	1	1	Fiberoptic colonoscopy through colostomy; for biopsy and/or collection of specimen by brushing or washing.
44390	1	1	Fiberoptic colonoscopy through colostomy; for removal of foreign body.
44391	1	1	Fiberoptic colonoscopy through colostomy; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
44392	1	1	Fiberoptic colonoscopy through colostomy; for removal of polypoid lesion(s).
			Rectum
Incision			
45000	3	1	Transrectal drainage of pelvic abscess..
45005	1	2	Incision and drainage of submucosal abscess, rectum.
45020	2	2	Incision and drainage of deep supralevator, pelvirectal, or retrorectal abscess.
Excision			
45170	3	2	Excision of rectal tumor, simple, transanal approach.
45180	3	3	Excision and/or electrodesiccation of malignant tumor of rectum, transanal approach; palliative.
45181	3	3	Excision and/or electrodesiccation of malignant tumor of rectum, transanal approach; therapeutic.
Endoscopy			
45355	1	1	Colonoscopy, with standard sigmoidoscope, transabdominal via colotomy, single or multiple.
45360	1	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; diagnostic procedure.

	Payment groups		
	Old	New	
45365	1	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for biopsy and/or collection of specimen by brushing or washing.
45367	1	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for removal of foreign body.
45368	1	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
45370	1	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for removal of polypoid lesion(s).
45378	1	2	Colonoscopy, fiberoptic, beyond splenic flexure; diagnostic procedure.
45379	1	2	Colonoscopy, fiberoptic, beyond splenic flexure; for removal of foreign body.
45380	1	2	Colonoscopy, fiberoptic, beyond splenic flexure; for biopsy and/or collection of specimen by brushing or washing.
45382	1	2	Colonoscopy, fiberoptic, beyond splenic flexure; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
45385	1	2	Colonoscopy, fiberoptic, beyond splenic flexure; for removal of polypoid lesion(s).
Repair			
45500	4	2	Proctoplastry; for stenosis.
45505	4	2	Proctoplastry; for prolapse of mucous membrane.
45521	1	1	Perirectal injection of sclerosing solution for prolapse; hospital.
45560	4	2	Repair of retocele (separate procedure).
Manipulation			
45900	1	1	Reduction of procidentia (separate procedure) under anesthesia.
*45910	1	1	Dilation of rectal structure (separate procedure) under anesthesia other than local.
45915	1	1	Removal of fecal impaction or foreign body (separate procedure) under anesthesia.
			Anus
Incision			
46000	2	3	Fistulotomy, subcutaneous.
46040	2	3	Incision and drainage of ischiorectal and/or perirectal abcess (separate procedure).
46045	2	2	Incision and drainage of intramural, intramuscular or submucosal abcess, transanal, under anesthesia.
*46060	2	2	Incision and drainage of isochiorectal or intramural abcess, with fistulectomy, submuscular.
46080	2	3	Sphincterotomy, anal, division of sphincter (separate procedure).
Excision			
46200	2	2	Fissurectomy, with or without sphincterotomy.
46211	2	2	Cryptectomy; multiple (separate procedure).
*46250	3	3	Hemorroidectomy, external, complete.
*46255	3	3	Hemorroidectomy internal and external, simple.
*46257	3	3	Hemorroidectomy internal and external, simple; with fissurectomy.
*46258	3	3	Hemorroidectomy internal and external simple; with fistulectomy, with or without fissurectomy.
46260	2	3	Hemorrhoidectomy, internal and external, complex or extensive.
46261	2	4	Hemorrhoidectomy, internal and external, complex or extensive; with fissurectomy.
*46262	2	4	Hemorrhoidectomy, internal and external, complex or extensive; with fistulectomy, with or without fissurectomy.
*46270	2	3	Fistulectomy; subcutaneous.
*46275	2	3	Fistulectomy; submuscular.
*46280	2	4	Fistulectomy; complex or multiple.
46285	2	1	Fistulectomy; second stage.
			Anus
Introduction			
46750	4	3	Sphincteroplasty, anal, for incontinence or prolapse; adult.
46753	4	3	Graft (Thiersch operation) for rectal incontinence and/or prolapse.
46754	4	2	Removal of Thiersch wire or suture.
46760	4	2	Sphincteroplasty, anal, for incontinence, adult, muscle transplant.
Destruction			
46924	1	1	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive, any method.
46937	2	2	Cryosurgery of rectal tumor; benign.
46938	2	2	Cryosurgery of rectal tumor; malignant.
			Liver
Incision			
*47000	2	1	Biopsy of liver, percutaneous needle.
			Abdomen, peritoneum, and omentum
Incision			
49000	4	4	Exploratory laparotomy, exploratory celiotomy (separate procedure).
Endoscopy			
*49300	4	2	Peritoneoscopy; without biopsy.
*49301	4	3	Peritoneoscopy; with biopsy.
49302	4	3	Peritoneoscopy with guided transhepatic cholangiography; without biopsy.
49303	4	3	Peritoneoscopy with guided transhepatic cholangiography; with biopsy.
Introduction			
49400	1	1	Pneumoperitoneum; initial.
49401	1	1	Pneumoperitoneum; subsequent.
49420	1	1	Insertion of intraperitoneal cannula or catheter for drainage or dialysis; temporary.
49421	1	1	Insertion of intraperitoneal cannula or catheter for drainage or dialysis; permanent.
49425	1	2	Peritoneal-venous shunt (e.g., Le Veen shunt).
49426	1	2	Revision of peritoneal-venous shunt.
			Hernioplasty, Herniorrhaphy, Herniotomy
Repair			
*49505	4	4	Repair inguinal hernia, age 5 or over.
*49510	4	4	Repair inguinal hernia, age 5 or over with orchiectomy, with or without implantation of prosthesis.

	Payment groups		
	Old	New	
*49515	4	5	Repair inguinal hernia, age 5 or over; with excision of hydrocele or spermatocele.
*49520	4	6	Repair inguinal hernia, any age; recurrent.
*49525	4	4	Repair inguinal hernia, any age; sliding.
49540	4	2	Repair lumber hernia.
*49550	4	4	Repair femoral hernia, groin incision.
49552	4	4	Repair femoral hernia, Henry approach.
*49555	4	5	Repair femoral hernia, recurrent, any approach.
*49560	4	4	Repair ventral (incisional) hernia (separate procedure).
*49565	4	4	Repair ventral (incisional) hernia (separate procedure); recurrent.
49570	4	4	Repair epigastric hernia, properitoneal fat (separate procedure); simple.
49575	4	4	Repair epigastric hernia, properitoneal fat (separate procedure); complex.
49581	4	4	Repair umbilical hernia; age 5 or over.
49590	4	3	Repair spigelian hernia.
			Urinary system
			Kidney
Incision			
50020	3	2	Drainage of perirenal or renal abscess (separate procedure).
50040	4	3	Nephrostomy, nephrotomy with drainage.
Excision			
50200	1	1	Renal biopsy, percutaneous by trocar or needle.
50205	4	3	Renal biopsy, percutaneous; by surgical exposure of kidney.
Introduction			
50390	1	1	Aspiration and/or injection of renal cyst or pelvis by needle, percutaneous.
50392	1	1	Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous.
50393	1	1	Introduction of ureteral catheter or stent into ureter through renal pelvis for drainage and/or injection, percutaneous.
50394	1	1	Injection procedure for pyelography (as nephrostogram, pyelostogram, antegrade pyeloureterograms) through nephrostomy or pyelostomy tube, or indwelling ureteral catheter (separate procedure).
50396	1	1	Manometric studies through nephrostomy or pyelostomy tube, or indwelling ureteral catheter.
50398	1	1	Change of nephrostomy or pyelostomy tube.
Endoscopy			
50553	1	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50559	1	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance with or without biopsy and/or fulguration.
50561	1	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
50570	1	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
50572	1	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50576	1	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration with or without biopsy.
50578	1	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance, with or without biopsy and/or fulguration
50580	1	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
			Ureter
Introduction			
50684	1	1	Injection procedure for ureterography or ureteropyelography through ureterostomy or indwelling ureteral catheter (separate procedure).
50690	1	1	Injection procedure for visualization of ilial conduit and/or ureteropyelography, exclusive of radiologic service (separate procedure).
Endoscopy			
50953	1	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50955	1	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy.
50957	1	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy.
50959	1	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance with or without biopsy and/or fulguration (not including provision of material).
50961	1	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
50970	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
50972	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50974	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy.
50976	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy.
50978	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance, with or without biopsy and/or fulguration (not including provision of materal).
50980	1	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.

	Payment groups		
	Old	New	
			Bladder
Incision			
51005	1	1	Aspiration of bladder; by trocar or intracatheter.
51010	1	1	Aspiration of bladder; with insertion of suprapubic catheter.
Introduction			
51600	1	1	Injection procedure for cystography or voiding urethrocystography.
51605	1	1	Injection procedure and placement of chain for contrast and/or chain urethrocystography.
51610	1	1	Injection procedure for retrograde urethrocystography.
51710	1	1	Change of cystostomy tube; complicated.
			Bladder
Repair			
51865	4	4	Cystorrhaphy, suture of bladder wound, injury or rupture; complicated.
51900	4	4	Closure of vesicovaginal fistula, abdominal approach.
			Ureter
Endocopy-cystoscopy, urethroscopy cystourethroscopy notes			
*52000	1	2	Cystourethroscopy (separate procedure).
52005	1	2	Cystourethroscopy; with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
52007	1	2	Cystourethroscopy; with ureteral catheterization and brush biopsy of ureter and/or renal pelvis.
52010	1	2	Cystourethroscopy: with ejaculatory duct catheterization, with or without irrigation, instillation, or duct radiography, exclusive of radiologic service.
			Bladder
Transurethral surgery (urethra, and bladder)			
52204	3	2	Cystourethroscopy, with biopsy.
52214	3	2	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands.
52224	3	2	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s), with or without biopsy.
52234	3	2	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 to 2.0 cm).
52235	3	3	Cystourethroscopy, with fulguration (including cryosurgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm).
52240	3	3	Cystourethroscopy, with fulguration (including cryosurgery) and/or resection of; LARGE bladder tumor(s).
52250	3	4	Cystourethroscopy with insertion of radioactive substance, with or without biopsy or fulguration.
52260	3	2	Cystourethroscopy, with dilation of bladder for interstitial cystitis; general or conduction (spinal) anesthesia.
52270	3	2	Cystourethroscopy with internal urethrotomy; female.
52275	3	2	Cystourethroscopy with internal urethrotomy; male.
52276	3	2	Cystourethroscopy with direct vision internal urethrotomy.
52277	3	2	Cystourethroscopy, with resection of external sphincter (sphincterotomy).
52281	3	2	Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy and injection procedure for cystography, male or female.
52283	3	2	Cystourethroscopy, with steroid injection into stricture.
52285	3	2	Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone.
52290	3	2	Cystourethroscopy; with ureteral meatotomy, unilateral or bilateral.
52300	3	2	Cystourethroscopy; with resection or fulguration of ureterocele(s), unilateral or bilateral.
52305	3	2	Cystourethroscopy; with incision or resection of orifice of bladder diverticulum, single or multiple.
52310	4	2	Cystourethroscopy, with removal of foreign body calculus or ureteral stent from urethra or bladder; simple.
52315	4	2	Cystourethroscopy, with removal of foreign body calculus or ureteral stent from urethra or bladder; complicated.
52317	4	1	Litholapaxy: crushing of fragmentation or calculus by any means in bladder and removal of fragments, simple; small (less than 2.5 c.m.).
52318	4	2	Litholapaxy: crushing of fragmentation of calculus by any means in bladder and removal of fragments, simple; complicated or large (over 2.5 c.m.).
52320	4	5	Cystourethroscopy (including ureteral catherization); with removal of ureteral calculus.
52330	4	2	Cystourethroscopy (including ureteral catherization); with manipulation, without removal of ureteral calculus.
52332	4	2	Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons of double-J type).
52335	3	2	Cystourethroscopy, with ureteroscopy and/or pyeloscopy (includes dilation of the ureter by any method).
Transuretheral Surgery (vesical neck and prostate)			
52340	3	3	Cystourethroscopy with incision, fulguration, or resection of bladder neck and/or posterior urethra (congenital valves, obstructive hypertrophic mucosal folds).
52500	3	3	Transurethral resection of bladder neck (separate procedure).
Transurethal surgery (uretha and bladder)			
52601	4	3	Transurethral resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included).
52606	4	1	Transurethral fulguration for postoperative bleeding occurring after the usual follow-up time.
52612	4	2	Transurethral resection of prostate; first stage of two-stage resection (partial resection).
52614	4	1	Transurethral resection of prostate; second stage of two-stage resection (resection completed).
52620	4	1	Transurethral resection; of residual obstructive tissue after 90 days postoperative.
52630	4	2	Transurethral resection; of regrowth of obstructive tissue longer than one year postoperative.
52640	4	2	Transurethral resection; of postoperative bladder neck contracture.
52650	4	2	Transurethral cryosurgical removal of prostate (postoperative irrigations and aspiration of sloughing tissue included).
52700	4	2	Transurethral drainage of prostatic abscess.
			Urethra
Incision			
53000	2	1	Urethrotomy or urethrostomy, external (separate procedure); pendulous urethra.
53010	2	1	Urethrotomy or urethrostomy, external (separate procedure); perineal urethra, external.
53020	2	1	Meatotomy, cutting of meatus (separate procedure); except infant.

	Payment groups		
	Old	New	
53040	2	2	Drainage of deep periurethral abscess
Excision			
53220	3	2	Excision or fulguration of carcinoma of urethra.
53230	3	2	Excision of urethral diverticulum (separate procedure); female.
53235	3	3	Excision of urethral diverticulum (separate procedure); male.
53240	3	2	Marsupialization of urethral diverticulum, male or female.
53265	3	2	Excision or fulguration; urethral caruncle.
53275	3	2	Excision or fulguration; urethral prolapse.
Repair			
53400	4	3	Urethroplasty; first stage, for fistula, diverticulum, or stricture, e.g., Johannsen type.
53405	4	2	Urethroplasty; second stage (formation of urethra), including urinary diversion.
53410	4	2	Urethroplasty, one-stage reconstruction of male anterior urethra.
53420	4	3	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; first stage.
53425	4	2	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; second stage.
53430	4	2	Urethroplasty, reconstruction of female urethra.
53440	4	2	Operation for correction of male urinary incontinence, with or without introduction of prosthesis.
53447	4	1	Removal, repair or replacement of inflatable sphincter including pump and/or reservoir and/or cuff.
53449	4	1	Surgical correction of hydraulic abnormality of inflatable sphincter device.
53450	4	1	Urethromeatoplasty, with mucosal advancement.
53460	4	1	Urethromeatoplasty, with partial excision of distal urethral segment (Richardson type procedure).
Suture			
53502	4	2	Urethrorrhaphy, suture of urethral wound or injury, female.
53510	4	2	Urethrorrhaphy, suture of urethral wound or injury; perineal.
53515	4	2	Urethrorrhaphy, suture of urethral wound or injury; prostatomembranous.
53520	4	2	Closure of urethrostomy or urethrocutaneous fistula, male (separate procedure).
Manipulation			
*53600	1	2	Dilation of urethral stricture by passage of sound or urethral dilator male; initial.
*53601	1	1	Dilation of urethral stricture by passage of sound or urethral dilator, male; subsequent.
*53605	1	2	Dilation of urethral stricture of vesical neck by passage of sound or urethral dilator, male, general or conduction (spinal) anesthesia.
*53620	1	1	Dilation of urethral stricture by passage of filiform and follower, male; initial.
*53621	1	1	Dilation of urethral stricture by passage of filiform and follower, male; subsequent.
*53660	1	1	Dilation of female urethra including suppository and/or instillation; initial.
*53661	1	1	Dilation of female urethra including suppository and/or instillation; subsequent.
*53665	1	1	Dilation of female urethra, general or conduction (spinal) anesthesia.
			Male genital system
			Penis
Incision			
54001	1	2	Slitting of prepuce, dorsal or lateral, (separate procedure); except newborn.
Excision			
54105	1	1	Biopsy of penis; deep structures.
54110	3	2	Excision of penile plaque (Peyronie disease).
54115	3	1	Removal foreign body from deep penile tissue (e.g., plastic implant).
54120	3	2	Amputation of penis; partial.
54125	4	2	Amputation of penis; complete.
54152	2	1	Circumcision, clamp procedure; except newborn.
54161	2	2	Circumcision, surgical excision other than clamp or dorsal slit; except newborn.
Introduction			
54205	1	1	Injection procedure for Peyronie disease; with surgical exposure of plaque.
54220	1	1	Irrigation of corpora cavernosa for priapism.
54230	1	1	Injection procedure for corpora cavernosography.
Repair			
54440	4	5	Plastic operation of penis for injury.
			Testis
Excision			
54505	1	3	Biopsy of testis, incisional (separate procedure); unilateral.
54506	1	3	Bilateral.
54510	1	2	Excision of local lesion of testis.
*54520	2	3	Orchiectomy, simply (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach; unilateral.
*54521	2	4	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach; bilateral.
54530	3	4	Orchiectomy, radical, for tumor; inguinal approach.
Repair			
54670	2	3	Suture or repair of testicular injury.
54680	4	3	Transplantation of testis(es) to thigh (because of scrotal destruction).
			Epididymis
Excision			
54700	2	2	Incision and drainage of epididymis, testis and/or scrotal space (e.g., abscess or hematoma).
54820	1	1	Exploration of epididymis, with or without biopsy.
54830	2	3	Excision of local lesion of epididymis.
*54840	3	4	Excision of spermatocele, with or without epididymectomy.
54860	3	4	Epididymectomy; unilateral.
54861	3	5	Epididymectomy; bilateral.
Repair			
54900	3	2	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral
54901	3	2	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral.
			Tunica Vaginalis

	Payment groups		
	Old	New	
Excision			
*55040	3	3	Excision of hydrocele; unilateral.
*55041	3	5	Excision of hydrocele; bilateral.
Repair			
55060	3	4	Repair of hydrocele (Bottle type).
Incision			
55120	1	2	Removal of foreign body in scrotum.
			Scrotum
Excision			
55150	3	1	Resection of scrotum.
Repair			
55175	3	1	Scrotoplasty; simple.
55180	3	2	Scrotoplasty; complicated.
			Vas Deferens
Repair			
55400	3	1	Vasovasostomy, vasovasorrhaphy; unilateral.
55401	3	5	Vasovasostomy, vasovasorrhaphy; bilateral.
			Spermatic Cord
Excision			
55500	3	3	Excision of hydrocele of spermatic cord, unilateral (separate procedure).
55520	3	4	Excision of lesion of spermatic cord (separate procedure).
*55530	4	4	Excision of varicocele or ligation of spermatic veins for varicocele (separate procedure).
55535	4	4	Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach.
55540	4	5	Excision of varicocele or ligation of spermatic veins for varicocele; with hernia repair.
			Seminal Vesicles
Incision			
55605	1	1	Vesiculotomy; complicated.
Excision			
55650	4	1	Vesiculectomy, any approach; unilateral.
55651	4	2	Vesiculectomy, any approach; bilateral.
55680	4	1	Excision of Mullerian duct cyst.
			Prostate
Incision			
*55700	1	2	Biopsy, prostate; needle or punch, single or multiple, any approach.
*55705	1	2	Biopsy, prostate; incisional any approach.
55720	1	1	Prostatotomy, external drainage of prostatic abscess, any approach; simple.
			Female Genital System
			Vagina
Perineum			
56000	2	2	Incision and drainage of perineal abscess (nonobstetrical).
			Vulva and Introitus
Incision			
56440	3	3	Marsupialization of Bartholin's gland cyst.
Destruction			
56515	3	3	Destruction of lesion(s), vulva; extensive, any method.
Excision			
56740	3	3	Excision of Bartholin's gland or cyst.
			Vagina
Incision			
57020	1	2	Colpocentesis (separate procedure).
Excision			
57105	3	2	Biopsy of vaginal mucosa; extensive, requiring suture (including cysts).
57130	3	2	Excision of vaginal septum.
Repair			
57268	4	2	Repair of enterocele, vaginal approach (separate procedure).
Manipulation			
*57400	1	2	Dilation of vagina under anesthesia.
*57410	1	2	Pelvic examination under anesthesia.
Endoscopy			
*57450	1	1	Culdoscopy, diagnostic.
			Cervix Uteri
Excision			
57520	2	2	Biopsy of cervix, circumferential (cone), with or without dilation and curettage, with or without Sturmdorff type repair.
Repair			
57720	3	3	Trachelorrhaphy, plastic repair of uterine cervix, vaginal approach.
Manipulation			
57820	2	3	Dilation and curettage of cervical stump.
			Corpus Uteri
Excision			
*58120	3	2	Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical).
			Ovary

	Payment groups		
	Old	New	
Excision			
58900	4	3	Biopsy of ovary, unilateral or bilateral (separate procedure).
Endoscopy-Laparoscopy			
*58980	4	4	Laparoscopy for visualization of pelvic viscera.
*58984	4	5	Laparoscopy for visualization of pelvic viscera; with fulguration of ovarian or peritoneal lesions.
*58985	4	4	Laparoscopy for visualization of pelvic viscera; with lysis of adhesions.
*58986	4	4	Laparoscopy for visualization of pelvic viscera; with biopsy (single or multiple).
*58987	4	4	Laparoscopy for visualization of pelvic viscera; with aspiration (single or multiple).
			Endocrine System
			Thyroid Gland
Excision			
60200	3	2	Excision of cyst or adenoma of thyroid, or transection of isthmus.
60220	4	2	Total thyroid lobectomy, unilateral.
60225	4	3	Total thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmus.
60280	3	4	Excision of thyroglossal duct cyst or sinus.
			Nervous System
			Skull, Meninges, and Brain
Puncture For Injection, Drainage or Aspiration			
61020	1	1	Ventricular puncture through previous burr hole, fontanelle, suture, or implanted ventricular catheter/reservoir; without injection.
61026	1	1	Ventricular puncture through previous burr hole, fontanelle, suture, or implanted ventricular catheter/reservoir; with injection of drug or other substance for diagnosis or treatment.
61050	1	1	Cisternal or lateral cervical puncture; without injection (separate procedure).
61070	1	1	Puncture of shunt tubing or reservoir for aspiration or injection procedure.
			Spine and Spinal Cord
Puncture For Injection, Drainage, or Aspiration			
62270	1	1	Spinal puncture, lumbar, diagnostic.
62273	1	1	Injection, lumbar epidural, of blood or clot patch.
62274	1	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, simple.
62276	1	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, differential.
62277	1	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, continuous.
62278	1	1	Injection of anesthetic substance, diagnostic or therapeutic; epidural or caudal, single.
62279	1	1	Injection of anesthetic substance, diagnostic or therapeutic; epidural or caudal, continuous.
62288	1	1	Injection of substance other than anesthetic, contrast, or neurolytic solutions; subarachnoid (separate procedure)
62289	1	1	Injection of substance other than anesthetic, contrast, or neurolytic solutions; epidural or caudal.
			Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System
Introduction/Injection of Anesthetic Agent (Nerve Block), Diagnostic or Therapeutic			
			Somatic Nerves
64408	1	1	Injection, anesthetic agent; vagus nerve.
64410	1	1	Injection, anesthetic agent; phrenic nerve.
64415	1	1	Injection, anesthetic agent; brachial plexus.
64417	1	1	Injection, anesthetic agent; axillary nerve.
64420	1	1	Injection, anesthetic agent; intercostal nerve, single.
64421	1	1	Injection, anesthetic agent; intercostal nerves, multiple, regional block.
64430	1	1	Injection, anesthetic agent; pudendal nerve.
64442	1	1	Injection, anesthetic agent; paravertebral facet joint nerve, lumbar, single level.
64443	1	1	Injection, anesthetic agent; paravertebral facet joint nerve, lumbar, each additional level.
			Sympathetic Nerves
64510	2	1	Injection, anesthetic agent; stellate ganglion (cervical sympathetic).
64520	2	1	Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic).
64530	2	1	Injection, anesthetic agent; celiac plexus, with or without radiologic monitoring.
Destruction by Neurolytic Agent (E.G., Chemical, Thermal, Electrical Radiofrequency)			
			Somatic Neves

	Payment groups		
	Old	New	
64600	2	1	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch.
64605	2	1	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale.
64610	2	1	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring.
64622	2	1	Destruction by neurolytic agent, paravertebral facet joint nerve, lumbar, single level.
64630	2	2	Destruction by neurolytic agent, pudendal nerve.
Exploration, Neurolysis or Nerve Decompression (Neuroplasty)			
*64702	3	1	Neurolysis; digital, one or both, same digit.
*64704	3	1	Neurolysis; nerve of hand or foot.
*64708	3	2	Neurolysis; major peripheral nerve, arm or leg; other than specified.
64712	3	2	Neurolysis, major peripheral nerve, arm or leg; sciatic nerve.
64713	3	2	Neurolysis major peripheral nerve, arm or leg; brachial plexus.
64714	3	2	Neurolysis, major peripheral nerve, arm or leg; lumbar plexus.
*64716	4	3	Neurolysis and/or transposition; cranial nerve (specify).
*64718	4	2	Neurolysis and/or transposition; ulnar nerve at elbow.
*64719	4	2	Neurolysis and/or transposition; ulnar nerve at wrist.
*64721	3	2	Neurolysis and/or transposition; median nerve at carpal tunnel.
64722	3	1	Decompression; unspecified nerve(s) (specify).
64726	3	1	Decompression; plantar digital nerve.
64727	4	1	Internal neurolysis by dissection, with or without microdissection (list separately in addition to code for primary neuroplasty).
Transection or Avulsion of Nerve			
64732	3	2	Transection or avulsion of; supraorbital nerve.
64734	3	2	Transection or avulsion of; infraorbital nerve.
64736	3	2	Transection or avulsion of; mental nerve.
64738	3	2	Transection or avulsion of; inferior alveolar nerve by osteotomy.
64740	3	2	Transection or avulsion of; lingual nerve.
64742	3	2	Transection or avulsion of; facial nerve, differential or complete.
64744	3	2	Transection or avulsion of; greater occipital nerve.
64772	3	2	Transection or avulsion of other spinal nerve, extradural.
Excision-Somatic Nerves			
64774	3	3	Excision of neuroma; cutaneous nerve, surgically identifiable.
64776	3	3	Excision of neuroma; digital nerve, one or both, same digit.
64778	3	2	Excision of neuroma; digital nerve, each additional digit (list separetely by this number).
*64782	3	3	Excision of neuroma; hand or foot, except digital nerve.
64784	3	3	Excision of neuroma; major peripheral nerve, except sciatic.
64786	3	3	Excision of neuroma; sciatic nerve.
64787	3	2	Insertion of plastic cap on nerve end.
64788	3	3	Excision of neurofibroma or neurolemmona; cutaneous nerve.
64790	3	3	Excision of neurofibroma or neurolemmoma; major peripheral nerve.
64795	3	2	Biopsy of nerve.
Excision-Sympathetic Nerves			
64802	4	2	Sympathectomy, cervical; unilateral.
64803	4	3	Sympathectomy, cervical; bilateral.
Nerve Repair by Suture (Neurorrhaphy)			
64830	4	5	Microdissection and/or microrepair of nerve (list separately in addition to code for nerve repair).
64831	4	4	Suture of digital nerve, hand or foot; one nerve.
64832	4	1	Suture of digital nerve, hand or foot; each additional digital nerve.
64834	4	2	Suture of one nerve, hand or foot; common sensory nerve.
64835	4	3	Suture of one nerve, hand or foot; median motor thenar.
64836	4	3	Suture of one nerve, hand or foot; ulnar motor.
64837	4	1	Suture of each additional nerve, hand or foot.
64840	4	2	Suture of posterior tibial nerve.
64856	4	2	Suture of major peripheral nerve, arm or leg, except sciatic; including transportation.
64857	4	2	Suture of major peripheral nerve, arm or leg, except sciatic; without transportation.
64872	4	2	Suture of nerve; requiring secondary or delayed suture (list separately in addition to code for primary neurorrhaphy).
64874	4	3	Suture of nerve; requiring extensive proximal mobilization, or transposition of nerve (list separately in addition to code for nerve suture).
64876	4	3	Suture of nerve; requiring shortening of bone of extremity (list separately in addition to code for nerve suture).
Neurorrhaphy With Nerve Graft			
64890	4	2	Nerve graft (includes obtaining graft), single strand, hand or foot; up to 4 cm length.
64891	4	2	Nerve graft (includes obtaining graft), single strand, hand or foot; more than 4 cm length.
64892	4	2	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length.
64893	4	2	Nerve graft (includes obtaining graft), single strand, arm or leg; more than 4 cm length.
64895	4	3	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; up to 4 cm length.
64896	4	3	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length.
64897	4	3	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; up to 4 cm length.
64898	4	3	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; more than 4 cm length.
64901	4	2	Nerve graft, each additional nerve; single strand.
64902	4	2	Nerve graft, each additional nerve; multiple strands (cable).
64905	4	2	Nerve pedicle transfer; first stage.
64907	4	1	Nerve pedicle transfer; second stage.
			Eye/Ocular Adnexa
			Eyeball
Removal of Eye			
*65091	4	3	Evisceration of ocular contents; without implant.
*65093	4	6	Evisceration of ocular contents; with implant.
*65101	4	3	Enucleation of eye; without implant.
*65103	4	4	Enucleation of eye; with implant, muscles not attached to implant.

	Payment groups		
	Old	New	
*65105	4	4	Enucleation of eye; with implant, muscles attached to implant.
65110	4	3	Exenteration of orbit (does not include skin graft), removal of orbital contents; only.
Secondary Implant procedures			
65130	3	3	Insertion of ocular implant secondary; after evisceration, in scleral shell.
65135	3	2	Insertion of ocular implant secondary; after enucleation, muscles not attached to implant.
65140	3	3	Insertion of ocular implant secondary; after enucleation, muscles attached to implant.
65150	3	2	Reinsertion of ocular implant; with or without conjunctival graft.
65155	3	3	Reinsertion of ocular impant; with use of foreign material for reinforcement and/or attachment of muscles to implant.
65175	3	1	Removal of ocular implant.
Removal of ocular foreign body			
*65230	1	1	Removal of foreign body, intraocular; from anterior chamber, magnetic extraction.
*65235	1	2	Removal of foreign body, intraocular; from anterior chamber, nonmagnetic extraction.
65245	4	2	Removal of foreign body, intraocular; from lens (without extraction lens), nonmagnetic extraction.
65260	4	2	Removal of foreign body, intraocular; from posterior segment, magnetic extraction, anterior or posterior route.
65265	4	3	Removal of foreign body, intraocular; from posterior segment, nonmagnetic extraction.
Repair of Laceration of eyeball			
65272	2	2	Repair of laceration; conjunctiva, by mobilization and rearrangement, without hospitalization.
65280	4	4	Repair of laceration; cornea and/or sclera, perforating, not involving uveal tissue.
65285	4	4	Repair of laceration; cornea and/or sclera, perforating, with reposition or resection of uveal tissue.
65290	3	3	Repair of wound, extraocular muscle, tendon and/or Tenon's capsule.
			Anterior Segment—Cornea.
Excision			
65400	1	1	Excison of lesion, cornea (keratectomy, lamellar, partial), except pterygium.
65410	1	2	Biopsy of cornea.
*65420	1	2	Excision or transposition of pterygium; without graft.
65426	1	5	Excision or transposition of pterygium; with graft.
Keratoplasty			
65710	4	6	Keratoplasty (corneal transplant), lamellar; autograft.
65720	4	6	Keratoplasty (corneal transplant), lamellar; homograft, fresh.
65725	4	6	Keratoplasty (corneal transplant), lamellar; homograft, preserved.
65730	4	6	Keratoplasty (corneal transplant), penetrating (except in aphakia); autograft.
65740	4	6	Keratoplasty (corneal transplant), penetrating (except in aphakia); homograft, fresh.
65745	4	6	Keratoplasty (corneal transplant), penetrating (except in aphakia); homograft, preserved.
65750	4	6	Keratoplasty (corneal transplant), penetrating, in aphakia.
			Anterior Segment-Anterior Chamber
Incision			
65800	1	2	Paracentesis of anterior chamber of eye (separate procedure); with diagnostic aspiration of aqueous.
65805	1	2	Paracentesis of anterior chamber of eye (separate procedure); with therapeutic release of aqueous.
65810	4	2	Paracentesis of anterior chamber of eye (separation procedure); with removal of vitreous and/or discission of anterior hyaloid membrane, with or without air injection.
65815	1	2	Paracentesis of anterior chamber of eye (separate procedure); with removal of blood, with or without irrigation and/or air injection.
Other procedures			
65865	1	1	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); goniosynechiae.
65870	1	4	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); anterior synechiae, except goniosynechiae.
65875	1	4	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); posterior synechiae.
65880	1	4	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); corneovitreal adhesions.
65900	4	4	Removal of epithelial downgrowth, anterior chamber eye.
65920	4	6	Removal of implanted material, anterior segment eye.
65930	4	5	Removal of blood clot, anterior segment eye.
66020	1	1	Injection, anterior chamber (separate procedure); air or liquid.
66030	1	1	Injection, anterior chamber (separate procedure); medication.
			Anterior Segment—Anterior Sclera
Excision			
66130	4	6	Excision of lesion, sclera.
66150	4	2	Fistulization of sclera for glaucoma; trephination with iridectomy.
66155	4	2	Fistulization of sclera for glaucoma; thermocauterization with iridectomy.
66160	4	2	Fistulization of sclera for glaucoma; sclerectomy with punch or scissors, with iridectomy.
66165	4	2	Fistulization of sclera for glaucoma; iridencleisis or iridotasis.
66170	4	3	Fistulization of sclera for glaucoma; trabeculectomy ab externo.
Repair			
66220	4	2	Repair of scleral staphyloma; without graft.
66225	4	3	Repair of scleral staphyloma; with graft.
Revision operation wound			
66250	4	1	Revision or repair of operative wound of anterior segment, any type, early or late, major or minor procedure.
			Anterior segment—iris, ciliary body
Iridotomy, Iridectomy			
66500	1	1	Iridotomy by stab incision (separate procedure); except transfixion.
66505	1	1	Iridotomy by stab incision (separate procedure); with transfixion as for iris bombe.
*66600	4	3	Iridectomy, with corneoscleral or corneal section; for removal of lesion.
66605	3	3	Iridectomy with corneoscleral or corneal section; with cyclectomy.
*66625	4	3	Iridectomy, with corneoscleral or corneal section; peripheral for glaucoma (separate procedure).
*66630	4	3	Iridectomy, with corneoscleral or corneal section; sector for glaucoma (separate procedure).
*66635	4	3	Iridectomy, with corneoscleral or corneal section; "optical" (separate procedure).

	Payment groups		
	Old	New	
Repair			
66680	4	3	Repair of iris, ciliary body (as for Iridodialysis).
66682	4	2	Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (e.g., McCannel suture).
Destruction			
66700	1	1	Cyclodiathermy; initial.
66701	1	1	Cyclodiathermy; subsequent.
66720	1	2	Cyclocryotherapy; initial.
66721	3	2	Cyclocryotherapy; subsequent.
66741	3	2	Cyclodialysis; subsequent.
66762	3	1	Coreoplasty by photocoagulation (one or more sessions) (e.g., for improvement of vision).
			Anterior segment-lens
Incision			
*66800	1	1	Discission of lens capsule; incisional technique (needling of lens); initial.
*66801	1	1	Discission of lens capsule; incisional technique (needling of lens); subsequent.
66821	1	2	Discission of secondary membraneous cataract ("after cataract") and/or anterior hyaloid; laser surgery (one or more stages).
Removal cataract			
*66830	4	4	Removal of secondary membranous cataract ("after cataract"), with corneoscleral section, with or without iridectomy (iridocapsulotomy, iridocapsulectomy).
*66840	4	4	Removal of lens material; aspiration technique, one or more stages.
*66850	4	6	Removal of lens material; phacofragmentation technique (mechanical or ultrasonic, e.g., phacoemulsification), with aspiration.
66915	4	2	Expression of lens, linear, one or more stages.
*66920	4	4	Extraction of lens with or without iridectomy; intracapsular, with or without enzymes.
*66930	4	5	Extraction of lens with or without iridectomy; intracapsular, for dislocated lens.
*66940	4	5	Extraction of lens with or without iridectomy; extracapsular (other than 66840, 66850, 66915).
66945	4	5	Extraction of lens with or without iridectomy; in presence of fistulization bleb and/or by temporal, inferior or inferotemporal route, intracapsular or extracapsular.
*66983	5	6	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure).
66984	5	6	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or phacoemulsification technique.
*66985	4	5	Insertion of intraocular lens subsequent to cataract removal (separate procedure).
Posterior segment-vitreous			
67005	4	3	Removal of vitreous, anterior approach (open sky technique or limbal incision); partial removal.
67010	4	3	Removal of vitreous, anterior approach (open sky technique or limbal incision); subtotal removal with mechanical vitrectomy (such as VISC or Rotoextractor).
67015	2	1	Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy).
67025	2	1	Injection of vitreous substitute, pars plana approach (separate procedure) excludes air or balanced salt solutions.
67030	2	1	Discission of vitreous strands (without removal), pars plana approach.
67036	4	3	Virectomy, mechanical, pars plana approach.
			Posterior segment-retinal detachment
Repair			
67101	4	3	Repair of retinal detachment, one or more sessions, same hospitalization, cryotherapy or diathermy, with or without drainage or subretinal fluid.
67107	4	3	Repair of retinal detachment (one or more stages, same hospitalization); scleral buckling (such as lamella excision, imbrication or encircling procedure), with or without implant, may include procedures 67101–67105.
67108	4	3	Repair of retinal detachment (one or more stages, same hospitalization); with vitrectomy, any method, with or without air tamponade, may include procedures 67101–67107 and/or removal of lens by same technique.
67109	4	3	Repair of retinal detachment (one or more stages, same hospitalization); by technique other than 67101–67108.
67120	4	2	Removal of implanted material, posterior segment, extraocular.
			Posterior segment-other procedures
Destruction-retina, choroid			
67208	1	1	Destruction of localized lesion of retina (e.g., maculopathy, choroidopathy, small tumors), one or more sessions; cryotherapy, diathermy.
67218	1	3	Destruction of localized lesion, retina or choroid (e.g., choroidopathy), one or more stages; radiation by implantation of source (includes removal of source).
67227	1	1	Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), one or more sessions; cryotherapy, diathermy.
Scleral repair			
67250	4	1	Scleral reinforcement (separate procedure); without graft.
67255	4	2	Scleral reinforcement (separate procedure); with graft.
*67311	4	3	Strabismus surgery on patient not previously operated on, any procedure, any muscle (may include minor displacement, e.g., for A or V pattern); one muscle.
67312	4	4	Strabismus surgery on patient not previously operated on, any procedure, any muscle (may include minor displacement, e.g., for A or V pattern); two muscles, one or both eyes.
*67313	4	5	Strabismus surgery on patient not previously operated on, any procedure, any muscle (may include minor displacement, e.g., for A or V pattern); three or more muscles, and/or adjustable suture, one or both eyes.
			Ocular adnexa-extraocular muscles
67320	3	4	Transposition of extraocular muscle (e.g., for paretic muscle), one or more stages, one or more muscles, with displacement of plane of action more than 5mm.
67331	3	4	Strabismus surgery on patient previously operated on; not involving reoperation of muscles.
67332	3	4	Strabismus surgery on patient previously operated on; involving reoperation of muscles.
Other procedures			
67350	3	1	Biopsy of extraocular muscle.
			Ocular adnexa-orbit
Exploration, excision			
67400	4	2	Orbitotomy without bone flap (frontal approach); for exploration, with or without biopsy.
67405	4	3	Orbitotomy without bone flap (frontal approach); with drainage only.
67412	4	3	Orbitotomy without bone flap (frontal approach); with removal of lesion.

	Payment groups		
	Old	New	
67413	4	5	Orbitotomy without bone flap (frontal approach); with removal of foreign body.
67415	1	1	Transconjunctival or aspirational biopsy.
Other procedures			
67550	4	4	Orbital implant (implant outside muscle cone); insertion.
67560	4	2	Orbital implant (implant outside muscle cone); removal or revision.
			Ocular adnexa-eyelids
Incision			
67715	1	1	Canthotomy (separate procedure).
Excision or removal of lesion involving more than skin (i.e., involving lid margin, tarsus, and/or palpebral conjunctiva)			
*67801	1	2	Excision of chalazion; multiple, same lid.
*67808	1	2	Excision of chalazion; under general anesthesia and/or requiring hospitalization, single or multiple.
67830	3	2	Correction of trichiasis; incision of lid margin.
67835	2	2	Correction of trichiasis; incision of lid margin, with free mucous membrane graft.
Tarsorrhaphy			
67880	1	3	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy.
67882	3	3	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy; with transportation of tarsal plate.
Repair blepharoptosis, lid retraction			
67901	1	5	Repair of blepharoptosis; frontalis muscle technique with suture.
67902	3	5	Repair of blepharoptosis; frontalis muscle technique with fascial sling (includes obtaining fascia).
67903	3	3	Repair of blepharoptosis; (tarso) levator resection, internal approach.
67904	3	4	Repair of blepharoptosis; (tarso) levator resection, external approach.
67906	3	3	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia).
67907	3	3	Repair of blepharoptosis; superior rectus tendon transplant.
67908	1	4	Repair of blepharoptosis; conjunctivo-tarso-levator resection (Fasanella-Servat type).
67909	1	3	Reduction of overcorrection of ptosis.
Repair ectropion, entropion			
*67914	3	3	Repair of ectropion; suture.
*67916	3	4	Repair of ectropion; blepharoplasty, excision tarsal wedge.
*67917	3	3	Repair of ectropion; blepharoplasty, extensive (e.g., Kuhnt-Szymanowski operation).
*67921	3	4	Repair of entropion; suture.
*67923	3	4	Repair of entropion; blepharoplasty, excision tarsal wedge.
*67924	3	4	Repair of entropion; blepharoplasty, extensive (e.g., Wheeler operation).
Reconstructive surgery, blepharoplasty involving more than skin (i.e., involving lid margin, tarsus, and/or palpebral conjunctiva)			
67935	2	1	Suture of recent wound, eyelid, involving lid margin, tarsus, and/or palpebral conjunctiva) direct closure; full thickness.
*67950	2	2	Canthoplasty (reconstruction of canthus).
67961	3	3	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, canthus, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; up to one-fourth of lid margin.
67966	3	3	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; over one-fourth of lid margin.
67971	3	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; up to two-thirds of eyelid, one stage or first stage.
67973	3	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; total eyelid, lower, one stage or first stage.
67974	3	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; total eyelid, upper, one stage or first stage.
67975	3	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; second stage.
			Ocular adnexa-conjunctiva
Excision, destruction			
68130	1	2	Excision of lesion, conjunctiva; with adjacent sclera.
Conjunctivoplasty			
68320	2	4	Conjunctivoplasty; with conjunctival graft or extensive rearrangement.
68325	2	4	Conjunctivoplasty; with buccal mucous membrane graft (includes obtaining graft).
68326	2	4	Conjunctivoplasty, reconstruction cul-de-sac; with conjunctival graft or extensive rearrangement.
68328	3	4	Conjunctivoplasty, reconstruction cul-de-sac; with buccal mucous membrane graft (includes obtaining graft).
Other procedures			
68360	2	2	Conjunctival flap; bridge or partial (separate procedure).
68362	2	2	Conjunctival flap; total (such as Gunderson thin flap or purse string flap).
			Ocular adnexa-lacrimal system
Excision			
68500	3	1	Excision of lacrimal gland (dacryoadenectomy), except for tumor; total.
68505	3	1	Excision of lacrimal gland (dacryoadenectomy), except for tumor; partial.
68510	3	1	Biopsy of lacrimal gland.
68520	3	3	Excision of lacrimal sac (dacryocystectomy).
Excision			
68540	4	3	Excision of lacrimal gland tumor; frontal approach involving osteotomy.
68550	4	3	Excision of lacrimal gland tumor; frontal approach.
Repair			
*68700	1	2	Plastic repair on canaliculi.
68720	3	3	Dacryocystorhinostomy (fistulization of lacrimal sac to nasal cavity).
68745	3	3	Conjunctivorhinostomy (fistulization of conjunctiva to nasal cavity); without tube.
68750	3	3	Conjunctivorhinostomy (fistulization of conjunctiva to nasal cavity); with insertion of tube or stent.
Probing and related procedures			
*68830	1	2	Probing of nasolacrimal duct, with or without irrigation, unilateral or bilateral; with insertion of tube or stent (without general anesthesia).
			Auditory system
			External ear
Excision			
69105	1	1	Biopsy external auditory canal.
69110	2	1	Excision external ear; partial, simple repair.

	Payment groups		
	Old	New	
69120	3	2	Excision external ear; complete amputation.
69140	2	1	Excision exostosis(es), external auditory canal.
69145	2	3	Excision soft tissue lesion, external auditory canal.
69150	4	3	Radical excision external auditory canal lesion; without neck dissection.
			Middle ear
Incision			
*69420	1	2	Myringotomy including aspiration and/or eustachian tube inflation.
69440	3	3	Middle ear exploration through postauricular or ear canal incision.
69450	3	1	Tympanolysis, transcanal.
Excision			
*69501	4	6	Transmastoid antrotomy ("simple" mastoidectomy).
Repair			
*69620	4	2	Myringoplasty (surgery confined to drumhead and donor area).
*69631	4	5	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; without ossicular chain reconstruction.
69632	4	5	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; with ossicular chain reconstruction, e.g., postfenestration.
69633	4	5	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; with ossicular chain reconstruction and synthetic prosthesis (e.g., total ossicular replacement prosthesis, TORP).
69635	4	6	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); without ossicular chain reconstruction.
69636	4	6	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); with ossicular chain reconstruction.
69637	4	6	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); with ossicular chain reconstruction and synthetic prosthesis (e.g., total ossicular replacement prosthesis, TORP).
69641	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); without ossicular chain reconstruction.
69642	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with ossicular chain reconstruction.
69643	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with intact or reconstructed wall, without ossicular chain reconstruction.
69644	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with intact or reconstructed canal wall, with ossicular chain reconstruction.
69645	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); radical or complete, without ossicular chain reconstruction.
69646	4	6	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); radical or complete, with ossicular chain reconstruction.
*69650	4	6	Stapes mobilization.
*69660	4	5	Stapedectomy with reestablishment of ossicular continuity, with or without use of foreign material.
69661	4	5	Stapedectomy with reestablishment of ossicular continuity, with or without use of foreign material; with footplate drill out.
69666	4	2	Repair oval window fistula.
69667	4	3	Repair round window fistula.
69670	4	3	Mastoid obliteration (separate procedure).
69676	4	3	Tympanic neurectomy; unilateral.
69677	4	4	Tympanic neurectomy; bilateral.
			External ear
Other procedures			
69700	2	3	Closure postauricular fistula, mastoid (separate procedure).
			Middle ear
Other procedures			
69720	4	2	Decompression facial nerve, intratemporal; lateral to geniculate ganglion.
69725	4	2	Decompression facial nerve, intratemporal; including medial to geniculate ganglion.
69740	4	2	Suture facial nerve, intratemporal, with or without graft or decompression; lateral to geniculate ganglion.
69745	4	2	Suture facial nerve, intratemporal, with or without graft or decompression; including medial to geniculate ganglion.
			Female genital
Gynecological and obstetrical			
*74741	2	2	Hysterosalpingography; complete procedure.

Addendum B

Proposed Reclassification of Certain Procedure Codes

The following procedure codes were reclassified from lower to higher payment groups because the cost data placed them in lower groups than similar but less complex procedures.

Procedure code	Actual group based on cost	Proposed group
11446	1	2
11606	1	2
11626	1	2
13132	2	3
13152	1	3
14061	1	3
14350	2	3
15515	3	4
15610	1	3
15630	1	3
15755	1	3
20245	2	3
20926	3	4
21338	3	4
21340	2	4
21365	4	5
23150	1	4
24160	1	2
25023	2	3
25263	1	2
25310	2	3
25320	1	3
25628	2	3
26124	3	4
26205	2	3
26474	1	2
26650	1	2
26686	1	3
27305	1	2
27792	2	3

Procedure code	Actual group based on cost	Proposed group
28011	1	2
28122	2	3
28175	1	3
28755	2	4
28760	2	4
28825	1	2
30450	5	6
31031	2	3
31535	1	2
37760	2	3
42120	3	4
43251	1	2
45020	1	2
46060	1	2
46262	3	4
49525	3	4
49575	3	4
52601	1	3
55535	3	4
65710	1	6
65745	4	6
65815	1	2
65875	1	4
66225	1	3
66630	2	3
67412	1	3
67906	1	3
67924	3	4
67966	1	3
68362	1	2
69150	1	3
69632	4	5
69637	4	6
69641	5	6

The following procedure codes were reclassified into lower payment groups because the cost data placed them in higher groups than similar but more complex procedures.

Procedure code	Actual group based on cost	Proposed group
11600	2	1
11620	3	1
11622	2	1
11624	2	1
11640	2	1
11771	4	3
12036	3	2
12056	3	2
14041	6	3
14300	5	4
15220	4	2
15221	4	2
15505	4	3
15510	5	4
15600	5	3
15720	3	2
19101	4	3
20240	3	2
20900	5	3
20902	5	4
21310	3	2
21453	6	3
21480	4	1
23000	3	2
23020	3	2
23066	3	2
23180	6	4
23515	5	3
24075	3	2
24120	4	3
24130	5	3
24340	4	3
24351	4	3
24352	6	3
24515	5	4
24575	5	3
24585	5	4
24665	5	4
25028	2	1
25100	4	2
25150	3	2
25265	4	3
25274	6	4
25312	6	4
25515	5	3
25535	2	1
25575	4	3
25605	5	3
25620	4	3
25635	6	1
26215	4	3
26230	6	2
26392	4	3
26410	4	3
26433	4	3
26434	4	3
26455	6	3
26460	4	3
26471	6	2
26480	4	3
26483	5	3
26485	5	2
26499	4	3
26516	2	1
26525	4	3
26685	5	3
26710	5	2
26730	3	2
26744	3	2
26841	5	4
26843	4	3
26860	4	3
26861	5	2
26862	5	4
27420	4	3
27635	4	3
27640	4	2
27654	6	3
27664	4	2
27675	4	2
27685	4	3
27686	6	3
27756	6	3
27766	4	3
28110	4	3
28111	4	3
28113	4	3
28173	5	3
28200	5	3
28208	5	3
28225	2	1
28240	4	3
28250	4	3
28260	4	3
28299	6	5
28405	3	2
28465	6	3
28500	4	3
28675	6	3
28820	3	2
29874	6	3
29881	6	3
30125	5	2
31070	3	2
31510	3	2
31515	3	1
31525	2	1
37700	4	2
37701	4	3
37720	4	3
37730	4	3
38731	4	3
38305	3	2
38760	4	2
40500	3	2
40510	3	2
40654	6	3
40814	3	2
40844	6	5
41000	2	1
42106	3	2
42107	6	2
42325	3	2
42665	2	1
43202	2	1
43215	3	1
46250	5	3
46260	6	3
46275	5	3
46750	6	3
46924	3	1
49300	5	2
49590	4	3
51010	3	1
52010	3	2
52224	3	2
52235	4	3
52270	5	2
52275	5	2
52285	3	2
52310	3	2
52315	3	2
52330	5	2
52340	5	3
53020	2	1
53230	4	2
53410	3	2
53520	3	2
54115	2	1
54152	2	1
55150	2	1
55400	6	1
60220	5	2
64702	3	1
64704	4	1
64708	3	2
64718	4	2
64719	3	2
64721	3	2
64722	2	1
64726	3	1
64732	4	2
64788	4	3
64832	4	1
64834	3	2
64835	6	3
64836	5	3
64872	3	2
64890	4	2
64895	6	3
65091	5	3
65101	4	3
65103	6	4
65130	6	3
65150	1	2
65280	5	4
65865	5	1
66150	3	2
66155	3	2
66160	4	2
66500	4	1
66600	5	3
66625	4	3
66635	4	3
66721	4	2
67005	6	3
67107	5	3
67320	6	4
67331	5	4
67332	5	4
67801	3	2
67830	3	2
67835	3	2
67975	6	3
68326	6	4
68750	6	3

Procedure code	Actual group based on cost	Proposed group
69661	6	5

Addendum C

TABLE A.—WAGE INDEX FOR URBAN AREAS

Urban Area (Constituent counties or county equivalents)	Wage index
Abilene, TX	0.8335
Taylor, TX	
Aguadilla, PR	.4624
Aguada, PR	
Aguadilla, PR	
Isabella, PR	
Moca, PR	
Akron, OH	1.0023
Portage, OH	
Summit, OH	
Albany, GA	.7748
Dougherty, GA	
Lee, GA	
Albany-Schenectady-Troy, NY	.8702
Albany, NY	
Greene, NY	
Montgomery, NY	
Rensselaer, NY	
Saratoga, NY	
Schenectady, NY	
Albuquerque, NM	1.0188
Bernalillo, NM	
Alexandria, LA	.8182
Rapids, LA	
Allentown-Bethlehem, PA-NJ	.9858
Warren, NJ	
Carbon, PA	
Lehigh, PA	
Northampton, PA	
Altoona, PA	.9474
Blair, PA	
Amarillo, TX	.9326
Potter, TX	
Randall, TX	
Anaheim-Santa Ana, CA	1.2031
Orange, CA	
Anchorage, AK	1.4619
Anchorage, AK	
Anderson, IN	.9175
Madison, IN	
Anderson, SC	.7839
Anderson, SC	
Ann Arbor, MI	1.1723
Washtenaw, MI	
Anniston, AL	.7847
Calhoun, AL	
Appleton-Oshkosh-Neenah, WI	.9792
Calumet, WI	
Outagamie, WI	
Winnebago, WI	
Arecibo, PR	.4401
Arecibo, PR	
Camuy, PR	
Hatillo, PR	
Quebradillas, PR	
Asheville, NC	.8501
Buncombe, NC	
Athens, GA	.7710
Clarke, GA	
Jackson, GA	
Madison, GA	
Oconee, GA	
Atlanta, GA	.9196
Barrow, GA	
Butts, GA	
Cherokee, GA	
Clayton, GA	
Cobb, GA	

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Coweta, GA	
De Kalb, GA	
Douglas, GA	
Fayette, GA	
Forsyth, GA	
Fulton, GA	
Gwinnett, GA	
Henry, GA	
Newton, GA	
Paulding, GA	
Rockdale, GA	
Spalding, GA	
Walton, GA	
Atlantic City, NJ	.9898
Atlantic, NJ	
Cape May, NJ	
Augusta, GA-SC	.8908
Columbia, GA	
McDuffie, GA	
Richmond, GA	
Aiken, SC	
Aurora-Elgin, IL	1.0123
Kane, IL	
Kendall, IL	
Austin, TX	1.0409
Hays, TX	
Travis, TX	
Williamson, TX	
Bakersfield, CA	1.1114
Kern, CA	
Baltimore, MD	1.0178
Anne Arundel, MD	
Baltimore, MD	
Baltimore City, MD	
Carroll, MD	
Harford, MD	
Howard, MD	
Queen Annes, MD	
Bangor, ME	.8907
Penobscot, ME	
Baton Rouge, LA	.8665
Ascension, LA	
East Baton Rouge, LA	
Livingston, LA	
West Baton Rouge, LA	
Battle Creek, MI	.9670
Calhoun, MI	
Beaumont-Port Arthur, TX	.9394
Hardin, TX	
Jefferson, TX	
Orange, TX	
Beaver County, PA	1.0368
Beaver, PA	
Bellingham, WA	1.0823
Whatcom, WA	
Benton Harbor, MI	.8436
Berrien, MI	
Bergen-Passaic, NJ	1.0299
Bergen, NJ	
Passaic, NJ	
Billings, MT	.9756
Yellowstone, MT	
Biloxi-Gulfport, MS	.8012
Hancock, MS	
Harrison, MS	
Binghamton, NY	.9107
Broome, NY	
Tioga, NY	
Birmingham, AL	.9226
Blount, AL	
Jefferson, AL	
Saint Clair, AL	
Shelby, AL	
Walker, AL	
Bismarck, ND	.9315

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Burleigh, ND	
Morton, ND	
Bloomington, IN	.9215
Monroe, IN	
Bloomington-Normal, IL	.9463
McLean, IL	
Boise City, ID	.9821
Ada, ID	
Boston-Lawrence-Salem-Lowell-Brockton, MA	1.0825
Essex, MA	
Middlesex, MA	
Norfolk, MA	
Plymouth, MA	
Suffolk, MA	
Boulder-Longmont, CO	1.0717
Boulder, CO	
Bradenton, FL	.8796
Manatee, FL	
Brazoria, TX	.8333
Brazoria, TX	
Bremerton, WA	.9407
Kitsap, WA	
Bridgeport-Stamford-Norwalk-Danbury, CT	1.1230
Fairfield, CT	
Brownsville-Harlingen, TX	.8538
Cameron, TX	
Bryan-College Station, TX	.9377
Brazos, TX	
Buffalo, NY	.9726
Erie, NY	
Burlington, NC	.7548
Alamance, NC	
Burlington, VT	.9464
Chittenden, VT	
Grand Isle, VT	
Caguas, PR	.4001
Caguas, PR	
Gurabo, PR	
San Lorenz, PR	
Aguas Buenas, PR	
Cayey, PR	
Cidra, PR	
Canton, OH	.9195
Carroll, OH	
Stark, OH	
Casper, WY	.9842
Natrona, WY	
Cedar Rapids, IA	.9242
Linn, IA	
Champaign-Urbana-Rantoul, IL	.9141
Champaign, IL	
Charleston, SC	.8467
Berkeley, SC	
Charleston, SC	
Dorchester, SC	
Charleston, WV	.9757
Kanawha, WV	
Putnam, WV	
Charlotte-Gastonia-Rock Hill, NC-SC	.8424
Cabarrus, NC	
Gaston, NC	
Lincoln, NC	
Mecklenburg, NC	
Rowan, NC	
Union, NC	
York, SC	
Charlottesville, VA	.8822
Albermarle, VA	
Charlottesville City, VA	
Fluvanna, VA	
Greene, VA	
Chattanooga, TN-GA	.9165

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Catoosa, GA	
Dade, GA	
Walker, GA	
Hamilton, TN	
Marion, TN	
Sequatchie, TN	
Cheyenne, WY	.8959
Laramie, WY	
Chicago, IL	1.1211
Cook, IL	
Du Page, IL	
McHenry, IL	
Chico, CA	1.1145
Butte, CA	
Cincinnati, OH-KY-IN	1.0319
Dearborn, IN	
Boone, KY	
Campbell, KY	
Kenton, KY	
Clermont, OH	
Hamilton, OH	
Warren, OH	
Clarksville-Hopkinsville, TN-KY	.7485
Christian, KY	
Montgomery, TN	
Cleveland, OH	1.0826
Cuyahoga, OH	
Geauga, OH	
Lake, OH	
Medina, OH	
Colorado Springs, CO	1.0047
El Paso, CO	
Columbia, MO	1.0378
Boone, MO	
Columbia, SC	.8450
Lexington, SC	
Richland, SC	
Columbus, GA-AL	.7406
Russell, AL	
Chattanoochee, GA	
Muscogee, GA	
Columbus, OH	.9296
Delaware, OH	
Fairfield, OH	
Franklin, OH	
Licking, OH	
Madison, OH	
Pickaway, OH	
Union, OH	
Corpus Christi, TX	.8801
Nueces, TX	
San Patricio, TX	
Cumberland, MD-WV	.8798
Allegany, MD	
Mineral, WV	
Dallas, TX	.9565
Collin, TX	
Dallas, TX	
Denton, TX	
Ellis, TX	
Kaufman, TX	
Rockwall, TX	
Danville, VA	.7621
Danville City, VA	
Pittsylvania, VA	
Davenport-Rock Island-Moline, IA-IL	.9739
Scott, IA	
Henry, IL	
Rock Island, IL	
Dayton-Springfield, OH	1.0107
Clark, OH	
Greene, OH	
Miami, OH	
Montgomery, OH	
Daytona Beach, FL	.8545
Volusia, FL	
Decatur, IL	.8966

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Macon, IL	
Denver, CO	1.1934
Adams, CO	
Arapahoe, CO	
Denver, CO	
Douglas, CO	
Jefferson, CO	
Des Moines, IA	.9824
Dallas, IA	
Polk, IA	
Warren, IA	
Detroit, MI	1.0911
Lapeer, MI	
Livingston, MI	
Macomb, MI	
Monroe, MI	
Oakland, MI	
Saint Clair, MI	
Wayne, MI	
Dothan, AL	.7892
Dale, AL	
Houston, AL	
Dubuque, IA	.9712
Dubuque, IA	
Duluth, MN-WI	.9477
St. Louis, MN	
Douglas, WI	
Eau Claire, WI	.8903
Chippewa, WI	
Eau Claire, WI	
El Paso, TX	.8849
El Paso, TX	
Elkhart-Goshen, IN	.9142
Elkhart, IN	
Elmira, NY	.9152
Chemung, NY	
Enid, OK	.9125
Garfield, OK	
Erie, PA	.9488
Erie, PA	
Eugene-Springfield, OR	1.0353
Lane, OR	
Evansville, IN-KY	.9963
Posey, IN	
Vanderburgh, IN	
Warrick, IN	
Henderson, KY	
Fargo-Moorhead, ND-MN	1.0031
Clay, MN	
Cass, ND	
Fayetteville, NC	.7983
Cumberland, NC	
Fayetteville-Springdale, AR	.7494
Washington, AR	
Flint, MI	1.1458
Genesee, MI	
Shiawassee, MI	
Florence, AL	.7255
Colbert, AL	
Lauderdale, AL	
Florence, SC	.7472
Florence, SC	
Fort Collins-Loveland, CO	1.0252
Larimor, CO	
Fort Lauderdale-Hollywood-Pompano Beach, FL	1.0424
Broward, FL	
Fort Myers-Cape Coral, FL	.8989
Lee, FL	
Fort Pierce, FL	1.0052
Martin, FL	
St. Lucie, FL	
Fort Smith, AR-OK	.8726
Crawford, AR	
Sebastian, AR	
Sequoyah, OK	
Fort Walton Beach, FL	.8210

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Okaloosa, FL	
Fort Wayne, IN	.9008
Allen, IN	
De Kalb, IN	
Whitley, IN	
Fort Worth-Arlington, TX	.9475
Johnson, TX	
Parker, TX	
Tarrant, TX	
Fresno, CA	1.0978
Fresno, CA	
Gadsden, AL	.8394
Etowah, AL	
Gainesville, FL	.8902
Alachua, FL	
Bradford, FL	
Galveston-Texas City, TX	1.0782
Galveston, TX	
Gary-Hammond, IN	1.0415
Lake, IN	
Porter, IN	
Glens Falls, NY	.8889
Warren, NY	
Washington, NY	
Grand Forks, ND	.9462
Grand Forks, ND	
Grand Rapids, MI	1.0058
Kent, MI	
Ottawa, MI	
Great Falls, MT	.9966
Cascade, MT	
Greeley, CO	1.0174
Weld, CO	
Green Bay, WI	.9692
Brown, WI	
Greensboro-Winston-Salem-High Point, NC	.8710
Davidson, NC	
Davie, NC	
Forsyth, NC	
Guilford,	
Randolph, NC	
Stokes, NC	
Yadkin, NC	
Greenville-Spartanburg, SC	.8961
Greenville, SC	
Pickens, SC	
Spartanburg, SC	
Hagerstown, MD	.8869
Washington, MD	
Hamilton-Middletown, OH	.9649
Butler, OH	
Harrisburg-Lebanon-Carlisle, PA	.9907
Cumberland, PA	
Daulphin, PA	
Lebanon, PA	
Perry, PA	
Hartford-Middletown-New Britain-Bristol, CT	1.0898
Hartford, CT	
Litchfield, CT	
Middlesex, CT	
Tolland, CT	
Hickory, NC	.8335
Alexander, NC	
Burke, NC	
Catawba, NC	
Honolulu, HI	1.1343
Honolulu, HI	
Houma-Thibodaux, LA	.8083
Lafourche, LA	
Terrebonne, LA	
Houston, TX	.9868

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Fort Bend, TX	
Harris, TX	
Liberty, TX	
Montgomery, TX	
Waller, TX	
Huntington-Ashland, WV-KY-OH	.9066
Boyd, KY	
Carter, KY	
Greenup, KY	
Lawrence, OH	
Cabell, WV	
Wayne, WV	
Huntsville, AL	.8208
Madison, AL	
Indianapolis, IN	.9941
Boone, IN	
Hamilton, IN	
Hancock, IN	
Hendricks, IN	
Johnson, IN	
Marion, IN	
Morgan, IN	
Shelby, IN	
Iowa City, IA	1.1630
Johnson, IA	
Jackson, MI	.9445
Jackson, MI	
Jackson, MS	.8439
Hinds, MS	
Madison, MS	
Rankin, MS	
Jackson, TN	.7506
Madison, TN	
Jacksonville, FL	.8923
Clay, FL	
Duval, FL	
Nassau, FL	
St. Johns, FL	
Jacksonville, NC	.7358
Onslow, NC	
Janesville-Beloit, WI	.8935
Rock, WI	
Jersey City, NJ	1.0599
Hudson, NJ	
Johnson City-Kingsport-Bristol, TN-VA	.8446
Carter, TN	
Hawkins, TN	
Sullivan, TN	
Unicoi, TN	
Washington, TN	
Bristol City, VA	
Scott, VA	
Washington, VA	
Johnstown, PA	.9060
Cambria, PA	
Somerset, PA	
Joliet, IL	1.0507
Grundy, IL	
Will, IL	
Joplin, MO	.8649
Jasper, MO	
Newton, MO	
Kalamazoo, MI	1.1352
Kalamazoo, MI	
Kankakee, IL	.8989
Kankakee, IL	
Kansas City, KS-MO	1.0064
Johnson, KS	
Leavenworth, KS	
Miami, KS	
Wyandotte, KS	
Cass, MO	
Clay, MO	
Jackson, MO	
Lafayette, MO	
Platte, MO	
Ray, MO	

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Kenosha, WI	1.0384
Kenosha, WI	
Killeen-Temple, TX	.9789
Bell, TX	
Coryell, TX	
Knoxville, TN	.8335
Anderson, TN	
Blount, TN	
Grainger, TN	
Jefferson, TN	
Knox, TN	
Sevier, TN	
Union, TN	
Kokoma, IN	.9352
Howard, IN	
Tipton, IN	
LaCrosse, WI	.9629
LaCrosse, WI	
Lafayette, LA	.9261
Lafayette, LA	
St. Martin, LA	
Lafayette, IN	.8736
Tippecanoe, IN	
Lake Charles, LA	.9172
Calcasieu, LA	
Lake County, IL	1.0904
Lake, IL	
Lakeland-Winter Haven, FL	.8261
Polk, FL	
Lancaster, PA	.9866
Lancaster, PA	
Lansing-East Lansing, MI	1.0251
Clinton, MI	
Eaton, MI	
Ingham, MI	
Laredo, TX	.7521
Webb, TX	
Las Cruces, NM	.8362
Dona Ana, NM	
Las Vegas, NV	1.0873
Clark, NV	
Lawrence, KS	.9748
Douglas, KS	
Lawton, OK	.8579
Comanche, OK	
Lewiston-Auburn, ME	.9034
Androscoggin, ME	
Lexington-Fayette, KY	.9227
Bourbon, KY	
Clark, KY	
Fayette, KY	
Jessamine, KY	
Scott, KY	
Woodford, KY	
Lima, OH	.9233
Allen, OH	
Auglaize, OH	
Lincoln, NE	.9287
Lancaster, NE	
Little Rock-North Little Rock, AR	.9376
Faulkner, AR	
Lonoke, AR	
Pulaski, AR	
Saline, AR	
Longview-Marshall, TX	.8037
Gregg, TX	
Harrison, TX	
Lorain-Elyria, OH	.9519
Lorain, OH	
Los Angeles-Long Beach, CA	1.2463
Los Angeles, CA	
Louisville, KY-IN	.9520
Clark, IN	
Floyd, IN	
Harrison, IN	
Bullitt, KY	
Jefferson, KY	

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Oldham, KY	
Shelby, KY	
Lubbock, TX	.9568
Lubbock, TX	
Lynchburg, VA	.8586
Amherst, VA	
Campbell, VA	
Lynchburg City, VA	
Macon-Warner Robins, GA	.8287
Bibb, GA	
Houston, GA	
Jones, GA	
Peach, GA	
Madison, WI	1.0167
Dane, WI	
Manchester-Nashua, NH	.9222
Hillsborough, NH	
Merrimack, NH	
Mansfield, OH	.9116
Richland, OH	
Mayaguez, PR	.4842
Anasco, PR	
Cabo Rojo, PR	
Hormigueros, PR	
Mayaguez, PR	
San German, PR	
McAllen-Edinburg-Mission,TX	.7655
Hidalgo, TX	
Medford, OR	.9701
Jackson, OR	
Melbourne-Titusville, FL	.8862
Brevard, FL	
Memphis, TX-AR-MS	.9644
Crittenden, AR	
De Soto, MS	
Shelby, TN	
Tipton, TX	
Merced, CA	1.0727
Merced, CA	
Miami-Hialeah, FL	1.0151
Dade, FL	
Middlesex-Somerset-Hunterdon, NJ	.9837
Hunterdon, NJ	
Middlesex, NJ	
Somerset, NJ	
Midland, TX	1.0576
Midland, TX	
Milwaukee, WI	1.0435
Milwaukee, WI	
Ozaukee, WI	
Washington, WI	
Waukesha, WI	
Minneapolis-St. Paul, MN-WI	1.1224
Anoka, MN	
Carver, MN	
Chisago, MN	
Dakota, MN	
Hennepin, MN	
Isanti, MN	
Ramsey, MN	
Scott, MN	
Washington, MN	
Wright, MN	
St. Croix, WI	
Mobile, AL	.8319
Baldwin, AL	
Mobile, AL	
Modesto, CA	1.1049
Stanislaus, CA	
Monmouth-Ocean, NJ	.9365
Monmouth, NJ	
Ocean, NJ	
Monroe, LA	.8471
Ouachita, LA	
Montgomery, AL	.8173

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Autauga, AL	
Elmore, AL	
Montgomery, AL	
Muncie, IN	.9565
Delaware, IN	
Muskegon, MI	.9620
Muskegon, MI	
Naples, FL	.9919
Collier, FL	
Nashville, TN	.8878
Cheatham, TN	
Davidson, TN	
Dickson, TN	
Robertson, TX	
Rutherford, TN	
Sumner, TN	
Williamson, TN	
Wilson, TN	
Nassau-Suffolk, NY	1.2359
Nassau, NY	
Suffolk, NY	
New Bedford-Fall River-Attleboro, MA	.9352
Bristol, MA	
New Haven-Waterbury-Meriden, CT	1.0639
New Haven, CT	
New London-Norwich, CT	1.0562
New London, CT	
New Orleans, LA	.9080
Jefferson, LA	
Orleans, LA	
St. Bernard, LA	
St. Charles, LA	
St. John The Baptist, LA	
St. Tammany, LA	
New York, NY	1.3092
Bronx, NY	
Kings, NY	
New York City, NY	
Putnam, NY	
Queens, NY	
Richmond, NY	
Rockland, NY	
Westchester, NY	
Newark, NJ	1.0808
Essex, NJ	
Morris, NJ	
Sussex, NJ	
Union, NJ	
Niagara Falls, NY	.8492
Niagara, NY	
Norfolk-Virginia Beach-Newport News, VA	.9196
Chesapeake City, VA	
Gloucester, VA	
Hampton City, VA	
James City Co., VA	
Newport News City, VA	
Norfolk City, VA	
Poquoson, VA	
Portsmouth City, VA	
Suffolk City, VA	
Virginia Beach City, VA	
Williamsburg City, VA	
York, VA	
Oakland, CA	1.4023
Alameda, CA	
Contra Costa, CA	
Ocala, FL	.8183
Marion, FL	
Odessa, TX	.8919
Ector, TX	
Oklahoma City, OK	1.0065

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Canadian, OK	
Cleveland, OK	
Logan, OK	
McClain, OK	
Oklahoma, OK	
Pottawatomie, OK	
Olympia, WA	1.0349
Thurston, WA	
Omaha, NE-IA	.9822
Pottawattamie, IA	
Douglas, NE	
Sarpy, NE	
Washington, NE	
Orange County, NY	.8828
Orange, NY	
Orlando, FL	.9356
Orange, FL	
Osceola, FL	
Seminole, FL	
Owensboro, KY	.8360
Daviess, KY	
Oxnard-Ventura, CA	1.2976
Ventura, CA	
Panama City, FL	.7882
Bay, FL	
Parkersburg-Marietta, WV-OH	.8828
Washington, OH	
Wood, WV	
Pascagoula, MS	.8929
Jackson, MS	
Pensacola, FL	.8241
Escambia, FL	
Santa Rosa, FL	
Peoria, IL	.9879
Peoria, IL	
Tazewell, IL	
Woodford, IL	
Philadelphia, PA-NJ	1.0935
Burlington, NJ	
Camden, NJ	
Gloucester, NJ	
Bucks, PA	
Chester, PA	
Delaware, PA	
Montgomery, PA	
Philadelphia, PA	
Phoenix, AZ	1.0079
Maricopa, AZ	
Pine Bluff, AR	.7767
Jefferson, AR	
Pittsburgh, PA	1.0240
Allegheny, PA	
Fayette, PA	
Washington, PA	
Westmoreland, PA	
Pittsfield, MA	.9946
Berkshire, MA	
Ponce, PR	.5513
Juana Diaz, PR	
Ponce, PR	
Portland, ME	.9461
Cumberland, ME	
Sagadahoc, ME	
York, ME	
Portland, OR	1.1292
Clackamas, OR	
Multnomah, OR	
Washington, OR	
Yamhill, OR	
Portsmouth-Dover-Rochester, NH	.9114
Rockingham, NH	
Strafford, NH	
Poughkeepsie, NY	.9597
Dutchess, NY	
Providence-Pawtucket-Woonsocket, RI	.9811

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Bristol, RI	
Kent, RI	
Newport, RI	
Providence, RI	
Washington, RI	
Provo-Orem, UT	.9278
Utah, UT	
Pueblo, CO	.9920
Pueblo, CO	
Racine, WI	.9299
Racine, WI	
Raleigh-Durham, NC	.9274
Durham, NC	
Franklin, NC	
Orange, NC	
Wake, NC	
Rapid City, SD	.8702
Pennington, SD	
Reading. PA	.9381
Berks, PA	
Redding, CA	1.0779
Shasta, CA	
Reno, NV	1.1202
Washoe, NV	
Richland-Kennewick, WA	.9688
Benton, WA	
Franklin, WA	
Richmond-Petersburg, VA	.8897
Charles City Co., VA	
Chesterfield, VA	
Colonial Heights City, VA	
Dinwiddie, VA	
Goochland, VA	
Hanover, VA	
Henrico, VA	
Hopewell City, VA	
New Kent, VA	
Petersburg City, VA	
Powhatan, VA	
Prince George, VA	
Richmond City, VA	
Riverside-San Bernardino, CA	1.1536
Riverside, CA	
San Bernardino, CA	
Roanoke, VA	.8346
Botetourt, VA	
Roanoke, VA	
Roanoke City, VA	
Salem City, VA	
Rochester, MN	1.0027
Olmstead, MN	
Rochester, NY	0.9558
Livingston, NY	
Monroe, NY	
Ontario, NY	
Orleans, NY	
Wayne, NY	
Rockford, IL	1.0245
Boone, IL	
Winnebago, IL	
Sacramento, CA	1.2140
Eldorado, CA	
Placer, CA	
Sacramento, CA	
Yolo, CA	
Saginaw-Bay City-Midland, MI	1.0597
Bay, MI	
Midland, MI	
Saginaw, MI	
St. Cloud, MN	.9662
Benton, MN	
Sherburne, MN	
Stearns, MN	
St. Joseph, MO	.8811
Buchanan, MO	
St. Louis, MO-IL	1.0165
Clinton, IL	

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Jersey, IL	
Madison, IL	
Monroe, IL	
St. Clair, IL	
Franklin, MO	
Jefferson, MO	
St. Charles, MO	
St. Louis, MO	
St. Louis City, MO	
Salem, OR	1.0416
Marion, OR	
Polk, OR	
Salinas-Seaside-Monterey, CA	1.2211
Monterey, CA	
Salt Lake City-Ogden, UT	.9508
Davis, UT	
Salt Lake, UT	
Weber, UT	
San Angelo, TX	.8302
Tom Green, TX	
San Antonio, TX	.8377
Bexar, TX	
Comal, TX	
Guadalupe, TX	
San Diego, CA	1.2350
San Diego, CA	
San Francisco, CA	1.4946
Marin, CA	
San Francisco, CA	
San Mateo, CA	
San Jose, CA	1.4323
Santa Clara, CA	
San Juan, PR	.5387
Barcelona, PR	
Bayoman, PR	
Canovanas, PR	
Carolina, PR	
Catano, PR	
Corozal, PR	
Dorado, PR	
Fajardo, PR	
Florida, PR	
Guaynabo, PR	
Humacao, PR	
Juncos, PR	
Juncos, PR	
Los Piedras, PR	
Loiza, PR	
Luguillo, PR	
Manati, PR	
Naranjito, PR	
Rio Grande, PR	
San Juan, PR	
Toa Alta, PR	
Toa Baja, PR	
Trojillo Alto, PR	
Vega Alta, PR	
Vega Baja, PR	
Santa Barbara-Santa Maria-Lompoc, CA	1.1428
Santa Barbara, CA	
Santa Cruz, CA	1.2017
Santa Cruz, CA	
Santa Fe, NM	.9362
Los Alamos, NM	
Santa Fe, NM	
Santa Rosa-Petaluma, CA	1.2943
Sonoma, CA	
Sarasota, FL	.9166
Sarasota, FL	
Savannah, GA	.8405
Chatham, GA	
Effingham, GA	
Scranton-Wilkes Barre, PA	.9318
Columbia, PA	
Lackawanna, PA	
Luzerne, PA	
Monroe, PA	
Wyoming, PA	
Seattle, WA	1.0907
King, WA	
Snohomish, WA	
Sharon, PA	.9198
Mercer, PA	
Sheboygan, WI	.9318
Sheboygan, WI	
Sherman-Denison, TX	.8285
Grayson, TX	
Shreveport, LA	.8994
Bossier, LA	
Caddo, LA	
Sioux City, IA-NE	.9248
Woodbury, IA	
Dakota, NE	
Sioux Falls, SD	.9552
Minnehaha, SD	
South Bend-Mishawaka, IN	.9605
St. Joseph, IN	
Spokane, WA	1.0823
Spokane, WA	
Springfield, IL	1.0040
Menard, IL	
Sangamon, IL	
Springfield, MO	.9074
Christian, MO	
Greene, MO	
Springfield, MA	.9758
Hampden, MA	
Hampshire, MA	
State College, PA	1.0303
Centre, PA	
Steubenville-Weirton, OH-WV	.9106
Jefferson, OH	
Brooke, WV	
Hancock, WV	
Stockton, CA	1.1743
San Joaquin, CA	
Syracuse, NY	.9730
Madison, NY	
Onondaga, NY	
Oswego, NY	
Tacoma, WA	1.0325
Pierce, WA	
Tallahassee, FL	.8531
Gadsden, FL	
Leon, FL	
Tampa-St. Petersburg-Clearwater, FL	.9125
Hernando, FL	
Hillsborough, FL	
Pasco, Fl	
Pinellas, FL	
Terre Haute, IN	.8090
Clay, IN	
Vigo, IN	
Texarkana, TX-Texarkana, AR	.8071
Miller, AR	
Bowie, TX	
Toledo, OH	1.1101
Fulton, OH	
Lucas, OH	
Wood, OH	
Topeka, KS	.9955
Shawnee, KS	
Trenton, NJ	1.0014
Mercer, NJ	
Tucson, AZ	.9639
Pima, AZ	
Tulsa, OK	.9346
Creeks, OK	
Osage, OK	
Rogers, OK	
Tulsa, OK	
Wagoner, OK	
Tuscaloosa, AL	.9515
Tuscaloosa, AL	
Tyler, TX	.9326
Smith, TX	
Utica-Rome, NY	.8211
Herkimer, NY	
Oneida, NY	
Vallejo-Fairfield-Napa, CA	1.2767
Napa, CA	
Solano, CA	
Vancouver, WA	1.0772
Clark, WA	
Victoria, TX	.7993
Victoria, TX	
Vineland-Millville-Bridgeton, NJ	.9580
Cumberland, NJ	
Visalia-Tulare-Porterville, CA	1.1418
Tulare, CA	
Waco, TX	.8585
McLennan, TX	
Washington, D.C.-MD-VA	1.1051
District of Columbia, DC	
Calvert, MD	
Charles, MD	
Frederick, MD	
Montgomery, MD	
Prince Georges, MD	
Alexandria, City, VA	
Arlington, VA	
Fairfax, VA	
Fairfax City, VA	
Falls Church City, VA	
Loudoun, VA	
Manassas City, VA	
Manassas Park City, VA	
Prince William, VA	
Stafford, VA	
Waterloo-Cedar Falls, IA	.9432
Black Hawk, IA	
Bremer, IA	
Wausau, WI	.9457
Marathon, WI	
West Palm Beach-Boca Raton-Delray Beach, FL	.9431
Palm Beach, FL	
Wheeling, WV-OH	.8761
Belmont, OH	
Marshall, WV	
Ohio, WV	
Wichita, KS	1.0469
Butler, KS	
Harvey, KS	
Sedgwick, KS	
Wichita Falls, TX	.8221
Wichita, TX	
Williamsport, PA	.8804
Lycoming, PA	
Wilmington, DE-NJ-MD	1.0125
New Castle, DE	
Cecil, MD	
Salem, NJ	
Wilmington, NC	.8602
New Hanover, NC	
Worcester-Fitchburg-Leominster, MA	.9460
Worcester, MA	
Yakima, WA	.9850
Yakima, WA	
York, PA	.9340
Adams, PA	
York, PA	
Youngstown-Warren, OH	.9942

TABLE A.—WAGE INDEX FOR URBAN AREAS—Continued

Urban Area (Constituent counties or county equivalents)	Wage index
Mahoning, OH	
Trumbull, OH	
Yuba City, CA	.9970
Sutter, CA	
Yuba, CA	

TABLE B—WAGE INDEX FOR RURAL AREAS

Nonurban Area	Wage index
Alabama	0.7005
Alaska	1.3922
Arizona	.8869
Arkansas	.7124
California	1.0428
Colorado	.8666
Connecticut	1.0013
Delaware	.8236
Florida	.8223
Georgia	.7385

TABLE B—WAGE INDEX FOR RURAL AREAS—Continued

Nonurban Area	Wage index
Hawaii	.9318
Idaho	.8489
Illinois	.8188
Indiana	.8104
Iowa	.8070
Kansas	.7927
Kentucky	.7754
Louisiana	.7856
Maine	.8191
Maryland	.8112
Massachusetts	1.0033
Michigan	.9036
Minnesota	.8605
Mississippi	.7215
Missouri	.7640
Montana	.8558
Nebraska	.7751
Nevada	.9817
New Hampshire	.8784
New Jersey [1]	
New Mexico	.8359
New York	.8124
North Carolina	.7650
North Dakota	.8463

TABLE B—WAGE INDEX FOR RURAL AREAS—Continued

Nonurban Area	Wage index
Ohio	.8609
Oklahoma	.7938
Oregon	1.0029
Pennsylvania	.8807
Puerto Rico	.5536
Rhode Island [1]	
South Carolina	.7232
South Dakota	.7668
Tennessee	.7162
Texas	.7591
Utah	.8782
Vermont	.8387
Virginia	.7833
Virgin Islands [1]	
Washington	.9806
West Virginia	.8414
Wisconsin	.8458
Wyoming	.9100

[1] All counties within the State are classified urban.

[FR Doc. 88-18480 Filed 8-17-88; 8:45 am]

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federal register

Thursday
August 18, 1988

Part V

Environmental Protection Agency

40 CFR Parts 141 and 142

Drinking Water Regulations; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[FRL-3380-2]

Drinking Water Regulations; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper

August 3, 1988.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: In this notice, EPA is proposing maximum contaminant level goals (MCLGs) and national primary drinking water regulations (NPDWRs) for controlling lead and copper in drinking water. These proposed regulations would control lead and copper in drinking water that is due both to their occurrence in source waters and to the corrosion of lead and copper plumbing materials by water. EPA is proposing an MCLG of zero for lead and an MCLG of 1.3 mg/l for copper. For both lead and copper, EPA is proposing an NPDWR consisting of a treatment technique requirement which would require optimal corrosion control to minimize lead and copper as corrosion by-products and public education to reduce exposure to lead as a corrosion by-product. In addition, EPA is proposing NPDWRs specifying maximum contaminant levels (MCLs) for lead and copper in water entering the distribution system, after any treatment: 0.005 mg/l for lead and 1.3 mg/l for copper. EPA is also soliciting comment on alternatives to some of these proposals related to treatment requirements, monitoring, and lead pipe replacement.

DATES: Written comments should be submitted by October 17, 1988. Public hearings will be held at the addresses indicated below under "**ADDRESSES**" on September 28 (and 29, if necessary), 1988 in Washington, DC; on October 3 (and 4, if necessary), 1988 in Chicago, IL; and on October 6 (and 7, if necessary), in Seattle, WA.

ADDRESSES: The Agency will hold public hearings on the proposal at three different locations indicated below:

1. GSA Regional Auditorium, Seventh and D Streets SW., Washington, DC 20407, September 28 (and 29, if necessary), 1988.
2. The Federal Building, Lake View Conference Center, 16th Floor, 230 S. Dearborn St., Chicago, IL 60604, October 3 (and 4, if necessary), 1988.
3. The Park Place Building, Room 12-A, 1200 Sixth Avenue, Seattle, WA 98101, October 6 (and 7, if necessary), 1988.

The hearings will begin at 9:30 a.m., with registration at 9:00 a.m. The hearings will end at 4:00 p.m., unless concluded earlier. Anyone wishing to make a statement at a hearing should notify, in writing, Lead Public Hearing Officer, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (301) 585-1597 (Juanita Bridgewater).

Oral and written statements may be submitted at the public hearing. Persons who wish to make oral presentations are encouraged to have written copies of their complete comments for inclusion in the official record.

The public docket for this rulemaking, including major supporting documents and public comments on the proposal, will be available for review and copying during normal business hours at the EPA Drinking Water Docket, 401 M Street SW., Washington, DC 20460. For access to docket materials, call (202) 382-3027 between 9 a.m. and 4 p.m. Eastern time.

Send written comments on the proposed rule to Lead and Copper Comment Clerk, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Gregory Helms, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 382-7575, or one of the EPA Regional Office contacts listed in "Supplementary Information," below. Information may also be obtained from the EPA Safe Drinking Water Hotline. The toll-free number is (800) 426-4791 and the Washington, DC number is (202) 382-5533. The hotline is open from 8:30 a.m. to 4:00 p.m. Eastern time.

SUPPLEMENTARY INFORMATION: Major documents supporting this proposal will be available at EPA Regional Offices.

EPA Regional Offices

I. JFK Federal Bldg., Room 2203, Boston, MA 02203, Phone: (617) 565-3610, Jerome Healey

II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264-1800, Walter Andrews

III. 841 Chestnut Street, Philadelphia, PA 19107, Phone: (215) 597-9873, Jon Capacasa

IV. 345 Courtland Street, Atlanta, GA 30365, Phone: (404) 347-2913, Wesley (Bo) Crum

V. 230 S. Dearborn Street, Chicago, IL 60604, Phone: (312) 353-2151, Joseph Harrison

VI. 1445 Ross Avenue, Dallas, TX 75202, Phone: (214) 655-7155, Thomas Love

VII. 726 Minnesota Ave., Kansas City, KS 66101, Phone: (913) 236-2815, Gerald R. Foree

VIII. 999 18th Street, Suite 500, Denver, CO 80202-2405, Phone: (303) 293-1424, Marc Alston

IX. 215 Fremont Street, San Francisco, CA 94105, Phone: (415) 974-0763, William Thurston

X. 1200 Sixth Avenue, Seattle, WA 98101, Phone: (206) 442-4092, Richard Thiel

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Glossary of Terms

Blood Lead Level or PbB Level: The concentration of lead in blood. The health effects of lead are indexed to the concentration of lead in the blood (rather than total exposure or intake), measured in micrograms of lead per deciliter of blood (ug/dl).

Corrosion: Dissolution or eroding of pipe or other plumbing material by water.

Distributed Water: Water leaving the water treatment facility and/or entering the distribution system.

Ends of The Distribution System: Those points in the water supply distribution system with low or no flow.

Fully Flushed Sample: Water collected from a tap that has been allowed to flow freely for 3–5 minutes.

Galvanic Corrosion: Corrosion of one metal accelerated by the presence of another metal with a different electrochemical potential (e.g., corrosion of lead solder is accelerated by the presence of cooper pipe).

Gooseneck or Pigtail: A short section of pipe used to connect the service line to the water main or the service line to the water meter. See Figure 1.

Lead Pipe: Any pipe containing >8 percent lead.

Lead Solder: Any solder containing >0.2 percent lead.

Morning First Draw Sample: A water sample collected at a consumer's tap that has been standing in the interior plumbing for 8–18 hours and is collected without prior flushing.

Optimal Corrosion Control Treatment: Corrosion control treatment which minimizes lead levels in targeted samples.

Random Daytime Grab Sample: A water sample collected at a consumer's tap after it has been opened at a random time of the day (standing time of the water unknown).

Service Connection: The entire connection between a building and the service main, including the service line and any gooseneck or pigtail connections between the service line and the main (See Figure 1).

Service Connection Sample: Water collected that has stood for 8–18 hours in a building service line. This sample may be collected by one of 3 methods: (1) Direct sampling of the service line; (2) tap sample collection based on a temperature change in the water; or (3) tap sample collection after flushing a volume of water equal to that contained in pipes leading from the tap to the service line.

Service Line: The section of pipe connecting the water main to the interior plumbing of a house or building. See Figure 1.

Targeted Samples: Samples which have been taken in accordance with the monitoring requirements to determine compliance with the treatment technique requirements for corrosion control.

Abbreviations

BAT: Best Available Technology
CWSS: Community Water Supply Survey
MCL: Maximum Contaminant Level
MCLG: Maximum Contaminant Level Goal
MDL: Method Detection Limit
MGD: Million Gallons per Day
NIRS: National Inorganics and Radionuclide Survey
NOMS: National Organics Monitoring Survey
NPDWR: National Primary Drinking Water Regulation
NSDWR: National Secondary Drinking Water Regulation
NTNCWS: Non-Transient Non-Community (Water System)
PQL: Practical Quantitation Limit
PWS: Public Water System
SDWA: Safe Drinking Water Act
VOC: Volatile Organic Chemical

I. Statutory Requirements

The Safe Drinking Water Act (42 U.S.C. 300f *et seq.)* ("SDWA" or "the Act") requires EPA to establish maximum contaminant level goals (MCLGs) and national primary drinking water regulations (NPDWRs) for contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons and which are known or anticipated to occur in public water systems. Section 1412(b)(3)(A). MCLGs and MCLs are to be proposed and promulgated simultaneously. Section 1412(b)(1).

MCLGs are Non-enforceable Health Goals

MCLGs are to be set at a level at which, in the Administrator's judgment,

"no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Section 1412(b)(4). The House Report on the bill that eventually became the SDWA of 1974 provides Congressional guidance on developing MCLGs:

[T]he recommended maximum contaminant level [renamed maximum contaminant level goal in the 1986 amendments to the SDWA] must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at the zero level. (H.R. Rep. No. 93–1185, Pg. 20, 1974)

NPDWRs Set the Enforceable Standards

NPDWRs include either MCLs or treatment technique requirements as well as compliance monitoring requirements. Section 1401(1). A treatment technique requirement can be set only if "it is not economically or technologically feasible to ascertain the level of the contaminant." Section 1412(b)(7)(A). The MCL for a contaminant must be set as close to the MCLG as is "feasible." Section 1412(b)(4). Feasible means "feasible with the use of the best technology, treatment techniques and other means, which the Administrator finds after examination for efficacy under field conditions and not solely under laboratory conditions are available (taking costs into consideration.)" Section 1412(b)(5). A treatment technique must "prevent known or anticipated adverse effects on the health of persons to the extent feasible." Section 1412(b)(7)(A).

Secondary MCLs

EPA sets national secondary drinking water regulations (NSDWRs) to control water color, odor, appearance, and other characteristics affecting consumer acceptance of water. The secondary regulations are not federally enforceable, but are considered guidelines for the States. Section 1401(2).

Amendments to the SDWA

The 1986 amendments to the SDWA established a list of 83 contaminants for which EPA is to develop MCLGs and NPDWRs. Lead and copper are among these contaminants, and this proposed rule is the first step in fulfilling this statutory requirement for lead and copper in drinking water.

II. Background

A. Regulatory Background

The current MCL for lead is 0.050 mg/l (see 40 CFR 141.11(b)). EPA promulgated this MCL as an interim drinking water regulation in 1975. For copper, there is currently a NSDWR of 1 mg/l. On November 13, 1985, EPA began the process of revising the standards for lead and copper by proposing MCLGs for them (50 FR 46936, November 13, 1985). Because the 1986 amendments to the SDWA require that MCLGs and NPDWRs be proposed and promulgated simultaneously, EPA must repropose MCLGs for contaminants for which MCLGs were originally proposed in the November 1985 notice, including lead and copper, when it proposes the corresponding NPDWRs. Accordingly, this notice, which proposes NPDWRs for lead and copper, also reproposes MCLGs for these contaminants. The MCLG proposed for lead in this notice (zero) is lower than the MCLG for lead proposed in November 1985. The MCLG proposed for copper is the same as that proposed in 1985 (1.3 mg/l).

1. Lead

The November 1985 notice proposed an MCLG for lead of 0.020 mg/l. This goal was based on an assessment of data on adverse health effects of lead on infants. The assessment concluded that blood lead levels of 15 to 20 ug/dl represented levels of concern for infants. Effects of lead found at these levels are discussed in detail in the November 1985 notice; more recent data on these and other effects are discussed below. The 1985 proposed MCLG of 0.020 mg/l for lead in water assumed that 15 ug/dl was the blood lead level of concern for infants, assumed that infants receive 100 percent of their lead exposure from drinking water, and used a factor of 0.16 ug/dl per ug/l lead to correlate water lead levels to blood lead levels (i.e., every 1 ug/l lead in drinking water was estimated to contribute about 0.16 ug/dl to a child's blood lead level). An uncertainty factor of 5 was used in the calculation to account for uncertainty in the data and provide a margin of safety.

There also are several positive carcinogenicity bioassays using different lead salts. Therefore, in the November 1985 notice, EPA classified lead as a Group B2 carcinogen (probable human carcinogen) according to the draft EPA Guidelines for Carcinogen Risk Assessment (since promulgated as final guidelines at 51 FR 33992, September 24, 1986). However, the proposed MCLG was not based on the carcinogenicity data because the doses used in the studies were much higher than the overt toxicity levels in humans, and because several epidemiology studies did not show an association between cancer and lead exposure in occupationally exposed workers.

In addition to directing EPA to revise the NPDWR for lead, the SDWA includes other provisions that affect lead contamination of drinking water. The 1986 SDWA amendments banned the use of lead solder or flux (i.e., solder or flux containing more than 0.2 percent lead) and lead-bearing pipes and fittings (i.e., pipes and fittings containing more than 8 percent lead). Section 1417. The lead ban was effective June 19, 1986. States were required to implement and enforce the lead ban as of June 19, 1988. EPA is developing a program to withhold 5 percent of Federal grants for drinking water implementation from States that fail to enforce the ban.

The SDWA also imposes special public notification requirements regarding lead in drinking water. Section 1417(a)(2). Public water systems are required to identify and provide notice to persons who may be affected by lead contamination in their drinking water, when such contamination results from either the use of lead in the construction materials of the system and/or corrosivity of the water supply sufficient to cause lead leaching from plumbing systems. This provision requires notification even if the system is in compliance with the current MCL for lead. EPA published final regulations to implement this requirement of the SDWA on October 28, 1987 (52 FR 41534). Under these regulations, systems were required to begin providing notice to consumers by June 19, 1988.

2. Copper

EPA proposed an MCLG of 1.3 mg/l for copper in the November 13, 1985 notice. This value was based on short-term effects of copper on humans at relatively high doses; no long-term effects at lower exposure levels have been predicted. No new data have become available since November 1985 that have altered EPA's evaluation of the health effects of copper.

B. Overview of Problem

1. Lead

Lead occurs in drinking water from two sources: (1) Lead in raw water supplies, i.e., source water, and (2) corrosion of plumbing materials in the water distribution system. Most of the lead in drinking water is a result of corrosion by water of plumbing materials containing lead.

EPA estimates that approximately 900 public water systems (or <1 percent of the community water systems in the country) may have water leaving the

water supply plant that has greater than 0.005 mg/l lead. In fact, some systems deliver water to customers that exceeds the current MCL of 0.050 mg/l. Because of concern about low level exposures to lead, as described in Section III.B.1. below, lead in source water even at low levels may be an important contributor to lead in drinking water in some systems.

Lead in drinking water as a by-product of corrosion results primarily from corrosion of plumbing materials in the distribution system and in buildings. The amount of lead in drinking water due to corrosion depends on a number of factors, including the amount and age of lead material present in the system to be corroded and the degree of corrosivity of the water.

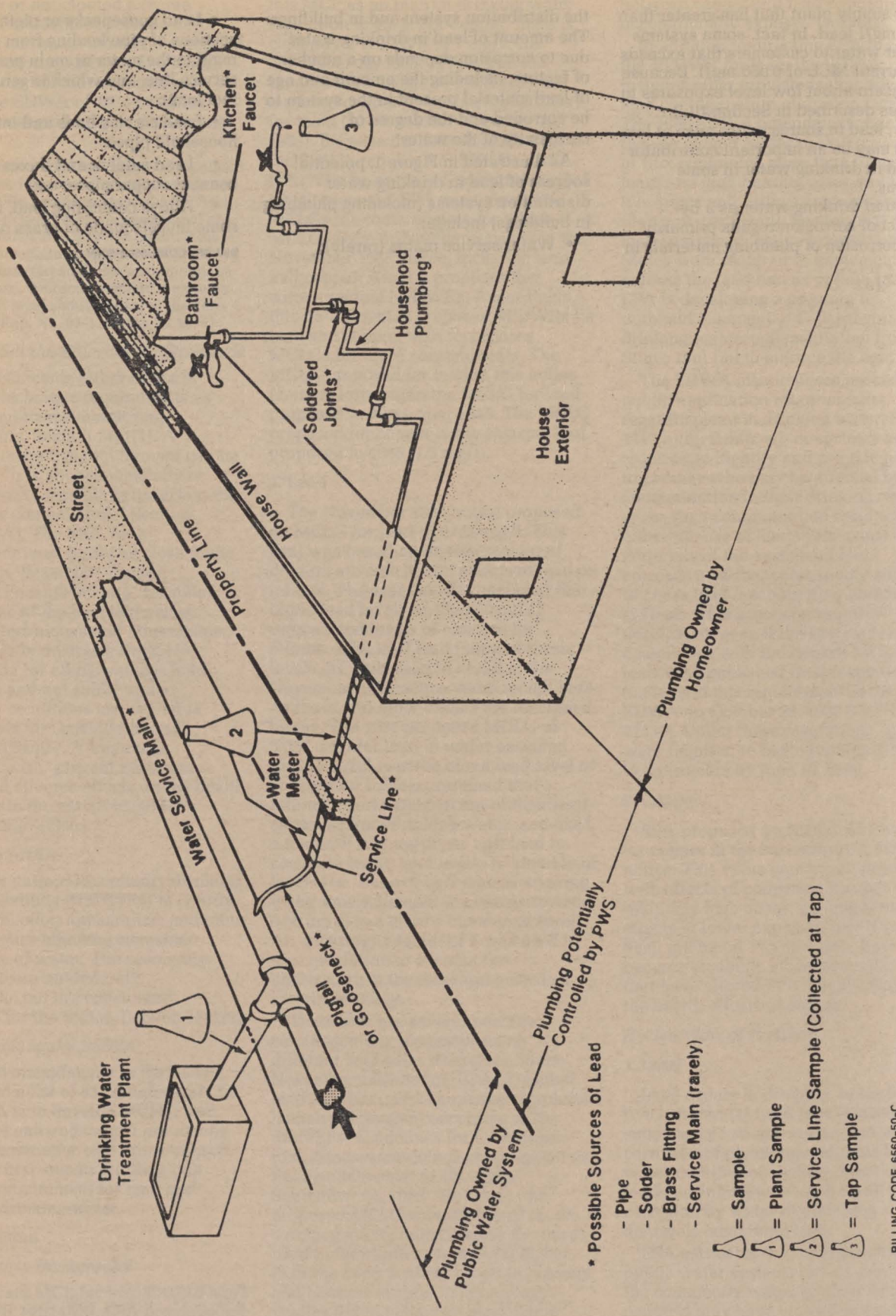
As illustrated in Figure 1, potential sources of lead in drinking water distribution systems (including plumbing in buildings) include:

- Water service mains (rarely);
- Lead goosenecks or pigtails (short sections of pipe leading from the water main to the meter or main portion of the service line, and which is genrally 6–8 feet long);
- Lead service lines and interior household pipes;
- Lead solders and fluxes used to connect copper pipes; and
- Alloys containing lead, including some faucets made of brass or bronze.

BILLING CODE 6560-50-M

Figure 1

Public Water System and Homeowner Plumbing



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Most public water systems serve at least some buildings with lead solder and EPA estimates that there are about 4.4 million lead service lines still in use in the U.S. About 25 percent of water suppliers have some lead service lines within their distribution system (EPA, 1987a). Lead service lines and interior plumbing are significant potential sources of lead in drinking water and can contribute large amounts of lead to water for the life of the pipe. Lead solder can contribute large amounts of lead to water for up to five years after installation, and longer if exposed to corrosive water (EPA 1986a). In addition, brass and bronze in faucets and fixtures can contain lead and there is evidence that they can be an important source of lead in drinking water that stands in the fixtures.

The amount of lead in drinking water also depends on the corrosivity of the water. All water is corrosive to metal plumbing materials to some degree, even water termed non-corrosive or water treated to make it less corrosive. The corrosivity of water to lead is influenced largely by the pH and total alkalinity of the water (water with low pH and/or low alkalinity water is more corrosive to lead than water with high pH and alkalinity). Galvanic corrosion of lead into water also occurs with lead-soldered copper pipes, due to differences in the electrochemical potential of the two metals. Grounding of household electrical systems to plumbing can exacerbate galvanic corrosion. There are other factors that also may affect water corrosivity, such as water temperature (seasonal variations in lead levels are common), and levels of free chlorine, total dissolved solids, and oxygen.

Lead levels in drinking water can vary considerably from system to system, among houses supplied by the same system, among different taps in the same house, and at different times of the day at a single tap. Factors that affect lead levels in water independent of the corrosivity of water include:

- The number and age of lead-soldered joints in the building and the quality of workmanship of the joints (new solder releases high amounts of lead and sloppy solder joints have more lead available to be leached);
- The contact time between the water and the lead (longer contact time results in higher lead levels so, for instance, morning first draw water samples have higher lead levels than samples with shorter standing times or flushed water samples); and
- The length and diameter of the lead service line (longer lines generally result in higher lead levels in water at the tap since the water is in contact with more lead, while smaller diameter pipes have a greater ratio of pipe surface to water volume so there is more contact between the lead and water which can result in higher lead levels, and small diameter pipes can also result in higher lead levels because of increased velocity of the water flow which causes scouring of the sides of the pipe).

2. Copper

The primary source of copper in drinking water is corrosion of copper pipes, which are widely used throughout the U.S. for interior plumbing of residences and other buildings; copper in source water is a problem for very few water supplies. In some cases, copper is a component of additives to drinking water used by suppliers to control the growth of algae. EPA estimates that only 66 water suppliers would need to install treatment to reduce copper in source water to the MCLG (EPA, 1988a).

Like lead in drinking water, the occurrence of copper in drinking water resulting from corrosion when copper is present in the distribution system, including interior plumbing, depends on the corrosivity of the water. Also, as with lead, all water is corrosive to copper to some degree. Corrosivity toward copper depends primarily on the pH of the water, with very low pHs associated with the highest levels of copper in water due to corrosion. Free chlorine levels also affect corrosion of copper; higher chlorine residual levels increase copper corrosion (Stone et al., 1987; Reiber et al., 1987; EPA, 1987b). Dissolved carbon dioxide and oxygen can also contribute to copper corrosion (Cohen and Meyers, 1987).

Many of the other factors that affect the corrosivity of water towards lead can also be expected to affect the corrosion of copper. For instance, flow rate, standing time, water temperature, and length of copper pipe can affect copper levels in drinking water (Maessen et al., 1985). There are few data on whether age of plumbing affects copper corrosion rates (EPA, 1987b; Rieber et al., 1987).

III. MCLGs for Lead and Copper

A. Exposure

1. Exposure to Lead

a. *General.* Assessing actual human exposure to lead is difficult due to the variability of lead levels at the tap and the existence of other exposure sources. As described above, water lead levels at any one tap vary throughout the day, and vary among taps with constant standing times due to differences in the amount of available lead to which the water is exposed.

People are exposed to lead from a variety of sources in addition to water, including food, air, and dust; the proportion of total exposure attributable to drinking water varies by individual. The typical drinking water contribution to total lead exposure for an average two-year-old child is estimated to be about 20 percent (EPA, 1988b), but this varies with different levels of lead in the water and with variations in other lead exposures, and can range from about five to 30 percent of total intake. For children with extraordinary exposures, such as those exposed to deteriorating lead paint, including paint chips or leaded-paint dust, or living near lead smelters or other point sources of airborne lead, those sources predominate and drinking water contributes a much lower, although still relevant, proportion of total exposure. For residents of buildings with new lead solder served with corrosive water, drinking water can be the primary source of exposure.

b. *Exposure to Lead Through Drinking Water.* The magnitude of human exposure resulting from the ingestion of lead in drinking water depends upon many factors. Patterns of consumption may vary among individuals, from those who flush taps before drinking to those who drink first flush water. There are few actual data on individual water consumption patterns (i.e., percent consumption of standing and flushed water) and the lead exposures that result from them. EPA is conducting a pilot study of drinking water consumption patterns which may provide additional data on this question for use in developing the final MCLG and enforceable standards. However, these data are not yet available.

The problem of assessing exposure from drinking water can be addressed by bracketing exposures. Assuming that an adult consumes two liters of water (one liter for children) per day from the same water supplier, morning first draw samples (or service connection samples if the service connection is lead) will represent a case of high exposure and fully flushed samples will represent the minimum exposure. For example, in a home where fully flushed samples are consistently 0.005 mg/l and morning first draw (or service connection) samples are consistently 0.010 mg/l, the occupants will have actual lead intake from drinking water of 0.005–0.010 mg/l, or a total of 0.010–0.020 mg/day for adults.

Patterson (EPA, 1981) conducted a national study of lead levels in drinking

water. Random daytime grab samples from taps that had been flushed for 30 seconds were collected from 580 cities in 47 states. While 30-second flushed random grab samples are not necessarily representative of actual human exposure, EPA believes that they are more representative of water consumed in the U.S. than are fully flushed samples since many people regularly consume some morning first draw water. Because these data portray neither an upper bound of exposure (morning first draw or lead service line sample levels) nor a lower bound of exposure (fully flushed) levels, they may more closely portray actual average exposure. Therefore, these data provide insight as to the magnitude of lead exposure via drinking water. In the Patterson study, which used a reporting limit of 0.010 mg/l, the national mean lead level in water was 0.029 mg/1. The midwest had the highest mean lead level (0.047 mg/l) and the south-central portion of the country had the lowest mean lead level (0.012 mg/l). The median value for the U.S. and for all of the regions of the country identified in the analysis was the reporting limit, 0.010 mg/l. An EPA analysis of the benefits of regulating lead in drinking water used these data to estimate that 42 million people in the U.S. may be exposed to lead levels in water of 0.020 mg/1 or greater (EPA, 1986a).

As discussed in Section III.B. below, the toxic effects of lead are correlated with blood lead levels rather than lead exposure levels or intake amounts. Therefore, it is important to understand the relationship between lead intake and blood lead levels. Many investigators have attempted to correlate blood lead levels with drinking water lead levels and estimate the contribution of water lead to blood lead levels. Several of these studies correlated morning first draw water lead levels with blood lead levels (U.K. Dept. of Environment, 1982; Thomas et al., 1979). Other studies correlate standing random daytime grab sample water lead levels with blood lead levels (Worth et al., 1981; Moore, 1977). While neither morning first draw nor standing random daytime grab data is a better predicator of blood lead level than the other, of the currently available data, both are better than fully flushed samples (EPA, 1986b). Duplicate diet studies by Ryu (1983) and Lacey et al. (1985) have correlated measured lead intake with blood lead levels, and can also be used to predict blood lead levels. EPA has used a correlation coefficient of 0.20 ug/dl per ug/1 derived from these last two studies to relate lead levels in drinking water to blood lead levels (EPA, 1988c).

c. *Non-Drinking Water Exposures to Lead.* There are several sources of lead exposure in addition to drinking water. Directly inhaled airborne lead and lead that settles out to dust and dirt from the air are important sources, especially for children who tend to play in the dirt and who often put their hands in their mouths. Other important sources of lead are air deposition on food crops, leaching to food from lead soldered cans, and in the case of exceptionally high exposures, lead paint.

Lead in air arises from industrial emissions and combustion of leaded gasoline in cars. EPA estimates that average urban air lead levels ranged between 0.2–0.4 ug/m^3 in 1986 (EPA, 1988d). Much higher levels are found in areas near stationary lead sources such as smelters and battery plants.

Ingestion of leaded paint chips and dust accounts for most of the reported cases of overt lead poisoning in children. Many local community health programs (especially in urban areas) screen the blood lead levels of children and identify high risk housing (i.e., those houses likely to have deteriorating lead paint) and assist with remediation of lead paint problems.

Food is also a source of lead exposure. Lead can contaminate food by uptake from soil, direct deposition on crops from the air, or use of lead solder to seal cans (especially with acidic foods such as tomatoes). The Food and Drug Administration has recommended the use of non-lead soldered cans for baby foods and encourages food processors to eliminate the use of lead-soldered cans for all foods. In the U.S., no baby foods are currently sold in lead-soldered cans and most domestic can manufacturers have voluntarily converted to lead-free cans for other foods as well. In addition, lead can contaminate food in the handling, transportation or preparation stages. Finally, food prepared with water, either in manufacturing or at home, can be contaminated by lead from the drinking water.

The Agency for Toxic Substances and Disease Registry (ATSDR) has compiled a report to Congress on lead hazards and exposures of children (ATSDR, 1988). The ATSDR report reviews the non-drinking water sources of lead exposure in greater detail than is presented here.

2. Exposure to Copper

Human exposure to copper results from a variety of sources, including drinking water. As described earlier, copper in drinking water occurs primarily as a result of the corrosion of copper plumbing pipes, although some copper occurs in raw water.

Patterson (EPA, 1981) measured copper levels in the 30-second flushed random daytime grab samples described above. In that survey, 3 percent of 772 samples exceeded 1 mg/l of copper and 19 percent exceeded 0.2 mg/l. The national average level of copper in water was 0.221 mg/l (median 0.04 mg/l), the south central U.S. had the lowest average levels (0.082, median, 0.02 mg/l), and the northeast had the highest average levels (0.526 mg/l; median, 0.06 mg/l).

Exposure to copper can also come through air and food. In a 1966 National Air Sampling Network survey, copper levels in the air were 0.01 and 0.26 μg/m^3 in rural and urban areas, respectively (U.S. Dept. of Health, Education, and Welfare, 1968). Airborne copper levels near copper smelters can range up to 2 μg/m^3, but even these high levels contribute only about 1 percent of normal daily intake. Copper is found in shellfish and organ meats, nuts, and dried legumes; dried vine and stone fruits and cocoa are especially rich in copper. Copper levels can range up to 400 μg/g in these foods (50 FR 46967, Nov. 13, 1985).

B. Toxicity

1. Health Effects of Lead

As noted above, the health effects of lead are generally correlated with PbB levels. Lead exposure across a broad range of blood lead (PbB) levels is associated with a continuum of pathophysiological effects, including interference with heme synthesis necessary for formation of red blood cells, anemia, kidney damage, impaired reproductive function, interference with vitamin D metabolism, impaired cognitive performance (as measured by IQ tests, performance in school, and other means), delayed neurological and physical development, and elevations in blood pressure (EPA, 1986b).

At this time, it is difficult to identify clearly what PbB level is an appropriate criterion or "threshold" below which there are no or only minimal risks of adverse health effects. Although there is some uncertainty regarding the point at which subtle biochemical or other changes combine to cause a discernable adverse effect on organs or systems in the body, effects clearly become more pronounced and broaden to cause more severe disruptions of the normal functioning of many organ systems as PbB levels increase. The following

considerations are important in determining a target PbB of concern to be used in setting an MCLG.

PbB levels above 30 μg/dl in young children are associated with clearly deleterious effects in several organ systems (EPA, 1986b). These include reduced hemoglobin synthesis (at 40 μg/dl), frank anemia (at 70 μg/dl), peripheral neuropathies (at 60 μg/dl), encephalopathy (at 80–100 μg/dl), and in some cases, death.

At levels below 25–30 ug/dl, many different, less obvious effects indicate interference by lead with normal physiological processes. The onset of signs of detectable heme synthesis impairment in many different organ systems occurs at PbB levels starting around 10–15 μg/dl, along with indications of pyrimidine and vitamin D metabolism interference and signs of altered nervous system activity (EPA, 1986b).

Evidence also indicated that fetal exposure at PbB levels around 10–15 μg/dl is associated with delays in early mental and physical development (EPA, 1986b; Davis and Svendsgaard, 1987).

In adults, several studies have found a small but consistent relationship between blood lead levels and blood pressure, with some indications of a continuous relationship down to the lowest levels measured. The blood pressure increases may be associated with some increased risk for more serious cardiovascular disease events, especially if PbB levels are chronically elevated (EPA, 1986a).

Some of the important effects of low-level lead exposures are:

1. Inhibition of pyrimidine-5-nucleotidase (Py-5-N) and delta-aminolevulinic acid dehydrase (ALA-D) activity, which appears to begin at a PbB level of 10 μg/dl or below (Angle et al., 1982). Hernberg and Nikkanen (1970) found 50 percent inhibition of ALA-D activity at PbB levels above 16 μg/dl. Inhibition of erythrocyte ALA-D appears to occur at virtually all blood lead levels measured so far, with no evident threshold (EPA, 1986b). Inhibition of ALA-D activity is manifested in increased levels of aminolevulinic acid (ALA) in blood and soft tissue, which appear to occur at PbB levels of about 40 μg/dl (O'Flaherty et al., 1980) and may occur at levels as low as 18 μg/dl (Meredith et al., 1978). Several studies indicate that increases of ALA in the brain interfere with the gamma-aminobutyric acid (GABA) neurotransmitter system in various ways (EPA, 1986b).

2. Elevated levels of erythrocyte protoporphyrin (EP) in red blood cells occurs at PbB levels as low as 15 μg/dl. This probably indicates a general interference in heme synthesis throughout the body, including interference in the functioning of mitochondria (Piomelli et al., 1980). Changes in heme metabolism have been reported perinatally at blood lead levels of 8–10 μg/dl (Lauwerys et al., 1978). Some studies that accounted for iron status show that children with low iron stores are more sensitive to lead in terms of heme biosynthesis interference (e.g., Mahaffey and Annest, 1986).

3. Interference with vitamin D metabolism has been associated with lead exposure with no apparent threshold down to the lowest PbB level measured (12 ug/dl) in studies by Rosen et al. (1980) and Mahaffey et al. (1982).

4. Correlations between lead exposure and changes in electrophysiological functioning of the nervous system have also been reported. These include correlations with: Changes in slow-wave electroencephalogram (EEG) patterns, increased latencies in brainstem auditory evoked potentials (Otto et al., 1981, 1982, 1985), and slowed nerve conduction in the auditory pathway associated with PbB levels with no clearly discernable threshold apparent down to 6 ug/dl (Schwartz and Otto, 1987). Also, peripheral nerve conduction velocities have been shown to be slowed in children, with significant correlation at PbB levels above 20 ug/dl (Landrigan et al., 1976; Schwartz et al., 1988).

5. As stated in recent reviews (Davis and Svendsgaard, 1987; EPA, 1986b), evidence from longitudinal studies in several different communities consistently indicates that perinatal exposure to blood lead levels as low as 10–15 ug/dl, and possibly lower, is linked to delays in early cognitive and physical development. Four independent studies show an association between maternal or cord blood lead levels at birth and reduced performance on a standard index of infant mental development through two years of age (e.g., Bellinger et al., 1984, 1987; Dietrich et al., 1987; Baghurst et al., 1987; Wolf et al., 1985). In addition, birth weight and the length of gestation appear to be reduced in prenatally lead-exposed infants in some of these studies (e.g., Dietrich et al., 1987; Bornschein et al., 1988; McMichael et al., 1986). Analyses also suggest that growth and stature are reduced in older children with PbB levels ranging from 5 to 35 ug/d1 (Schwartz et al., 1986), with supporting evidence from other studies of children at higher PbB levels (Lauwerys et al., 1986) and of experimental animals (Grant et al., 1980). Other aspects of physical development may also be disturbed by prenatal lead exposure (Davis and Svendsgaard, 1987; EPA, 1986b).

6. Recent studies of IQ effects in black children of uniformly low socioeconomic status (SES), so that SES was not a confounder, have shown a highly significant association between IQ and blood lead across a range of 6 to 47 ug/d1 (Schroeder et al., 1985; Schroeder and Hawk, 1987). Other recent cross sectional studies also provide consistent evidence of IQ deficits in children at PbB levels below 25 ug/dl (Fulton et al., 1987; Hatzakis et al., 1987).

Finally, based on the weight of evidence, EPA has classified lead as a probable human carcinogen (Group B2), because some lead compounds cause real tumors in experimental animals (EPA, 1988e). EPA (1986b) noted that lead may act as a promoter or initiator of carcinogenesis and that *in vitro* studies support the genotoxic and carcinogenic role of lead. However, EPA recommends that quantitative estimates of the carcinogenic potency of lead not be used for the purpose of risk assessment, because of the considerable uncertainty in the estimates. As EPA has stated previously, "lead has been observed to increase tumorigenesis rates in animals only at relatively high concentrations, and therefore it does not appear to be a potent carcinogen." (EPA, 1986b). At low levels, the non-cancer effects of lead are of greatest concern for regulatory purposes.

In reviewing the information presented in the Agency's 1986 Air Quality Criteria Document, EPA's Clean Air Science Advisory Committee concluded that the various effects starting at PbB levels around 10–15 ug/dl or even lower in young children "may be argued as becoming biomedically adverse" (EPA, 1986c).

Although no threshold is apparent for various measures of lead toxicity, some distinction can be made between PbB levels where risks of effects appear more likely (10–15 ug/dl and higher) and levels where risks are less certain (below 10–15 ug/dl). Therefore, 10–15 ug/d1 constitutes an appropriate range of concern for health effects that warrant avoidance.

2. Health Effects of Copper

The health effects of copper were discussed in detail in EPA's 1985 MCLG proposal (50 FR 46967, November 13, 1985). No new relevant information on the health effects of copper that alters the conclusions reached in that notice has become available. The information presented in the November 1985 notice is summarized here.

Copper is toxic to humans at high levels and is nutritionally essential at lower doses. Acute exposure to high copper levels in test animals and humans can cause gastrointestinal distrubances, liver damage, renal damage, hemolytic anemia, and glucose-6-phosphate dehydrogenase (G6PD) inhibition. Chronic toxicity data are limited.

Two groups are at increased risk from copper exposure. Individuals with Wilson's disease, an inborn error in copper metabolism, are at higher risk than the general public. The metabolic error in Wilson's disease allows copper to accumulate in the liver, brain, kidney, and cornea, causing hemolytic anemia, neurological abnormalities, and corneal opacity. In addition, individuals with existing G6PD deficiencies may also be at greater risk of experiencing toxic effects from copper exposure.

On the other hand, copper is regarded as nutritionally essential because it is required in many enzymatic reactions in mammals. Copper deficiency can result in decreased iron absorption and iron deficiency, and may also lead to reproductive abnormalities. The National Academy of Sciences has recommended 2-3 mg/day copper as a safe and adequate intake (NAS, 1980).

Copper is classified in EPA's Group D (insufficient data) for carcinogenic potential. Copper is generally negative in mutagenicity bioassays and copper produced equivocal results in carcinogenicity bioassays. Bioassays using oral copper were negative; subcutaneous injection of copper compounds has been reported to induce tumor formation in one sex and strain of mice.

C. Development of the MCLGs

1. MCLG for Lead

EPA is proposing to set the MCLG for lead at zero, based on subtle effects at low blood lead levels, the overall Agency goal of reducing total lead exposures, and probable carcinogenicity at very high doses. Specifically, the basis for proposing the MCLG at zero is:

1. The occurrence of a variety of low level effects for which it is currently difficult to identify clear threshold PbB levels below which there are no risks of adverse health effects;

2. The Agency policy goal that drinking water should contribute minimal lead to total lead exposures because a substantial portion of the sensitive population already exceeds acceptable blood lead levels; and

3. The classification of lead as a Group B2 (probable human) carcinogen.

As discussed above, effects of concern have been associated with blood lead levels beginning at 10-15 ug/d1 in adults, children, and fetuses. Below 10 ug/dl, biochemical and other cellular level effects of questionable health significance have been reported. Therefore, for purposes of this regulation, EPA considers 10-15 ug/dl to be an appropriate range of concern for health effects that warrant avoidance.

Lead affects a wide range of organ systems; it can adversely affect the blood, the nervous system, normal growth and development, the kidneys, the reproductive system, and the cardiovascular system. An MCLG of zero is appropriate because there are no clearly discernable thresholds for some of these effects.

Another reason for setting the MCLG at zero is the fact that a portion of the population most sensitive to lead effects already has blood lead levels above the levels that pose a risk of causing some adverse effects. Although average blood lead levels are expected to be near 4-6 ug/dl in children in 1990 when this rule would take effect (EPA, 1988f), many individual children would still have PbB levels above 10 ug/dl (excluding children with lead paint/pica exposures, whose exposure from those sources overwhelms exposure from other sources), the lower bound of the range of concern. Because many children now have blood lead levels above the level of concern, EPA's policy goal is that drinking water contribute minimal additional lead to existing body burdens of lead.

Finally, EPA reviewed data on lead's potential carcinogenicity in determining the appropriate MCLG. Although difficulties in evaluating the dose-response data for lead prevent estimation of its carcinogenic potency, the data nonetheless clearly indicate that lead is carcinogenic in test animals. As explained by EPA in adopting MCLGs for other carcinogenic contaminants, the Agency does not believe that a threshold exists for carcinogenic effects (50 FR 46894, November 13, 1985). EPA therefore believes that, for carcinogens, zero is the level at which no known or anticipated effects occur with an adequate margin of safety, and EPA has established a policy of setting MCLGs at zero for compounds classified as Group A or B carcinogens. Setting the MCLG for lead at zero is consistent with that policy.

EPA has received a request from Multinational Business Services, Inc. ("MBS") to reconsider the Agency's policy of establishing MCLGs of zero for carcinogens and instead establish MCLGs for carcinogenic contaminants at calculated negligible risk levels. EPA considered adopting finite, risk-based MCLGs when it promulgated MCLGs for five carcinogenic volatile organic chemicals in (VOCs) 1985. EPA decided that, given the nonthreshold nature of carcinogenic effects, the zero MCLG option best fulfilled the mandate of the SDWA to establish MCLGs "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." See 49 FR 24347-24348 (June 12, 1984) and 50 FR 46895-46896 (November 13, 1985). The Agency's decision to set MCLGs of zero for these five contaminants was upheld in *Natural Resources Defense Council* v. *Thomas*, 824 F.2d 1211 (D.C. Cir., 1987).

In its request, MBS contends that the recent decision by the U.S. Court of Appeals for the District of Columbia Circuit in *Natural Resources Defense Council* v. *EPA*, 824 F.2d 1146 (1987) ("*Vinyl Chloride*"), which construed the Agency's duties under section 112 of the Clean Air Act, applies to the establishment of MCLGs under the SDWA.

The Agency does not believe that the court's analysis in *Vinyl Chloride* must be applied to the setting of MCLGs. That decision construed the specific language of section 112 of the Clean Air Act and the legislative history of that provision. Section 1412 of the SDWA differs from section 112 of the Clean Air Act both in terms of its language and legislative history. Furthermore, the role of the MCLG as a non-enforceable health goal, the first step in the process of determining the enforceable MCL or treatment technique, is unique to the SDWA. In light of the distinctions between section 112 of the Clean Air Act and section 1412 of the SDWA, the Agency does not believe that following the *Vinyl Chloride* analysis in setting MCLGs is either necessary or appropriate. For these reasons, and the reasons described in the VOC rulemaking, EPA believes at this time that it is appropriate to set MCLGs for nonthreshold contaminants at zero. Nonetheless, the Agency has included the request submitted by Multinational Business Services in the record for this rulemaking, and the Agency intends to fully address that submission and any related comments when the Agency publishes the final MCLG for lead.

Public Comments: In 1985, a total of eight individuals and organizations commented on the proposed MCLG of 0.02 mg/l for lead. The public comments and EPA's responses are summarized below:

Comment Summary: Some commenters stated that the proposed MCLG of 0.02 mg/l for lead was appropriate. There was some disagreement among the commenters on whether an uncertainty factor of 5 or 10 (which would yield an MCLG of 0.01 mg/l) should be used.

EPA Response: For the reasons outlined above, EPA is now proposing an MCLG of zero for lead and so a discussion of what the safety factor would be is much less relevant than when a non-zero MCLG was proposed. The National Academy of Sciences and others suggest that a safety factor of 10 should be used when extrapolating from data obtained in human epidemiology studies to the general population. This was meant to address well-defined, known toxic endpoints. The endpoints in the case of lead exposure are extremely subtle enzymic and physiologic occurrences, and are not comparable to the traditional toxic endpoints. There is considerably less uncertainty about health effects from lead than from any other chemical. Excellent human data are available. Therefore, there is less need to apply the usual uncertainty factors in this case and a lower uncertainty factor is appropriate.

Comment Summary: Some commenters disagreed with the MCLG of 0.02 mg/l proposed for lead. One maintained that it has not been proven that low level lead exposure has adverse health effects and, therefore, the present level of 0.05 mg/l is fully protective and should not be decreased. Another commenter stated that since the primary sources of lead exposure are air and dust, available funds should be spent on reducing exposure from sources such as leaded gasoline and lead-based paint rather than drinking water, and cited a study by Morse et al. (1979) in support of the contention that drinking water lead does not increase blood lead levels.

EPA Response: EPA disagrees that low level lead exposure does not pose a health risk. The literature reviewed by this commenter is cursory and very selective, and only literature supportive of the commenter's perspective was included in the comment. EPA has reviewed and evaluated all relevant literature. In the November 1985 proposal, the Agency cited the Ryu et al. (1983) study as being the appropriate study to determine the effects of low level lead exposure on blood levels in infants, the most vulnerable subpopulation. In addition, EPA has reviewed further studies, discussed above, which also support the conclusion that there are adverse health risks at low level exposure levels.

EPA agrees that lead exposure from air, dust, and paint are important. These exposures are being addressed by other agencies such as the Department of Housing and Urban Development, and within EPA by other offices such as the Office of Air and Radiation (OAR). The study by Morse, et al. (1979) concluded that increased concentrations (over source water levels) of lead in soft, acidic drinking water are transported by distribution pipes. While the authors concluded that they could determine no level of drinking water lead that would increase blood lead levels, the data base was too small to produce statistically valid results. In addition, the average blood lead level in both the control group and the case group of children six years old and younger both exceeded 15 ug/dl. The blood lead levels of the one- and two-year-olds was >20 μg/dl. When blood lead levels are high, the relationship between blood lead and water lead appears to be relatively obscured by the higher body burden, in both the study and the control groups.

2. MCLG for Copper

EPA proposed an MCLG of 1.3 mg/l for copper in the November 1985 notice. As noted above, no new data that change the conclusions presented in that notice have become available since its publication. EPA is, therefore, reproposing an MCLG of 1.3 mg/l for copper.

The proposed MCLG of 1.3 mg/l for adults and children was based on a Lowest Observed Adverse Effect Level (LOAEL) of 5.3 mg/day from human clinical case studies in which 5.3 mg was the lowest acute oral dose at which gastrointestinal effects were seen (Chuttani et al., 1965). An uncertainty factor of two was applied, and daily consumption of 2 liters of water per day by an adult was assumed. Ten-day and longer exposure values were not derived because the data were inadequate.

Public Comments: Fourteen individuals and organizations commented on the MCLG proposed for copper in 1985. Several commenters agreed that it was reasonable to use short-term toxicity data as the basis for the proposed MCLG of 1.3 mg/l.

Several commenters thought that an MCLG for copper was unnecessary and that it would be more appropriate to issue a health advisory for the contaminant. The reasons included: (1) Inadequate adverse health effects data, (2) limited occurrence of copper in drinking water, and (3) the fact that copper is present in drinking water due to corrosion of copper pipes; thus, treatment at the water supply plant would not solve the problem of elevated copper concentrations.

EPA Response: EPA does not agree that there are inadequate health effects data for regulating copper. The data indicate that copper is a health risk at levels above 1.3 mg/l in water (although it is beneficial at lower levels); acute exposure to copper has resulted in gastrointestinal effects, such as nausea and diarrhea, as discussed in the 1985 proposal and above. EPA agrees that copper is not commonly found above the proposed MCLG, but high levels of copper have occasionally been detected in drinking water supplies across the country, and high levels of copper can leach from pipes in areas with corrosive water. Thus, EPA believes an MCLG and NPDWR are justified to protect against adverse health effects. In addition, Congress listed copper as one of 83 drinking water contaminants mandated for regulation in the 1986 amendments to the SDWA. Since EPA did not substitute another contaminant in place of copper (as authorized by section 1412(b)(2) of the SDWA), it remains on the list of 83 contaminants for which EPA must promulgate an MCLG and NPDWR.

IV. National Primary Drinking Water Regulations for Lead and Copper

A. Occurrence

1. Occurrence of Lead and Copper in Source Water and Distributed Water

a. *Lead.* There are several national surveys of lead occurrence in water leaving the treatment plant and entering the distribution system (distributed water). Well water drawn for drinking water generally has very low lead concentrations. In a national drinking water survey of nearly 1000 randomly chosen groundwater supplies completed in 1987 (the National Inorganics and Radionuclides Survey or NIRS), about 5 percent of the drinking water samples collected from fully flushed taps exceeded 0.005 mg/l of lead (EPA, 1988g). However, recent samples taken to determine the effect of the measurement point on estimates of lead in distributed water indicate that lead as a by-product of corrosion may enter fully flushed tap samples and be attributed erroneously to source water. Therefore, EPA resampled the supplies in NIRS that showed positive results for lead. EPA found very few samples above 0.005 mg/l of lead when the sampling point was moved to the entry point to the distribution system. Based on these new data, EPA estimates that approximately 90% groundwater

suppliers (or 1 percent of the community and non-transient, non-community water systems) may have water leaving the treatment plant that has greater than 0.005 mg/l lead (EPA 1988a).

A significant portion of the total lead present in surface waters exists as part of the suspended solids. This portion comes from natural soil lead augmented by atmospheric deposition and discharges by industrial and municipal discharges to surface water. The level of lead in water drawn from rivers and streams is slightly lower than the concentration found in groundwater. Eighty-six percent of the raw surface water samples analyzed by Fishman and Hems (1976) contained less than 0.010 mg/l of lead and less than 1 percent contained over 0.050 mg/l. However, the concentration of lead in distributed water from these sources may be much lower due to removal by treatment, e.g., sedimentation, prior to distribution.

The National Organic Monitoring Survey (NOMS, 1976) also provided data on the quality of fully flushed water from surface water supplies. The level of lead in the samples in this survey ranged from 1–10 μg/l.

Based on this information, EPA estimates that about 99 percent of the 219 million people in the United States using public water supplies (both surface and groundwater sources) are exposed to distributed water levels between 0 and 0.005 mg/l, and that about 2 million people are served by distributed water with levels of lead greater than 0.005 mg/l.

b. *Copper.* Copper levels above the proposed MCLG are rarely found in raw drinking water supplies or in distributed water. In the NIRS study (EPA, 1988g), which surveyed 983 randomly selected groundwater supplies, 85 percent of all fully flushed tap samples had copper levels below 0.06 mg/l; and 98 percent of such samples had copper levels below 0.46 mg/l. Less than 1 percent of the samples had copper levels above 1.0 mg/l. The maximum value found was 2.37 mg/l. In the 1969 Community Water Supply Survey (CWSS), samples were taken from 678 groundwater supplies, 109 surface water supplies, and 182 supplies of unknown or mixed origin (a total of 969 systems). For the groundwater supplies, the maximum copper level found was 0.47 mg/l and the mean of the positive measurements (i.e., those exceeding the detection limit of 0.1 μg/l) was 0.075 mg/l. For the surface water supplies, the maximum copper value found was 0.304 mg/l, and the mean of the positive measurements was 0.066 mg/l. EPA estimates that only 66 water suppliers would need to install treatment to lower copper levels to the MCLG (EPA, 1988a).

2. Occurrence of Lead and Copper as By-Products of Corrosion

a. *Lead.* Even when water leaving the water treatment plant is relatively lead-free, pipes, solder, and fixtures containing lead are corroded by water resulting in contamination of the water. Lead present in plumbing materials can be mobilized, resulting in significantly higher levels at the user's tap than in the water leaving the treatment plant. Three factors are particularly important in determining the degree of corrosion. First, the combination of copper pipes with solder containing lead found in most households can result in elevated lead levels due to galvanic corrosion. Galvanic corrosion is especially important in the case of newly-installed solder, which is particularly reactive. Therefore, people living in housing with lead-soldered plumbing less than five years old are at risk of having high levels of lead in drinking water. Second, the corrosivity of the water towards lead is a major factor influencing the occurrence of lead as a corrosion by-product. Third, regardless of age, water that has been in contact with lead pipe or solder for a period of time will contain higher lead levels than flushed water from the same pipe.

While the critical factors affecting lead levels in drinking water are well recognized, there are not sufficient quantitative data available to determine the national distribution of lead levels in drinking water at the tap in much detail. EPA has some morning first draw data, but these data were not collected in a systematic fashion and are therefore not nationally representative of lead levels at the tap. For example, of the 40 individual cities which collected and provided data to EPA, some targeted new housing or other high risk taps while others took random samples. In addition, certain geographic areas are severely under-represented. These data portray lead levels in cities with several water types, including both waters considered very corrosive towards lead and those considered to be relatively noncorrosive. Thus, these data are most useful for assessing the lead levels likely to occur under specific water quality conditions and with different plumbing materials. These systems have frequently measured levels of lead in morning first draw samples as high as 1–2 mg/l. A detailed presentation and analysis of these data appears in the Treatment and Occurrence Support Document (EPA, 1988h).

As described earlier, in the Patterson (1981) study, random daytime grab samples flushed for 30 seconds were collected and analyzed for lead. Flushing for 30 seconds will tend to result in samples with lower lead levels compared with levels that might be found in morning first draw samples and random daytime grab samples, because of the lower average standing time, tend to be lower also. The Patterson data are useful because of the large number of samples taken (782 samples), and because the geographic distribution of the samples was representative of the country (58 cities in 47 States were sampled). The percentage of samples collected from each State generally reflects the State population, except for California, which was slightly under-represented, and Illinois, which was somewhat over-represented. In the study, 60 percent of all samples were less than or equal to 0.010 mg/l, 84 percent were less than 0.020 mg/l, 97 percent were less than 0.050 mg/l, and 3 percent werer greater than or equal to 0.050 mg/l. (Information on lead levels below 0.010 mg/l are not available from this study, as the reported analytic detection limit was 0.010 mg/l.)

Because lead in tap water occurs primarily as a by-product of corrosion, the extent of moderately or highly corrosive water can give an indication of the potential extent of lead in tap water. The extent of corrosive water in the U.S. has been evaluated in several studies. The U.S. Geological Survey (USGS) (Durfor and Becker, 1964, as reported by EPA, 1986a) found that 17 States had very soft (corrosive) water (less than 60 mg/l as $CaCO_3$). The first National Health and Nutrition Examination Survey (NHANES I) was conducted by the National Center of Health Statistics (Greathouse and Osborne, 1980, as reported by EPA, 1986a). It showed similar results: about one-third of the country had very soft water (under 60 mg/l as $CaCO_3$). The American Water Works Association (AWWA) has estimated that about 66 percent of public water systems deliver water with pH<8 and/or carbonate alkalinity <30 mg/l (EPA, 1988a). Also, data reported by public water supplies to the States pursuant to 40 CFR § 141.42(d) indicate that as many as 80 percent of public water systems may deliver moderately or highly corrosive water, as indicated by pH <8 and/or alkalinity <30 mg/l (EPA, 1988i).

As explained above, lead levels in tap water can be particularly high when lead solder is less than five years old, due to galvanic action between lead solder and copper pipes (Oliphant, 1982 and 1983). A recent study by EPA (1986a) estimated the extent of housing

likely to contain lead solder particularly susceptible to galvanic corrosion by estimating the number of new houses in the U.S. Based on the number of new housing starts in 1983 and 1984, EPA estimated in 1986 that there were about 3.5 million new housing units less than 2 years old. About 8.1 million people were estimated to live in new homes served by public water supplies. Using the same method, the Agency now estimates that about 4.3 million homes are three to five years old and they house about 11 million poeple served by public water supplies.

b. *Copper.* Patterson (EPA, 1981) also measured copper levels in the 30-second partially flushed samples taken at random times during the day. In that study, 3 percent of the samples had copper levels exceeding 1 mg/l and 19 percent exceeded 0.2 mg/l. The national average was 0.221 mg/l (median=0.04 mg/l). The south central U.S. had the lowest average levels (average=0.82; median=0.02 mg/l), and the northeast had the highest average levels (average=0.526 mg/l; median=0.06 mg/l).

B. Regulatory Approach

In developing a regulatory approach for controlling lead and copper in drinking water, EPA was confronted with several problems. As described in the previous section, lead and copper differ in a very basic way from other drinking water contaminants because they generally do not occur in significant amounts in source water; rather, they generally enter the water in the distribution system from the corrosive action of the water in contact with plumbing materials containing lead and copper. Thus, the traditional regulatory approach, which is based on removing drinking water contaminants at the treatment plant prior to distribution, will have little or no effect on lead and copper levels at the consumer's tap (except for systems with lead and/or copper in their source water). Second, much of the lead- and copper-bearing plumbing material is privately owned (i.e., inside of buildings) and outside the public water system's control, which, in turn, restricts the regulatory options available, since national primary drinking water regulations only apply to public water systems.

Third, the occurrence of lead and copper contamination emanating from corrosion of plumbing systems within individual residences and other buildings introduces a wide source of potential variability among lead and copper levels that will be present in water samples taken at the tap. This problem makes it difficult for EPA to set uniform numbers, i.e., MCLs, for these contaminants that can be met at taps throughout a public water system.

Today's notice proposes a two-part approach to address the two sources of lead and copper in drinking water (corrosion of plumbing in the distribution system and source water contamination): A treatment technique requiring corrosion control to reduce leaching of lead and copper and public education to reduce exposure, and MCLs applicable to water entering the distribution system. This section explains EPA's rationale for this approach.

1. Treatment Technique Considerations

As explained earlier, the Safe Drinking Water Act, as amended in 1986, requires EPA to promulgate NPDWRs for 83 contaminants including lead and copper. Section 1412(b)(1). The Act does not distinguish between the two very different ways in which contaminants can enter drinking water: As by-products of corrosion versus occurrence in source water. The Act states that an NPDWR must contain an MCL or a treatment technique, and that EPA is authorized to promulgate a treatment technique in lieu of an MCL if it finds that it is not "economically or technologically feasible to ascertain the level of the contaminant." Sections 1401(1)(C) and 1412(b)(7)(A).

In developing the proposed regulation, EPA considered whether it was feasible to adequately monitor drinking water for the parameters of concern. Although it is feasible to measure accurately the amount of lead in a given water sample down to the practical quantitation limit (PQL), 0.005 mg/l (as described below), and copper down to the MCLG, these measurements alone bear little relation to the major issue of concern—the rate and extent of corrosion of lead and copper from plumbing materials.

As explained earlier, there can be considerable variability in lead and copper levels at the tap; even under constant water conditions (e.g., pH, alkalinity, temperature, and other parameters), there will be variability depending on the age and configuration of the building's plumbing. In addition, because water suppliers begin with different source waters, after corrosion control treatment to achieve particular levels of specified water quality parameters (e.g., pH = 8) lead and copper levels can still vary (assuming there is at least some of each of these metals in the plumbing system).

Generally, application of an effective treatment technology to remove contaminants will result in predictable contaminant levels in the finished water. Thus, measuring these levels will indicate whether treatment was effectively applied. For instance, application of reverse osmosis treatment to influent water with lead and copper levels in a specified range will reliably reduce the amount of lead and copper to certain levels; thus, measuring the effluent lead and copper levels will indicate whether the treatment was effective. In contrast, a single measurement of the lead or copper level at an individual tap is not a meaningful measure of the efficacy of any corrosion control treatment that is being applied because lead and copper levels at the tap can vary for reasons other than treatment effectivness. Since the resulting lead and copper levels will vary from system to system (and even from tap to tap within a system) after corrosion control treatment is applied, it is technologically infeasible to ascertain whether the lead or copper level at a tap at a single point in time represents effective application of the best available treatment technology, assuming BAT is optimal corrosion control treatment. The only way to tell whether a given system has optimized corrosion control treatment is to determine which specific water conditions, such as pH level, result in the lowest lead or copper levels for that system.

In conclusion, because of the variability of the occurrence of lead and copper within and among water systems, the Agency is unable to select a single level of lead or copper in drinking water that indicates whether a system has implemented optimal corrosion control treatment. Unfortunately, there is no known reliable index or measure of water corrosivity towards lead and copper plumbing materials either. Therefore, EPA is proposing treatment technique requirements to control lead and copper as corrosion by-products.

2. Problems with Setting an MCL at the Tap

EPA considered whether it could set MCLs at the tap for lead and copper that were based on optimal corrosion control treatment, as well as removal of lead and copper from source water at the treatment plant. Under section 1412(b)(4) of the Act, the MCL must be set as close to the MCLG as feasible. "Feasible" means "feasible with the use of the best technology, treatment techniques and other means which the administrator finds * * * are available (taking cost into consideration)" (BAT). Section 1412(b)(5). Thus, in setting MCLs for lead and copper based on optimal

corrosion control treatment, EPA would have to determine what levels of these contaminants are "feasible" to achieve using this technology. In considering what levels are feasible to achieve, EPA must consider the range of conditions a public water system faces. Some customers may have plumbing containing only small amounts of lead and copper (so leaching is less likely), while others may have plumbing that contains large amounts of lead, possibly as new lead solder (so leaching is more likely).

In determining what is feasible, EPA also must consider the extent of the public water system's responsibility under the Safe Drinking Water Act for contaminant levels at the tap, especially for contaminants entering the water from the distribution system after any treatment, i.e., corrosion by-products. Under section 1411, NPDWRs apply to "public water systems." Section 1401(4) defines "public water system" as:

> A system for the provision to the public of piped water for human consumption * * *. Such term includes (A) any collection, treatment, storage, and distribution facilities under control of the operator of such system * * * and (B) any collection or pretreatment storage facilities not under such control * * *.

It is important to note that this definition clearly distinguishes between facilities under the system's control and facilities that are not. Furthermore, the term "public water system" specifically includes "distribution facilities under control of the operator of such system"; yet "distribution facilities" are not listed among the facilities *not* under the system's control that are nonetheless included in the definition of public water system. Thus, it appears that while Congress included distribution systems within the public water system's control, it deliberately excluded distribution facilities not under the system's control, e.g., customers' plumbing, from the definition of "public water system." EPA believes this provision precludes the Agency from promulgating an NPDWR that holds a public water system liable for conditions in the parts of the distribution system that are outside its control. This is a reasonable interpretation since the public water system does not generally have control over these facilities and thus should not be held responsible for them.

Because the public water system is not responsible for distribution facilities outside its control, the question arises as to what MCLs based on corrosion control are feasible for lead and copper given that the standard must take into account the range of conditions occurring in these facilities, i.e., in customers' plumbing. In other words, in setting MCLs for lead and copper based on optimal corrosion control treatment (and any necessary technology to remove lead and/or copper in the source water), EPA would have to select levels that are feasible for large public water systems to meet, regardless of the type and age of the plumbing in its customers' homes; any more stringent MCL would hold the system liable for a violation caused by distribution facilities outside its control, which would be inconsistent with the Act's definition of public water system.

In reviewing the data available, it appears that any MCL for lead at the tap that would be feasible, i.e., achievable by systems that have installed the best available technology (assuming BAT consists of some technology that removes any lead in the source water and optimal corrosion control treatment), regardless of the condition of its customers' plumbing, would be relatively high, perhaps a maximum of 0.030–0.040 mg/l in single samples of morning first draw water, or an average of 0.015–0.020 mg/l in morning first draw samples. EPA believes these levels represent unnecessarily high exposures for large segments of the population.

It has been suggested that, rather than selecting an MCL that systems could meet regardless of homeowner plumbing, EPA should set a more stringent MCL and make variances available for systems that cannot meet it because of homeowner plumbing. Under section 1415 of the Act, variances are available to systems which cannot meet an MCL "because of characteristics of the raw water sources which are reasonably available to the systems." EPA believes Congress intended that variances should be available when levels of the regulated contaminant were so high in the source water that BAT could not remove sufficient quantities to meet the MCL, or when some other characteristic of the source water prevented the best available technology from achieving the MCL. In the case of corrosion by-products such as lead and copper, any exceedence of an MCL at the tap after application of BAT (assuming it consists of technology to remove these contaminants in the source water and installation of optimal corrosion control treatment) would not be the result of extraordinary levels of the contaminant in the source water. Rather, the exceedence would be due to the addition of lead and/or copper from leaching of materials in the distribution system including plumbing in individual houses. This rules out the first basis for the variance, i.e., levels too high for effective removal by BAT. Arguably, however, a system could get a variance on the second basis, i.e., because the nature of its raw water source is such that, even after installation of BAT (assuming BAT consists of a technology to remove any lead and/or copper in the source water and optimal corrosion control treatment), the system could not meet the MCL. At least three problems arise with this approach, however.

The first problem is that variances are temporary in nature; section 1415 assumes eventual compliance with the standard when a variance is granted. This section specifically requires that every variance be accompanied by a schedule for coming into compliance; this schedule must require compliance "as expeditiously as practicable." However, it is likely that, in cases where the MCL violation is a result of corrosion of private plumbing, there will not be sufficient measures that a public water system can take unilaterally to achieve compliance. Thus, no reasonable compliance plan (much less a schedule for implementing it) could be devised. The second problem is that many, if not all, systems would require variances because at least a few, if not many, buildings served by them are likely to have lead and/or copper plumbing that are not under the water supplier's control. The Agency does not believe it makes sense to promulgate an MCL that many systems not only cannot meet now, but also could not meet at some future time. Furthermore, the Act requires that an MCL must be feasible. In determining what is feasible, the legislative history of both the Safe Drinking Water Act of 1974 and the 1986 amendments indicates that EPA is to consider whether the technology is reasonably affordable by regional and large metropolitan public water systems (see H.R. Rep. No. 93–1185, p. 18 (1974) and statement of Senator Durenberger, 132, *Cong. Rec.* S6287 (daily ed., May 12, 1986)). Large systems are not less likely than smaller systems to serve homes with lead and/or copper plumbing; in fact, they are probably more likely to serve at least some such homes since they serve so many customers. EPA believes that an MCL that most large systems (as well as many small systems) cannot meet when they install BAT is not feasible under the Act. The third problem is that a system qualifies for a variance under section 1415 only if operation under the variance will not result in an unreasonable risk to health. Assuming there is some lead level(s) and some copper level(s) which represent an unreasonable risk to health, then any system exceeding these

levels would not qualify for a variance. Thus, the systems that "need" the variance the most (i.e., those least capable of meeting the MCL because they are the furthest from compliance) would not qualify for it.

Despite these considerations, some interested parties nonetheless have indicated that they believe MCLs at the tap are appropriate for regulating lead and copper. EPA solicits comments on the details of such a regulation, including suggestions on overcoming the difficulties associated with an MCL approach that are described above. Specifically, commenters should specify the appropriate MCL and the basis for selecting this value, what monitoring requirements should apply (e.g., whether the NPDWR should allow systems to avoid monitoring at residences with high lead and/or copper content in their household plumbing), and whether systems that have installed BAT and still cannot meet the MCL because of private plumbing should be considered permanently out of compliance (and thus subject indefinitely to public notification requirements and citizen suit enforcement actions to compel compliance).

3. MCLs Applicable to Water Entering the Distribution System

While EPA recognizes that most of the lead and copper found in drinking water from the tap is added by plumbing after the water leaves the treatment plant, as described above, in an estimated one percent of the systems, lead and/or copper may occur at high levels in the source water. Therefore, EPA evaluted the feasibility of establishing MCLs for lead and copper in distributed water, i.e., MCLs that would apply, and for which compliance could be monitored as the water enters the distribution system, after any treatment. Such MCLs would not be subject to the problems associated with establishing MCLs to control contributions of lead and copper due to corrosion and monitoring for compliance with such MCLs. These MCLs would reduce total lead and copper levels by removing these contaminants when they occur in source water.

4. Summary of Proposed Regulatory Approach

In conclusion, most of the lead and copper found in drinking water at the tap is added by plumbing after the water leaves the treatment plant. In a few systems, lead and/or copper may occur at high levels in the source water. Therefore, the most important step a public water system can take to control lead and copper levels at the tap is to install optimal corrosion control treatment. However, it is technically infeasible to set MCLs at the tap for these contaminants because no single lead or copper measurement, or any other water parameter, indicates whether treatment was effectively applied, i.e., corrosion control treatment has been optimized. Consequently, in this rule, EPA is proposing an NPDWR consisting of a treatment technique requirement that would require optimal corrosion control treatment. In addition, this MPDWR would require public education when lead levels exceed certain values even after optimal corrosion control treatment.

In addition, the Agency is proposing MCLs for lead and copper that would apply to water leaving the drinking water treatment plant (if the water is treated) and entering the distribution system. By limiting lead and copper in distributed water, this proposal would result in contaminant levels closer to the MCLGs than would be possible with the treatment technique rule alone. Together, these three NPDWRs (one for lead and copper as corrosion by-products, one for lead in source water, and one for copper in source water) would address the contamination of drinking water by lead and copper.

Today's proposal would fulfill the goal of the SDWA by requiring an important reduction in the levels of lead and copper present in consumers' water. EPA believes the resulting lead and copper levels would be as close to the MCLG as is feasible. In addition, EPA believes that these proposed NPDWRs (establishing "no-action levels" of an average lead level of 0.010 mg/l lead, 1.3 mg/l or less copper in 95 percent or more samples, and pH >8 in 95 percent or more samples to trigger treatment, and a no-action level of an average of 0.010 mg/l lead and 0.020 mg/l or less lead in 95 percent or more samples to trigger public education) would be protective of public health. The Agency expects that implementation of this proposal would result in large reductions in the number of people who experience blood lead levels above the range of concern of 10–15 ug/dl, and above 25 ug/dl, the level above which CDC recommends medical intervention. Section X.A of this notice presents estimates of the benefits associated with the proposal.

C. Treatment for Lead and Copper in Source Water

EPA evaluated technologies for treatment of lead and copper in source water to determine which are BAT. Table 1 summarizes the technologies identified by EPA for the removal of these drinking water contaminants. Table 2 lists the removal efficiencies that are attainable through the use of the identified technologies. Examination of these technologies indicates that they are capable of reducing contaminant levels from the maximum levels of occurrence in source water to the proposed MCLG for copper and down to 0.005 mg/l for lead. Table 3 shows the removal efficiencies that would be required of treatment technologies to reduce the maximum expected influent concentrations down to 1.3 mg/l for copper and 0.005 mg/l for lead (listed as "MCL-Effluent Concentration" in the table. The influent concentrations assumed correspond to maximum observed occurrence levels in drinking water sources.

TABLE 1.—CANDIDATE BEST AVAILABLE TECHNOLOGIES (BATS) FOR THE REMOVAL OF LEAD AND COPPER FROM DRINKING WATER SUPPLIES

Contaminant	Technologies			
	Coagulation/ Filtration	Ion exchange	Lime softening	Reverse osmosis
Lead	X	X	X	X
Copper	X	X	X	X

TABLE 2.—REMOVAL EFFICIENCIES OF CANDIDATE BATS[1,2]

[in percent]

Contaminant	Technologies (percent removal)			
	Coagulation/Filtration	Ion exchange	Lime softening	Reverse osmosis
Lead	80–99	up to 95	97–99	90–99
Copper	60–95	up to 95	90–96	90–99

[1] *Source:* "Technologies and Costs for the Removal of lead from Potable Water Supplies." Office of Drinking Water, October 23, 1984. Revised Final Draft.
[2] *Source:* "Technologies and Costs for the Removal of Copper from Potable Water Supplies." Office of Drinking Water, June 15, 1985. First Draft.

TABLE 3.—REMOVAL EFFICIENCIES NECESSARY TO ACHIEVE SPECIFIED EFFLUENT CONCENTRATIONS

Contaminant	Occurrence-influent concentration	MCL—effluent concentration	Percent removal required to achieve Proposed MCL
Lead	0.100 mg/l	0.005 mg/l	95
Copper	10 mg/l	1.3 mg/l	87

The costs for the removal of these contaminants, assuming the same influent and effluent levels cited in Table 3, using various technologies, are summarized in Tables 4, 5, 6, and 7. The general assumptions used to develop the treatment costs include: Late 1986 chemical costs, capital costs amortized over 20 years at a 10 percent interest rate, late 1986 engineering fees, contractor overhead and profit, and late 1986 power and fuel costs and labor rates.

TABLE 4.—SAMPLE ESTIMATED COSTS OF REMOVAL OF CONTAMINANTS FROM SOURCE WATER BY VARIOUS TECHNOLOGIES INCLUDING WASTE DISPOSAL COST [1]

[cents/1,000 gallons, 1986 dollars]

Contaminant/technology	Population served				
	25–100	500–1000	1001–3300	3301–10,000	>1,000,000
Lead					
Ion exchange	270	100	74	69	32
Reverse osmosis	620	320	260	220	160
Lime softening		230	140	180	68
Coagulation/Filtration		160	91	90	24
Copper					
Ion exchange	250	94	67	60	30
Reverse osmosis	540	300	230	190	140
Lime softening		43	21	9	1
Coagulation/Filtration		160	90	82	23

[1] Costs derived from: "Cost Supplement to Technologies and Costs for the Removal of Lead from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; "Cost Supplement to Technologies and Costs for the Removal of Copper from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; and "Technologies and Costs for the Treatment and Disposal of Waste By-Products from Water Treatments for the Removal of Inorganic and Radioactive Contaminants." ODW. Sept. 23, 1986. Revised Draft.

TABLE 5.—SAMPLE ESTIMATED CAPITAL COSTS FOR REMOVAL OF LEAD AND COPPER [1] BY VARIOUS TECHNOLOGIES FOR SELECTED SYSTEM SIZE CATEGORIES

[millions 1986 dollars]

Contaminant/technology	Population served		
	25–100	3300–10,000	>1,000,000
Lead			
Ion exchange	0.09	1.4	170
Reverse osmosis	0.13	4.8	1,140
Lime softening		1.4	310
Coagulation/Filtration	0.17	3.0	380
Copper			
Ion exchange	0.09	1.3	160
Reverse osmosis	0.11	3.4	1,060
Lime softening		0.23	1.3
Coagulation/Filtration	0.20	2.3	340

[1] Costs derived from: "Cost Supplement to Technologies and Costs for the Removal of Lead from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; "Cost Supplement to Technologies and Costs for the Removal of Copper from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; and "Technologies and Costs for the Treatment and Disposal of Waste By-Products from Water Treatments for the Removal of Inorganic and Radioactive Contaminants." ODW. Sept. 23, 1986. Revised Draft.

TABLE 6.—SAMPLE ESTIMATED ANNUAL INCREASE IN HOUSEHOLD WATER BILLS DUE TO APPLICATION OF BATS FOR REMOVAL OF LEAD AND COPPER REMOVAL [1] FOR SELECTED SYSTEM SIZE CATEGORIES

[dollars household/yr; 1986 dollars]

Contaminant/technology	Population served		
	25–100	3,300–10,000	>1,000,000
Lead:			
Ion exchange	270	69	32
Reverse osmosis	620	220	160
Lime softening	.....	180	68
Coagulation/Filtration	.....	12	2
Copper:			
Ion exchange	250	60	30
Reverse osmosis	540	190	140
Lime softening	.....	9	1
Coagulation/Filtration	.....	82	23

[1] Cost derived from: "Cost Supplement to Technologies and Costs for the Removal of Lead from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; "Cost Supplement to Technologies and Costs for the Removal of Copper from Potable Water Supplies." ODW. Jan. 19, 1987. First Draft; and "Technologies and Costs for the Treatment and Disposal of Waste By-Products from Water Treatments for the Removal of Inorganic and Radioactive Contaminants." ODW. Sept. 23, 1986. Revised Draft.

TABLE 7.—WASTE BY-PRODUCT DISPOSAL COSTS FOR PUBLIC WATER SYSTEMS—ALTERNATIVES WITH LOWEST COST [1]

[cents/1,000 gallons drinking water produced; 1986 dollars]

Contaminant/Technology	Population	25–100	101–500	501–1000	1001–3300	3301–10K	1,000,000
	Flow (MGD)	0.013	0.004	0.1333	0.40	1.30	650
Sludges:							
Lime softening							
Dewatering and land disposal [2]	550	240	120	80	60	40	
Land application	1200	380	150	80	50	60	
Coagulation/filtration							
Sanitary sewer discharge							
—Copper	190	62	28	15	5	1	
—Lead	160	48	22	10	4	0	
Dewatering and land disposal [2]	300	120	55	30	20	7	
Brines:							
Ion exchange							
Discharge to POTW [3]	100	71	45	25	12	2	
Reverse osmosis							
Direct discharge	85	42	20	11	5	0	
Discharge to POTW	220	150	90	47	27	10	

[1] Draft, "Technologies and Cost for the Treatment and Disposal of Waste By-products from Water Treatments for the Removal of Inorganic and Radioactive Contaminants." ODW. Sept. 23, 1986. Revised Draft.
[2] Dewatering by nonmechanical methods, e.g., lagoons and drying beds.
[3] Publicly owned treatment works.

Costs for individual plants may vary from those shown, depending on local circumstances. However, based on available information, the costs in Tables 4–7 are representative of typical system costs using these technologies. Two different models have been used to calculate the costs in Tables 4–7. A small system cost model has been used for systems that serve less than 3,300 people. This model assumes that a package treatment plant would be installed to treat the water. The model used for systems serving more than 3,300 people assumes that the treatment plant would be built in the field.

Costs of treatment will be less than shown in Tables 4, 5, 6, and 7 if contaminant concentration levels encountered in the raw water are lower than the maximum occurrence levels used for the supporting calculations. EPA expects this to be the case in most instances. For example, if the contaminant level in the raw water is half of the maximum occurrence level, then treatment costs could be expected to be approximately 20 to 50 percent lower than the costs presented. However, costs of treatment could be higher if, for instance, there are additional site-specific treatment or storage requirements. The various removal technologies considered are described in more detail below.

1. Ion Exchange

This notice proposes to designate sodium cation exchange to remove lead and copper as BAT because of its demonstrated ability to reduce levels of lead and copper to 0.005 mg/l for lead and to the proposed MCLG for copper, at reasonable costs. Sodium cation exchange resins and ion exchange equipment are readily available commercially. Sodium cation exchange has been successfully used in the field, and pilot plant studies demonstrate that this technology can be used to remove up to 95 percent of lead and up to 95 percent of copper from water. Ion exchange treatment can be implemented effectively for all sizes of treatment facilities. The cost of employing ion exchange for removal of lead and copper in drinking water has been estimated for source water lead concentrations of 0.100 mg/l and source water copper concentrations of 10 mg/l and are included in Tables 4, 5, 6, and 7. Blending can significantly reduce ion exchange equipment requirements and

operating costs, since then only a portion of the raw water has to be treated. Ion exchange is adversely affected by the presence of turbidity, iron, and organic contaminants. Pretreatment may therefore be necessary in some cases. Also, ion exchange can soften water, making it more corrosive, especially if calcium breakthrough is used as the indicator for resin regeneration.

2. Reverse Osmosis

EPA also is proposing to designate reverse osmosis (RO) technology as BAT because it has been demonstrated to be effective in removing lead and copper at reasonable costs. RO has been widely used on a full scale basis for the reduction of other contaminants, and pilot plant studies demonstrate that this technology is capable of removing 95 percent of lead (when source water lead is 0.100 mg/l) and 95 percent of copper (when source water copper is 10 mg/l) from drinking water. The costs of employing RO to reduce these contaminants from these levels in drinking water are presented in Tables 4, 5, 6, and 7. A major disadvantage of RO is that in removing dissolved solids from water, and thereby softening it, RO makes the water more corrosive toward lead and copper in plumbing. Thus, source water treated by this process would require subsequent corrosion control treatment to raise pH and stabilize the water before distribution.

RO performance is adversely affected by the presence of turbidity, iron, manganese, silica, or scale-producing constituents in source water. If pretreatment is not already in place to remove these constituents, the cost to install the pretreatment technologies (e.g., pH adjustment, filtration, application of scale prevention additives) may be considerable.

In the case of contamination of source water by several contaminants, in addition to lead and/or copper, the RO process may offer an especially desirable and cost effective approach to their removal. Blending can reduce costs, as only a portion of the water may need to be treated.

3. Lime Softening

Lime softening can achieve 97 to 99 percent removal of lead at pH levels of 9.0 to 10.5 and 90 to 96 percent removal of copper at pH levels of 9.0 to 11.5, as indicated by laboratory and pilot plant studies. This technology is considered BAT because it has been demonstrated to reduce lead and copper in water to 0.005 mg/l for lead and the proposed MCLG for copper at reasonable costs. Lime softening has been widely and effectively used on a full scale basis for the reduction of hardness. The costs of installing new lime softening facilities to reduce contaminant concentrations in drinking water from 0.10 mg/l to 0.005 mg/l for lead and 10 mg/l the MCLG for copper are shown in Tables 4, 5, 6, and 7. One advantage of lime softening is that it increases the pH of the water and thus reduces its corrosivity.

4. Coagulation/Filtration

EPA is proposing coagulation/filtration technology as BAT for lead and copper removal because of its demonstrated ability to reduce levels of lead and copper to the proposed MCLG for copper and 0.005 mg/l for lead at reasonable costs.

Laboratory and pilot plant studies indicate that conventional coagulation/filtration using alum, and in some cases, ferric sulfate coagulant, can achieve 80 to 95 percent removal of lead at pH levels of 8.0 or above, and can achieve 60 to 95 percent removal of copper at these same pHs. Removal efficiencies are estimated based on source water lead levels of 0.10 mg/l and copper of 10 mg/l. Published studies (EPA, 1978) suggest that site-specific raw water quality indicators, such as pH, significantly affect the removal efficiency of alum when used to treat ground water. However, data are not available which specifically identify all optimum operating conditions of coagulation/filtration treatment for lead and copper removal.

Coagulation/filtration is very effective when ferric sulfate is used as the coagulant. In pilot-scale studies, greater than 95 percent removals have been achieved using this coagulant. When alum is used as the coagulant in doses above 20 mg/l, removal efficiencies of 95 percent have been achieved in surface water. For ground water, either much larger alum doses or pH adjustment is required to achieve 95 percent removal of lead. Coagulation/filtration has been used on a full scale basis for the reduction of other contaminants in water, including turbidity, particulate matter, and microbial contaminants (EPA, 1978). Estimated costs to reduce lead and copper using conventional coagulation/filtration are shown in Tables 4, 5, 6, and 7.

5. Selection of BAT

In conclusion, the Agency believes that, of the technologies that can remove lead and copper from source water, ion exchange, reverse osmosis, lime softening, and coagulation/filtration fulfill the requirements of the SDWA as BAT for lead and copper in source water. These treatment technologies have high efficiencies for lead and copper removal from source water, and the cost of these technologies for large public water systems is reasonable. Under the Act, other treatment technologies could be used to remove lead or copper. However, a system would be required to install one of the BATs in order to be eligible for a variance from the MCL.

All of the technologies proposed as BAT are currently available, have been installed in public water systems, and are compatible with other water treatment processes in different regions of the U.S. Furthermore, these technologies are available and effective for the reduction of these contaminants from the maximum levels of occurrence in source water to 0.005 mg/l for lead and to the proposed MCLG level for copper (1.3 mg/l).

D. Treatment for Lead and Copper as Corrosion By-products

1. Corrosion Control

All water is corrosive to metallic plumbing materials to some degree; the relative corrosivity of a given water supply depends on a variety of factors. There is no single corrosivity index that can predict water corrosivity to lead and copper, and the water of each water supplier may be minimally corrosive to these metals under slightly different finished water quality conditions.

The degree of water corrosivity toward lead and copper plumbing materials depends largely on the pH and alkalinity of the water, although a number of additional factors, such as temperature, flow rate, free chlorine levels, age of plumbing materials, and other factors are important as well. While the use of specific plumbing materials in buildings is not under the control of water suppliers, water chemistry parameters are. Therefore, adjustment of water quality parameters, especially pH and alkalinity, to minimally corrosive ranges and addition of corrosion inhibitors are the primary methods of corrosion control treatment available to public water systems to minimize lead and copper levels.

The corrosivity of acidic water toward lead plumbing materials is well documented (EPA, 1982; Hoyt et al., 1979; O'Brien et al., 1976; Lyon and Lenihan, 1977; Gregory and Jackson, 1984). Water with pH below 8.0, and especially below 7.0, tends to be more corrosive toward lead and copper than water with pH greater than 8.0, and more corrosive water tends to produce water samples with higher lead and copper levels.

The alkalinity of water, which is related to pH, is also an important factor in determining its corrosivity and, in turn, its likelihood of producing high lead and copper levels at the tap. Water contains alkalinity in several forms, including carbonate ion, bicarbonate ion, and hydroxyl ion, in equilibrium. The pH of the water largely determines which of these species predominates in the equilibrium. At pHs less than 8.3, equilibrium favors the bicarbonate form. At pHs between 8.3 and 10, equilibrium tends toward the carbonate form, and pHs above 10 favor hydroxyl.

Under certain chemical conditions (especially high pH), the carbonate in water will react with lead in the plumbing to form a film of basic lead carbonate or other relatively insoluble salt on the interior surface of the pipes and solder. This film isolates the lead metal from the water and thus slows the rate at which lead from the pipes or solder is dissolved into the water. Carbonate also limits the amount of lead the water will hold in solution.

Depending on the raw water quality, treating the water to minimize its corrosivity may require the adjustment of pH and alkalinity, individually or simultaneously. Experience in field and laboratory studies indicates that stabilization of the water can reduce corrosion and reduce levels of lead substantially (EPA, 1982; Karalekas et al., 1983; Karalekas et al., 1978; EPA, 1988h). In addition, the presence of carbonate is an important factor in stabilizing the pH of the water because it adds buffering capacity. Without the buffering capacity imparted by the carbonate water pH can decrease as it moves through the distribution system.

There are also other methods for a water supplier to reduce the corrosivity of its water. These include the use of corrosion inhibitors, such as orthophosphates, and the adjustment of free chlorine levels (EPA, 1987c). Sodium hexametaphosphate has also been used as a corrosion inhibitor, as have other chemicals, although they may not be as effective as orthophosphates.

The rate of copper corrosion is also dependent on pH. However, alkalinity appears to be a less important factor than in copper corrosion than lead corrosion. Corrosion of copper pipe is rapidly accelerated at pHs below 5.0; morning first draw samples at pHs less than 5.5 will likely exceed 1.0 mg/l. The copper concentrations will increase with decreasing pH, increasing temperature, and decreasing age of copper pipe. As pH is increased to 8.0 and above, the rate of copper corrosion is reduced. The chemical behavior of copper and lead are similar so that most treatments (such as pH and alkalinity adjustment) to lower the solubility of lead will have a similar effect on copper. For instance, the pH level for effective lead corrosion control is 8.0 or greater, and this is also an appropriate pH for control of copper corrosion. Therefore, EPA has determined that properly applied corrosion control for lead will also adequately control copper concentrations (AWWARF, 1985).

a. *Methods of pH Adjustment.* Adjustment of pH is one of the most common methods of reducing corrosion in water distribution systems. In many instances, if sufficient alkalinity is present, pH adjustment is adequate to control the corrosivity of water.

The least expensive and most commonly used chemical for pH adjustment is sodium hydroxide (NaOH, or caustic soda); potassium hydroxide may also be used in water with high sodium levels. Lime (especially in the form of calcium carbonate slurry) addition is also used commonly for pH adjustment. Experience in field, pilot plant, and laboratory tests indicates that a substantial reduction of lead and copper in drinking water may be achieved by pH adjustment. Estimated costs for pH adjustment using sodium hydroxide to control corrosion of lead and copper range from $0.67/1,000 gallons for systems serving less than 100 persons to $0.03/1,000 gallons for systems serving more than 1,000,000 persons. Estimated costs for pH adjustment using lime to control corrosion of lead and copper range from $0.85/1,000 gallons for systems serving fewer than 100 persons to $0.006/1,000 gallons for systems serving more than 1,000,000 persons (EPA, 1988h).

The Metropolitan Regional Water Authority (MRWA), which supplies water to Boston, Massachusetts, and surrounding communities, has implemented corrosion control by pH adjustment. (The MRWA used to be called the Metropolitan District Commission, or MDC.) The raw water is low in hardness, alkalinity, total dissolved solids, and pH. Prior to the start of corrosion control, treatment consisted of chlorination and ammoniation only.

The treatment program implemented by MRWA consists of adding 14 mg/l of caustic (50 percent NaOH) to treat 300 million gallons/day (MGD). The pH of the finished water is increased to 8.5 at the reservoir after treatment but before distribution. The alkalinity of the finished water is only slightly increased as a result of this treatment.

Samples were collected in from twelve to fourteen homes served by MRWA over a period of five years. The homes selected for the sampling program have lead service lines. Three samples were taken at each location representing first draw water (i.e., water in the interior plumbing), water from the service line, and water in the main (i.e., fully flushed water). The goal of the program was to reduce most samples to less than 0.050 mg/l. Since the sampling program began before the implementation of the corrosion control treatment, the effectiveness of this treatment toward its goal can be evaluated.

The results of this analysis have been published (Karalekas et al., 1983). In this article, the data from the fourteen locations were evaluated differently from the approach EPA is proposing in this rule for determining compliance. However, the effectiveness of the treatment in reducing lead levels can still be evaluated from the data. In this article, the results of all three samples from all locations sampled were averaged. The average lead concentration ranged from 0.060 mg/l to 0.128 mg/l between February 1976 and May 1977, before the use of NaOH to adjust pH began. The average lead concentration dropped substantially after the start of this treatment; except during two interruptions in the pH adjustment treatment, the average lead concentration was reduced consistently to below 0.050 mg/l (ranging from 0.010 mg/l to 0.050 mg/l), MRWA's target lead concentration.

In addition, the City of Seattle, Washington, has adjusted the pH of its Cedar River supply in an effort to control corrosion (EPA, 1988h). The treatment program implemented by Seattle in 1983 consists of adding 2 mg/l of lime as CaO to adjust the pH from 7.5 to 8.2. The total alkalinity in the raw water varies seasonally from 16.3 mg/l to 23 mg/l as $CaCO_3$.

Sampling to determine the extent of the problem began in 1979 and is still ongoing. Two samples are taken at each location. The first sample is a standing sample (not morning first draw) and the second sample is a flushed sample. The mean lead concentration for the Cedar River supply standing samples dropped from 0.0103 mg/l to 0.0038 mg/l after treatment. The percentage of standing samples with lead concentrations less than 0.010 mg/l rose from only 50 percent before treatment of 93.8 percent after treatment.

These data demonstrate that adjustment of pH can effectively reduce the corrosivity of water towards lead in interior plumbing and can greatly reduce the levels of lead in tap water.

b. *Methods of Alkalinity Adjustment.* For waters that are low in carbonate or bicarbonate alkalinity, pH adjustment alone is often insufficient to control corrosion because there are insufficient carbonate ions in the water to form a protective layer on the interior surface of the pipes or lead solder. In those low alkalinity waters, carbonate ion must be added to form the insoluble carbonates. Soda ash (Na_2CO_3) or sodium bicarbonate ($NaHCO_3$) is typically added for this purpose.

Lime (calcium oxide slurry) or sodium hydroxide, in conjunction with soda ash (sodium carbonate) and sodium bicarbonate, may be used together to adjust pH and carbonate alkalinity simultaneously. These methods are cost-effective and are practiced by many water suppliers already. Estimated costs for treating the water using these chemicals range from $1.49/1,000 gallons for systems serving 25 to 100 persons to $0.08/1,000 gallons for systems serving more than 1,000,000 persons (EPA, 1988h).

A program to control corrosion combining pH and alkalinity adjustment was implemented by the City of Bennington, Vermont, on its water supply in August 1977. The treatment program consists of adding 3 mg/l of sodium hydroxide to adjust the pH from 5.0 to 7.2 and 10 mg/l of sodium bicarbonate to adjust the alkalinity from less than 1 mg/l to 15 mg/l as $CaCO_3$. The goal of the program was to reduce average lead levels to less than 0.050 mg/l. Samples were collected periodically from nine to eleven homes from April 1977 to November 1980. Three samples were taken at each location, representing first draw water (i.e., water in the interior plumbing), water in the service line, and water in the main (i.e., fully flushed water). The mean lead concentration for the first flush samples was reduced from 0.101 mg/l to 0.0342 mg/l as a result of the treatment. The mean lead concentration in the service line samples was reduced from 0.184 mg/l to 0.0302 mg/l and the mean lead concentration in the fully flushed samples was reduced from 0.102 mg/l to 0.0167 mg/l as a result of this treatment. In addition, the number of samples with lead concentrations less than 0.010 mg/l increased as a result of the corrosion control treatment. While only 2.6 percent of the first flush samples contained less than 0.010 mg/l lead before treatment, after treatment was implemented, 20.9 percent of the first flush samples contained less than 0.010 mg/l lead (EPA, 1988h).

In 1983, the City of Seattle, Washington began adjusting pH and alkalinity of its Tolt River supply. The treatment program consists of adding 2 mg/l of lime as CaO to adjust the pH from 6.2 to 8.2 and 9 mg/l of sodium carbonate as Na_2CO_3 to adjust the total alkalinity from 4 to 12 mg/l as $CaCO_3$.

The study of the Tolt River supply was conducted at the same time as the study on Seattle's Cedar River supply, and the sampling procedure was the same as described in the discussion of the Cedar water supply above. The mean lead concentration for the standing samples from the Tolt River supply dropped from 0.0102 mg/l before treatment to 0.0041 mg/l after treatment. The percentage of standing samples with lead concentrations less than 0.010 mg/l increased as a result of treatment from 50 to 90.3 percent (EPA, 1988h).

These data show that increasing pH and alkalinity within appropriate concentration limits can effectively reduce the corrosivity of water towards lead in interior plumbing and greatly reduce the levels of lead in tap water.

c. *Corrosion Inhibitors.* Corrosion inhibitors control corrosion by accelerating or enhancing the formation of a protective film to serve as a barrier between the water and the pipe or solder surfaces. The most commonly used corrosion inhibitors include orthophosphates and silicates (although silicates may be more effective for reducing corrosion of iron or galvanized pipe than lead and copper pipe and solder). Recent data indicate that zinc orthophosphate may be the most effective corrosion inhibitor for lead pipe and solder (AWWARF, 1985).

Corrosion inhibitors have been used for years to reduce water corrosion by all sizes of water systems. Estimated costs for controlling corrosion with inhibitors range from $0.91/1,000 gallons for systems serving less than 100 persons to $0.007/1.000 gallons for systems serving more than 1,000,000 persons (EPA, 1988h).

d. *Consideration of Disinfection Needs in Designing Corrosion Control Treatment.* Use of corrosion inhibitors or adjusting the pH and alkalinity of water to reduce its corrosiveness toward lead and copper can have unintended effects on the quality of finished water. Water treatment should be carefully designed to account for the following circumstances.

Adjustment of pH can affect the effectiveness of disinfectants. For instance, if systems use chlorination for disinfection, elevation of pH should be delayed, to the extent possible, until just prior to when the water enters the distribution system. This will maximize the contact time during which disinfection with chlorine is most efficient (since chlorination is most effective at low pHs) while also optimizing corrosion control in the distribution system.

Since elevated pHs may increase trihalomethane (THM) formation in the distribution system, systems using surface water sources should assure maximum THM precursor removal by optimizing the clarification process prior to increasing the pH. Systems using groundwater sources with high concentrations of THM precursors may need to install treatment to remove such precursors (e.g., membrane filtration) or use alternative disinfectants to free chlorine (e.g., chlorine dioxide or ozone followed by chloramines) in order to achieve adequate disinfection, minimize THM formation, and control corrosion at the same time. In certain cases, THM formation and the need to remove THM precursors may be reduced if orthophosphates or another corrosion inhibitor is used, as these chemicals work best at pHs somewhat below 8.

e. *Materials Benefits of Corrosion Control Treatment.* EPA recently published an analysis of the benefits of reducing lead levels in drinking water (EPA, 1986a). This analysis included an estimate of the materials benefits (in terms of reduced pipe corrosion and failure, increased service life for water meters, etc.) that are likely to result from requiring water suppliers to install corrosion control treatment. The report estimated that the materials benefits alone of corrosion control would exceed by more than two times the costs of implementing the treatment.

Further, a National Bureau of Standards report estimated that 20 percent of the costs of reported damage from water supply corrosion costs were avoidable by the use of control measures (Bennett et al., 1979). The national annual costs of damage from corrosion in the water supply field were estimated at $700 million in 1975 (or $1,300 million in 1986 dollars). However, these costs are only for distribution systems; often far greater corrosion costs are incurred through damage to interior piping and plumbing systems within buildings (Ryder, 1980). Corrosion control by suppliers would reduce these damages as well.

2. Lead Service Connection Replacement

EPA evaluated requiring the replacement of lead service, lines, goosenecks, and other lead distribution system piping to control lead in drinking water. The Agency has estimated that there are approximately 4.4 million lead service lines in use in the U.S. and that

about 25 percent of all public water suppliers have at least some lead service lines. The number of lead service lines as a percentage of total service lines in any community with lead services varies from one percent to 80 percent (Chin and Karalekas, 1984). While most cities stopped installing lead services after about 1940, at least one large city (Chicago) continue to require their use until late 1986.

Lead service lines can contribute significantly to lead levels in tap water, especially where water is corrosive. In Karalekas et al. (1976), for example, lead levels in samples from lead service lines (called "early morning samples" in this study) averaged 0.104 mg/1 as compared to morning first draw levels (called "standing samples") in those same homes which averaged 0.053 mg/1. Similarly, Pocock (1980) and the U.K. Department of the environment (1982) found an elevation in lead levels in morning first draw samples in homes without interior lead plumbing but with lead service lines (called "communication pipe" in Pocock); these first draw levels were lower than in homes with interior lead plumbing and higher than in homes without any lead pipes (either as interior plumbing or as service lines). Because lead service lines can raise lead levels at the tap, and for reasons related to system operation and maintenance (e.g., to avoid anticipated pipe failures), several communities around the United States have already begun programs to replace lead service lines.

The studies cited above as well as unpublished data from two other cities (see Tables 8 and 9) indicate that not all houses with lead service lines have high lead levels at the tap, expecially where water is relatively non-corrosive. The reasons for this vary. One possible explanation is that over time an insoluble protective coating can build up on the interior surface of the lead pipe, preventing (or reducing) the leaching of lead into the water. The buildup of this film is subject to conditions that can vary from house to house including the age of the plumbing, the occurrence of physical disturbances such as the ground freezing or nearby road repair, fluctuations in pH or water pressure, and the length and diameter of the lead pipe. Another possible explanation is that the samples taken in some of these studies may not have fully captured the contribution from the lead service line, e.g., if morning first draw samples, rather than service line samples, were taken (morning first draw samples are not a reliable predictor of the contribution from the service line). This can be seen in the Karalekas, et al. (1976) data cited above: the service line samples, which were intended to capture the effect of the lead pipes on tap water, showed the highest lead levels. In the Pocock (1980) data as well, the presence of lead service lines raised the morning first draw lead levels only slightly. Given the available data, EPA cannot currently quantify, on a national basis, the contributions of lead service lines and other lead connections to lead levels at the tap, or the anticipated change in lead levels after corrosion control treatment is in place. EPA solicits data to help clarify this issue.

TABLE 8.—AVERAGE LEAD CONCENTRATION FOR LEAD VS NON-LEAD SERVICE LINES [1, 2]

City	Pipe type	pH	Alk [3]	Morning first draw average (Pb in μg/l)	Service line average (Pb in μg/l)	Fully flushed average (Pb in μg/l)	Number of sampes	Vol.
Chicago	Lead	8.3	109	13	15	8	201	500
	Iron	8.3	109	3		<3	73	500
Louisville	Lead	8.6		8	5	3	34	250
	Copper	8.4		9	3	2	12	250
St. Louis	Lead	9.0	50	<1	<1	<1	2	1,000
	Copper	9.0	50	4	3	<1	9	1,000

[1] Source: EPA, 1988*h*.
[2] Values are for reported sample sizes.
[3] Alk = alkalinity in mg/l as $CaCO_3$.

TABLE 9.—RANGE OF LEAD CONCENTRATION FOR LEAD VS. NON-LEAD SERVICE LINES [1, 2]

City	Pipe type	pH	Alk [3]	Morning first draw average (Pb in μg/l)	Service line average (Pb in μg/l)	Fully flushed average (Pb in μg/l)	Number of samples	Vol.
Chicago	Lead	8.3	109	<3–85	<3–127	<3–44	201	500
	Iron	8.3	109	<3–6		<3	73	500
Louisville	Lead	8.6		ND–29	ND–15	ND–15	34	250
	Copper	8.4		ND–19	ND–7	ND–5	12	250
St. Louis	Lead	9.0	50	<1	<1	<1	2	1,000
	Copper	9.0	50	<1–13	1–10	<1	9	1,000

[1] Source: EPA, 1988*h*.
[2] Values are for reported sample sizes.
[3] Alk = alkalinity in mg/l as $CaCO_3$.

A further complication of the pipe replacement issue is that ownership and/or control of the service line often is split between the public water system and the property owner. Depending on State law or regulations or local ordinances, some public water systems own and/or control service lines and other connections up to the property line, others own and/or control the service line and other connections up to the building (especially if the water meter is located inside the building), and still others own and/or control the service line and other connections only up to the curb. (See Figure 1 for a schematic drawing of the parts of the water supply and distribution system.)

EPA believes that, in general, its authority to require replacement of service lines and other connections ends where the water supplier ownership or control of the lines end. EPA has conducted a limited study of some large

cities, which indicates that these water suppliers generally limit maintenance on water pipes to those portions they own (EPA 1987d). However, several cities have authority to enter private property to perform work on water lines under special circumstances (EPA 1988j); in such cases, the property owner is generally billed for the work performed.

Several cities currently conduct programs to accelerate the replacement of portions of the lead services and goosenecks under their control. San Francisco, CA, began a program in the early 1960's, and replaces approximately 11,500 linear feet of service line per year at an average cost of $40 per linear foot. The service line from the water main to the water meter is replaced with polybutylene, copper, or ductile iron, depending on line diameter. New Haven, CT, has replaced all lead and galvanized steel service lines (from the water main to the meter) and began accelerated replacement of lead gooseneck connections in 1976–77. New Haven has replaced 15,000 of an original 30,000 lead goosenecks to date, at a rate of about 1,000 per year. Akron, OH began replacing lead and galvanized steel service lines from the water main to the curb in 1964, and has replaced about 1,000 service lines per year since then. In all of these cases, the service line replacement was funded by operating revenues paid by the customers. Washington, DC has a program under which they city will replace its portion of lead service lines provided that the building owner replaces his or her portion.

While many studies indicate that lead service connections can contribute to tap water levels of lead, EPA currently has no data to quantify the extent of reductions in lead levels that might be achievable by partial replacement (i.e., by replacing only that portion under the ownership and/or control of the PWS). One study (Britton and Richards, 1980) found temporary increases in lead levels at the tap following the replacement of part of a lead service line with copper piping. As the authors noted, this probably resulted from the dislodgement of the protective coating on the inside of the pipe, possibly aggravated by the application of new lead solder to connect the new pipe, and the occurrence of galvanic corrosion related to the introduction of a dissimilar metal. Because EPA does not have the authority to require the replacement of lead service lines owned and controlled by private property owners, the Agency is concerned that a requirement to replace lead service lines would result in only partial replacement of many such lines. EPA solicits any available data on the effect of partial and full lead service line replacement programs on lead levels at the tap. EPA also solicits information on the extent of the authority of public water systems over lead service lines and connections under State law and local ordinances.

3. Public Education About Lead in Drinking Water

EPA has conducted public education programs and has found that well designed and implemented programs can be an effective means of reducing public exposures to environmental hazards. Public education programs have effectively changed the knowledge and/or behavior of their audiences. Examples of such programs are the State and EPA radon programs and programs to educate residents near Superfund sites about the degree of hazard presented by improperly disposed chemicals at these sites.

Since 1986 EPA has sponsored a major program to educate the public about the dangers of exposure to radon. Many elements of this program have actually been carried out by State and local governments. The program has included monitoring of homes and other buildings for radon in the air, and development and testing of innovative exposure reduction methods, including both prevention and removal techniques. Information has been conveyed throughout the community through an ongoing program of pamphlets, public service announcements, television specials, public meetings, and other means. As a result of this program, many people have become aware of the effects of exposure to radon on health and have taken steps to determine their exposure and protect themselves.

A second successful public education program deals with health risks associated with specific hazardous waste disposal sites under CERCLA (Superfund). Federal, State, and local governments, together with private parties, provide intensive information to people living or working near hazardous waste sites. Using the methods discussed above, affected persons have learned about the nature of the dangers they may face and have learned appropriate steps to reduce their current and possible future exposures to contaminants at these hazardous waste sites.

All public education programs have two basic elements: the content of the program and the method of delivering the information.

a. *Content of the Program.* An effective public education program for lead in drinking water includes information about:

(a) The health reasons for concern about lead exposure, including identification of sensitive subpopulations;

(b) Sources of lead exposure (including non-drinking water sources) and a plan to identify the sources of specific problems in individual houses that are identified as having lead levels above a maximum value;

(c) Means of reducing lead exposure from drinking water, including tap flushing and suggestions for modifying water use patterns to conserve water given the benefits of flushing.

b. *Conveyance of Message.* The effectiveness of public education programs varies depending upon how the message is conveyed to the community in general and to key groups in the community. For example, bill enclosures, public service announcements, pubilic meetings, and messages on water bills will vary in effectiveness since they present the message in different ways and to different consumers.

Identification of key groups in the community can be important in improving the effectiveness of public education programs in reducing exposure to lead by targeting them for more intensive public education efforts. Key groups can include residence in areas identified as at risk for high lead levels in drinking water or houses that actually have been tested and found to have high lead levels; schools and other buildings that have a high proportion of children in their population; and institutions that may serve a high proportion of pregnant women.

Finally, the frequency and duration of the various aspects of a public education program can influence its success.

4. Selection of Treatment Technique Requirements for Controlling Corrosion By-Products

In the above discussion, EPA has reviewed three potential methods of reducing lead and copper as corrosion by-products in drinking water: Corrosion control treatment, pipe replacement, and public education. Based on its evaluation of the available information, EPA considers corrosion control and public education to be effective and feasible methods of reducing lead and copper as corrosion by-products in drinking water. Thus, they are both included as requirements of the proposed rule. Lead service line replacement was also considered. EPA believes that in many cases replacement

of lead service lines and connections may reduce the lead levels in tap water. However, there may be temporary risks associated with partial pipe replacement. Because of these potential risks, as well as uncertainty about the effectiveness of partial or complete service line replacement as a final control step after implementation of corrosion control treatment, EPA is not proposing service line replacement as BAT for controlling lead as a corrosion by-product in drinking water. However, as explained below, EPA is requesting comment and data on this subject and is considering adopting pipe replacement as a requirement of the final rule.

E. Proposed Regulation

EPA is proposing an MCL for lead in distributed water of 0.005 mg/1 and an MCL for copper in distributed water of 1.3 mg/1. Compliance would be measured at the entry point to the distribution system.

The Agency is also proposing a treatment technique requirement to control lead and copper which enters water as corrosion by-products. The proposed treatment technique consists of optimal corrosion control treatment to minimize lead corrosion, and public education. It would be triggered by three "no-action" levels, as measured in targeted samples: an average lead concentration in targeted samples of less than or equal to 0.010 mg/1, a copper concentration of 1.3 mg/1 or less in at least 95 percent of the targeted samples, and pH greater than or equal to 8.0 in at least 95 percent of the targeted samples. If all three levels are met, "no action" would be required; the PWS would be deemed in compliance with the treatment technique. If any of these three levels is not met by a system, the system would be required to install or improve its corrosion control treatment. In addition, if the average lead level of 0.010 mg/1 or a fourth "no-action" lead level of 0.020 mg/1 or less (in at least 95 percent of the targeted samples taken for compliance) was exceeded, the PWS would be required to conduct a public education program to encourage consumers to reduce their exposures to lead in drinking water.

The Agency is seeking comment on six major alternatives which are permutations of this proposal. First, EPA is considering treating the fourth no-action level, 0.020 mg/1 or less of lead in at least 95 percent of the targeted samples, the same as the first three no-action levels. Thus, a system that did not meet this fourth no-action level would be required to install or improve its corrosion control treatment. The second alternative would add an additional "no-action level" of total alkalinity greater than or equal to 30 mg/1 in 95 percent of more samples to trigger treatment. As in the first alternative, a system that did not meet this no-action level would be required to install or improve corrosion control treatment. The third alternative would eliminate the pH no-action level and rely only on lead levels measured at the tap to determine whether corrosion control treatment is required. Under the fourth alternative EPA is considering, a system would be required to replace lead service lines and connections that were found to contribute 0.005 mg/1 lead or more to lead levels in tap water even after installation of optimal corrosion control treatment. The fifth alternative under consideration is a two-tier approach to monitoring which could increase the efficiency of sampling and accuracy of determinations regarding whether additional corrosion control treatment was required. This alternative may also reduce the number of samples required of larger public water systems. A sixth alternative EPA is considering would eliminate the MCLs for lead and copper in distributed water.

This section and the following section on monitoring describe each part of the proposal and these alternatives, and explains the rationale for selecting the proposed rule provisions and for considering each alternative. EPA requests comment on the proposal itself, as well as the alternatives. In response to the public comments, EPA may promulgate any of these alternative options or any combination of these options. Persons should, accordingly, comment fully on all these options.

In its July 8, 1987 (52 FR 12876) notice promulgating NPDWRs for eight VOCs, EPA added a definition of a non-transient non-community (NTNC) water system to the general definitions section in 40 CFR §141.2. The definition of a non-transient non-community water system is as follows:

> a "non-transient non-community water system" means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over six months per year.

In that rulemaking, EPA applied the NPDWRs for the VOCs to these NTNC water systems. EPA also stated in that notice its intent to apply future drinking water standards to NTNC water systems. Accordingly, EPA is proposing to apply the NPDWRs for lead and copper proposed in today's notice to NTNC water systems as well as to community water systems. EPA recognizes that some of the provisions of the proposed regulations would not easily apply to NTNC systems. Therefore, where appropriate, EPA is proposing modified provisions for NTNC water systems to better suit the special circumstances of the NTNC system. Unless otherwise noted, all requirements in this proposal would apply to community water systems and NTNC water suppliers in the same way.

1. Lead and Copper MCLs

Based on the analysis of treatment technologies in Section IV.B.3., above, and an assessment of the PQL in Section V.A., below, EPA is proposing an MCL of 0.005 mg/1 for lead in water as the water enters the distribution system. The treatment technologies proposed as BAT in Section IV.B.3., (i.e., ion exchange, reverse osmosis, lime softening, and coagulation/filtration) can reduce lead occurring in source water to 0.005 mg/1 at reasonable cost. Based on an analysis of the same treatment technologies, EPA proposes to set an MCL for copper in water entering the distribution system of 1.3 mg/1. The treatment technologies proposed as BAT in Section IV.B.3. are capable of reducing copper found in source water to this level at reasonable cost.

EPA considered making these MCLs applicable to fully flushed water at the tap, rather than to treated water entering the distribution system. However, EPA is concerned that distribution system and household plumbing materials might contribute to fully flushed lead levels at the tap as water moves through the pipes, and tap levels therefore may not reflect the effective application of treatment to reduce lead and copper occurring in source water. Although EPA has few data on such contributions, especially on contributions after application of the corrosion control treatment which would be required by this rule, the available data indicate that plumbing materials can contribute to lead and copper levels in fully flushed samples (EPA, 1988h).

Therefore, EPA is proposing to require that compliance with the MCLs for lead and copper be measured at the entry point(s) to the distribution system. Water suppliers with more than one well or entry point to the distribution system would be required to monitor at each entry point to ensure identification of all sources requiring treatment. Where several wells draw from the same aquifer, States would be allowed to identify wells representative of the aquifer for monitoring if there is no treatment; monitoring of the remaining wells would not be required. States would also be allowed to reduce the

total number of samples by the use of composite samples, described in Section V.C.1. below.

Measuring at the entry point to the distribution system would accurately reflect whether the treatment of the source water was effectively applied. While contributions to the lead and copper content of fully flushed water from plumbing materials in the distribution system may be small, even a contribution of 0.001 mg/l from corrosion could result in a violation of the lead MCL when in fact the source water has been treated to reduce lead levels in the source water to below the MCL. A larger contribution would be required for copper, but the same concern exists. EPA solicits comments on both the proposed approach and the alternative of requiring that the MCLs apply to fully flushed water at the consumer's tap.

To demonstrate compliance with the MCL for lead, water suppliers would be required to monitor lead in water entering the distribution system and maintain the lead level at or below 0.005 mg/l in all samples. To be in compliance with the MCL for copper, water suppliers would be required to monitor copper levels in water entering the distribution system and maintain the copper level at or below 1.3 mg/l in all samples. These requirements would apply to both community water systems and non-transient, non-community water systems. Monitoring would begin no later than the dates specified in Section V.C.1 (depending on system size).

It has been suggested that an MCL for contaminants entering the distribution system is a contradiction in terms because an MCL, by definition, is a standard that must be met at the tap. Proponents of this view argue that the SDWA, the legislative history of the Act, and EPA's own regulations support this interpretation.

The Safe Drinking Water Act defines an MCL as "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." Section 1401(3). It certainly could be argued that, under this definition, MCLs must be met in water that actually flows from the user's tap. Indeed, the House Report on the bill that eventually became the Safe Drinking Water Act of 1974 states that "[s]ince drinking water regulations are intended to be met at the consumer's tap, the committee anticipates that monitoring would include tap sampling." (H.R. Rep. No. 93–1185, p. 13, 1974). On the other hand, it could be argued that "water which is delivered to any user" refers to water that leaves the part of the distribution system that is owned or controlled by the public water system and enters the portion of the distribution system that is owned or controlled by the user, e.g., homeowner. This interpretation would be consistent with the definition of "public water system" in section 1401(4) of the Act which, as discussed earlier, does not include distribution facilities that are not owned or controlled by the public water system.

In determining where MCLs apply, EPA's regulations are not conclusive. In 40 CFR 141.2(c), EPA defines "maximum contaminant level" as:

> the maximum permissible level of a contaminant in water which is delivered to the free flowing outlet of the ultimate user of a public water system, except in the case of turbidity where the maximum permissible level is measured at the point of entry to the distribution system. Contaminants added to the water under circumstances controlled by the user, except those resulting from corrosion of piping and plumbing caused by water quality, are excluded from this definition.

The "free flowing outlet of the ultimate consumer of a public water system" apparently refers to the user's tap. Under this interpretation, all MCLs, except the MCL for turbidity, apply at the tap. However, many of the NPDWRs the Agency has promulgated appear inconsistent with this definition because they do not require monitoring, and therefore compliance, at the user's tap. For instance, the NPDWR for coliform bacteria requires that "samples * * * be taken at points which are representative of the conditions within the distribution system." 40 CFR 141.21(a). While this provision does not preclude sampling at the consumer's tap, it does not require it. Some NPDWRs actually preclude compliance monitoring at the tap. For instance, in 40 CFR 141.24(g)(1), the NPDWRs for VOCs that EPA promulgated in 1987 state that "[g]round water systems shall sample at points of entry to the distribution system representative of each well." Also, the NPDWR for fluoride requires sampling at the entry points to the distribution system. 40 CFR 141.23(g)(1). Other NPDWRs are silent; for instance, most of the NPDWRs for inorganic contaminants (other than fluoride) do not specify the sampling (or compliance) point. See 40 CFR 141.23.

Of course, for contaminants other than corrosion byproducts, sampling at the tap is not critical since water leaving a treatment plant is generally expected to remain consistent in quality throughout the distribution system, including the portion owned or controlled by the consumer. In fact, for some contaminants, the level at the tap may even be lower than the level at the entry point to the distribution system because of dilution (e.g., mixing of sources) or volatilization of contaminants from water.

Thus, EPA's regulatory definition of MCL arguably is inconsistent with both the statutory definitions of "MCL" and "public water system" and the monitoring requirements for many current MCLs. EPA believes it is important to clarify that, for all contaminants regulated under the Safe Drinking Water Act, the point of compliance is defined by the monitoring requirements of each NPDWR. Therefore, in this notice, EPA is proposing to amend the definition of "maximum contaminant level" to match the statutory definition. Then, for each NPDWR that specifies an MCL, the Agency will specify the monitoring requirements, including the sampling locations, which will in turn define the point of compliance. In the case of the lead and copper MCLs, therefore, the sampling point and point of compliance would be the entry point to the distribution system. While these levels may not necessarily be the "maximum levels delivered to any user," because lead and/or copper levels will probably increase from corrosion within the distribution system, these MCLs, measured as specified in the proposed rule, (1) would indicate whether the treatment for lead and copper in source water was effective, and (2) assess the minimum lead and copper levels that can occur at the tap.

2. Treatment Requirement for Lead and Copper as Corrosion By-Products

The treatment technique required by this rule consists of optimal corrosion control treatment (to minimize lead and copper leaching) and public education (to reduce exposure to lead). Systems could comply with the treatment technique either by installing treatment and conducting a public education program, or by meeting specified "no-action levels" for parameters of concern. Thus, under this proposal, systems that meet specified levels for lead, copper, and pH, i.e., no-action levels, would be deemed in compliance with the treatment technique requirement and would not be required to install or improve treatment of their water. Systems that do not meet the no-action levels would be required to either improve or install corrosion control treatment adequate to meet the no-action levels or else demonstrate that they have optimized treatment, i.e., that the delivered water is minimally

corrosive towards lead. In addition, if one or both lead no-action levels are exceeded, the system would be required to conduct a public education program.

EPA is proposing no-action levels as a screen to limit the total number of public water systems which would need to make a detailed demonstration that they have optimized corrosion control treatment. These limits are called "no-action levels" because no further actions are required if they are met. Thus, under this proposal, a system that meets the no-action levels, i.e., 95 percent of samples at the tap with pH 8, lead levels at the tap of 0.010 mg/l or below as an average, and 95 percent of copper levels at the tap of 1.3 mg/l or below, would be considered to have minimally corrosive water and would be considered in compliance with the corrosion control portion of the treatment technique requirement. Such a system would not be required to perform a detailed demonstration that it had installed optimal corrosion control treatment. A system that meets the average of 0.010 mg/l of lead and 95 percent or more of its samples are less than or equal to 0.020 mg/l lead would be considered to be in compliance with the public education portion of the treatment technique requirement.

To determine whether it meets the no-action levels, the water system would first take morning first draw and service connection samples from kitchen taps in targeted residences as described in Section V.B.2. below. For systems serving more than 3,300 people, the first round of monitoring (four quarters) would be required to be completed during the 15 months after promulgation of the final rule. Water suppliers serving 500 to 3,300 people would have 27 months from promulgation to complete the initial monitoring. Systems serving fewer than 500 people would be required to complete the initial monitoring 39 months after promulgation of the final regulations. Non-transient non-community water systems would be required to complete their required monitoring according to this schedule, depending on the number of people served by the system. All other time deadlines are expressed in terms of time elapsed since the deadline for completion of the initial monitoring. These requirements are summarized in Figure 2. The remainder of this section describes these requirements in more detail.

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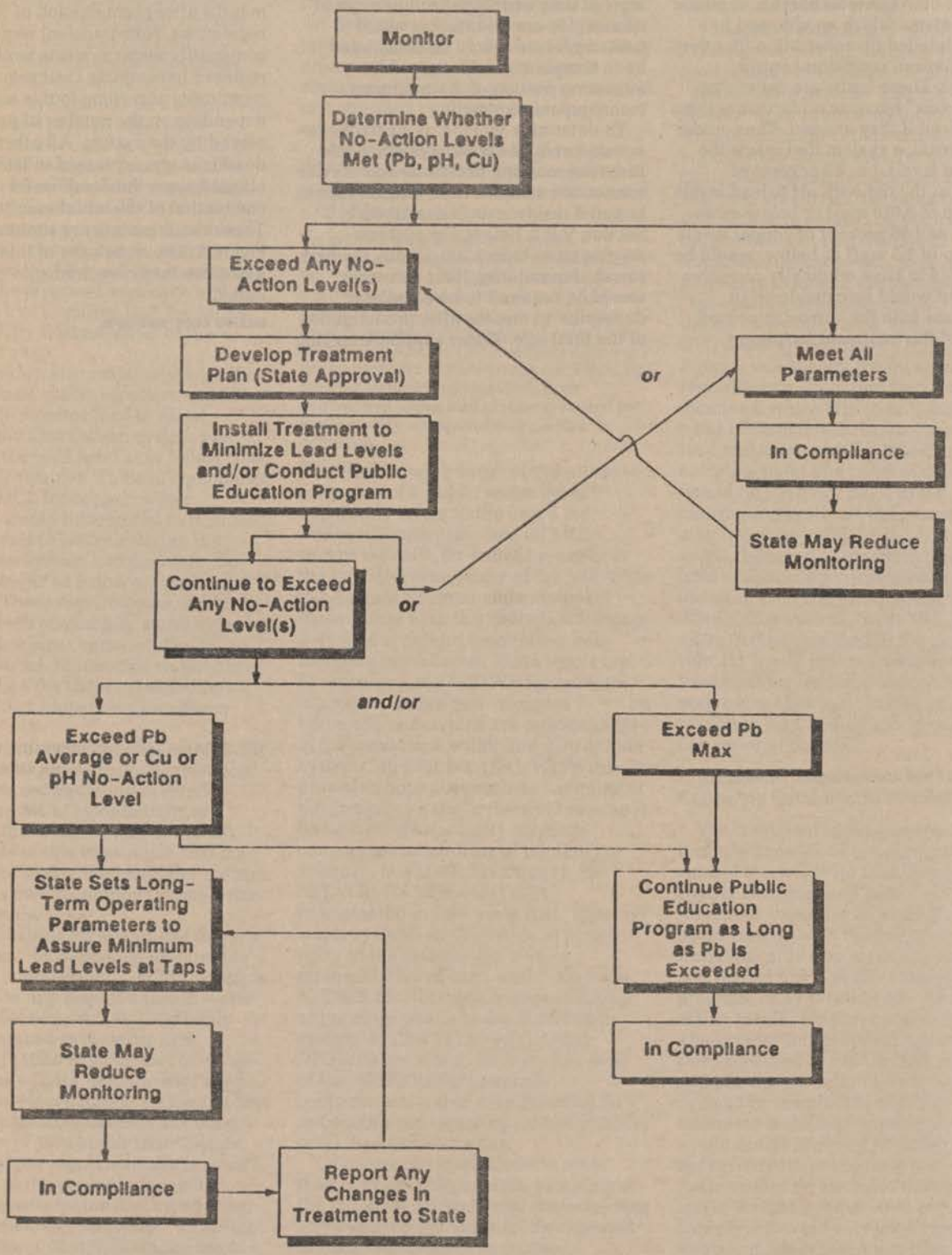
Figure 2

Treatment Technique Requirement



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Systems failing to meet the no-action levels by the deadline for completion of the initial monitoring would be required to install corrosion control treatment, and/or public education, depending on which of the no-action levels is exceeded. Corrosion control treatment and public education would be required to be implemented according to a State-approved or issued treatment plan. The treatment plan would contain specific steps that each water supplier would be required to take to ensure that either the no-action levels are met, or optimal corrosion control treatment and/or public education are implemented, on a specified schedule. All systems would be required to complete installation of any treatment required by the treatment plan within three years after approval of the plan.

Water systems serving 3,300 or more people and failing to meet anyone of the no-action levels would be required to apply for approval of a treatment plan by submitting a proposed treatment plan to the State within one year after the deadline for completion of the initial monitoring. These systems would required to include in their treatment plan the following steps: (1) Design and implementation of pipe loop, laboratory, pilot scale and/or field studies; (2) analysis of the data generated in these studies to estimate optimal operating conditions to minimize corrosion of lead; (3) installation of the treatment in the entire water supply system; (4) monitoring to evaluate the effectiveness of the treatment; (5) additional adjustment of the treatment if no-action levels continues to be exceeded; and (6) if, after installation and adjustment of treatment, any of the no-action levels continue to be exceeded, submission to the State of all data collected and an analysis demonstrating that the corrosion control treatment being applied was optimal, i.e., that lead levels were minimized.

The State would be required to review the system's analysis and determine whether treatment was optimal. Once the State determines that treatment is optimal, the State would also specify required operating parameters and values (such as pH, total alkalinity, or corrosion inhibitor dose rate or residual) to ensure that optimal treatment continues. These operating parameters may vary by season to account for seasonal variations in water corrosivity. States would be expected to periodically review and revise the specified operating parameters if long-term monitoring shows increasing average lead levels, or that different values for the specified parameters result in lower lead levels.

Water systems serving fewer than 3,300 people would be required to apply to the State for a treatment plan if any of the no-action levels is exceeded at the end of the initial monitoring period. Systems would be required to submit or apply for the plan within one year after the close of the initial monitoring period. States would specify the required corrosion control treatment in the treatment plans for these systems. The treatment plans would include a schedule for completion of Steps 3–6 described above for systems serving more than 3,300 persons. States would also specify final operating parameters for these systems after treatment is applied and follow-up monitoring conducted. EPA is proposing that States specify the appropriate treatment for these systems because most smaller systems are unlikely to have the resources and expertise necessary for determining what corrosion control treatment is appropriate. However, systems that wish to develop and submit their own treatment plan rather than request one from the State are encouraged to do so.

a. *Corrosion Control*—i. *No-Action Levels.*

As described above, if pH is 8.0 or greater (in 95 percent of targeted samples), lead levels in targeted samples have an arithmetic average of 0.010 mg/l or lower, the maximum lead level in 95 percent of targeted samples does not exceed 0.002 mg/l, and the copper levels in 95 percent of targeted samples does not exceed 1.3 mg/l, the system would be deemed in compliance with the treatment technique requirement and need not install or improve corrosion control treatment.

The value of 0.010 mg/l as an arithmetic average for lead levels is based on engineering considerations. EPA reviewed the available literature and data on lead levels in standing samples (water standing in the pipes 8–18 hours), compared with the various plumbing materials water quality factors (particularly pH and alkalinity) present. Analysis of these data indicates that, for those water suppliers having water with pH 8 and total alkalinity greater than 30 mg/l, even in the presence of some lead plumbing materials, average tap lead levels of 0.010 mg/l were achieved.

Systems with no lead problem or only a small lead problem (e.g., no lead service lines and few houses with new lead solder) would be able to meet the average of 0.010 mg/l relatively easily, especially if they meet the no-action level for pH. Some systems may have more difficulty consistently meeting the average. For example, as described above, Boston, MA and Bennington, VT have had serious lead problems in the past due to large numbers of lead service lines and residences with interior lead plumbing combined with water which was extremely corrosive before treatment, and thus have instituted corrosion control programs aimed at reducing lead to below 0.050 mg/l. Both raised their pH to above 8.0 at the treatment plant, and Bennington raised its raised their alkalinity some. Because alkalinity levels remain low, pH levels are not maintained throughout the system. Although both communities achieved substantial reductions in morning first draw lead levels, and met their own program goals of reducing tap lead levels below 0.050 mg/l, neither is meeting the 0.010 mg/l target as an average. However, the treatments developed for these cities may not be optimal for their water; additional reductions are likely to be possible.

The proposed treatment technique requirement would include a no-action level for copper equal to the MCLG, 1.3 mg/l, as a 95th percentile of the data in morning first draw water. This level is based on a review of the literature and data on copper levels in morning first draw samples. These data indicate that with good corrosion control, particularly pH adjustment, copper levels in morning first draw water can be consistently reduced to the MCLG or lower (EPA, 1988h).

ii. *Treatment Plan Requirements.* If a water supplier did not meet one or more no-action levels, it would be required to submit or apply for (depending on their size) a treatment plan. The plan would be designed to result in having the system meet the no-action levels or, if the system did not meet the pH and/or average lead level after applying optimal treatment, demonstrate that lead levels in tap water had been minimized. (The treatment plan would also include public education requirements if the average or maximum lead level is not met. This aspect of the treatment plan is discussed in a later section.) Systems must submit or apply for a treatment plan within one year after the end of the initial monitoring period showing that any no-action level has been missed.

The contents of the plan, including items such as specific schedules, studies, and installation of treatment, would become effective and enforceable upon approval or issuance of the plan by the State. Factors affecting the scope and detail necessary for successful optimization showings include: Local

water chemistry conditions, size and complexity of the distribution system, and the presence of other water treatments which can affect the design and effectiveness of potential corrosion control measures. Compliance would be determined based on whether a system had fulfilled each step of the approved plan on time and in a manner meeting minimum Federal and State criteria.

After the system has taken all the steps required by the plan, the State would evaluate the results and specify operating conditions for future compliance. The system would be required to operate in the manner specified by the State (either meeting the no-action levels or operating under other conditions approved by the State that minimize the corrosivity of the water towards lead) to remain in compliance in future monitoring periods. Failure to meet the no-action levels or demonstrate that treatment is optimal would be a violation of the treatment technique requirement. Systems that meet all the no-action levels during the initial monitoring period, but exceed one or more of them during a subsequent monitoring period, would have one year after their monitoring data showed an exceedance of any no-action level to either meet the no-action level or submit or apply for a treatment plan.

(A) *Large and Medium Size Systems.* Systems serving more than 3,300 persons would be required to submit a proposed plan which describes the system's approach to obtaining the information necessary to install or improve treatment sufficient to achieve the no-action levels or to demonstrate that corrosion control treatment has minimized lead levels at the tap due to corrosion. EPA expects that water suppliers facing situations more complicated than average, such as large systems, would need to perform more elaborate studies to determine optimal operating conditions. A simpler than average evaluation may suffice in cases where the choice of appropriate corrosion control is fairly obvious. The treatment plan for these systems would include the following specific steps and a schedule for completing each step:

Step 1: Pipe loop, laboratory, pilot scale studies, and/or field studies demonstrating reductions in lead and copper levels in actual or simulated standing samples corresponding to application of optimal corrosion control treatment.

To identify and demonstrate to the State that water is minimally corrosive towards lead or achieve the no-action levels, water suppliers would be required to conduct pipe loop, laboratory, pilot-scale, and/or field studies investigating the effects of changes in corrosion control treatment and corresponding changes in lead dissolution. These studies should include investigations of the effects of varying pH over the range of 8.0 to 10.0, and at several total alkalinity levels.

Those ground water systems with pH below 8.0 that are saturated or nearly saturated with $CaCO_3$, and that wish to continue operating in the pH range, should demonstrate in the laboratory that precipitation problems could occur if pH adjustment is implemented. If these bench-scale studies indicate that $CaCO_3$ would precipitate at elevated pH, then these systems should concentrate their optimization analysis on the use of corrosion inhibitors such as zinc orthophosphate.

In addition, systems which prefer to operate outside the required pH range because of other water treatment considerations (such as preference for using corrosion inhibitors, which function better at lower pH, e.g., pH <8.0, so formation of trihalomethanes and other disinfection by-products is less likely) also could apply for treatment plan approval. Systems that want to operate outside the minimum pH must also describe use of any corrosion inhibitors which provide optimum protection outside the preferred pH range, and show in pipe loop or other studies approved by the State in the treatment plan that lead levels under these conditions are higher than lead levels which result under the water supplier's preferred operating conditions. The supplier must test a range of corrosion inhibitor doses and sufficient alternative operating conditions to show that the lead levels cannot be lowered using other treatments such as alternative corrosion inhibitors.

If a pipe loop study is used to evaluate different treatments, then the pipes used for the study must be representative of the plumbing in the system that is causing the lead problem. Lead pipes would be required if lead service connections are used within the system. Lead-soldered copper joints must be used if the lead problem is the result of corrosion of these joints within the system. Because of differences in conditions between residences and pipe loops, the loops will generally not predict the precise treatment necessary and resultant lead levels for a system. However, they will accurately predict trends and provide data to plan a treatment strategy and to design and test pilot and field scale studies, as part of the treatment scale-up and adjustment.

Step 2: Analysis of the data generated in Step 1 above to identify water quality conditions under which lead levels in morning first draw and service connection samples (i.e., standing samples) are expected to be minimized.

The purpose of the studies conducted under the treatment plan is to identify water quality conditions under which corrosion of lead into tap water is minimized and to demonstrate that lead levels in water have been minimized under the operating conditions for which the water supplier seeks approval (if it cannot meet the no-action levels after installing or improving treatment). The results of the studies should clearly and unambiguously show the relationship between minimal water lead content and the proposed operating conditions. That is, data gathered under both the operating conditions identified by the water supplier as optimal and alternative conditions would be required. The State would evaluate the data to assure that the chosen conditions provide the lowest possible lead levels.

In conducting these studies, there may be a period before the full effect of the pH adjustment is expected to be realized. The system would analyze standing samples from the pipe loop or other experimental set up for lead during this period to assess the effectiveness of the pH adjustment. Those systems that do not meet the average lead level at any of the pHs within the specified range (i.e., 8–10) would then analyze the generated data to determine the optimum pH, i.e., the pH which results in the lowest lead levels. The system would then adjust the pH to the optimum pH and establish permanent operating levels for pH and any other parameters specified by the State.

For systems which choose to investigate corrosion inhibitors, lead levels resulting from a range of doses would be required, and would be compared with the results of studies using pH adjustment above.

Based on these analyses, a treatment strategy and estimated operating parameters for minimizing corrosivity of water in the whole system would be identified.

Step 3: Installation and operation of corrosion control treatment in the water system as a whole.

EPA anticipates that most of the overall demonstration of optimal treatment would be completed in the laboratory or in a pilot plant as part of Step 1. Only after a PWS has determined the general requirements for treatment would EPA expect it to apply

the treatment in the distribution system. EPA believes this sequential process is important to assure that protective coatings are not accidentally disturbed during the trials, and to allow systems to make cost-efficient decisions regarding treatment strategies and the installation of new equipment.

The system would be required to scale up its laboratory treatment to install it in the system as a whole within three years of approval of the treatment plan. The goal of the scale-up would be to identify full scale treatment that would achieve in the system as a whole the operating parameters identified in Step 2 above as likely optimal operating parameters, or to meet the no-action levels.

Step 4: Monitoring to determine the efficacy of the treatment as installed.

The treatment plan must require monitoring of the full-scale implementation of the operating conditions determined from the laboratory and pilot studies. Monitoring would be required at the same sites used to evaluate compliance with the no-action levels.

Systems adjusting pH (and alkalinity) may have a several-month stabilization period before the full effect of the corrosion control treatment is realized. The pH level will stabilize first, while lead levels may continue to fall as a film builds up on the inside of the pipes. Systems should sample at the targeted sites during this period to determine the effectiveness of the corrosion control treatment. This monitoring should show lead levels decreasing and stabilizing over time as the treatment takes effect. Once the system has stabilized, samples from the targeted sites would be analyzed for lead to demonstrate the effectiveness of the treatment at full scale.

Step 5: Adjustment of the installed treatment as necessary to ensure that lead levels are minimized.

Once the general treatment steps are determined and installed to treat the full system to meet the water quality parameters identified, EPA expects that most water suppliers would need to fine-tune the treatment to account for normal differences between laboratory or pilot plant designs and full scale operations. The installed treatment must also be adjusted for seasonal variations in water quality which can greatly affect the corrosivity of the water. Water suppliers must adjust the installed treatment as necessary to account for differences between projections based on laboratory or pilot plant data and full-scale operations by performing minor adjustments or pH or other parameters to try to reduce the lead levels.

If, upon implementation of the operating parameters identified by the system in the laboratory studies, a system meets the no-action levels for four consecutive quarters, then the system has adjusted its corrosion control treatment sufficiently and no further adjustment would be required.

Note that because tap water must meet the proposed no-action levels or be shown to be minimally corrosive towards lead, water suppliers would be required to adjust corrosion control treatment to account for any blending of water from different sources. There can be significant changes in water chemistry associated with blending. Therefore, suppliers must demonstrate that each blended product meets the requirements of the regulations. A related issue is that of the division of responsibility for treatment among wholesalers and retailers of water. Retailers may add or blend sources of water provided by several wholesalers. Therefore, EPA is proposing to place ultimate responsibility for the degree of corrosivity of the water on the retailers. EPA solicits comment on this approach and requests data to support any alternative approaches suggested.

Step 6: If any no-action levels are still exceeded after installing or improving treatment and making all adjustments, systems must submit to the State an analysis of all treatment and resulting lead levels demonstrating that treatment is optimal and lead levels are minimized for the specific system.

This report would include a compilation of all the data generated in the course of study and treatment implementation. It must clearly show that additional treatment would not reduce lead levels further. Test results outside the operating parameters identified as optimal must be included. Once the State accepts the analysis and approves a set of operating conditions as optimal, those conditions would become the required operating parameters for that system for the future.

Suppliers serving more than 3,300 persons that wish to change other concurrent treatments that might reduce the effectiveness of the approved corrosion control treatment, or experience significant change in the population served or in the extent of the distribution system, would be required to submit to the State for approval new corrosion control data from studies which reflected the new conditions under which the supplier wishes to operate. These conditions must show that corrosion of lead continues to be minimized.

(B) *Small Systems.* Systems serving fewer than 3,300 persons that do not meet the no-action levels simply would be required to apply to the State for a treatment plan. States would determine what type of corrosion control treatment would result in the minimization of lead levels at the tap and specify this treatment in the plan. (Systems that preferred to develop and submit their own treatment plan would be allowed to do so.) The treatment plan would contain the same performance standard as that required from larger systems—installation of corrosion control treatment to either meet the no-action levels or minimize the corrosivity of tap water towards lead, and an effective program of public education if one or both of the no-action levels are exceeded after treatment. The activities required of small systems to meet this performance standard would be tailored to their ability to perform detailed analyses of alternative corrosion control treatments and to conduct public education programs. For example, rather than conducting pipe loop, laboratory, pilot-scale, or field studies to determine optimal treatment, the State would specify the type of treatment small systems are to install. The State would be responsible for determining what treatment is most likely to be effective in each system. Once the treatment is designated, the responsibilities of small systems would be very similar to those of larger systems. The systems would install and fine-tune the full scale treatment, monitor tap water to assure treatment effectiveness, and continue to meet the no-action levels (if achieved by the specified treatment) or to operate under conditions approved by the State.

EPA recognizes that some corrosion treatments may be difficult to implement for small water suppliers without full-time personnel to monitor and maintain operations. EPA has therefore identified technologies which may be appropriate for the smallest water suppliers, i.e., those serving fewer than 500 persons. Soda ash (sodium carbonate) may be appropriate for some of these small systems. Other systems may require treatment with lower maintenance requirements; limestone bed contactors (calcite contactors) provide a possible alternative. In a limestone contactor, water is closed to the atmosphere and flows through and dissolves a packed bed of crushed limestone or another source of calcium carbonate. Such devices can reduce lead levels in morning first draw drinking water by five-fold and copper by more than 50-

fold (EPA, 1987d). These devices need relatively low maintenance (although they require occasional backwashing), are effective and relatively low in cost, and provide a viable treatment alternative for many small systems. However, there are a few limitations associated with calcite contactors. First, this technology may not be effective for systems with source water that is already saturated with $CaCO_3$. Second, systems that do use this treatment technology may not meet the no-action level for pH, especially if the source water has low pH and low total alkalinity. This treatment technology may need to be coupled with another treatment technology to achieve the no-action levels for both pH and lead. Dolomite contactors may provide treatment similar to that of calcite contactors. While water suppliers may use any treatment to minimize water corrosivity, EPA believes the treatment methods described above may be more practical for the smallest systems, and encourages States to consider them seriously in developing treatment plans for these PWSs.

The treatment plan for systems serving 3,300 or fewer persons would include a schedule for installing and adjusting the treatment designated by the State, and would include the following specific steps, which correspond to Steps (3)–(5) for larger systems (described above):

Step 1: Installation and operation of the corrosion control treatment required by the State in the water system as a whole, within three years of issuance of the treatment plan.

Step 2: Monitoring to determine the efficacy of the treatment as installed.

Step 3: Adjustment of the installed treatment as necessary to ensure that lead levels are minimized.

Step 4: If one or more no-action levels are still exceeded after installation and adjustment of treatment by the system, the State would analyze all treatment and resulting lead levels to determine whether treatment is optimal, i.e., lead levels are minimized, for the specific system. Monitoring data supporting the conclusion that treatment is optimal must be submitted to the State.

Suppliers serving fewer than 3,300 persons that wish to change other concurrent treatments that might reduce the effectiveness of the approved corrosion control treatment, or experience significant change in the population served or in the extent of the distribution system, would be required to notify the State of the proposed changes. States may disapprove the changes and require modifications necessary to preserve the minimal corrosivity of the water.

b. *Public Education.* Under this proposal, those water suppliers (of all sizes) exceeding one or both of the no-action levels for lead (either the average or the maximum) would be required to conduct a public education program to reduce exposure to lead. The public education program would be a part of the treatment plan. Public education would begin as soon as the State approves or issues the treatment plan which includes public education program. States could approve or issue a treatment plan in two steps to allow the public education programs to begin as quickly as possible. In these cases, the State would approve the part of the treatment plan that contains the public education program first, without waiting for final analysis and approval of the corrosion control portion. Two-part approval would be especially useful when the corrosion control laboratory work and scale-up analysis is complicated.

The proposed public education program differs both from the general public notification requirements and the special lead public notification requirements under sections 1414 and 1417 of the Safe Drinking Water Act (see 52 FR 41534, October 28, 1987). First, the public education program would be an ongoing requirement of the NPDWR for lead and copper, for as long as one or both no-action level is exceeded, as opposed to the special lead notification requirement, which is basically a one-time notice. Second, the public education program under this proposal would be required to include intensive interaction between the PWS and its customers to educate them about lead in drinking water, whereas the general public notification program is passive; it simply notifies customers of violations. As explained in Section III. above, excess levels of lead in drinking water supplies can pose a risk to public health. A well designed and executed public education program can induce public water system customers to voluntarily modify their water use behavior, mitigating risks that may result from lead leaching into drinking water.

Water suppliers would be required to design public education programs to meet three performance standards, one regarding program content, a second regarding program delivery, and a third regarding program evaluation, as described below.

i. *Program Content.* The public education program would include information on health reasons for concern about lead exposure, including, in qualitative and quantitative terms, information on specific potential health effects associated with excess blood lead levels and the possible contribution of drinking water to them. As described in detail earlier, these effects include interference with heme synthesis, anemia, kidney damage, impaired reproductive function and fetal effects, interference with vitamin D metabolism, impaired cognitive performance (as measured by IQ tests, performance in school, and other means), delayed physical and neurological development, and elevations in blood pressure (EPA, 1986b). Also, the consumer would be advised that the risks associated with lead in drinking water may be aggravated by exposure to lead from other sources. Other sources include lead from paint chips or paint dust, occupational and home hobby exposures (e.g., smelting, electronics), inhalation of airborne lead, and ingestion of lead in food, especially lead that leaches into food from lead-soldered containers.

Besides identifying the nature of the problem associated with lead in drinking water, the public education program would be required to provide information that the consumer may use to evaluate the probability of excess levels of lead in his or her own household water supply. This information must include the potential for excess lead levels in the water as the water leaves the water supplier and the potential for further increases in the lead levels as a result of corrosion of water supply system components. In addition, the public education program must advise consumers to examine the service line, pipes, and soldered joints in their homes for lead, and faucets and other fixtures for brass, which may commonly contain lead; how to have their water analyzed by a commercial laboratory to determine the lead content; and to contact the PWS for additional information. The program must also include specific information on the banning of materials containing lead for use in drinking water systems. The PWS should be prepared to respond to public inquiries on any issues related to lead in drinking water. EPA solicits comment on additional information that the public education program should include.

The public education program would be required to advise consumers of the actions that may be taken to immediately reduce exposure to lead levels in drinking water that exceed the maximum no-action level, i.e., 0.020 mg/l. These actions include: Non-wasteful flushing of taps (such as dishwashing) before any water from a tap is

consumed or used for any type of cooking or other food preparation including preparation of baby formula; using only cold water for drinking or the preparation of any food or formula; possibly replacing portion of the service line owned by the consumer or landlord if it is made of lead and is contributing significant amounts of lead to the drinking water; ensuring that all plumbing repair work is performed using lead-free solder (explaining that the use of lead solder in drinking water systems is illegal); and providing an electrical ground for household wiring other than the household plumbing system if permitted by local building and electrical codes. The Agency invites comments on the effectiveness of these or any other actions that may be used to effect an immediate reduction in exposure to drinking water lead.

The public education program would require the identification of any actions already taken by any official parties within the community to evaluate, quantify, and/or reduce the levels of lead in drinking water and must publicize the results of compliance and other monitoring for lead (including results of any monitoring arranged by the PWS at the request of a consumer, as described below).

ii. *Program Delivery.* The delivery of the public education program is defined by three factors: The audience, the media used to deliver the program, and the frequency and duration with which the program is delivered.

EPA believes that often it would be appropriate to target the education program to specific segments of the public. For instance, residences with known high lead levels, lead service lines, or lead solder less than five years old would be targeted. However, if many or nearly all of the residences are at high risk, then the program should be conducted community-wide.

The Agency expects many systems already have much information regarding plumbing materials in the distribution system and in homes. Under 40 CFR 141.42(d) systems were required to identify whether lead from pipe, solder, caulking, interior lining of distribution mains, alloys and home plumbing was present, and report the results to the States by 1983. Systems are strongly encouraged to use the results of this identification to assist in the estimation of the prevalence of high risk houses and to assist the targeting of public education programs to those areas of the community most likely to have a large proportion of residences with high lead levels in their water.

Public water systems also would be required to consider whether it is appropriate to target customers on the basis of traits other than geographic location and household plumbing type. For instance, available data indicate that children and developing fetuses are more susceptible to the effects of lead in drinking water than adults are. Therefore, public water systems could target programs to customers that are associated with children and pregnant women. These customers include families, child day care providers, schools, and hospitals. Systems could also target customers with other traits or characteristics that are known to correlate with sensitivity to elevated levels of lead in drinking water supplies such as persons having occupational or other high enviromental exposure, e.g., people working in or living near lead smelters. In addition, bilingual information would be required to be disseminated to non-English speaking portions of the targeted population.

As a part of the public education program, EPA is proposing to require that water suppliers offer a program of extended monitoring, beyond the compliance monitoring requirements. The goal of the extended monitoring is to allow all customers to easily determine lead levels and sources in their own household water, especially in cases where the household was not among the residences chosen for compliance monitoring. EPA expects this provision to increase substantially the effectiveness of the public education program in reducing exposure to lead in drinking water.

Under the extended monitoring requirement, water suppliers would be required to offer all customers the opportunity to have household water tested for lead. The public water supplier would not be required to provide this service for free, but would be allowed to pass the costs of gathering and analyzing the samples on to the customers who elected to participate in the program. The supplier itself could gather, analyze, and report the results to the customer, or the supplier could make arrangements with any certified laboratory to provide the analyses to the customer. In this way, customers would gain easy access to quality water sampling services, and not be subjected to repeated trial-and-error in finding reasonably priced, qualified sampling services. At the same time, the public water supplier could minimize its burden in providing the sampling services by making arrangements with an outside laboratory.

EPA strongly recommends that water suppliers assist customers in identifying the sources of high water lead levels when they are found. The supplier could advise customers to collect samples representative of water that has stood in the service line overnight and a fully flushed sample from the tap. Comparison of the service line sample with the fully flushed sample would allow the customer to identify the source of elevated water lead levels and to take appropriate steps to effectively limit further exposure. For example, if the service line sample shows elevated lead levels, a lead service line may be present. The customer would then be able to determine the value of service line replacement as a means of reducing exposure.

If the alternative of having the public water supply remove lead service lines that it owns and/or controls and offer to remove the remainder for the customer at cost (as discussed below) is adopted, these additional samples would enable suppliers to determine which service lines must be replaced. If the fully flushed sample shows elevated lead levels, this would indicate that the lead is entering the house from the water supply either in the distributed water leaving the plant or as a result of corrosion of pipes owned or under the control of the water supplier. If only the morning first draw sample showed elevated lead levels, the customer could be fairly confident that the lead was originating within his/her residence.

EPA believes that the appropriate medium for public education and schedule for delivery of a public education program are largely a function of the target population. Thus, under this proposal, systems would be required to tailor the form of delivery of the public education program to the nature and size of the target population. For instance, if the target is all residents of a large city, a radio or television Public Service Announcement (PSA) would be appropriate. Conversely, if the target is all residents of a single neighborhood or small town, a public meeting in the neighborhood school would be appropriate. Some other possible methods for public education include preparation of pamphlets or brochures for mass distribution and setting up local telephone hotlines (if used in conjunction with other education methods). The severity of the high lead levels is another factor systems should consider in determining the appropriate medium of education and intensity of the program.

Non-transient non-community water systems serve different populations than community water systems, and thus have different public education requirements. Instead of the requirements described above, NTNC

water systems would be required to take the following actions for the duration of the period during which public education is required: (1) Publicly post informational posters in a prominent place; (2) hold at least one public meeting annually to educate water consumers about lead in drinking water and to answer questions about the subject; and (3) distribute brief informational pamphlets on lead in drinking water at least quarterly.

Public water systems serving more than 3,300 persons would be required to submit the proposed content of the public education program, as well as the manner in which the system would implement it, to the State for review and approval before implementation as a part of the treatment plan. In order to speed implementation of public education, States could approve the part of the treatment plan which covers public education before approving the rest of the treatment plan.

As with public notification requirements, public education programs are the responsibility of the water supplier. However, recognizing that not all systems would have the expertise to conduct such a program in an effective manner, EPA encourages systems to develop joint agreements with State or local public health agencies which have experience in presenting information on health hazards to the public. EPA also encourages systems to coordinate their activities with other local or State programs designed to reduce exposure to lead. For example, local childhood lead screening programs may include complementary public education activities.

Under this proposal, a public education program would include a series of events. For example, a single effort could include several public meetings, a series of PSAs, and a mailing of pamphlets. This series of events could occur over a period of time (e.g., several weeks). The public education program, consisting of each of its individual events, would be required to occur at the rate of four times per year for as long as the system is required to conduct a public education program (i.e., as long as one of the two lead no-action levels is exceeded). For example, a note could be placed on each water bill that says "Are you aware of the possible effects of lead in your drinking water? You should be. Contact _____ for more information."

iii. *Program Evaluation.* Under this proposal, a water system which serves more than 10,000 customers and conducts a public education program would be required to evaluate the program, within 12 months after the program is undertaken, to determine the extent to which it has been effective. The system must show that consumers have knowledge about lead in drinking water. The evaluation would consist of a survey of customers to determine whether they had acquired useful information that enabled them to reduce their exposures to lead in drinking water. Based on this evaluation, the system would determine if and how the program would be modified to increase the program's effectiveness if modification is determined by the State to be necessary to ensure the program's continued effectiveness.

3. Alternatives to the Proposed Treatment Technique

The SDWA requires EPA to set NPDWRs as close to the MCLG as is feasible. EPA believes the proposed rule meets this standard and also is protective of public health. However, EPA is considering several alternatives in addition to the proposed rule. They are discussed in detail below. EPA may decide to promulgate a rule which incorporates any one or more of these alternatives. For example, EPA may retain the average lead no-action level and eliminate the pH no-action level, and delete the MCL for lead in distributed water. Alternatively, EPA may modify the proposal by having the maximum lead no-action level trigger treatment, requiring replacement of those lead service connections which contribute significant amounts of lead to tap water, and/or adopt an alternative approach to monitoring. Accordingly, the Agency especially requests comments on each of these alternative approaches and combinations of alternatives.

a. *Use of Maximum Lead No-Action Level to Trigger Treatment.* EPA is considering an alternative to the proposal which would likely result in lead levels in water somewhat closer to the proposed goal of zero. This alternative is similar to the proposal except that corrosion control treatment in addition to public education would be triggered if the lead level in more than 5 percent of the samples exceeded 0.020 mg/l. Systems that did not meet this additional no-action level would be required to reduce the corrosivity of water until it no longer exceeded this level or demonstrated to the State that it had minimized the corrosivity of its water, in addition to conducting public education. (Under the proposed rule, systems failing to comply with the no-action level of 0.020 mg/l or less in 95 percent or more of samples would be subject to the public education requirement only.)

EPA expects that some systems that meet the average lead no-action level would not be able to meet the maximum. Thus, more water suppliers would be required to install or improve corrosion control treatment, and to demonstrate to the States that the treatment they had installed resulted in compliance with the no-action levels or was optimal. Two groups of water suppliers would be affected in this way. Some water suppliers that would meet the proposed no-action level average of 0.010 mg/l without any treatment or additional treatment (beyond that already in place) may fail to meet the "maximum" of 0.020 mg/l. In addition, water suppliers that would already be required under the proposal to improve water treatment to meet the average of 0.010 mg/l might have to improve their treatment more if they must try to meet both the average and the "maximum" of 0.020 mg/l. If they could not meet both levels, they would be required to demonstrate that the water is minimally corrosive. EPA is unable to precisely estimate the increased number of water suppliers that would be affected but it is likely to be several thousand.

Since more systems would be treating their water to make it less corrosive than under the proposed rule, more people would consume water with less lead than under the proposals (although precise estimates of these reductions are not available). EPA seeks comment on this alternative because this alternative would result in water lead levels closer to the MCLG of zero, thus reducing consumers' exposure to lead more than the approach proposed today. This reduced exposure would result in some additional health benefits with potential theoretical benefits under this alternative that could be substantial. However, EPA is concerned that many more water suppliers may have to demonstrate to the State that they have optimized corrosion control or that new or improved treatment results in meeting the no-action levels. It is unclear whether the States would be able to sustain a time-consuming and technical interaction with an increased number of facilities over several years while at the same time assuring effective implementation of the other drinking water regulations. Therefore actual benefits may be less than the theoretical benefits and may not be substantially different than the proposed alternative. Because of this concern, EPA is also considering two variations to this alternative which may reduce the magnitude of this implementation

problem. The first is raising the maximum no-action level to trigger corrosion control treatment to 0.030 mg/l to better assure that this alternative could be implemented while still providing additional health benefits by limiting high lead exposures. The second variation would substitute the no-action level of 0.020 mg/l or less lead in 95 percent or more sample in place of the two no-action levels in the proposal (average level of 0.010 mg/l for lead and pH >8 in 95 percent or more samples) and have only one no-action level to trigger both corrosion control treatment and public education. EPA requests comment on all of these alternatives.

b. *Use of Total Alkalinity No-Action Level to Trigger Treatment.* EPA is considering an alternative to the proposal which would likely result in lead levels in water somewhat closer to the proposed goal of zero. This alternative is similar to the proposal except that corrosion control treatment would be triggered if the total alkalinity in 95 percent or more samples was not 30 mg/l or higher. Systems would be required to reduce the corrosivity of water until it exceeded this level or demonstrated to the State that it had minimized the corrosivity.

EPA expects that some systems that meet the average lead no-action level and the no-action pH level would not be able to meet the total alkalinity no-action level. Thus, more water suppliers would be required to install or improve corrosion control treatment, and to demonstrate to the States that the treatment they had installed resulted in compliance with the no-action levels or was optimal. Two groups of water suppliers would be affected in this way. Some water suppliers that would meet the proposed no-action level average of 0.010 mg/l lead and the no-action level for pH without any new or additional treatment (beyond that already in place) may fail to meet the total alkalinity no-action level of 30 mg/l. In addition, water suppliers that would already be required under the proposal to improve water treatment to meet the average of 0.010 mg/l and/or the pH >8 might have to improve their treatment more than necessary to meet the average and the pH only to try to meet the total alkalinity of 30 mg/l. If they could not meet all three levels, they would be required to demonstrate that the water is minimally corrosive. EPA is unable to precisely estimate the increased number of water suppliers that would be affected but it may be about a thousand.

Since more systems would be treating their water to make it less corrosive than under the proposal, more people would consume water with less lead than under the proposal (although precise estimates of these reductions are not available). This alternative would result in water lead levels closer to the MCLG of zero, thus reducing consumers' exposure to lead more than the approach proposed today. EPA seeks comment on this alternative because this reduced exposure would result in some additional health benefits with potential theoretical benefits under this alternative that could be substantial. Actual benefits may be less than the theoretical benefits and may not be substantially different than the proposed alternative. However, EPA is concerned that more water suppliers may have to demonstrate to the State that they have optimized corrosion control. If average lead levels are equal to or below 0.010 mg/l, but the alkalinity fails to meet the specified level, additional treatment may not substantially reduce lead levels further. Therefore, including alkalinity may cause some systems to incur additional costs unnecessarily. EPA solicits comment on this alternative.

c. *Eliminating the pH No-Action Level.* The proposed regulation would require that water suppliers adjust the pH of their water to 8 or above, unless they demonstrate that corrosion is minimized at lower pH levels, as part of the corrosion control treatment technique. EPA believes this parameter represents the outer bound of water that is minimally corrosive to lead. However, concern with using pH as a fixed regulatory requirement has been raised. If average lead levels are equal to or below 0.010 mg/l, but the pH fails to meet the specified level, additional treatment may not substantially reduce lead levels further. Therefore, including pH may cause some systems to incur additional cost unnecessarily.

Because of this concern, EPA solicits public comment on an alternative in which the pH value is not a regulatory no-action level but only guidance. Under this alternative, determination of compliance with the treatment technique requirement would be based solely on the lead and copper levels found in the sampled residences. The MCL of 0.005 mg/l for lead in water leaving the treatment plant would still apply, as would the MCL of 1.3 mg/l for copper. If samples exceed the average of 0.010 mg/l, the PWS would be required to install corrosion control treatment and conduct a public education program as in the proposed rule. Those systems that continue to exceed the 0.020 mg/l lead no-action level in more than five percent of targeted samples must also conduct public education. Once lead was reduced to below the 0.010 mg/l average, or the water supplier demonstrated that optimal corrosion control treatment was being applied, the water supplier would be in compliance with the treatment technique requirement.

Under this alternative, suppliers would not be required to measure pH as part of compliance monitoring. However, systems that did not meet the no-action average level for lead would be required to monitor pH and examine the effects of increasing pH above 8 as part of the optimization demonstration.

This alternative could result in less public health protection because fewer systems may be required to install corrosion control treatment. The pH requirement, in conjunction with the lead average no-action level, would trigger treatment in more systems than would the lead average alone. In addition fewer small systems may be required to install treatment under this alternative because these systems are required to take fewer lead and copper samples. Because of the reduced monitoring, more of these systems are likely to have undetected lead levels above the no-action level and thus would not be required to install or improve treatment; the pH no-action level "catches" some of these systems and requires them to control corrosion. Thus final lead levels may not be as close to the proposed MCLG of zero as under the proposed approach.

Note that the actual reduction in benefit in this alternative may be somewhat smaller than the theoretical reduction because it is easier to administer. Therefore, the actual benefits may not be substantially different than the proposed approach.

Theoretically, one way to overcome this problem with this alternative would be for EPA to increase the number of lead samples required by PWSs, especially small systems. However, EPA is concerned that small systems may be unable to take the additional number of samples necessary to assure protection of public health. EPA is especially interested in comment on the trade-off between the proposal and improving this alternative by increasing the number of samples required.

d. *Lead Service Line Replacement Program.* EPA considered requiring replacement of lead service lines and connections in cases where they contribute measurable amounts of lead to the tap water, but is not now proposing this program. EPA particularly solicits public comment both on the specific alternative described below including the materials evaluation and

monitoring requirements, as well as any alternatives that might better achieve EPA's goals in a better and less burdensome way.

The program EPA is considering would require the replacement of lead service lines and connections that, after implementation of any corrosion control treatment, continue to contribute measurable amounts of lead to drinking water (0.003 mg/l or more), and that are under the ownership or control of the PWS. This alternative would have three components: (1) A full materials evaluation (i.e., identification of all buildings served by lead service lines or connections), (2) monitoring at all buildings with lead service lines or connections, and (3) the replacement of lead service lines and connections under the ownership or control of the system that are found to contribute 0.003 mg/l or more to lead levels at the tap. Obviously, no such program would be required in communities in which no lead service lines or connections have been used.

The program considered by EPA would require replacing only those pipes that contribute measurable amounts to lead levels at the tap. Communities that have residences with lead service lines in their targeted sample set (as described in Section V.C.2.) would be candidates for the lead service line replacement program. If the service line sample of any house in the targeted monitoring set exceeded 0.020 mg/l, the system would be requried to identify and take service line samples from a number of residences equal to the number of required samples for compliance monitoring. If five percent or more of the total service line samples from this expanded sample exceeded 0.020 mg/l, the service line replacement program would be triggered for that system.

Once the service line replacement program was triggered, the system would be required to take the three steps listed above: inventory all lead service lines and connections in the community, test each of them, and replace all portions of those connections owned or controlled by the system contributing measurable amounts of lead to the drinking water.

Under this program, EPA would establish two rebuttable presumptions. The first rebuttable presumption would be that lead service lines and connections contribute to lead levels at the tap. The water supplier would first be required to conduct a full inventory of the materials used in the water system and to locate all lead service lines, goosenecks, pigtails, and other lead materials. A materials evaluation should already have been conducted under the requirements of the 1980 amendments to the National Interim Primary Drinking Water Regulations (45 FR 57332, August 27, 1980, 40 CFR 141.42(d)). If not previously done, suppliers would be required to conduct a complete materials evaluation. To rebut the presumption and avoid replacing the lead service lines and other connections, the PWS would be required to monitor each home in the community with a lead service connection or pipe to determine whether the lead service contributes measureable amounts of lead to lead levels at the tap. Specifically, the PWS would have to take a service connection sample and fully flushed sample and demonstrate that the service connection sample has lead levels that are no more than the fully flushed sample from the same tap. This presumption must be rebutted for each lead connection the system wishes to avoid replacing.

The second presumption is that the water supplier owns or controls and therefore can replace, the lead components up to the wall of the building served. In this case, the PWS would be required to replace the entire length of each lead service connection contributing measurable lead to water, from the water main to the building wall, including lead goosenecks, pigtails, and any other lead connections. This presumption could be rebutted by the water supplier by citing local ordinances or State statutes, or in the case or private suppliers, the contract between the system and their customers, that might limit the extent of the PWS' control. Water supplies that rebut the second presumption would have to replace only the portion of each service line and those connections under their ownership or control that contribute a measurable amount of lead to the water.

Lead service connections would be required to be replaced on a fixed schedule as part of the system's treatment plan. No water supplier would be allowed longer than 15 years (starting when the service connection replacement program is triggered unless the system is granted an exemption under Section 1416 of the Act) to replace all lead service connections that require replacement. Water suppliers would be required to replace, or test and rebut the presumptions, for a number of lead services equal in number to at least five percent of the total service connections in the community each year until all those requiring it are replaced. EPA would set the 15-year time limit because this schedule accelerates replacement over current practice.

e. *No MCL for Distributed Water.* Instead of the proposed two-part approach consisting of MCLs for lead and copper in distributed water and a treatment technique for lead and copper as corrosion by-products, EPA considered an alternative which would establish only a treatment technique for those contaminants which can enter water from source water and as a by-product of corrosion. The alternative would resemble the proposed approach except there would be no MCL for lead and copper in distributed water. Under this alternative, systems meeting the no-action level average of 0.010 mg/l and having 0.020 mg/l or less lead in 95 percent of targeted samples, and having 1.3 mg/l or less copper in 95 percent of targeted samples would be in compliance with the treatment technique requirement.

A system not initially meeting the lead average or copper no-action levels would be allowed to employ whatever combination of corrosion control and source water treatments the system chooses to meet the no-action level. Systems still failing to meet the no-action levels by the specified date (either due to source water or corrosion problems) would be required to obtain a State-approved treatment plan. The treatment plan would contain two elements: (1) Steps to reduce lead levels to below the no-action levels or to demonstrate that source water controls and corrosion control treatment are optimal if the no-action average lead level of 0.010 mg/l were not met, and (2) a public education program if the lead average were not met or if five percent of lead samples exceeded 0.020 mg/l. Under this alternative, systems would generally be required to take the following steps to reduce the lead levels in water:

(1) Conduct a study to determine the amount of lead in morning first draw samples that originates in the source water and the amount originating as a corrosion by-product, in the residences monitored for compliance (monitoring would be conducted in targeted residences, as in the proposed rule).

(2) If lead in source water was found to be above 0.010 mg/l, the system would be required to install lead removal technology including any of those that would remove lead from source water to below 0.010 mg/l is described as BAT in Section IV.C. above.

(3) If lead as a corrosion by-product was found to be above 0.010 mg/l as an average, the system would be required to install corrosion control treatment, as described in Section IV.D.1. above.

(4) If neither source water lead nor corrosion by-product lead were individually above 0.010 mg/l (either naturally or because of treatment installed in (2) or (3) above), but the combination of them was above 0.010 mg/l, the system would be required to install either lead removal treatment as described in (2) above, or corrosion control treatment as described in (3) above, or both. The precise combination chosen would be up to the system, as long as the levels in targeted samples were reduced to 0.010 mg/l or lower as a average. If, after installation of treatment, average lead levels in targeted samples remain above 0.010 mg/l, systems would be required to install any additional treatment required by the State (either lead removal or corrosion control treatment), or if none existed, demonstrate to the State that treatment (especially corrosion control treatment) already installed was being operated in a manner that minimized lead levels.

(5) If, after installation of all the treatment described in (2)–(4) above, morning first draw lead levels remained above an average of 0.010 mg/l or if lead levels are 0.020 mg/l or less in 95 percent of targeted samples, the system would be required to conduct a public education program.

A potential advantage offered by this alternative is that it offers a PWS the opportunity to determine for themselves and implement the most efficient combination of treatments to minimize lead levels at the tap. A disadvantage of this option is that it would allow systems to distribute water at levels between 0.005 and 0.010 mg/l in cases where lower levels are possible.

V. Monitoring

A. Analytic Methods

1. Background

NPDWRs must include "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels, including quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system * * *." Section 1401(1)(D).

EPA evaluated the analytic methods for lead, copper, and pH with respect to the accuracy of recovery (lack of bias) and precision (good reproducibility) in the range of the MCLs and no-action levels being considered. The primary purpose of this evaluation was to determine:

- Whether analytic methods are technically available to measure these contaminants in drinking water;
- What are reasonable expectations of technical performance by analytic laboratories at the proposed MCL and no-action levels; and
- The costs of analysis for these contaminants.

The selection of appropriate analytic methods for compliance with these regulations includes consideration of the following factors:

- Reliability (i.e., precision/accuracy) of the analytical results;
- Specificity in the presence of interferences;
- Availability of sufficient equipment and trained personnel to implement a national monitoring program;
- Rapidity of analysis to permit routine use; and
- Cost of analysis to water supply systems.

2. Specific Analytic Methods

There are analytic methods available and approved by EPA for the determination of lead in drinking water, as listed in Table 10. There is no currently approved method for copper because there is currently no primary MCL for it. The analytic methods listed in this table have been used for many years to meet the compliance monitoring requirements specified in the interim NPDWR for lead.

TABLE 10.—CURRENTLY APPROVED METHODS FOR ANALYZING LEAD UNDER THE INTERIM REGULATIONS

Methodology	Reference (Method Number)		
	EPA [1]	ASTM [2]	SM [3]
Atomic absorption; furnace technique	239.2	D3559-78A or B	301A-II or III
Atomic absorption; direct aspiration	239.1		
Inductively coupled plasma	[4] 200.7A		

[1] "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, OH (EPA-600/4-79-020), March 1979. Available from ORD Publications, CERI, EPA, Cincinnati, OH 45268. (The technique applicable to total metals must be used.)

[2] Annual Book of ASTM Standards, Part 31 Water, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

[3] "Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1975.

[4] "Inductively-Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, September 1985, U.S. EPA, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268.

Table 11 lists the analytic methods that EPA is proposing today for compliance with the copper MCL, revised lead MCL, and treatment requirements for both lead and copper described in this proposed rule. EPA is proposing to approve neither the atomic absorption direct aspiration technique nor the inductively coupled plasma technique for measuring lead to determine compliance with today's proposal because the method detection limits for these two techniques are too high to determine the low concentrations of lead in drinking water proposed in this rule.

TABLE 11.—PROPOSED METHODS FOR ANALYZING LEAD AND COPPER

Contaminant	Methodology	Reference (Method Number)			
		EPA [1]	ASTM [2]	SM [3]	Other
Lead	Atomic absorption; furnace technique	239.2	D3559-85D	304	
Copper	Atomic absorption; furnace technique	220.2	D1688-84F	304	
	Atomic absorption; direct aspiration	220.1	D1688-84D or E	303A-A or B	

TABLE 11.—PROPOSED METHODS FOR ANALYZING LEAD AND COPPER—Continued

Contaminant	Methodology	Reference (Method Number)			
		EPA [1]	ASTM [2]	SM [3]	Other
	Inductively coupled plasma	[4]200.7A			

[1] "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, OH (EPA-600/4-79-020), Revised March 1983. Available from ORD Publications, CERI, EPA, Cincinnati, OH 45268. (For approved analytical procedures for metals, the technique applicable to total metals must be used.)

[2] Annual Book of ASTM Standards, Vol. 11.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

[3] "Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1985.

[4] "Inductively-Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, September 1985, U.S. EPA, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268.

EPA has determined that the analytic methods listed in Table 11 are technically and economically feasible for routine use in compliance monitoring for lead and copper. The costs associated with the analysis of these metals are within the economic means of water supply systems. The cost for analyzing lead and copper is estimated at about $6 to $30 per metal per sample. (The actual analytical costs may vary with the laboratory, analytical technique selected, the total number of samples, and other factors.) Also, the number of laboratories that routinely participate in EPA's Water Supply and Water Pollution performance evaluation studies indicates that there are many laboratories available that have the capability to analyze for lead and copper in drinking water using these methods.

Below is a description of each of the techniques EPA is proposing to approve for analysis of lead and copper in drinking water. EPA requests public comment on the technical adequacy as well as the economic feasibility of the proposed analytic techniques.

a. *Atomic Absorption Methods.* Levels of lead and copper in solution may be determined by atomic absorption (AA) spectroscopy. There are two techniques that may be used: Direct aspiration and the furnace technique. EPA is proposing to allow use of the direct aspiration technique only to analyze for copper because this method cannot analyze the low levels of lead specified in this proposal. In direct aspiration, the sample is aspirated into a flame and atomized. A light beam is directed through the flame into a monochromator and onto a detector that measures the amount of light absorbed by the atomized element in the flame. Because each metal has its own characteristic absorption wavelength, a source lamp composed of that element is used which makes the method relatively free from spectral or radiation interferences. The amount of energy of the characteristic wavelength absorbed in the flame from the metal being analyzed is proportional to the concentration of the element in the sample. In the furnace technique, a sample is placed in a graphite tube in a furnace, evaporated to dryness, charred, and atomized. Because the percentage of available analyte atoms vaporized and dissociated for absorption in the graphite tube is greater using this method than the percentage of available analyte atomized in the flame of the direct aspiration AA method, the furnace technique can detect lower concentrations.

Low-level analyses of lead in drinking water using atomic absorption methods must be performed with uncontaminated glassware. Retained lead is most likely to occur on the ground glass surface of volumetric glassware. EPA recommends that laboratories avoid the problem of contamination by using a separate set of glassware for low-level lead analyses. Also, particular attention should be given to glassware cleaning by ensuring that all ground glass surfaces are soaked and held in contact with cleaning acid for a minimum of two hours.

b. *Inductively Coupled Plasma (ICP)—Atomic Emission Spectrophotometric Method.* This method (also known as "EPA Method 200.7") describes a technique for the simultaneous or sequential multi-element determination of trace elements in solution. This method is applicable to the measurement of copper only; it is not yet sensitive enough to measure lead for purposes of this regulation. (Further improvement in the method may make it appropriate for measurement of lead at a later date. If so, EPA would then consider approving this method for measuring lead.) The basis of the method is the measurement of atomic emission by an optical spectroscopic technique. Samples are nebulized and the aerosol that is produced is transported to the plasma torch where excitation occurs. Characteristic line emission spectra are produced by a radio frequency inductively coupled plasma (ICP). The spectra are dispersed by a grating spectrometer and the intensities of the lines are monitored by photomultiplier tubes. The photocurrents from the photomultiplier are processed and controlled by a computer system. A background correction technique is required to compensate for variable background contributions to the determination of trace elements. Background levels must be measured adjacent to analyte lines on samples during analysis.

The appendix to EPA Method 200.7, entitled "Inductively Coupled Plasma—Atomic Emission Analysis of Drinking Water," describes a technique for concentrating the sample prior to analysis. Under this proposal, systems would be required to follow this concentration technique in processing drinking water supply samples prior to ICP emission spectrometric analysis for copper.

3. *Method Detection Limits and Practical Quantitation Limits*

Generally, EPA defines the method detection limit (MDL) as the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the true value is greater than zero. The practical quantitation limit (PQL) is the lowest concentration that can be reliably achieved by well-operated laboratories within specified limits of precison and accuracy during routine laboratory operating conditions. Differences between the MDLs and PQLs are expected; the PQL is generally about 5 to 10 times the MDL for relatively clean matrices such as finished drinking water. (See EPA 1987e, and 50 FR 46902, November 13, 1985, for a detailed discussion of MDLs and PQLs.)

The PQL may be determined through interlaboratory studies, such as performance evaluations (PE) studies. However, if data are not available from interlaboratory studies, the PQLs may be estimated. In such cases, EPA believes that a PQL set at 10 times the MDL achieved by good laboratories is generally a fair expectation for routine operation of most qualified State and

commercial laboratories. The use of "five times the MDL" instead of "10 times the MDL" to set the PQL may be appropriate when other considerations suggest that the PQL should be lower, e.g., see discussion of the PQL for vinyl chloride in the final NPDWRs for volatile organic chemicals, July 8, 1987 (52 FR 25690).

Detection limits have been estimated for the available analytical techniques for lead and copper and are summarized in Table 12. Detection limits for lead and copper traditionally have been based on a concentration that corresponds to a specified instrument signal-to-noise ratio (i.e., peak height to background). The detection limits for ICP using the concentration technique (1 μg/l for copper and 0.005 mg/l for lead) were calculated based upon MDLs. The MDL approach involves the determination of method detection limits using a procedure defined in Appendix B to 40 CFR Part 136 (analytic methods for wastewater pollutants). EPA is using the MDL concept to calculate limits of detection for analytes in all newly developed methods for determination of drinking water contaminants.

TABLE 12. DETECTION LIMITS FOR AVAILABLE ANALYTICAL METHODS FOR COPPER AND LEAD

Contaminant	Proposed MCLG (μg/l)	Analytic method	Detection limit (μg/l)
Copper	1,300	Atomic absorption; furnace.	1
	.....	Atomic absorption; direct aspiration.	20
	.....	Inductively coupled plasma.	*6(1)
Lead	0	Atomic absorption; furnace.	1
	.....	+Atomic absorption; direct aspiration.	100
	.....	+Inductively coupled plasma.	*(5)

*Using the concentration technique in Appendix A to the EPA Method 200.7.

+EPA is not proposing to approve these methods for lead because the detection limits are too high to detect low concentrations of lead in drinking water.

The PQLs for lead and copper were determined based primarily upon the detection limits and the results from PE studies. The PQL for lead was determined using EPA and State laboratory data from Water Supply (WS) PE studies #12–17. The PQL for copper was determined using EPA and State laboratory data from Water Pollution (WP) PE studies #12–16, since copper is not included in WS studies. These results are considered to be optimum since they are drawn from experienced laboratories operating under conditions where they knew they were being tested, using standard samples in distilled water and without interferences. Actual day-to-day operations in a wide variety of laboratories using "real" samples of natural tap water would be expected to produce somewhat poorer results, i.e., have wider performance ranges, especially at the lower concentrations.

EPA used the following procedure to determine the PQLs for lead and copper using the PE study data:

1. Regression equations were generated for precision and accuracy using the EPA and State laboratory data for lead and copper.

2. The percent recovery and relative standard deviation were used to estimate the 95 percent confidence limits. The percent recovery and relative standard deviation were calculated at the proposed MCLG for copper using the regression equations generated from the laboratory data for the contaminant. For lead, the percent recovery and relative standard deviation cannot be calculated at the proposed MCLG because it is zero. Therefore, another concentration must be used to calculate the 95 percent confidence limits. This value is set as close as possible to the proposed MCLG. The lowest MDL for any of the methods used to detect lead is 0.001 mg/l (for the atomic absorption furnace method). The minimum PQL for this method is "five times the MDL" or 0.005 mg/l using the "five to 10 times the MDL" criterion. This value was selected as the appropriate concentration to calculate the 95 percent confidence limits from the regression equations. The percent recovery, relative standard deviation, and the 95 percent confidence limits for lead and copper are summarized in Table 13.

TABLE 13.—95 PERCENT CONFIDENCE LIMITS FOR DETECTION OF LEAD AND COPPER

Contaminant	MCLG (mg/l)	Percent recovery	Relative standard deviation	95 percent confidence limits (percent of true value)
Lead	[1] 0.005	107	21	65–149
Copper	1.3	99	4	91–107

[1] The calculations are made assuming that 0.005 mg/l is the lowest possible PQL instead of zero. For further explanation, see the discussion above.

Sources: USEPA 1983–1985, Water Supply PE studies #12–17 and Water Pollution PE Studies #11–16.

3. EPA and State laboratory data for each contaminant were evaluated to determine the limits for the "plus or minus percent of the true value" that most closely approximated the 95 percent confidence limits. They are summarized in Table 14.

TABLE 14.—PROPOSED ACCEPTANCE LIMITS FOR LEAD AND COPPER

Contaminant	MCLG (mg/l)	Acceptance limits (plus or minus percent of true value)	PQLs (mg/l)
Lead	[1] (0)0005	30	0.005
Copper	1.3	10	0.050

[1] The calculations are made assuming a minimum possible PQL of 0.005 mg/l instead of zero. For further explanation, see the discussion above.

4. The proposed PQLs for lead and copper were set based on the available data at a concentration where at least three-quarters of the EPA and State laboratories were within the specified acceptance range. These PQLs are summarized in Table 14.

Public comments are requested on the PQLs for lead and copper.

4. pH—Electrometric Method

EPA is proposing to approve the electrometric method for measuring the pH of drinking water samples collected to determine compliance with this proposed rule. The references for this method appear in Table 15 below. Under this method, the pH of a sample is determined electrometrically using either a glass electrode in combination with a reference potential, or using a

combination electrode. The pH meter must provide accurate and reproducible results within ±1 pH unit and should be equipped with a temperature compensation unit. The pH meter may need to be adjusted to compensate for water temperature. Samples should be analyzed in the field at the time of sampling.

TABLE 15. METHODOLOGY FOR ANALYZING FOR pH AND TOTAL ALKALINITY

Parameter	Methodology	Reference (Method Number)			
		EPA [1]	ASTM [2]	SM [3]	Other
pH	Electrometric	150.1	D 1293-84	423	
Total Alkalinity (as $CaCO_3$, mg/l)	Titrimetric	310.1	D 1067-82A	403	

[1] "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, OH (EPA-600/4-79-020), March 1985. Available from ORD Publications, CERI, EPA, Cincinnati, OH 45268.
[2] Annual Book of ASTM Standards, Vol. 11.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.
[3] "Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1985.

5. Total Alkalinity—Titrimetric Method

Under the titrimetric method, total alkalinity is measured by titration to an electrochemically determined end point pH of 4.5. The sample must not be filtered, diluted, concentrated, or altered in any way. The sample would be required to be refrigerated to 40°C and run as soon as practical. The sample bottle should be air tight and should not be opened before analysis. The pH measured at the tap must be provided with this sample so that an accurate alkalinity measurement can be made.

Under this procedure, the alkalinity is calculated using the following formula:

$$\text{Alkalinity, mg } CaCO_3/l = \frac{A \times N \times 50{,}000}{\text{ml sample}}$$

where:
A = ml standard acid used.
N = normality of standard acid.

For low alkalinities, the titration is stopped at a pH in the range of 4.3 to 4.7. The volume of titrant required to reach that pH and the specific pH are recorded. The sample is next titrated to a pH exactly 0.3 pH units lower and the volume of titrant required to reach this end point is recorded. (Method 403, Standard Methods for the Examination of Water and Wastewater, 16th edition, 1985).

For low alkalinities, total alkalinity is calculated by the following formula:

$$\text{Total alkalinity, mg } CaCO_3/l = \frac{(2B - C) \times N \times 50{,}000}{\text{ml sample}}$$

where:
B = ml titrant to first recorded pH.
C = total ml titrant to reach pH 0.3 units lower.
N = normality of standard acid.

B. Laboratory Approval

EPA recognizes that the effectiveness of the proposed regulations depends upon the ability of analytical laboratories to measure lead and copper reliably at relatively low levels. pH measurements must be reliable as well. EPA's regulations specify that only approved laboratories can analyze compliance samples (40 CFR 141.28).

EPA's existing drinking water Laboratory Certification Program (LCP) has established the use of external checks of performance to evaluate the ability of laboratories to analyze samples for specific contaminants and to produce data within specific limits. For this purpose, EPA provides performance evaluation (PE) samples to laboratories on a regular basis; participation in this program is a prerequisite for a laboratory to achieve certification and to remain certified for analyzing compliance samples. Achieving acceptable performance in these studies of known test samples provides some indication that the laboratory is following proper practices. Unacceptable performance may be indicative of problems that could affect the reliability of the compliance data generated for specific contaminants.

Unacceptable performance by any laboratory may trigger an investigation to establish the possible cause(s) and to take corrective action. EPA recognizes that even a superior analytical laboratory occasionally produces data that are outside the acceptable limits for statistical reasons rather than any actual analytic problem. A provision for rapid follow-up analysis if a laboratory fails the initial determination is necessary to decrease the likelihood of statistical error and to determine if a real problem exists.

EPA's present PE sample program and the approaches used in the determination of laboratory performance requirements were discussed at 50 FR 46907 (November 13, 1985). Acceptable performance has historically been set by EPA using two different approaches: Regressions from performance of pre-selected laboratories or specified accuracy requirements. EPA requested public comment on these approaches in the November 13, 1985 notice. Most commenters on that notice supported the use of a "plus or minus percent of the true value" approach to derive acceptance limits instead of generating performance requirements from study statistics. EPA agrees with these commenters that this is the best approach and will specify accuracy requirements in the revised regulations whenever possible.

1. Laboratory Performance for Lead and Copper

EPA has evaluated performance data gathered from past PE studies to set performance requirements for lead and copper analysis. The available PE data indicate that both the precision and the accuracy attained for specific inorganic contaminants are contaminant-specific. For example, the percent recoveries are 99 percent for copper and 107 percent for lead while the relative standard deviations are 4 percent for copper and 21 percent for lead. The "plus or minus percent of the true value" acceptance limits have been derived for each contaminant taking into consideration the expected precision and accuracy and using 95 percent confidence limits to estimate the acceptance limits. For example, the acceptance limits for copper using 95 percent confidence limits would be 99 percent ±2x (4 percent) or 91 to 107 percent of the "true value." Thus, a ±10 percent of the "true value" acceptance limit is approximately equal to the 95 percent confidence limits. The acceptance limits would apply to concentrations equal to or more than the PQL.

The acceptance limits are summarized below:

Contaminant	Acceptance limits
Copper	±10% at >0.050 mg/L
Lead	±30% at >0.005 mg/L

Public comments are requested on the acceptance limits for lead and copper.

2. Laboratory Performance for Total Alkalinity

The approval criteria for the pH analysis is different from all of the other approval criteria because pH analysis is done in the field. 49 FR 43234, Oct. 26, 1984. The pH analyses would be conducted in the targeted homes with a pH meter. The pH papers would not be permitted for this analyses. The pH meter must meet the specifications listed in the available methods (see Table 15). Under the proposal the pH analyses must be conducted by samplers who have been certified to use pH meters. This is especially necessary because exposure of the sample to air changes sample pH when the sample contains anions such as carbonate (EPA 1982). However, the analyses conducted on site may be limited by either a lack of certified samplers or a lack of pH meters. EPA requests comment on the pH approval criteria.

Therefore, EPA is proposing to allow systems which serve 3,300 persons or less collect the pH sample and send it to a certified laboratory for analysis. EPA is aware that this exception will often result in a systematic bias of the pH readings to more frequent misses of the no-action levels, and encourages systems to consider carefully the tradeoff between ease of analysis and analytical accuracy (EPA, Method 150.1, Methods for Chemical Analysis of Water and Wastes, revised March 1983). EPA requests comment on whether non-field testing of samples should be allowed for systems that serve fewer than 3,300 persons.

EPA is considering and taking comment on a requirement that water systems meet a specific alkalinity value in their water in addition to the proposed no-action levels. It is also critical to know the alkalinity of the water in order to determine the type and extent of appropriate corrosion control treatment. EPA therefore solicits public comment on the following laboratory certification requirements that would be necessary if the alkalinity requirement were adopted in the final rule.

Laboratories that meet the approval criteria for metal analyses would also be required to meet the performance requirements for total alkalinity analyses because, under the proposal, all of these analyses are required for samples taken from the targeted homes (as explained below), and EPA would require all analyses for a set of samples to be conducted at the same laboratory. EPA has evaluated performance data gathered from past PE studies to set the performance requirements for total alkalinity. However, the procedure for selecting the performance requirements is different than the procedure for the metal analyses because there is no MDL or PQL for the analysis of total alkalinity. Since laboratories must meet the approval criteria for total alkalinity in addition to the criteria for the metals, the percentage of laboratories that can achieve this criteria must be higher than that of the metals so that only a very few laboratories that pass the criteria for metals are eliminated because of a failure to meet the alkalinity criteria. Therefore, ±20 percent of the "true value" has been selected as the approved criteria for total alkalinity. In the data from the PE studies, at least 90 percent of the EPA and State laboratories are typically able to measure total alkalinity within ±20 percent of the true value when the active amount is greater than or equal to 30 mg/L.

C. Monitoring Protocols

As explained above, water suppliers would be required to monitor a variety of parameters in order to demonstrate compliance with the proposed rule. These parameters include lead and copper levels at entry points to the distribution system and at taps, and pH at taps. As described below, community and non-transient non-community water systems would have different monitoring requirements for determining compliance with the corrosion control treatment techniques of this proposal.

For the purposes of averaging, all lead levels measured between the PQL (i.e., 0.005 mg/L) and the MDL (0.001 mg/L) would be averaged for the compliance determination. All lead levels below the MDL of 0.001 mg/L would be reported as zero and averaged as such. Lead levels reported below an MDL larger than 0.001 mg/L would be reported as that MDL and averaged as such.

1. Monitoring for Compliance with the MCLs

Water suppliers would be required to sample water as it enters the distribution system after any treatment to determine compliance with the MCLs for lead and copper. Water suppliers relying solely on ground water would be required to take only one sample per year per entry point to the distribution system. Water suppliers relying on surface water as their source would be required to take one sample each quarter to account for seasonal variations in contaminant levels. Water suppliers with both surface and groundwater sources would be required to monitor quarterly all entry points to the distribution system. States would have the discretion to identify representative wells for sampling (if there is no treatment or blending) for systems with multiple wells drawing from the same aquifer.

For the first round of MCL monitoring (which would last one year), historical data meeting the monitoring requirements specified in the proposed rule could be used in lieu of new data if the historical data were collected in a manner consistent with the final regulations. The total number of samples could be reduced by the use of composite samples at the discretion of the State. Combinations of samples from up to five sources would be allowed. If the concentration in the composite sample indicates that one or more of the samples may exceed the MCL, follow-up sampling would be required at each sampling point in the composite.

Follow-up sampling would be required if the reported concentration of a five-sample composite exceeds the method detection limit. For copper, an accurate analysis of one-fifth of the MCL is not a problem. For lead, however, the method detection limit is equivalent to the detection limit for the furnace atomic absorption technique. Laboratories should determine their method detection limit for this method by the procedure listed in Appendix B to 40 CFR Part 136. Laboratories should be able to achieve a method detection limit of 0.001 mg/L and data should be reported down to this concentration. If a laboratory is unable to achieve an MDL of 0.001 mg/L or lower, then sample compositing would not be permitted.

If the result of one analysis exceeds the MCL for lead or copper, the system would be out of compliance and the procedures for public notification must be followed. However, States would have the discretion to allow one additional sample to be collected as soon as possible (not to exceed two weeks from the date of the initial sample) at the same sampling location to verify the original results. In this case, if the average of the two samples analyzed exceeds the MCL, the system would be out of compliance and procedures for public notification must be followed. If the average is less than

the MCL, the system would be in compliance, the first sample results not withstanding. Systems exceeding the MCL would be required to sample more frequently than the minimum federally mandated requirements. The State must specify the increased monitoring frequency.

For community water systems, if there have been no violations for the most recent two years of monitoring, States could reduce the standard monitoring requirements to as infrequently as once every five years for systems serving fewer than 500 persons and any system serving 500 or more persons which is supplied only by ground water. For systems using surface water sources or a combination of surface and groundwater and serving more than 500 persons, monitoring could be reduced to once per quarter for one year, repeated every five years. No reductions in monitoring would be allowed for non-transient non-community water systems.

All systems would be required to begin monitoring to determine compliance with the MCLs according to the schedule in Table 16.

Table 16.—Starting Dates for Monitoring

System size	Monitoring to begin no later than—
>3,300	3 months after publication of final rule.
500–3,300	15 months after publication of final rule.
<500	27 months after publication of final rule.

EPA is phasing in the monitoring by system size in the same manner it has in previous NPDWRs to give systems time to learn about and implement the new requirements and to ease the burden on analytic laboratories which may not be able to cope with a sudden increase in the number of samples requiring analysis.

2. Monitoring for Compliance with the Corrosion Control Treatment Technique Requirement

Compliance with the corrosion control treatment technique requirement would be determined based on pH, lead, and copper levels at the tap. All systems would be required to begin monitoring for compliance with the treatment technique according to the schedule in table 16. Monitoring for each of these parameters at a targeted set of sample sites (see Section IV.C.2.a.i. for a discussion of how sites are to be selected) would be required quarterly for systems serving more than 3,300 persons, and less frequently for smaller systems. States may reduce monitoring frequency for systems serving more than 3,300 persons once compliance is established. Because the lead and copper no-action levels are measured as average and 95th percentile values, compositing is not allowed for samples collected to determine whether the no-action levels are met.

Values for pH are not expected to vary throughout the day at any given location, although they may vary among locations. However, lead and copper levels at the tap do vary considerably depending upon a variety of factors, including the standing time of the water in the plumbing pipes. Determination of whether the no-action levels were met would be determined by morning first draw and service connection samples. A morning first draw sample is the first sample taken after water has stood in the building's plumbing overnight, or for 8–18 hours, without flushing. (Flushing means running the water without capturing the water for sampling.)

A service connection sample is a sample of water that has been standing for 8–18 hours in the building service connection (service line and other connections). Service connection samples may be collected by several methods. One is to flush the tap until there is a temperature change (decrease) in the water. The colder water is that which has stood outside the house in the service connection. Another method is to measure pipe length and diameter from the tap to the service line and flush the volume estimated to be contained in the household plumbing before the service connection. Once the house water is flushed, the service connection sample is collected. A final method of collecting a sample representative of a service connection is to insert a sampling tap in the service line. However, this last method has the disadvantage of scraping bare a portion of the metal surface. This bare surface may result in temporarily high lead levels.

Morning first draw samples and service connection samples must be one liter in volume and collected at the cold water kitchen tap of targeted residences. Systems which have lead service connections would have to collect one half the required number of samples connection.

EPA expects that for community water systems the residences sampled would generally be single-family houses, but systems could include apartments and other multiple-family housing where such housing constitutes more than 20 percent of the housing served by the community. For non-transient non-community water systems, a morning first draw sample would be required from the tap or other outlet typically used to draw water for human consumption, in each building served by the NTNC system. The rationale for these requirements is as follows:

- One of the important determinants of lead and copper levels in drinking water is the standing time of the water in plumbing pipes. Water that has not stood in the pipes (i.e., fully flushed water) will generally have the lowest lead and copper levels of any sample taken at that tap. Water that has stood in the pipes for long periods will have higher lead and copper levels; water standing in pipes 8–18 hours ("standing samples") represents the highest levels that will routinely be found in drinking water. Standing samples would be required for several reasons. First, monitoring of water standing overnight, or some other specific long standing time (i.e., 8–18 hours), provides a consistent basis for measuring the progress of corrosion control treatment towards reducing levels of lead and copper. Standing samples represent the high end of actual human exposures are variable and are not known precisely (because people drink water from a variety of sources and also water that has a variety of standing times), actual exposure to lead and copper via drinking water will generally be no higher than levels found in standing samples.
- Sample volume also has an important effect on lead and copper levels in standing samples. The first 100 milliliters or so can have high levels from leaching lead out of faucets because lead is used in the manufacture of brass and bronze, which are often used in faucets and fittings. The next 400–500 milliliters represent water standing in the pipes near the faucet, and also may have high lead levels because of the numerous lead soldered joints that can lead up to the faucet (Lassovszky, 1984). Taking a one-liter sample represents less extreme lead levels than those generally found in a smaller sample because the initial high concentrations will be diluted by the later part of the sample, which contains lower concentrations. Because of the variation in lead levels with sample volume, EPA is proposing one liter as the standard sample volume for all samples.

Although nearly all the data provided to EPA by systems has been collected from one-liter samples, the question of the cost of shipping one-liter bottles to the laboratory has been raised to EPA. One approach to reduce the weight and bulk would be to collect 500-ml samples

instead. However, 500-ml samples will generally show a higher proportion of lead concentration from the faucet and a lower proportion from far and nearby lead soldered joints, than will 1 liter samples. However, because it is unlikely that an individual would consume an entire liter of water represented by a standing sample, EPA requests comment on an alternative sample volume of 500 ml. This alternative may better reflect a typical exposure. EPA estimates that 500 ml samples will show consistently higher concentrations of lead and copper than 1 liter samples, thus increasing the relative protectiveness of the proposed rules.

An alternative approach to lower the weight would be to collect one-liter samples and transfer a 500-ml aliquot to another bottle for shipment and analysis. The Agency is reluctant to adopt this approach because lead adheres to containers very easily. This increases the probability of sampling error and would likely show a consistent, unacceptable downward bias. The Agency solicits comment on this potential problem and possible approaches for minimizing it.

a. *Location of Sampling Sites.* Because the likelihood of high lead and copper levels in drinking water is not randomly distributed among buildings served by a given public water system, EPA is proposing that monitoring for compliance with the treatment technique requirement be targeted to residences most likely to have lead problems. Targeting for copper is not necessary because, in targeting for lead, copper corrosion problems should be identified simultaneously. Lead, copper, and pH would all be measured at the same set of residences. Systems would be required to identify a sampling pool that includes 50 percent more sites than the number required for monitoring each monitoring period (which varies by system size), to ensure that systems can get access to an adequate number of sites. The specific residences to be actually sampled would be selected randomly from the targeted set of residences. Once the system monitors the minimum number of sites, it would be required to use them every monitoring period. If one or more of these initial sites is no longer accessible, the system may, with State concurrence, substitute an alternative monitoring point from its sampling pool with the same characteristics as the initial point.

i. *Targeted Monitoring and Materials Evaluation.* To ensure that systems sample residences most likely to experience elevated levels of lead in tap water due to corrosion, water suppliers first would be required to conduct a materials evaluation to identify an adequate number of these high risk residences for monitoring. High risk residences are defined to include those that are at the ends of the distribution system and either: (1) Have lead service connections and/or lead interior plumbing; or (2) have lead solder that is less than five years old. "Ends of the distribution system" means those areas of low or no flow, sometimes known as "dead-ends." In communities where lead service connections are present, the group of residences selected would be required to include an equal number of residences for morning first draw and service connection samples. By targeting high risk residences for lead sampling, EPA believes that the monitoring would be more likely to identify high lead levels in communities where they exist, thus better assuring a high degree of public health protection. Targeting also would reduce the number of samples required to provide this level of public health protection.

To conduct the materials evaluation and identify sites for targeted monitoring, each system would be required, at a minimum, to consider the information identified by the State pursuant to 40 CFR 141.42(d). As necessary, the system must consider:

(A) Plumbing codes, permits, and records in the files of the community building department that indicate the plumbing materials installed within residences, including:

- Lead in piping, solder, caulking, interior lining of distribution mains, alloys, and home plumbing;
- Copper in piping, alloys, service lines, and home plumbing;
- Galvanized piping, service lines, and home plumbing.

(B) Inspections and records of the distribution system that indicate the material composition of the distribution lines, service lines, and connections.

(C) Existing water quality information, including results of prior analyses of water in the system or from individual residences, indicating residences in which the lead level of the water may be of concern.

(D) Design plans of the distribution system indicating residences that are served by the ends of the distribution system (i.e., areas of low or no flow).

The evaluation could be conducted based on building permits and other records, inspections of the distribution system and buildings, information from customers, or other means that reliably characterize the materials used in the construction of the distribution system and plumbing in buildings served. In conducting the materials evaluation, the system would not be required to examine every building served for the presence of lead materials.

Water suppliers that assert that there are insufficient residences in either of the two targeted categories (residences at the ends of the distribution system with either (1) lead service connections and/or lead interior plumbing, or (2) lead solder less than five years old) would be required to document this assertion to the State as follows:

1. *Lead service connections and interior plumbing.* The system would document via the materials evaluation that lead services, goosenecks, pigtails, or interior lead piping were never used in portions of the community served by the ends of the system or have all been replaced. If this could not be determined by records, the system would be required to inspect the service lines and connections, and interior plumbing, of all housing and other buildings constructed before 1940 (few lead service lines were used after this date) and show that no service lines or connections, or interior plumbing, are composed of lead or lead-containing materials.

2. *Lead solder.* The system would demonstrate that the State or community has had in effect and has consistently and successfully enforced a ban on lead solder use comparable to the Federal ban for five years, or that no lead solder was ever used in construction or residences and other buildings in the community served by the ends of the distribution system.

If the public water system could not identify a sufficient number of residences that have the required characteristics, the public water system would be required to demonstrate this to the State as described above and add to the sampling pool, as equally distributed as possible, residences that either: (1) Contain lead solder that is less than five years old; or (2) are serviced by lead service connections, as appropriate. If the public water system still could not establish a sampling pool sufficiently large to meet the monitoring requirements of this section, the public water system would be required to add to the sampling pool a number of residences with lead solder (i.e., solder more than five years old) for sampling sufficiently large to meet the monitoring requirements of this section.

While State approval of monitoring plans would not be required, States would have the authority to disapprove any monitoring plan that does not meet the targeting requirements. A system with a disapproved monitoring plan

would be in violation of the regulations until the State approved a revised plan.

EPA solicits comment on the proposed criteria for selecting the targeted samples.

ii. *Non-Residential Monitoring Alternative.* As described above, EPA is proposing that compliance monitoring be conducted at targeted residences. Based on information from hundreds of water suppliers which have successfully collected standing samples from residences during the last ten years, the Agency expects that virtually all systems will be able to gain access to the required number of residences, especially since many consumers will welcome the information it provides them about the quality of their own drinking water supply. Under the extremely unlikely event that a system is unable to get access to take the required number of samples, EPA may consider allowing an exception to the requirement. Under this rare circumstance, the system would have to demonstrate to the State that it had made several good faith efforts to collect the required samples, including describing to each customer the direct benefits of the sampling. Then the system would have to provide samples from other locations with plumbing characteristics nearly identical to those encountered in targeted residences. For example, a PWS may be able to identify non-residential taps to supplement the accessible residential taps to reach the required number of monitoring sites. These non-residential taps would be required to be connected to plumbing with a configuration and daily water use patterns very similar to those found in single-family residences, to approximate lead levels that would be found in such residences. A second approach might be for a PWS to construct a plumbing system to simulate that found in a home. This simulation would need to be located at the ends of the distribution system, and have either (1) a lead service connection or lead interior plumbing (if there were any lead service connections in the system or its customers' plumbing), or (2) lead solder that is less than five years old. The system would have to assure that the water use patterns in this simulation closely resembled those found in a residence, to ensure the lead levels measured approximate those in private residences.

EPA requests comment on this and any other last-resort sampling approaches which may allow systems to obtain tap samples which represent the water quality found in targeted residences.

b. *Number of Sample Sites.* Two major factors affect the selection of a suitable number of sample sites. First is the degree of certainty that levels and prevalence of lead and copper in water have been identified accurately (more samples result in greater certainty) throughout the community. Second is the cost and ease of implementation of the sampling system (more samples are more costly and a plan requiring more samples may be more difficult to implement). In designing the sampling plan, EPA considered several important design criteria. These include: The number of samples taken per monitoring period (by system size), the length of the monitoring period, the targeted monitoring approach, and the desire to know in advance the maximum total number of samples which would be required from each supplier. Having considered these factors and criteria, EPA has developed a proposal which is relatively low in cost and easy to implement. It clearly defines the number of samples required from each system and it requires the minimum number of samples from small systems.

EPA is also considering an alternative sampling plan and may adopt it in the final rules. Compared to the proposal, this alternative would provide greater certainty about the lead and copper levels and reduce the monitoring costs for large systems, but it may increase monitoring costs for small systems. EPA solicits comment on both the proposed and the alternative sampling plans described below. EPA is interested in how it might improve the proposed approach to increase the certainty it provides regarding lead and copper levels and how it might improve the alternative to make it less costly to implement. In particular, EPA solicits comments on the proposed and alternative approaches to monitoring including the choice of standard levels, appropriate numbers of samples, frequency of sampling, methods for evaluating sample results relative to the no-action levels, and the design of compliance rules within the context of a sampling and evaluation program.

i. *Proposed Approach.* Under the approach proposed by this notice, the number of sample sites would be based on system size. Water suppliers would be required to monitor on this schedule starting by the date specified in Table 16. Under the proposed approach, the system would collect one sample from each sample site (i.e., targeted residence) according to the frequency listed in Table 17 until compliance is established by meeting all no-action levels for at least one year or by completing implementation of a State-approved treatment plan (whichever is later). Thereafter State may reduce the required monitoring frequency for systems serving more than 3,300 persons to a minimum of, one annual sample set taken during July, August, or September from each site. Systems serving 500–3,300 persons would take one sample set during July, August or September and repeat the sampling at least every two years. Systems serving fewer than 500 persons would take one sample set during July, August, or September and repeat the sampling at least five years. Non-transient non-community water systems would not be allowed to reduce their monitoring. Any additional samples taken (beyond those required by the regulation) which a system wants to use to determine whether the no-action levels are met must meet the targeting criteria discussed above.

TABLE 17.—NUMBERS OF SAMPLES AND FREQUENCY OF SAMPLING FOR THE LEAD AND COPPER CORROSION TREATMENT REQUIREMENT UNLESS REDUCED BY THE STATE

Population served	Number of samples
>100,000	50/quarter.
10,001–100,000.	30/quarter.
3,301–10,000	20/quarter.
500–3,300	10/year for 1 year, repeated every 2 years.
<500	10/year in one year, repeated every 5 years.

ii. *Alternative Sampling Plan.* EPA is also considering an alternative to the proposed sampling plan and may adopt it in the final rules. This alternative, although somewhat more complex in design, would require, for many systems, fewer or an equal number of samples than required under the proposed sampling scheme.

The alternative plan is based on a double sampling scheme developed by Dodge and Romig (1959). The plan uses a two-tier approach. A supplier would be required to obtain a relatively small number of samples in the first stage and then, based on the outcome of the initial sampling, would be either relieved of further sampling for that monitoring period or required to obtain additional samples during that monitoring period to determine whether the system was in compliance or needed to take further action. In localities where lead levels at the tap are generally either quite low or quite high, sampling would probably be limited to the first tier.

A benefit of this approach is that no system fails to meet a no-action level (or alternative approved by the State after a system has demonstrated optimization) on the basis of just one exceedance. However, this benefit comes at a cost of increased sampling in some circumstances for the smallest systems.

Table 18 specifies the number of samples to be obtained for systems serving populations of various sizes (leftmost column). The following discussion explains how the alternative sampling plan would be used to determine whether a PWS meets the no-action level for a maximum of 0.020 mg/l lead. After testing the appropriate number of samples in Stage 1, a system would "pass" and be excused from further sampling if no (zero) samples exceeded the lead maximum no-action level. If the number of such exceedances was greater than the specified allowable number (rightmost column), the system would "fail" and also be excused from further sampling, but would be required to take further actions. For example, if the system has not yet installed or improved corrosion control treatment, it would be required to do so. In cases where the number of exceedances in Stage 1 was not greater than the allowable number, systems would be required to collect the number of additional samples indicated for Stage 2. Passing or failing would depend on the total number of exceedances in the combined groups of samples. For example a system serving 100,000 persons that obtained more than a total of three samples with lead levels above the maximum no-action level in 40 samples would fail and having to undertake corrosion control treatment. Figure 3 illustrates the decision process involved in applying this scheme.

TABLE 18.—NUMBERS OF SAMPLES REQUIRED IN STAGE 1 AND STAGE 2 OF DOUBLE-SAMPLING PLAN [1]

Population size	Number of samples		Allowable exceedances
	Stage 1	Stage 2	
<500	10	5	1
500-3,300	10	10	1
3,301-10,000	20	10	1
10,001-100,000	25	15	2
>100,000	30	20	3

[1] Frequency of sampling would be the same as under the proposed approach. Stage 1 and Stage 2 samples would be taken in the same monitoring period.

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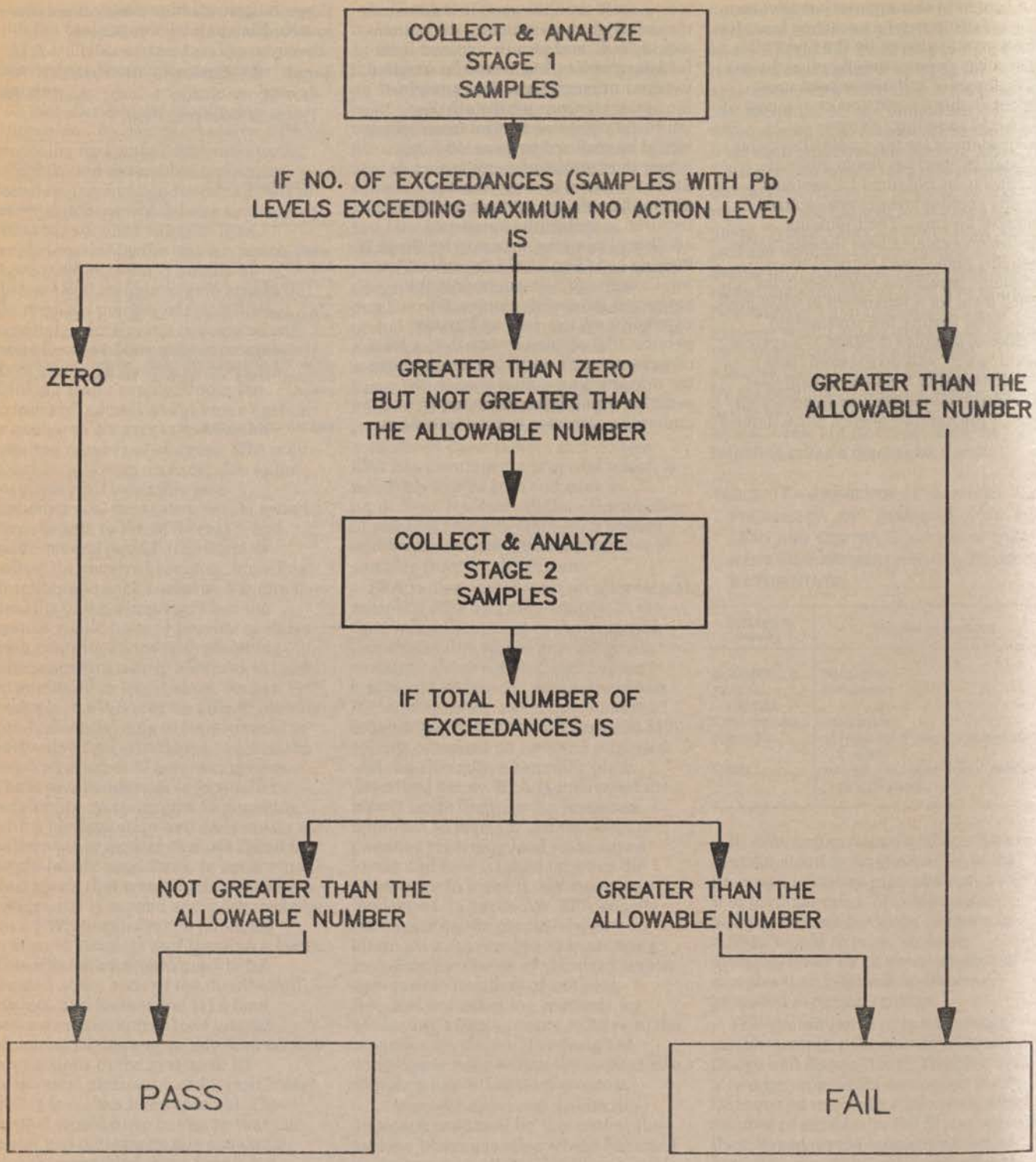

FIGURE 3 DOUBLE SAMPLING DECISION PROCESS.

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If the samples are representative of the taps under consideration, application of this scheme provides 90 percent confidence that not more than 14 percent exceedances would occur among the taps (Svensgaard, 1988).

3. Monitoring Requirements for Non-transient Non-community Water Systems

Non-transient non-community water systems would be required to monitor water entering the distribution system once every five years for compliance with the MCLs for lead and copper. To demonstrate compliance with the treatment technique requirement, NTNC water systems would be required to monitor lead, copper, and pH (in a morning first draw or service connection sample) at least one tap annually during the months of July, August, or September in each building served by the NTNC water system. The monitored tap would be required to be the tap most frequently used for water consumption, such as a kitchen tap.

4. Additional Data Collection

EPA is currently collecting additional data to support this regulation for lead and copper in drinking water, particularly data on lead service line replacement. EPA solicits any additional data on pipe replacement or any other aspect of this proposal from the public.

EPA has developed a monitoring protocol for measuring lead in drinking water and guidance for using it which is more detailed than the protocol required under the proposed regulations. This more detailed protocol is available to the public from EPA. EPA welcomes data from samples taken under this protocol which may help to answer any of the issues highlighted in this proposal.

The monitoring protocol offers a means to determine whether a shorter standing time such as 30 minutes may be successfully substituted for the 8 to 18 hour standing time that would be required for morning first draw samples. In addition, the guidance would assist water suppliers in locating the sources of lead in drinking water (i.e., water mains, service lines, or interior plumbing). This information would assist systems in establishing sampling points for targeted monitoring and for focusing public education programs.

EPA may be able to provide technical assistance to a limited number of water suppliers which are interested in conducting extensive lead monitoring, and are willing to share all data with EPA in exchange for the support. Specifically, EPA is interested in before-and-after treatment data from individual residences served by water suppliers instituting corrosion control treatment and before-and-after data from individual residences in communities replacing PWS-owned or -controlled portions of lead service lines or connections. This information also could be used to assist decisions among the various options described in this proposal, in particular. Data from various tap samples taken before and after treatment would assist the Agency in further assessing the alternative of requiring replacement of lead service lines and connections under the ownership or control of water suppliers. Collection of systematic data of this type also may allow the Agency to better estimate the costs and benefits of the rule.

VI. Public Notification

Under section 1414(c)(1) of the Act, each owner or operator of a public water system must give notice to persons served by it of (1) any violation of an MCL, treatment technique requirement, or testing provision prescribed by an NPDWR; (2) failure to comply with any monitoring requirement under section 1445(a) of the Act; (3) existence of a variance or exemption; and (4) failure to comply with the requirements of a schedule prescribed pursuant to a variance or exemption. The 1986 amendments required that within 15 months of enactment, EPA amend its current public notification regulations to provide for different types and frequencies of notice based on the differences between violations which are intermittent or infrequent and violations which are continuous or frequent, taking into account the seriousness of any potential adverse health effects which may be involved.

EPA promulgated regulations revising the public notification requirements on October 28, 1987 (52 FR 41534). The regulations require that public notices for MCL, treatment technique violations and violations of a variance or exemption ("Tier 1 violations") contain mandatory health effects language specifying concisely and in nontechnical terms what adverse health effects may occur as a result of the violation. States and water utilities remain free to add additional information to each notice, as deemed appropriate for specific situations. Community water systems (CWSs) with Tier 1 violations must notify the public by newspaper or mail or hand delivery. Community water systems which fail to comply with any monitoring or testing requirements, which are granted variances or exemptions, or are required to give newspaper notice repeated quarterly by mail or hand delivery, with additional notice required at State discretion. NTNC systems may either notify in the same manner as CWSs or post a notice continuously.

Violations of the lead or copper MCLs or the treatment technique requirements of this rule would be Tier 1 violations. Violations of the treatment technique requirement include but are not limited to any of the following:

(1) Failure to submit or apply for (depending on system size) a treatment plan by the date required, if required.

(2) Failure to implement any treatment plan requirement by the date specified in the treatment plan, including failure to implement required corrosion control treatment, failure to demonstrate to the State's satisfaction that treatment is optimal, failure to continue required treatment.

(3) Failure to design and implement a public education program, if required.

For Tier 1 violations, EPA is proposing the following mandatory health effects language:

Lead

The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that lead is a health concern at certain exposure levels. Lead is a soft, dull, gray metal that has frequently been used in water supply plumbing materials, especially flux, solder, pipes, and brass and bronze fixtures. Lead usually contaminates drinking water as a result of the corrosion of these plumbing materials by the water they carry. Lead has been shown to cause a variety of adverse health effects in humans and animals. In humans, lead has been shown to interfere with the formation of red blood cells (heme synthesis), cause anemia, cause kidney damage, impair reproductive function, reduce birth weight, cause premature birth, delay physical and mental development in babies and young children, impair mental abilities in children, and increase blood pressure in adults. Many of these effects have been observed at relatively low exposure levels. Studies on animals indicate that lead may also cause cancer at high doses. EPA has set an enforceable drinking water standard at 0.005 ppm (parts per million) for lead leaving the treatment plant and entering the distribution system. EPA also requires public water systems to treat their water to minimize lead contamination resulting from the corrosion of plumbing materials when lead in tap water that has been standing overnight exceeds an average of 0.010 ppm. Drinking water that meets these standards is associated with little of this

risk and should be considered safe to drink.

Copper

The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that copper is a public health concern at certain levels. Copper is an orange metal that is commonly used for plumbing pipes in homes and other buildings. Copper generally contaminates drinking water as a result of the corrosion of copper pipes by the water they carry. When copper corrodes, the water and sink are often stained green. Copper is an essential nutrient, but at high doses it has been shown to cause stomach and intestinal distress, liver and kidney damage, and anemia. Persons with Wilson's disease may be at higher risk from copper toxicity than the general public. EPA has set an enforceable drinking water standard for copper at 1.3 ppm (parts per million) for water leaving the treatment plant and entering the distribution system. EPA also requires public water systems to treat their water to control copper contamination resulting from the corrosion of plumbing materials when copper in tap water that has been standing overnight exceeds 1.3 ppm in more than 5 percent of samples. Drinking water that meets this standard is associated with little to none of this risk and should be considered safe to drink.

VII. Variances and Exemptions

A. Variances from MCLs and Exemptions from the MCLs and Treatment Technique Requirements

Under the Safe Drinking Water Act, variances from MCLs and exemptions from MCLs and treatment technique requirements are permitted only if the granting of the variance or exemption will not result in an unreasonable risk to health (URTH). Sections 1415(a)(1)(A) and 1416(a)(3). States with primacy have authority to grant variances and exemptions.

Variances from MCLs may be granted to water suppliers that have applied BAT but which fail to meet the MCL using that technology. Section 1415(a)(1)(A). Variances from MCLs are generally designed to address cases in which the source water is so contaminated that even application of BAT is insufficient to effectively reduce contaminant levels to below the MCL. Water suppliers that obtain variances from MCLs must be placed on a schedule to come into compliance with the MCL "as expeditiously as practicable" and must implement any additional control measures in the interim prescribed by the State.

Exemptions from both MCLs and treatment technique requirements may be granted to water suppliers due to compelling factors (including economic factors). Section 1416(a). Systems granted an exemption receive additional time to install BAT or the required treatment technique. The exemption may be extended for up to 3 years if the system makes certain showings. Section 1416(b)(2) (A) and (B). Systems which serve fewer than 500 persons may obtain extendable two-year extensions under certain conditions. Section 1416(b)(2) (C). As with variances, exemptions must include a schedule for compliance and requirements for implementing any necessary interim control measures.

EPA is not now proposing to designate by rule a specific level of lead or copper in drinking water that constitutes an unreasonable risk to health. To date, the Agency has not established in regulations URTH levels for any contaminant. However, as for other contaminants, EPA intends to publish guidance regarding what drinking water contaminant levels would constitute an unreasonable risk to health for States to use in deciding whether to grant variances or exemptions to public water systems. This guidance will be available for public review and comment and will be completed by the time the final regulation for lead in drinking water becomes effective.

B. Variances From the Treatment Technique Requirements

The Act also allows variances from treatment technique requirements, but these are fundamentally different from variances from MCLs. Variances from treatment technique requirements are granted to water suppliers that do not need to implement the treatment because they have high quality source water, so treatment is unnecessary to protect the health of persons served by the water supply. Section 1415(a)(1)(B).

Because of the design of the treatment technique requirement for corrosivity proposed in this rule, EPA believes that the need for variances from the proposal treatment technique requirement would be rare. Specifically, since the proposed rule requires systems to optimize corrosion control, i.e., lower lead levels as much as technically feasible with corrosion control treatment, by definition, all public water systems could comply with the treatment technique requirements.

The only case in which application of corrosion control treatment would not be necessary or beneficial in reducing lead levels is the rare community that has no lead or copper materials in its plumbing and distribution system, including private residential plumbing. Such communities may include new trailer home parks or other developments of prefabricated housing which were constructed using all plastic piping. If a water supplier could demonstrate that no plumbing materials containing lead have been used in the construction of any homes in the community or in any distribution facilities, a variance from the treatment technique requirement could be granted.

EPA solicits comment on granting of variances from the treatment technique requirements, especially whether there are other conditions under which the treatment technique may not be necessary or beneficial for reducing lead and copper exposures via drinking water.

C. Point-of-Use (POU) and Point-of-Entry (POE) Devices and Bottled Water

EPA believes that central treatment should be the primary means of attaining MCLs and providing water equivalent to water treated as set out in an NPDWR prescribing a treatment technique, such as the corrosion control technique set out in this proposal. However, although the long-term goal for these systems is to comply with NPDWRs with centrally treated and distributed water, under this proposal EPA would allow the State to require the use of POU devices or bottled water to avoid an unreasonable risk to health, as a condition of receiving a variance or an exemption. This may be especially appropriate in the case of exemptions for small systems, i.e., systems with less than 500 connections, because their exemptions may be extended for one or more two-year periods. The goal of application of non-central treatment or bottled water is to provide water of equivalent quality to that which would be provided by a traditional well-operated central treatment facility.

In prescribing the use of POU devices, the State would be required to impose the conditions outlined below. If a PWS distributes bottled water as a control measure, the PWS must ensure that one of the following conditions is met:

(1) The bottled water must be subject to a monitoring program that provides adequate assurances that the water meets all MCLs. The public water system must monitor the bottled water for lead and copper and all other MCLs in the first quarter that it supplies water to the public, and annually thereafter. Results of the monitoring program would be provided to the State annually; or

(2) The public water system must receive a certification from the bottled water company that (a) the bottled water supplied has been taken from an "approved source" as defined in 21 CFR 129.3(a); (b) the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g)(1)–(3); and (c) the bottled water does not exceed the MCLs or quality limits set out in 21 CFR 103.35. The public water system would be fully responsible for the provision of sufficient quantities of bottled water to every person supplied by the public water system including delivery via a door-to-door bottled water delivery system.

These conditions constitute the minimum standards for protection of public health.

Point-of-entry devices for removal of lead or copper from drinking water would not be allowed to achieve compliance with this proposed rule because they do not prevent lead or copper from entering the water after it leaves the device. Many such devices provide reverse osmosis (RO) or ion exchange treatment, and can actually make water more corrosive, potentially resulting in higher lead levels at the tap.

VIII. State Implementation

The primary implementation agencies for drinking water regulations are the States. Fifty-four out of 57 jursidictions have applied for and received primary enforcement responsibility for the public water supply supervision program (primacy). To implement the federal regulations for drinking water contaminants, States must adopt their own regulations which are at least as stringent as the federal regulations. This section of today's proposal describes the provisions the States would be required to adopt to implement this proposed rule.

One of the deficiencies in the existing program implementation regulations in 40 CFR Part 142 which EPA plans to correct in an NPRM later this year is that the regulations do not require States with primacy to revise their programs following EPA promulgation of new or revised NPDWRs or to adopt the new or revised requirements, nor do they specify a procedure for doing so. EPA intends to propose amendments which would require States to revise their programs following the promulgation of new or revised NPDWRs to maintain primary enforcement responsibility. Under the SDWA, EPA has had a strong and continuing policy of approving only those State programs that adopted the full EPA program, e.g., all NPDWRs; States cannot obtain partial or conditional primacy. EPA intends to continue this "full primacy" policy as it implements the 1986 SDWA amendments. (Partial primacy would be confusing; the State would be implementing part of the program and EPA the other, and it would be unclear which provisions of Federal and state law applied to a given public water system.)

As part of the amendments to the primacy regulations, EPA is planning to propose procedures for revising State programs that are similar to those in Part 142 for obtaining initial primacy. The amendments would require States to meet the basic requirements for obtaining primary enforcement responsibility (see 40 CFR 142.10) for each new or revised NPDWR and any primacy requirements specific to the new or revised NPDWR which EPA has established. It is anticipated that such regulation-specific requirements would be necessary only in those situations where the NPDWR provides flexibility to the State on how to accomplish a particular requirement. If these regulation-specific requirements are needed, EPA will promulgate them at the same time it promulgates the NPDWR. Today's proposal includes regulation-specific requirements that a State would be required to include in a program revision to adopt the proposed lead and copper NPDWRs. EPA solicits comments only on these specific requirements. Comments on the broader changes to the primacy requirements in Part 142 will be solicited when those changes are proposed. Today EPA is also proposing the changes to the reporting and recordkeeping requirements needed to implement the lead and copper NPDWRs. EPA also solicits comments on these requirements. EPA's proposed changes to Part 142 are explained below.

A. Special Primacy Requirements for States To Adopt 40 CFR Part 142, Subpart I—Control of Lead and Copper

The regulations proposed at 40 CFR Part 141, Subpart I, Control of Lead and Copper, provide the State discretion with regard to how the objectives of the rule are achieved. For instance, the State must approve a system's demonstration that it has minimized the corrosivity of its water and must approve the system's final operating parameters. In these cases and other instances where the State has discretion, State regulations would be required to augment the general national regulations to establish enforceable requirements and to inform each public water system to what specific requirements it is subject.

To ensure that the State program includes all the elements necessary for an effective, enforceable program, this notice proposes that to obtain approval of a program revision to adopt the NPDWRs for lead and copper, the State's request for approval would be required to include the following:

(1) The procedure or criteria the State will use for determining the frequency with which a system must monitor, including the monitoring frequency after a system has exceeded the lead or copper MCL. The State must include a procedure for notifying the system of the new monitoring requirements with which it must comply and for enforcing these requirements.

(2) The requirement for a materials evaluation to identify monitoring locations, specifying the elements which must be included in the evaluation. Further, the State must specify how a system can demonstrate to the State that sufficient residences with the required characteristics for monitoring are not available.

(3) The procedures/criteria the State will use to evaluate treatment plans submitted by systems serving more than 3,300 persons, to develop treatment plans for systems serving fewer than 3,300 persons, to approve treatment plans, and to evaluate treatment and public education performed by systems under the treatment plans, in accordance with proposed § 141.85. The State must also specify (a) the criteria it will use to determine that corrosivity has been minimized if the system is still not meeting the no-action levels after installing or improving treatment, and (b) a method of informing the system of its new approved operating parameters.

(4) The criteria the State will use to evaluate data submitted by a system on the effectiveness of its public education program and to determine whether the system must modify subsequent public education efforts.

(5) Procedures the State will use to provide systems serving 3,300 or fewer persons with treatment plans.

B. State Reporting and Recordkeeping Requirements

In this notice, EPA is proposing changes to the existing reporting and recordkeeping requirements to implement the proposed lead and copper NPDWRs. These changes would require States to keep records of:

(1) Any system which has been allowed to reduce the frequency at which it monitors for compliance with (a) the lead and copper MCLs and/or (b) the no-action levels which trigger the

treatment technique requirements, or other approved operating parameters.

(2) Any system which is required to perform increased monitoring and the frequency of that monitoring.

(3) Approvals of treatment plans as specified in proposed § 141.84.

(4) All determinations that systems that have finished implementing treatment plans have begun meeting the no-action levels or have minimized the corrosivity of their water.

(5) All evaluations of public education programs and of all determinations that systems are required to modify subsequent public education programs.

This proposal would also amend the State reporting requirements to implement the lead and copper NPDWRs. States would be required to provide EPA quarterly a list of systems which:

(a) May reduce their monitoring frequency in accordance with proposed § 141.86 (c) and/or (d)(4).

(b) Are required to increase their monitoring frequency in accord with § 141.86(c)(4).

(c) Have received State approval for their treatment plan, or for systems serving 3,300 or fewer persons that have received a treatment plan from the State.

(d) Have successfully demonstrated that optimal corrosion control has been installed. This report should indicate whether the system is now meeting the no-action levels or operating under other parameters approved by the State. In the latter case, the report should specify the new parameters.

States would also be required to report any evaluations of public education programs and any determinations that a system must modify subsequent public education programs. Under the existing regulations, States must provide EPA a summary of violations of primary drinking water regulations; therefore; no additional requirement for reporting violations to EPA is specified in this proposal.

EPA solicits comments on all the proposed changes, including recordkeeping, reporting, and the special primacy requirements, to Part 142 to implement the NPDWRs for lead and copper also proposed today. Comments should specifically address the appropriateness of these requirements, the effect of these new requirements on State programs, and the ability of the State to implement the requirements of the rule.

C. System Reporting and Recordkeeping Requirements

In order to facilitate implementation and enforcement of the regulations proposed today, water systems would be required to maintain records of and report to the state information relating to the proposed regulation.

Systems that serve more than 500 persons would be required to report to the State the results of all monitoring required by this subpart within 10 days of the end of each calendar quarter the system is in operation for any period of time. Systems that serve 500 or fewer persons would be required to report such results to the State within 10 days of the end of each calendar year such system is in operation for any period of time. All systems would be required to certify that the information submitted is accurate. To the extent systems perform more monitoring than required by the proposed regulations, the systems would be required to include the results of the additional monitoring in their reports to the State. Systems would be required to include the identification and location of sampling sites monitored in their reports of monitoring data.

Systems operating under an approved treatment plan would be required to, according to a schedule established by the State, report to the State the system's progress in completing the treatment plan's interim steps. All systems applying corrosion control treatment, would be required to report any changes in treatment, including changes to treatment for purposes other than corrosion control and cessation of treatment due to mechanical or operating failures, within 14 days of the change in treatment.

Systems operating under an approved treatment plan containing a public education program would be required to report the system's progress in completing the public education program requirements in the reports submitted to the State. If the public education program is being targeted to particular segments of the consumer population, a description of how this targeting is consistent with the proposed regulations would be required to provide data to the State that indicate that, as a result of the public education program, the users' knowledge about lead in drinking water enables them to alter voluntary their water use patterns to reduce consumption of lead-contaminated water.

The proposed regulations would also establish a general reporting authority, which would allow the Administrator to require a system to establish and maintain such records, reports, or information as the Administrator deems necessary to determine whether the system has acted or is acting in compliance with the proposed regulations.

IX. Review by the Science Advisory Board

As required by the SDWA, EPA's Science Advisory Board (SAB) was offered the opportunity to review this proposal. They met on June 2 and 3 1988 in Cincinnati, Ohio. The SAB's comments will be considered and factored into the final rule together with the comments from the public received during the comment period.

X. Impact of this Regulation

A. Regulatory Impact Analysis

Under Executive Order 12291, this action is a major regulatory action, because it will have a major financial or economic impact on the country. As required by the Executive Order, EPA conducted a Regulatory Impact Analysis (RIA) that is available for review as part of the docket for this rulemaking (EPA 1988a). This regulation has been reviewed by the Office of Management and Budget as required by Executive Order 12291.

Costs

EPA analyzed the economic impact of this regulation in two separate parts: The impact attributable to the control of lead and copper in source water (the "MCL impacts," in Table 19) and the impact attributed to the corrosion control requirements (also shown in Table 19).

TABLE 19.—SUMMARY COST IMPACTS OF PROPOSED LEAD AND COPPER REQUIREMENTS [1]

	Lead (5 ug/l)		Copper (1,300 ug/l)		Total [2]
MCL Impacts					
Systems Affected	880		66		950
National Cost of Treatment ($M):					
Capital	320		35		350
O&M (Annual)	30		3		30
Annualized [3]	55		5		60
Annual Cost per Family ($/yr) by System size (people served):					
Very Small (25-500)		340		380	
Small (501-3,300)		91		130	
Medium (3,301-50,000)		28		70	
Large (Over 50,000)		9		50	
Treatment Technique Requirement Impacts					
Systems Affected		53,000 [4]			
National Cost of Treatment ($M)					
Capital		630			
O&M (Annual)		160			
Annualized		210			
Optimization Demonstrations (Annual in $M)		2			
Public Education (Annual in $M)		12			
Annual Cost per Family ($/yr) by System size (people served):					
Very Small (25-500)		27.0			
Small (501-3,300)		4.6			
Medium (3,301-50,000)		2.5			
Large (Over 50,000)		0.7			
Total Cost of Rule ($M)	MCL		Corrosion control		Total
Capital	350		630		980
O&M (Annual)	37		160		200
Annualized	60		220		[5] 280

[1] Costs are expressed in 1988 Dollars. Totals may not tally due to independent rounding.
[2] Assuming no co-occurrence of lead and copper.
[3] Annual cost of capital 3% over 20 years plus 1 year of O&M.
[4] Includes double counting of some systems which will have to treat for source water contamination as well as for concentrations at the tap exceeding the no-action level. 42,978 systems are estimated to install treatment, and conduct public education programs and optimization demonstrations only.
[5] Includes annualized capital, O&M, optimization demonstration, and public education costs, but excludes state implementation costs of $16 m per year.

It is estimated that about 880 systems would exceed the proposed MCL for lead at the entry point to the distribution system and thus need to treat their source water. About 66 systems would exceed the proposed MCL for copper at the entry point to the distribution systems and thus need to treat their source water. On an annualized basis, the compliance costs for the lead and copper MCLs would be about $60 million.

There are cost impacts associated with the treatment technique (corrosion control and public education) requirements as well. These impacts have been broken into three tiers, reflecting the stepped nature of the proposal and its alternatives. Systems would incur treatment costs when they fail to meet the no-action levels. Approximately 53,000, or 66 percent of all systems would be expected to incur costs under the proposed treatment technique requirements. On an annualized basis, corrosion control treatment optimization demonstration and public education would result in costs of about $221 million.

Monitoring costs would be incurred by all of the approximately 79,000 community and non-transient, non-community systems. EPA estimates that the national annualized cost of monitoring for this proposal would be about $12 million per year (Table 20).

Table. 20.—Monitoring Costs of the Proposed Lead and Copper Requirements*

Systems Affected	79,000
National Cost ($M1988)	
Annual Monitoring	12
Cost per Family by System Size ($1988/year/Household)	
Very Small (25–500)	$0.88
Small (501–3,300)	0.30
Medium (3,301–50,000)	0.19
Large (over 50,000)	0.02
Total Annual Cost of Monitoring ($M1988)	
Very Small (25–500)	$1.60
Small (301–3,300)	2.20
Medium (3,301–50,000)	6.90
Large (over 50,000)	1.40

* Rounded to two significant digits.

The entire proposal, including both the MCL and treatment technique requirements for lead and copper, would require about 54,000 systems to add $980 million in capital equipment, and incur $200 million per year to operate and maintain it. Monitoring costs are expected to be $12 million per year. State implementation costs are estimated to increase by approximately $16 million. On an annualized basis, the cost of the rule is expected to be nearly $280 million for capital, operation and maintenance, monitoring, and State implementation.

The uncertainty in the costs, particularly for small systems, has not been fully evaluated. Based on comments and further analysis, an addendum to the draft Regulatory Impact Analysis to be completed when this rule is promulgated will evaluate these uncertainties.

Benefits

The systems that incur the costs of complying with the proposed rule are likely to be the same systems that experience the health and materials benefits. The materials benefits of this regulation may be as high as $500 million per year. These benefits would pay for the entire cost of this rule if considered on a national basis.

The Agency evaluated the expected health benefits of the proposed rule. The Agency estimated the number of children who would be expected to experience decreased blood lead levels as a result of reduced water lead levels. In particular, EPA examined the effects of changing the water lead distribution experienced by people served by systems which are expected to install or improve corrosion control treatment

after missing the no-action levels. In the first step of the analysis, EPA estimated the proportion of children expected to have their blood lead levels reduced to below 10, 15, or 25 ug/dl as a result of reductions in water lead levels (Marcus and Holtzman, 1988). EPA estimates that about 138 million people are served by PWSs that would be expected to install corrosion control treatment (EPA 1988a). Of these, about 8.8 million are children aged 6 months to 5 years. Therefore, EPA estimates that 264,000 to 704,000 children in this age group would have blood lead levels reduced to below 10 ug/dl, 88,000 to 176,000 children would have their blood lead levels reduced to below 15 ug/dl, and 3,500 to 5,300 would have blood lead levels reduced to below 25 ug/dl. The estimates are presented in a range to reflect the uncertainty regarding the water lead levels that would result from compliance with the proposal.

Other groups of the exposed public would also be expected to experience benefits from the proposed rule, including fetuses, infants, older children, and adults. The particular types of health effects that would be avoided by these persons are discussed in *Reducing Lead in Drinking Water: A Benefits Analysis* (EPA, 1986a). However, the Agency has not calculated the proportion or number of persons in each of these categories who would be brought below specified blood lead levels.

Figure 4 summarizes the health effects associated with various blood lead levels of concern. These include reduced IQ and stature decrements in children, premature birth, low birthweight, slowed mental and physical development in fetuses and infants, and hypertension in adult men.

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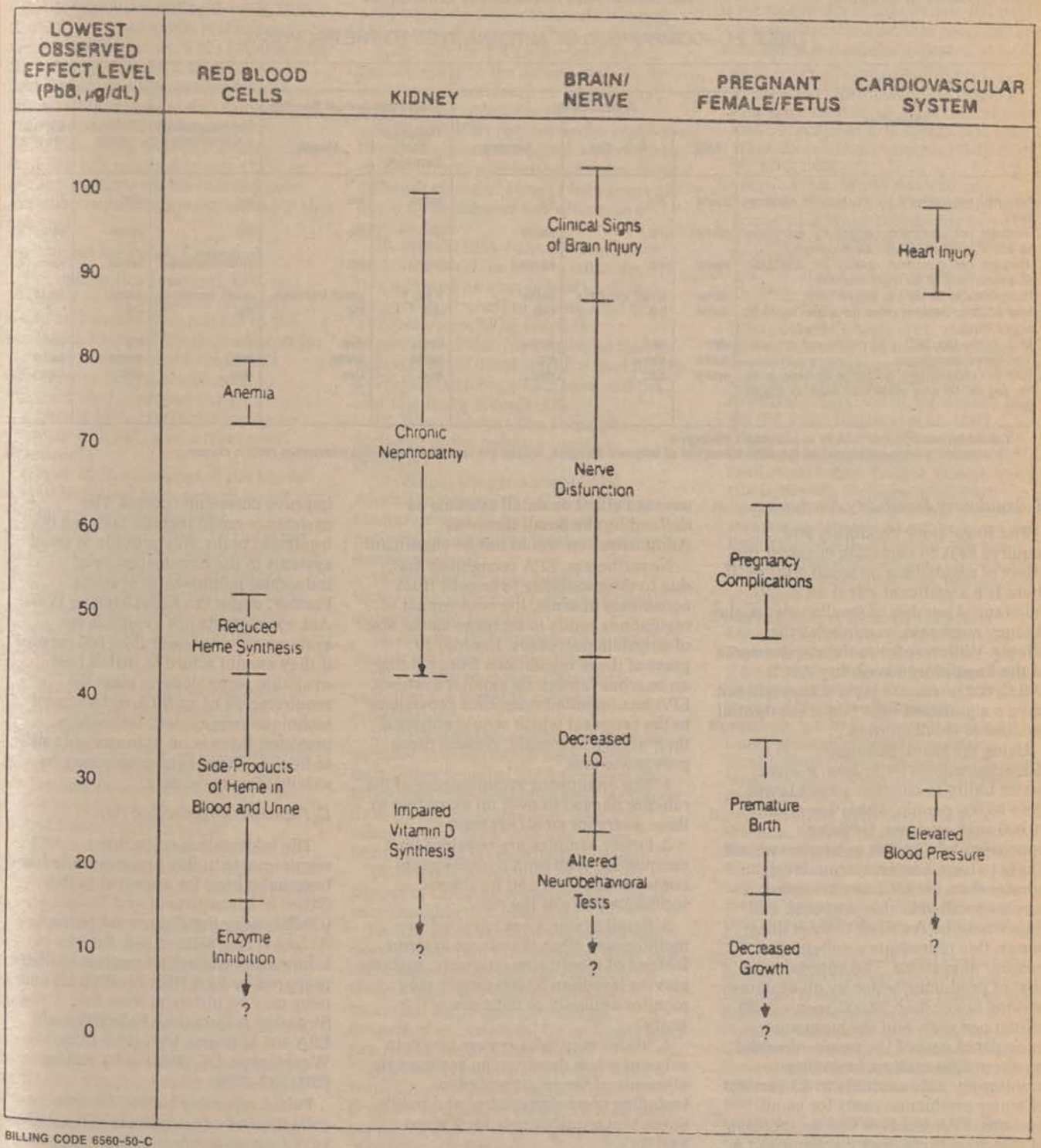
Figure 4

ADVERSE HEALTH EFFECTS OF LEAD



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The Agency also considered the relative benefits of the proposed approach compared to those which might be expected to occur if one or more of the alternatives discussed above were adopted. In each case, the actual outcome of adopting an alternative approach is uncertain. Therefore, Table 21 presents a qualitative comparison of the proposal with the alternatives. Costs, benefits, administrative complexity, and enforceability are considered. Expected net benefits are listed as the same as the proposal, less than the proposal, or greater than the proposal. For example, difficult problems of implementation could limit the reductions in water lead levels that might otherwise be expected from adoption of an alternative.

TABLE 21.—COMPARISON OF ALTERNATIVES TO THE PROPOSAL

Alternative	1			2		3	4	5
	Annual Costs			Theoretical Annual Benefits		Administrative Complexity	Enforce-ability	Expected Benefit [1]
	MCL	Corr. Ctrl	Monitrg	Reduced Mat Damages	Health			
1. National requirement for Pb service replacement.	same	inc	inc	same	inc	inc	dec	?
2. Require opt corrosion control for *additional* no-action level of 20 ug/l as maximum.[2].	same	inc	same	inc	inc	inc	same	same (?)
3. Require opt corrosion control for *additional* no-action level of 30 mg/l alkalinity.	same	inc	same	inc	inc	small increase	same	same (?)
4. Raise max to 30 ug/l to trigger trtmt	same	small increase	same	? inc ?	small increase	small increase	same	same (?)
5. Max of 20 to *replace* other no-action levels to trigger trtmt.	same	inc	dec	inc	inc	inc	inc	?
6. MCL at the tap, MCL=30 maximum	dec	dec	same	dec	dec	dec	inc	dec
7. Two-tiered sampling	same	same	inc	same	same	inc	same	same
8. Elim pH requirement, guidance assume or as Pb avg of 10 only no-action level to trigger trtmt.	same	dec	dec	dec	dec	dec	dec	same (?)

[1] Considers net effect of factors in columns 1 through 4.
[2] "Maximum" means measured as the 95th percentile of targeted samples, unless the two-tiered sampling alternative (#6) is chosen.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires EPA to explicitly consider the effect of regulations on small entities. If there is a significant effect on a substantial number of small systems, the Agency must seek to minimize the effects. With respect to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 602 *et seq.*, today's action will not have a significant effect on a substantial number of small entities.

Using the Small Business Administration's definition, a small water utility is one that serves fewer than 50,000 people. There are about 78,000 such systems. Of these, approximately 53,000, or 68 percent, are likely to have contamination levels greater than the MCLs or no-action levels specified in this proposal, and thus would be required to treat their water; this represents a substantial number of systems. The approximate cost of producing water by all systems serving fewer than 50,000 people is $9 billion per year, and the maximum annualized cost of the proposal would be about $281 million, including monitoring. This amounts to 3.1 percent of water production costs for small systems. EPA believes that an increase of this magnitude does not represent a signficant economic impact. Therefore, although the rule will affect a substantial number of small systems, the average effect on small systems as defined by the Small Business Administration would not be significant.

Nevertheless, EPA recognizes that, due to their inability to benefit from economies of scale, the cost impact of regulations tends to increase as the size of a system decreases. In order to prevent these regulations from placing an onerous burden on smaller systems, EPA has included numerous provisions in the proposal which would enhance their ability to comply. Among these provisions are:

1. The monitoring requirements of the rule are phased in over an extra two to three years for small systems.

2. Fewer samples are required for compliance with both the maximum contaminant level and treatment technique parts of the rule.

3. Small systems are required to monitor less often than large systems. Instead of monitoring quarterly, systems serving less than 50,000 people may monitor annually or once every five years.

4. States may take system size into account when determining appropriate elements of the treatment plan, including corrosion control and public education requirements for a given system.

The Agency encourages States to provide technical assistance to small systems which need to install or improve corrosion control. The assistance could include tailoring the treatment plans they provide to small systems to the circumstances of individual public water systems. Further, under the Safe Drinking Water Act, exemptions are available for systems serving fewer than 500 persons if they cannot afford to install best available technology to meet the requirements of an MCL or treatment technique requirement technology, provided there is no unreasonable risk to health. These exemptions may be extended as necessary.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection request has been prepared by EPA (ICR No 0270.12) and a copy may be obtained from Eric Strassler, Information Policy Branch; EPA 401 M Street, SW. (PM-223); Washington, DC 20460 or by calling (202) 382-2709.

Public reporting burden for this collection of information is estimated to vary from an average of 1 to 1.4 hours per response, including time for reviewing instructions, searching existing data sources, gathering and

maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

XI. Request for Public Comment

Throughout this proposal, EPA has requested public comment on many issues and approaches related to this regulation. Many of the major issues for comment are repeated here for the convenience of those who wish to comment on this proposed rule.

1. Should EPA control corrosion by-products with MCLs or a treatment technique?

2. Is an MCL measured at the tap to control both lead from source water and as a by-product of corrosion appropriate? What would be the basis for selecting the level? What monitoring requirements should apply? Should systems that have installed BAT and still cannot meet the MCL at the tap because of private plumbing be considered permanently out of compliance?

3. Should EPA establish national requirements for lead service line replacement?

4. EPA solicits data on contributions of lead service lines and other lead connections to lead levels at the tap, and on lead levels after corrosion control treatment is in place.

5. EPA solicits data on the effect of partial and full lead service line replacement programs on lead levels at the tap.

6. Should EPA reduce to 500 ml the sample size for determining whether a system meets the no-action levels and/or the source water MCLs for distributed water?

7. Should EPA adopt one or more of the following alternatives to this proposal: Treating the fourth no-action level, a maximum of 0.020 mg/l of lead measured as the 95th percentile of targeted samples, the same as the first four no-action levels; adding total alkalinity of 30 mg/l as an additional no-action level to trigger treatment; requiring a system to replace lead service lines and connections that are found to contribute significantly to lead in tap water even after installation of optional corrosion control; a two-tiered approach to monitoring which may increase the efficiency of sampling, so fewer samples might be required of most public water systems; and eliminating pH as a no-action level?

8. Should the MCLs for lead and copper apply at the entry points to the distribution system or to fully flushed water at the consumer tap?

9. Should EPA require water suppliers to adjust corrosion control treatment to account for any blending of water from different sources? How? Please provide any data to support any alternative approaches.

10. Should EPA raise the maximum no-action level for lead to 0.030 mg/l (if it is adopted as a no-action level that triggers treatment) to assure that this alternative could be feasibly implemented; and/or substitute the no-action level of 0.020 mg/l for lead for the average of 0.010 mg/l for lead and pH and alkalinity measures?

11. What information should be included in the public education program?

12. Would the proposed public education program and/or any other similar actions reduce exposure to potentially excessive levels of lead in drinking water?

13. Are the proposed analytical techniques technically adequate and economically feasible?

14. Are the PQL acceptance limits for copper and lead appropriate?

15. Are the proposed criteria for selecting the targeted samples appropriate?

16. EPA requests additional data on samples in accordance with EPA's lead monitoring protocol. EPA is especially interested in corrosion control treatment data which compares lead levels in morning first draw samples before treatment and levels after treatment.

17. What specific level of lead or copper in drinking water constitutes an unreasonable risk to health?

18. Should EPA allow variances and exemptions from the proposed rule? Are there other conditions (in addition to those described) under which the treatment technique may not be necessary or beneficial for reducing lead exposures via drinking water?

19. Are the requirements that a State would be required to include in a program revision to adopt the lead and copper NPDWRs proposed in this regulation appropriate?

21. What will be the effects of the proposed requirements on State programs?

XII. References

The following references are referred to in this notice and are included in the public docket together with other correspondence and information. The public docket is available as described at the beginning of this notice. All public comments received on this proposal are included in the public docket.

Agency for Toxic Substances and Disease Registry (ATSDR). Nature and Extent of Childhood Lead Poisoning in Children in the U.S.: A Report to Congress. U.S. Dept. of Health and Human Services (July 1988). [ATSDR, 1988]

American Water Works Association Research Foundation (AWWARF). Internal Corrosion of Water Distribution Systems. (Cooperative Research Report), (1985). [AWWARF, 1985]

Angle, C.R. et al. Erythrocyte Nucleotides in Children—Increased Blood Lead and Cytidine Triphosphate. Pediatr. Res. Vol. 16 (1982), 331–334. [Angle et al., 1982]

Baghurst, P.A. et al. The Port Pirie Cohort Study: Lead Effects on Pregnancy Outcome and Early Childhood Development. NeuroToxicology. Vol. 8, No. 3 (1987), 395–402 (PB-9445). [Baghurst et al., 1987]

Bellinger, D.C. et al. Early Sensory-Motor Development and Prenatal Exposure to Lead. Neurobehav. Toxicol. Teratol. Vol. 6 (1984), 387–402. [Bellinger et al., 1984]

Bellinger, D.C. et al. Longitudinal Analyses of Prenatal and Postnatal Lead Exposure and Early Cognitive Development. The New England Journal of Medicine. Vol. 316, No. 17 (April 23, 1987), 1037–1043. [Bellinger et al., 1987]

Bennett, L.H. et al. Economic Effects of Metallic Corrosion in the United States. Paper 79. NACE '79 Forum, Atlanta, GA (March 1979) as reported in: Ryder (1980). The Costs of Internal Corrosion in Water Systems. [Bennett et al., 1979]

Bornschein, R.L. et al. Effects of Prenatal Lead Exposure on Infant Size at Birth (Draft). University of Cincinnati College of Medicine, Dept. of Enviro. Health (1988). [Bornschein et al., 1988]

Britton, A., MRSC (Members) and W.N. Richards, BSc MPhil, FRCS (Member). Factors Influencing Plumbosolvency in Scotland. Originally presented as: A pot pourri on plumbosolvency. At a Scientific Section Symposium on Plumbosolvency (November 1980). [Britton and Richards, 1980]

Chin, D. and Karalekas, P. Lead Product Use Survey of Public Water Supply Distribution Systems Throughout the U.S. (1984) In: U.S. Environmental Protection Agency. Plumbing Materials and Drinking Water Quality: Proceedings of a Seminar. Water Engineering Research Laboratory (February 1985) at 132–146. [Chin and Karalekas, 1984]

Chuttani, H.K. et al. Acute Copper Sulfate Poisoning. American Journal of Medicine. Vol. 39 (November 1965), 849–854. [Chuttani et al., 1965]

Cohen, A. and Myers, J.R. Mitigating Copper Pitting through Water Treatment. Journal

AWWA (February, 1987), 58–61. [Cohen and Meyers, 1987]
Davis, J.M. and Svendsgard, D.J. Lead and Child Development. Nature. Vol. 329 (Sept. 24, 1987), 297–300. [Davis and Svendsgard, 1987]
Dietrich et al. Effects of Low-Level Fetal Lead Exposure on Neurobehavioral Development in Early Infancy. University of Cincinnati College of Medicine. Cincinnati, Ohio (November 1987). [Dietrich et al., 1987]
Dodge, H.F. and Romig H.G. Sampling Inspection Tables: Single and Double Sampling. 2nd ed. (1959) LC 59–6763 (published by Wiley Interscience. [Dodge and Romig, 1959]
Durfor, C.N. and Becker, E. Chemical Quality of Public Water Supplies of the U.S. and Puerto Rico (1962). Hydrologic Investigations Atlas HA–200. U.S. Geological Survey (1964) as reported in: EPA (1986a). Reducing Lead in Drinking Water: A Benefits Analysis. [Durfor and Becker, 1964]
Federal Register. Vol. 43, No. 194. National Primary and Secondary Ambient Air Quality Standards (Thursday, Oct. 5, 1978). [43 FR 46246–46261, Oct 5, 1978]
Federal Register. Vol. 45, No. 168. Interim Primary Drinking Water Regulations; Amendments, Final Rule (Wed. August 27, 1980), 57332–57357. [45 FR 57332–57357, Aug 27, 1980]
Federal Register. Vol. 49, No. 114. National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals, Proposed Rule (Tues. June 12, 1984), 24330–24355. [49 FR 24330–24355, June 12, 1984]
Federal Register. Vol. 50, No. 219. National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals, Final Rule (Wed. Nov. 13, 1985), 46880–46901. [50 FR 46880–46901, Nov. 13, 1985]
Federal Register. Vol. 50, No. 219. National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals, Proposed Rule (Wed. Nov. 13, 1985), 46902–46932. [50 FR 46902–46932, Nov. 13, 1985]
Federal Register. Vol. 50, No. 219. National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals, and Microorganisms, Proposed Rule (Wed. Nov. 13, 1985), 46936–47022. [50 FR 46936–47022, Nov. 13, 1985]
Federal Register. Vol. 51, No. 185. Guidelines for Carcinogen Risk Assessment, Final Guidelines (Wed. Sept. 24, 1986), 33992–34003. [51 FR 33992–34003, Sept. 24, 1986]
Federal Register. Vol. 52, No. 130. National Primary Drinking Water Regulations; Monitoring for Unregulated Contaminants, Final Rule (Wed. July 8, 1987), 25690–25717. [52 FR 25690–25717, July 8, 1987]
Federal Register. Vol. 52, No. 208. Drinking Water Regulation; Public Notification, Final Rule (Wed. Oct. 28, 1987), 41534–41550. [52 FR 41534–41550, Oct. 28, 1987]
Fishman and Hems, 1976
Fulton, M. et al. Influence of Blood Lead on the Ability and Attainment of Children in Edinburgh. The Lancet. Vol. 1, No. 8544 (May 30, 1987), 1221–1226. [Fulton et al., 1987]
Grant, L.D. et al. Chronic Low-Level Lead Toxicity in the Rat. Toxicology and Applied Pharmacology. Vol. 56 (1980), 42–58 (PB–4202). [Grant et al., 1980]
Greathouse, D.G. and Osborne, R.H. Preliminary Report on Nationwide Study of Drinking Water and Cardiovascular Diseases. J. of Envir. Path. and Toxicol. 3 (1980), 65–76 as reported in: EPA (1986a). Reducing Lead in Drinking Water: A Benefits Analysis. [Greathouse and Osborne, 1980]
Gregory, R. and Jackson, P.J. Central Water Treatment to Reduce Lead Solubility. Water Resource Centre. Prepared for the AWWA Annual Conference. Dallas, TX (1984). [Gregory and Jackson, 1984]
Hatzakis, A. et al. Psychometric Intelligence and Attentional Performance Deficits in Lead-Exposed Children. International Conference of Heavy Metals in the Environment. Vol. 1 (September 1987), 204–209, (CEP Consultants Limited). [Hatzakis et al., 1987]
Hernberg, S. and Nikkanen, J. Enzyme Inhibition by Lead Under Normal Urban Conditions. The Lancet. Vol. 1 (January 10, 1970), 63–64. [Hernberg and Nikkanen, 1970]
House Report No. 1185, 93rd Cong. 2d Sess., (1974) at 13 and 20. [H.R. Rep. No. 93–1185, 1974]
Hoyt, B.P. et al. Evaluating Home Plumbing Corrosion Problems. Journal AWWA (December 1979), 720–725. [Hoyt et al., 1979]
Karelekas, P.C. et al. Lead and Other Trace Metals in Drinking Water in the Boston Metropolitan Area. Journal of the New England Water Works Association. Vol. 90, No. 2. (February 1976). [Karalekas et al., 1976]
Karalekas, P.C. et al. Alternative Methods for Controlling the Corrosion of Lead Pipe. Journal of the New England Water Works Association (June 1978). [Karalekas et al., 1978]
Karalekas, P.C. et al. Control of Lead, Copper, and Iron Pipe Corrosion in Boston. Journal AWWA (February 1983), 92–95. [Karalekas et al., 1983]
Lacey, R.F. et al. Lead in Water, Infant Diet, and Blood: The Glasgow Duplicate Diet Study. The Science of the Total Environment. Vol. 41 (1985), Elsevier Science Publishers B.V. Amsterdam, printed in the Netherlands. [Lacey et al., 1985]
Landrigan, P.J. et al. Increased Lead Absorption with Anemia and Slowed Nerve Conduction in Children Near a Lead Smelter. Journal of Pediatrics. Vol. 89 No. 6 (December 1976), 904–910 (PB–1353). [Landrigan et al., 1976]
Lassovszky, P. Effect on Water Quality from Lead and Nonlead Solders in Piping. Heating/Piping/Air Conditioning (October 1984) 51–58. [Lassovszky, 1984]
Lauwerys, M.C. et al. Comparison of Biometric Data of Children with High and Low Levels of Lead in Blood. American Journal of Physical Anthropology. Vol. 69 (1986), 42–58. [Lauwerys et al., 1986]
Lauwerys, R. et al. Placental Transfer of Lead, Mercury, Cadmium, and Carbon Monoxide in Women. I. Comparison of the Frequency Distributions of the Biological Indices in Maternal and Umbilical Cord Blood. Environ. Res. Vol. 15 (1978), 278–289 (PB–3735). [Lauwerys et al., 1978]
Lyon, T.D.B. and Lenihan, J.M.A. Corrosion in Solder Jointed Copper Tubes Resulting in Lead Contamination of Drinking Water. Br. Corros. J. Vol. 12, No. 1 (March 1977). [Lyon and Lenihan, 1977]
Maessen, O. et al. Metal Mobilization in Home Well Water Systems, in Nova Scotia. Journal AWWA (June 1985), 73–80. [Maessen et al., 1985]
Mahaffey, K.R. et al. Association Between Age, Blood Lead Concentration, and Serum, 1,25-dihydroxycholecalciferol Levels in Children. The American Journal of Clinical Nutrition. Vol. 35 June 1982), 1327–1331 (PB–4615). [Mahaffey et al., 1982]
Mahaffey, J.R. and Annest, J.L. Association of Erythrocyte Protoporphyrin with Blood Lead Level and Iron Status in the Second National Health and Nutrition Examination Survey, 1976–1980. Environmental Research. Vol. 41 (1986), 327–338. [Mahaffey and Annest, 1986]
Marcus, A.H. and Holtzman, A.P. Estimates of the Fraction of U.S. Children Benefiting from Reduced Water Lead Concentrations (Draft). (June 30, 1988). [Marcus and Holtzman, 1988]
McMichael, A.J. et al. The Port Pirie Cohort Study: Maternal Blood Lead and Pregnancy Outcome. Journal of Epidemiol, Commun. Health. Vol. 40 (1986), 18–25. [McMichael et al., 1986]
Meredith, P.A. et al. Delta-aminolevulinic Acid Metabolism in Normal and Lead-Exposed Humans. Toxicology. Vol. 9 (1978), 1–9. [Meredith et al., 1978]
Moore, M.R. Lead in Drinking Water in Soft Water Areas—Health Hazards. Sci. Total Environ. Vol. 7 (1977), 109–115 as reported in: U.S. Environmental Protection Agency (1986b). Air Quality Criteria Document. Vol. 3 at 11–32. [Moore, 1977]
Morse, D. et al. Exposure of Children to Lead in Drinking Water, American Journal of Public Health. Vol. 19, No. 7 (July 1979), 711–712. [Morse et al., 1979]
National Academy of Sciences. Drinking Water and Health (1980). Vol. 3. [NAS, 1980]
O'Brien, J.E. et al. Lead in Boston Water: Its Cause and Prevention. JNEWWA. Vol. 90.2 (January 1976), 173–180. [O'Brien et al., 1976]
O'Flaherty, E.J. et al. The Renal Handling of Δ-Aminolevulic Acid in the Rat and in the Human. Toxicology and Applied Pharmacology. Vol. 55 (1980), 423–432 (PB–5577). [O'Flaherty et al., 1980]
Oliphant, R.J. Lead Contamination of Potable Water Arising from Soldered Joints. ISWA Congress, Zurich as reported in: EPA (1986a), Benefits Analysis. [Oliphant, 1982]
Oliphant, R.J. Summary Report on the Contamination of Potable Water by Lead from Soldered Joints. Water Research Centre (Nov. 1983). [Oliphant, 1983]
Otto, D.A. et al. Effects of Age and Body Lead Burden on CNS Function in Young Children. I. Slow Cortical Potentials. Electroencephalography and Clinical Neurophysiology. Vol. 52 (1981), 229–239 (PB–3391). [Otto et al., 1981]
Otto, D.A. et al. Effects of Low to Moderate Lead Exposure on Slow Cortical Potentials in Young Children: Two Year Follow-up

Study. Neurobehavioral Toxicology and Teratology. Vol. 4 (1982), 733–737 (PB–5015). [Otto et al., 1982]
Otto, D.A. et al. 5-Year Follow-up Study of Children with Low-to-Moderate Lead Absorption: Electrophysiological Evaluation. Vol. 38 (1985), 168–186 (PB–6543). [Otto et al., 1985]
Piomelli, S. et al. The Effects of Low-Level Lead Exposure on Heme Metabolism. Low-Level Lead Exposure: The Clinical Implications of Current Research, Raven Press (1980), 67–73 (PB–3437M). [Piomelli et al., 1980]
Pocock, S.J. Factors Influencing Household Water Lead: A British National Survey. Archives of Environmental Health. Vol. 35, No. 1 (January/February 1980), 45–51. [Pocock, 1980]
Reiber, S.H. et al. Corrosion Monitoring and Control in the Pacific Northwest. Journal AWWA (February 1987), 71–74. [Reiber et al., 1987]
Rosen, J.F. et al. Reduction in 1,25-Dihydroxyvitamin D in Children with Increased Lead Absorption. New England Journal of Medicine. Vol. 302 (May 15, 1980), 1128–1131 (PB–4987). [Rosen et al., 1980]
Ryder, R.A. The Costs of Internal Corrosion in Water Systems. Journal AWWA (May 1980), 267–279. [Ryder, 1980]
Ryu, J.E. et al. Dietary Intake of Lead and Blood Lead Concentration in Early Infancy. American Journal Dis. Child. Vol. 137 (Sept. 1983), 886–891. [Ryu et al., 1983]
Schroeder, S.R. et al. Separating the Effects of Lead and Social Factors on IQ. Environmental Research. Vol. 38 (1985), 144–154. [Schroeder et al., 1985]
Schroeder, S.R., and Hawk, B. Child-Caregiver Environmental Factors Related to Lead Exposure and IQ (1986). In: Schroeder, S.R., ed. Toxic Substances and Mental Retardation: Neurobehavioral Toxicology and Teratology. Washington, DC. (in press, AAMD monograph series). [Schroeder and Hawk, 1986]
Schroeder and Hawk, 1987
Schwartz, J. et al. Relationship Between Childhood Blood Lead Levels and Stature. Pediatrics. Vol. 77, No. 3 (1986), 281–288. [Schwartz et al., 1986]
Schwartz, J. et al. Threshold Effect in Lead-Induced Peripheral Neuropathy. The Journal of Pediatrics. Vol. 112, No. 1 (January 1988), 12–17. [Schwartz et al., 1988]
Schwartz, J. and Otto, D. Blood Lead, Hearing Thresholds, and Neurobehavioral Development in Children and Youth. Archives of Environmental Health. Vol. 42, No. 2 (May/June 1987), 153–160 (PB–9455). [Schwartz and Otto, 1987]
Stone, A. et al. The Effects of Short-Term Changes in Water Quality on Copper and Zinc Corrosion Rates. Journal AWWA (February 1987), 75–82. [Stone et al., 1987]
Thomas, H.F. et al. Relationship of Blood Lead in Women and Children to Domestic Water Lead. Reprinted from Nature (MacMillan Journals Limited). Vol. 282, No. 5740 (December 13, 1979), 712–713. [Thomas et al., 1979]
United Kingdom Department of the Environment, Central Directorate on Environmental Pollution. The Glasgow Duplicate Diet Study (1979/1980). Pollution Report No. 11 (1982). [U.K. Dept. of Environment, 1982]
U.S. Department of Health, Education and Welfare. Air Quality Data from the National Air Sampling Networks and Contributing State and Local Networks. National Air Pollution Administration (Publication No. APTD 68–9, 1966). National Technical Information Service No. PB195155. [U.S. Dept. of Health, Education and Welfare, 1966]
U.S. Environmental Protection Agency. Corrosion in Water Distribution Systems. Prepared by J. Patterson, Patterson Associates, Inc. (March 1981) for ODW. [EPA, 1981]
U.S. Environmental Protection Agency. Corrosion in Potable Water Systems (Final Report). Prepared by David W. DeBerry et al., SumX Corporation under EPA contract No. 68–01–5834 (February 1982). [EPA, 1982]
U.S. Environmental Protection Agency. Reducing Lead in Drinking Water: A Benefits Analysis (Draft Final Report). Office of Policy, Planning, and Evaluation (December 1986). [EPA, 1986a]
U.S. Environmental Protection Agency. Air Quality Criteria for Lead, Volumes I–IV, Environmental Criteria and Assessment Office, Research Triangle Park, NC, EPA–600/8–83/028aF (June 1986). [EPA, 1986b]
U.S. Environmental Protection Agency. Letter to EPA Administrator Lee Thomas from M. Lippman, Clean Air Scientific Committee indicating the approval of the Air Quality Criteria for Lead document (August 29, 1986). [EPA, 1986c]
U.S. Environmental Protection Agency. Costing Scenarios for Alternative MCLs for Lead (Draft). Prepared by Science Applications International Corporation (August 10, 1987) under EPA contract no. 68–03–3348. [EPA, 1987a]
U.S. Environmental Protection Agency. Project Summary: Corrosion in Water Distribution Systems of the Pacific Northwest. Water Engineering Research Laboratory. Cincinnati, OH (November 1987). [EPA, 1987b]
U.S. Environmental Protection Agency. Lead in Drinking Water Workshop August 13 and 14, 1987 (Final Report). Prepared by Viking Systems International, Inc. (November 1987). [EPA, 1987c]
U.S. Environmental Protection Agency. Memorandum to Stephen W. Clark from John E. Dyksen, Malcolm-Pirnie, Inc. regarding Survey of Utility Access to Service Lines (December 31, 1987). [EPA, 1987d]
U.S. Environmental Protection Agency. Project Summary: Limestone Bed Contractors for Control of Corrosion at Small Water Utilities. Water Engineering Research Laboratory. Cincinnati, OH (February 1987). [EPA, 1987e]
U.S. Environmental Protection Agency. Volatile Organic Chemicals: Methods and Monitoring Document (Final). Criteria and Standards Division (June 1987). [EPA, 1987f]
U.S. Environmental Protection Agency. Regulatory Impact Analysis of Proposed National Primary Drinking Water Regulations for Lead and Copper (Draft). Prepared by Wade Miller Associates, Inc. (June 1, 1988). [EPA, 1988a]
U.S. Environmental Protection Agency. Memorandum to Greg Helms, ODW from Rob Elias, ECAO/TRP regarding the Total Human Exposure Model for Lead (plus attachments), (March 29, 1988). [EPA, 1988b]
U.S. Environmental Protection Agency. Relationship Between Infant Blood Lead Concentrations and Lead in Water or Liquid Diet (Draft Report). Prepared by A. Holtzamn and A. Marcus, Battelle—Columbus Division (May 11, 1988) under EPA contract no. 68–02–4246. [EPA, 1988c]
U.S. Environmental Protection Agency. National Air Quality and Emissions Trends Report, 1986. Office of Air Quality Planning and Standards (February 1988). [EPA, 1988d]
U.S. Environmental Protection Agency. Review of the Carcinogenic Potential of Lead Associated with Oral Exposure (Final). Carcinogen Assessment Group, Office of Health and Environmental Assessment (July 1988). Prepared for ODW, OSW, and OERR (SuperFund). [EPA, 1988e]
U.S. Environmental Protection Agency. Memorandum to Jeanne Briskin, ODW from Jeff Cohen, OAQPS regarding Estimating 1980 Baseline Blood Level Averages for Children (July 5, 1988). [EPA, 1988f]
U.S. Environmental Protection Agency. Memorandum to Arthur Perler, Science and Technology Branch from Jon Langtin, Water Supply Technology Branch regarding Distribution Tables for NIRS Results (Feb. 23, 1988). [EPA, 1988g]
U.S. Environmental Protection Agency. Treatment and Occurrence Document (1988). [EPA, 1988h]
U.S. Environmental Protection Agency. Ciccone, 1988. [EPA, 1988i]
U.S. Environmental Protection Agency. Memorandum to Jeanne Briskin, ODW from Neil Stoloff and Larry Oates, ICF Inc. regarding Selected Standards Governing Service Line Ownership and Control (May 5, 1988). [EPA, 1988j]
U.S. Environmental Protection Agency. Performance Evaluation Studies: Water Supply Studies #12–17.
U.S. Environmental Protection Agency. Performance Evaluation Studies: Water Pollution Study #11.
U.S. Environmental Protection Agency. Performance Evaluation Studies: Water Pollution Studies #12–16.
U.S. Environmental Protection Agency. NOMS.
Wolf, et al. Intrauterine Lead Exposure and Early Development. In: Lekkas, T. D. ed. International Conference: Heavy Metals in the Environment (September). Athens, Greece, v.2. (1985) Edinburgh, United Kingdom: CEP Consultants, Ltd.; pp. 153–155. [Wolf, et al., 1985]
Worth, D. et al. Lead in Drinking Water: The Contribution of Household Tap Water to Blood Lead Levels. Environmental Lead. Academic Press Inc., (1981). [Worth, et al., 1981]

List of Subjects in 40 CFR Parts 141 and 142

Chemicals, Reporting and recordkeeping requirements, Water supply, Administrative practice and procedure, Incorporation by reference.

Dated: August 9, 1988.

Lee M. Thomas,

Administrator.

For the reasons set forth in the preamble, Title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300g–6, 300j–4, and 300j–9.

2. Section 141.2 is amended by removing the paragraph designations and placing the definitions in alphabetical order, by revising the definitions of "maximum contaminant level," and adding the following new definitions in alphabetical order to read as follows:

§ 141.2 Definitions.

* * * * *

"Corrosion inhibitor" means a substance, such as zinc orthophosphate, capable of reducing the corrosivity of water toward plumbing materials, for example, by forming a protective film on the interior surface of the plumbing materials.

* * * * *

"Distributed water" means water entering the water distribution system after any treatment that may be applied.

* * * * *

"Ends of the distribution system" means areas of the distribution system with low or no water flow in water mains.

* * * * *

"Maximum contaminant level" means the maximum permissible level of a contaminant in water that is delivered to any user of a public water system.

* * * * *

"Morning first draw sample" means a sample of tap water that has been standing in plumbing pipes for 8 to 18 hours and is collected without flushing.

* * * * *

"Optimal corrosion control treatment" is corrosion control treatment which minimizes lead levels in targeted samples.

* * * * *

"pH" means the condition represented by the negative logarithm of the effective hydrogen-ion concentration or hydrogen-ion activity expressed in gram equivalents per liter. pH is used to express both acidity and basicity on a scale whose values run from 0 to 14 with 7 representing neutrality; numbers less than 7 indicate a more acidic solution, and numbers greater than 7 indicate a more basic solution.

* * * * *

"Residence," for the purpose of Subpart I of this part only, means, in the case of a community water system, a house or other dwelling unit. In the case of a non-transient non-community water system, residence means any building served by the public water system.

* * * * *

"Service connection" means the pipe, gooseneck, pigtail, and any other fitting connecting the water main to the building inlet.

"Service connection sample" means a sampling of water that has been standing for 8–18 hours in the building service connection.

* * * * *

"Targeted sample" is a sample taken in accordance with § 141.86(d).

3. Section 141.32 is amended by reserving paragraphs (e)(10)–(12) and adding paragraphs (e)(13) and (14) to read as follows:

* * * * *

§ 141.32 Public notification.

* * * * *

(e) * * *

(10)–(12)—[Reserved]

(13) *Lead.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that lead is a health concern at certain exposure levels. Lead is a soft, dull, gray metal that has frequently been used in water supply plumbing materials, expecially flux, solder, pipes, and brass and bronze fixtures. Lead usually contaminated drinking water as a result of the corrosion of these plumbing materials by the water they carry. Lead has been shown to cause a variety of adverse health effects in humans and animals. In humans, lead has been shown to interfere with the formation of red blood cells (heme synthesis), cause anemia, cause kidney damage, impair reproductive function, reduce birth weight, cause premature birth, delay physical and mental development in babies and young children, impair mental abilities in children, and increase blood pressure in adults. Many of these effects have been observed at relatively low exposure levels. Studies on animals indicated that lead may also cause cancer at high doses. EPA has set an enforceable drinking water standard at 0.005 ppm (parts per million) for lead leaving the treatment plant and entering the distribution system. EPA also requires public water systems to treat their water to minimize lead contamination resulting from corrosion of plumbing materials when lead in tap water that has been standing overnight exceeds an average of 0.010 ppm. Drinking water that meets these standards is associated with little of this risk and should be considered safe to drink.

(14) *Copper.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that copper is a health concern at certain exposure levels. Copper is an orange metal that is commonly used for plumbing pipes in homes and other buildings. Copper generally contaminates drinking water as a result of the corrosion of copper pipes by the water they carry. When copper corrodes, the water and sink are often stained green. Copper is an essential nutrient, but at higher doses it has been shown to cause stomach and intestinal distress, liver and kidney damage and anemia. Persons with Wilson's disease may be at higher risk from copper toxicity than the general public. EPA has set an enforceable drinking water standard for copper at 1.3 ppm (parts per million) for water leaving the treatment plant and entering the distribution system. EPA also requires public water systems to treat their water to control copper contamination resulting from the corrosion of plumbing materials when copper in tap water that has been standing overnight exceeds 1.3 ppm in more than 5 percent of samples. Drinking water that meets this standard is associated with little to none of this risk and should be considered safe to drink.

4. A new Subpart I is added to read as follows:

Subpart I—Control of Lead and Copper

Sec.
141.80 Applicability.
141.81 MCLGs for lead and copper.
141.82 MCLs and BAT for lead and copper.
141.83 Treatment technique requirement.
141.84 Treatment plan.
141.85 Public education program.
141.86 Analytic and monitoring requirements for lead and copper MCLs and treatment technique requirements.
141.87 Reporting and recordkeeping.

Subpart I—Control of Lead and Copper

§ 141.80 Applicability.

Unless otherwise indicated, each of the provisions of this subpart applies to community water systems and non-transient non-community water systems (hereinafter referred to as "systems").

§ 141.81 MCLGs for lead and copper.

The maximum contaminant level goals (MCLGs) for lead and copper are as follows:

Contaminant	MCLG in mg/l
(1) Lead	Zero.
(2) Copper	1.3

§ 141.82 MCLs and BAT for lead and copper.

(a) The following MCLs for lead and copper apply to water entering the distribution system, after any treatment:

Contaminant	MCL in mg/l
(1) Lead	0.005
(2) Copper	1.3

(b) The Administrator, pursuant to section 1412(b)(6) of the Act, hereby identifies the following as the best technology, treatment technique, or other means available (BAT) for achieving compliance with or issuing variances from the MCLs for lead and copper:

Contaminant	BAT
(1) Lead	(1), (2), (3), (4)
(2) Copper	(1), (2), (3), (4)

Key to BATs in Table.
1 = Coagulation/Filtration.
2 = Ion Exchange.
3 = Lime softening.
4 = Reverse Osmosis.

§ 141.83 Treatment technique requirement.

(a) This rule establishes a treatment technique requirement to control lead and copper as corrosion byproducts. The treatment technique requirement consists of optimal corrosion control treatment (to minimize lead in drinking water) and public education (to reduce exposure to lead in drinking water). A system that meets the no-action levels specified in paragraphs (b)(1)(i)-(iv) of this section is deemed in compliance with the treatment technique requirement of this paragraph.

(b) The specific steps a system must take to comply with the treatment technique requirement of paragraph (a) of this section depend on the lead level, copper level, and pH measured as specified in § 141.86 (a) and (d) of this part. These steps are set out below:

(1) The no-action levels are as follows:

(i) The arithmetic average lead level of the required samples is less than or equal to 0.010 mg/l;

(ii) The lead level in at least 95 percent of the required samples is less than or equal to 0.020 mg/l;

(iii) The copper level in at least 95 percent of the required samples is less than or equal to 1.3 mg/l;

(iv) The pH is greater than or equal to 8.0 in at least 95 percent of the required samples.

(2) If a system cannot meet one or more of the no-action levels specified in paragraph (b)(1) of this section, it must obtain and implement a State-approved treatment plan, as specified below:

(i) If the arithmetic average lead level in the required samples exceeds 0.010 mg/l, the State-approved treatment plan must require the system to install optimal corrosion control treatment, as specified in § 141.84 of this part, and to conduct a public education program, as specified in § 141.85 of this part.

(ii) If the lead level exceeds 0.020 mg/l in more than five percent of the required samples, the State-approved treatment plan must require the system to conduct a public education program, as specified in § 141.85 of this part.

(iii) If the lead level exceeds 1.3 mg/l in more than five percent of the required samples, the State-approved treatment plan must require the system to install optimal corrosion control treatment, as specified in § 141.84 of this part.

(iv) If the pH is less than 8.0 in more than five percent of the required samples, the State-approved treatment plan must require the system to install optimal corrosion control treatment, as specified in § 141.84 of this part.

(c) Each system must meet the no-action levels specified in paragraph (b)(1) of this section, or submit or apply for a State-approved treatment plan as specified in § 141.84 of this part, according to the following schedule (which corresponds to one year after the monitoring required by §141.86(b) of this part is to be completed):

System size (# persons served)	Deadline
>3,300	(enter date 27 months after publication of final rule).
500-3,300	(enter date 39 months after publication of final rule).
<500	(enter date 51 months after publication of final rule).

(d)(1) A system that fulfills the treatment technique requirements of paragraph (a) of this section by meeting the no-action levels in paragraph (b)(1) of this section, by the deadline specified in paragraph (c) of this section, and fails to meet one or more of the no-action levels during a subsequent monitoring period (the length of the monitoring period, which varies by system size and system type, is specified in § 141.86 of this part), must comply with paragraph (b)(2) of this section. Such a system must submit or apply for a State-approved treatment plan under §141.84 of this part within one year after any such failure to meet the no-action level(s).

(2) A system that meets the no-action levels in paragraph (b)(1) of this section after implementing a treatment plan approved by the State under § 141.84 of this part must continue to meet the no-action levels each subsequent monitoring period.

Failure to meet one or more of the no-action levels is a violation of the treatment technique requirement.

(3) A system that does not meet the no-action levels after implementing the treatment plan approved by the State under § 141.84 of this part and demonstrating to the State that it has minimized the corrosivity of its water toward lead must operate within the parameters approved by the State as optimal for reducing corrosion of lead. Failure to operate within one or more of the parameters is a violation of the treatment technique requirement.

§ 141.84 Treatment plan.

The treatment plan describes the specific steps a system must take to comply with the treatment technique requirement in § 141.83(a) of this part and specifies a schedule for completing these steps for systems that do not meet one or more no-action levels specified in § 141.83(b) of this part. Failure to complete any step by the deadline specified in the plan for that step is a violation of the treatment technique requirement.

(a)(1) As specified in § 141.83(b)(2) of this part, the treatment plan must require optimal corrosion control treatment when:

(i) The system exceeds the no-action average lead level as specified in § 141.83(b)(1)(i) of this part;

(ii) The system exceeds the no-action copper level as specified in § 141.83(b)(1)(iii) of this part; or

(iii) The system fails to meet the no-action pH level as specified in § 141.83(b)(1)(iv) of this part.

(2) Systems serving more than 3,300 persons must develop and submit a treatment plan to the State for review and approval. The treatment plan must explain how the system will achieve the following steps, and provide a schedule for completing each step:

(i) Design and implementation of appropriate pipe loop, laboratory, pilot scale, and/or field studies demonstrating reductions of lead levels in simulated morning first draw and service connection samples that correspond to application of various corrosion control treatments, such as:

(A) pH adjustment;

(B) Alkalinity adjustment; and/or

(C) Addition of corrosion inhibitors;

(ii) Analysis of the data generated in paragraph (a)(2)(i) of this section that identifies the water quality conditions under which lead levels in morning first draw and service connection samples are expected to be minimized;

(iii) Installation and operation of corrosion control treatment in the water supply system as a whole to ensure delivery to residences of water meeting the water quality conditions identified in paragraph (a)(2)(ii) of this section within three years after the State approves the treatment plan;

(iv) Monitoring to determine the effectiveness of the corrosion control treatment by comparing lead levels in morning first draw and service connection samples at residences designated for monitoring, as specified in § 141.86 of this part, after installation of corrosion control treatment with:

(A) The no-action levels for lead specified in § 141.83(b)(1) of this part, and

(B) The lead levels in morning first draw and service connection samples predicted based on the analysis performed in paragraph (a)(2)(ii) of this section;

(v) Additional adjustment of the corrosion control treatment if the lead levels in morning first draw or service connection samples from residences designated for monitoring, as specified in § 141.86 of this part, exceed the no-action level specified in § 141.83(b)(1)(i) of this part; and

(vi) If the system is still exceeding the no-action levels after application of all treatment, an analysis of all treatment and resulting lead levels must be prepared and submitted to the State.

(3) For systems serving 3,300 or fewer persons, the system must request a treatment plan from the State. The State will specify the required treatment. The treatment plan must include the following steps, and a schedule for completing each step:

(i) Installation and operation in the water supply system of the corrosion control treatment specified by the State (such as pH control, alkalinity control, and/or use of corrosion inhibitors) within three years after the State issues the treatment plan;

(ii) Monitoring to determine the effectiveness of the corrosion control treatment by comparing lead levels in morning first draw and service connection samples at residences designated for monitoring, as specified in § 141.86 of this part, after installation of corrosion control treatment with the applicable no-action levels for lead specified in § 141.83(b)(1) of this part; and

(iii) Additional adjustment of the corrosion control treatment if the lead levels in morning first draw or service connection samples from residences designated for monitoring, as specified in § 141.86 of this part, exceed the no-action level specified in § 141.83(b)(1)(i) of this part.

(4) If lead levels in morning first draw or service connection samples continue to exceed the no-action level specified in § 141.83(b)(1)(i) of this part after completion of the steps described in paragraph (a)(2) of this section (for systems serving more than 3,300 persons) or paragraph (a)(3) of this section (for systems serving 3,300 or fewer persons), the State must evaluate the treatment and monitoring data and determine whether the corrosion control treatment applied by the system is optimal, i.e., minimizes the corrosivity of water towards lead. If the State determines that the system has minimized the corrosivity of water towards lead i.e., the treatment is optimal, the system must continue to operate within the parameters specified by the State as constituting optimal treatment. Final operating parameters specified by States must account for seasonal variations in water corrosivity and lead levels.

(5) Systems serving more than 3,300 persons that wish to change other concurrent treatments that might reduce the effectiveness of the approved corrosion control treatment, or experience significant change in the population served or in the extent of the distribution system, would be required to submit to the State for approval new corrosion control data from studies which reflect the new conditions under which the supplier wished to operate, except for temporary changes required to respond to an emergency situation. Permanent operating conditions must assure that treatment is optimal Temporary changes in treatment must be reported to the State within five days. Changes in treatment lasting more than five days are considered permanent changes in treatment.

(6) Systems serving less than 3,300 persons that wish to change other concurrent treatments that might reduce the effectiveness of the approved corrosion control treatment, or experience significant change in the population served or in the extent of the distribution system, would be required to notify the State of the proposed changes. States may disapprove the changes and require any modifications necessary to assure that treatment is optimal.

(7) States may, at their discretion, periodically review and revise approved treatment plans and final operating parameters as warranted, to ensure that no-action levels continue to be met or that treatment remains optimal.

(b)(1) The treatment plan must contain public education provisions when:

(i) A system exceeds the no-action average lead level specified in § 141.83(b)(1)(i) of this part; or

(ii) A system exceeds the no-action maximum lead level specified in § 141.83(b)(1)(i)(ii) of this part.

(2) A system must conduct a public education program in accordance with its State-approved treatment plan once the State approves it (for systems serving more than 3,300 persons) or issues it (for systems serving 3,300 or fewer persons), as long as paragraph (b)(1)(i) or (ii) of this section applies.

(3) The portion of the treatment plan that addresses the pubic education program must conform to the requirements of § 141.85 of this part.

§ 141.85 Public education program.

The public education program must be designed to provide users served by the system with information that will enable them to modify their water use behavior or take other measures to mitigate the risks to human health associated with excess levels of lead in drinking water that cannot be controlled by central water treatment.

(a) *Targeting of the public education program.* Community water systems must either:

(1) Direct the public education program required by this section to the entire population of users served by the system; or

(2) Based on the results of the materials evaluation described in § 141.86(d) of this part or any other

information available to the system, target the public education program to particular segments of the consumer population that may be receiving drinking water at the tap that exceeds the no-action levels of § 141.83(b)(1)(i) or (ii) of this part. A community water system must identify such segments on the basis of factors that include but are not limited to:

(i) Known increased potential for exposure to excess levels of lead in drinking water (e.g., areas where lead service lines are known to exist, areas where very new or very old buildings exist, areas located at the ends of the water distribution system); or

(ii) Known to be more susceptible to the adverse effects of lead (e.g., children, pregnant women, or groups of individuals exposed to additional sources of lead, including occupational exposure or other environmental exposure).

(b) *Supplemental monitoring and notification of results.* (1) As part of the public education program, community water systems must offer to sample or arrange to have sampled by a certified Laboratory the water of any customer who requests it to determine the lead content of drinking water at the customer's residence. The system is not required to pay for the sampling or analysis, nor is the system required to collect and analyze these samples itself.

(2) Each customer whose residence is sampled as part of the system's compliance monitoring, as specified in § 141.86 of this part, and each customer who requests supplemental monitoring, as specified in paragraph (b)(2) of this section, must be informed of the results of the analysis performed on his or her residence.

(c) *Content of the public education program.* The public education program required of community and non-transient non-community systems by this section must include but is not limited to the following:

(1) Information explaining the causes of excess levels of lead in drinking water. Such causes include but are not limited to:

(i) Excess levels of lead in source water;

(ii) The corrosivity of water toward plumbing materials containing lead;

(iii) The presence of lead pipes or connections;

(iv) The existence of newly-installed lead solders (generally less than five years old);

(v) Water remaining in contact with plumbing containing lead for extended periods of time;

(vi) The use of water from the hot water tap for consumption; and

(vii) Grounding of electrical systems to lead-bearing plumbing.

(2) Information explaining the potential health effects of exposure to excess levels of lead. Such effects include but are not limited to:

(i) Delayed neurological and physical development in children and infants;

(ii) Impaired cognitive performance in children (as measured by IQ tests, performance in school, and other means);

(iii) Elevations in blood pressure in adults;

(iv) Interference with heme synthesis (the ability of blood to absorb oxygen);

(v) Interference with vitamin D metabolism;

(vi) Anemia (low red blood-cell count);

(vii) Kidney damage:

(viii) Impaired reproductive function;

(ix) Complications in pregnancy and other fetal effects; and

(x) Potential carcinogenicity.

(3) Information explaining that the risks associated with lead in drinking water may be aggravated by exposure to lead from other sources. These sources include but are not limited to:

(i) Occupational or home hobby exposures (e.g., exposure from smelting, electronics, or other operations that involve the use of lead);

(ii) Inhalation of airborne lead from paint dust, leaded gasoline engine exhaust, and smelter or battery recycling; and

(iii) Ingestion of lead from lead paint chips, lead that settles out of the air as dust and dirt, and lead-contaminated crops and foodstuffs, including contamination from lead-soldered food containers and improperly glazed pottery.

(4) Actions that have been taken by the system or community to evaluate, quantify, or reduce the levels of lead in drinking water. Such actions include but are not limited to:

(i) Modifications to the applicable plumbing code to ban the use of lead solders, fluxes, and pipes, pursuant to the lead ban of Subpart E of this part;

(ii) Compliance monitoring conducted pursuant to § 141.86 of this part and any supplemental monitoring conducted pursuant to paragraph (b) of this section; and

(iii) Other actions the system has taken to evaluate, quantify, or reduce the levels of lead in drinking water.

(5) Information that the user may use to evaluate the probability that excess levels of lead exist in the user's drinking water supply. Such information must include the likelihood that excess lead levels exist in water as it leaves the system and the potential for further increases in lead levels as a result of corrosion of water distribution system components. In addition, the public education program must recommend that the user:

(i) Determine whether the user's faucets, water holding tanks, service lines, pipes, and soldered joints contain lead;

(ii) Contact the system for additional information; and

(iii) If the potential for excess levels of lead in the user's drinking water appears to be substantial, have the user's water analyzed to determine the water's lead content.

(6) Actions that the user can take to reduce short-term and long-term exposures to lead in drinking water. Such actions include but are not limited to:

(i) Flushing each water tap for at least three minutes, or until the water is as cold as it will get, before any water from that tap is consumed or used for any type of cooking or preparation of food, beverages (including ice), or baby formula;

(ii) Replacing privately-owned and privately-controlled lead service lines with pipes that are lead-free;

(iii) Ensuring that all plumbing repair work is performed using lead-free pipe, solder, and flux (as defined in Subpart E of this part); and

(iv) If allowed by the local electrical code, providing an electrical ground for the user's wiring other than the user's plumbing system.

(d) *Delivery of the public education program by community water systems.* (1) Community water systems must deliver the public education program in a form that is tailored to the nature and size of the target population, as determined under paragraph (a) of this section. The system must present all materials associated with the public education program in plain English (and in other languages where appropriate) that can be understood readily by the layperson. The means by which the system delivers the public education program may include but are not limited to:

(i) Public service announcements broadcast on radio and television stations;

(ii) Public announcements published in local newspapers;

(iii) Public meetings;

(iv) Informational notices in water utility bills;

(v) Pamphlets or brochures; and

(vi) In combination with the means specified in paragraphs (d)(1) (i) through (v) of this section, local telephone hotlines.

(2) When designing and implementing a public education program, community systems water must, to the extent practicable, coordinate with appropriate local authorities including but not limited to:

(i) The city, county, or municipal council;

(ii) The Mayor's, City Administrator's, or County Commissioners' office;

(iii) The local department of public health;

(iv) The local department of environmental protection; and

(v) The local government office responsible for administering lead-screening programs, if not listed elsewhere in this paragraph.

(3) Community water systems must repeat public education programs at least quarterly as long as the level of lead in drinking water exceed one or both no-action levels specified in § 141.83(b)(1) (i) and (ii) of this part during the previous monitoring period.

(e) *Delivery of the public education program by non-transient non-community water systems.* Non-transient non-community water systems must:

(1) Publicly post informational posters on lead in drinking water in a public place;

(2) Hold at least one public meeting annually to educate water consumer's about lead in drinking water and to answer questions on the subject; and

(3) Distribute brief informational pamphlets on lead in drinking water at least quarterly.

(f) *Evaluation of the public education program.* Community water systems serving more than 10,000 persons must, within 12 months after a public education program is undertaken, and every 24 months thereafter, evaluate the extent to which the program is effective. As part of the evaluation, the system must demonstrate to the State that, as a result of the public education program, users' knowledge about lead in drinking water enables them to alter voluntarily their water use patterns to reduce consumption of lead-contaminated water. The demonstration must be based on public survey (by mail, telephone, or in person) to evaluate the effectiveness of the public education program. Based on the results of this evaluation, the system must modify subsequent public education efforts, if such modification is determined by the State to be necessary to ensure the effectiveness of the public education program in reducing lead consumption.

§ 141.86 Analytic and monitoring requirements for lead and copper MCLs and treatment technique requirements.

(a) *Analytic provisions.* Only the analytic methods specified below, or methods otherwise approved by EPA, may be used to determine compliance with the MCLs for lead and cooper specified in § 141.82(a) of this part and to determine whether a system meets the no-action levels specified in §141.83(b)(1) of this part. Results must be reported in the units specified by the analytic method used. The following methods are incorporated by reference with the approval of the Director of the Federal Register under 5 U.S.C. 552(a):

(1) Lead:

(i) Method 239.2, Atomic Absorption Furnace Technique.

"Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, Ohio (EPA-600/4-79-020), March 1985. Available from ORD Publications, CERI, EPA, Cincinnati, Ohio 45268. (For analyzing lead and copper, the technique applicable to total metals must be used.) and;

(ii) Method D3559-85D, Atomic Absorption Furnace Technique.

Annual Book of ASTM Standards, Vol. II.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103; and

(iii) Method 3043Q, Atomic Absorption Furnace Technique.

"Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Assoication, American Water Works Association, Water Pollution Control Federation, 1985.

(2) Copper:

(i) Method 220.2

"Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, Ohio (EPA-600/4-79-020), March 1985. Available from ORD Publications, CERI, EPA, Cincinnati, Ohio 45268. (For analyzing lead and copper, the technique applicable to total metals must be used.); and

(ii) Method D1688-84F

Annual Book of ASTM Standards, Vol. II.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103; or

(iii) Method 304, Atomic Absorption Furnace Technique;

"Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1985; and

(iv) Method 220.1, Atomic Absorption Direct Aspiration;

"Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, Ohio (EPA-600/4-79-020), March 1985. Available from ORD Publications, CERI, EPA, Cincinnati, Ohio 45268. (For analyzing lead and copper, the technique applicable to total metals must be used.); and

(v) Method D-1687-84D or E, Atomic Absorption Direct Aspiration;

Annual Book of ASTM Standards, Vol. II.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103; and

(vi) Method 303A or B, Atomic Absorption Direct Aspiration; "Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1985; and

(vii) Method 200.7A, Inductively-coupled plasma.

"Inductively-Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, September 1985, U.S. Cincinnati, Ohio 45268.

(3) pH:

(i) Method 150.1, Electrometric.

"Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, Ohio (EPA-600/4-79-020), March 1985. Available from ORD Publications, CERI, EPA, Cincinnati, Ohio 45268.

(ii) Method D1293-84A Electrometric.

Annual Book of ASTM Standards, Vol. II.01, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103; and

(iii) Method 423, Electrometric.

"Standard Methods for the Examination of Water and Wastewater," 16th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1985.

Each analysis must be performed by a laboratory approved by EPA or the State except that analyses of pH must be conducted in the field by a technician approved by the State as specified in Part 136 of this title.

(4) Analyses under this section shall only be conducted by laboratories that have received approval by EPA or the State. To obtain approval, laboratories must:

(i) Analyze performance evaluation samples which include lead and copper provided by the EPA Environmental Monitoring and Support Laboratory or equivalent samples provided by the State; and

(ii) Achieve quantitative acceptance limits as follows:

(A) Lead: ±30 percent of the actual amount in the Performance Evaluation sample when the active amount is greater than 0.005 mg/l,

(B) Copper: ±10 percent of the actual amount in the Performance Evaluation sample when the active amount is greater than 0.050 mg/l, and

(C) pH: ±0.1 pH units of the actual pH when actual pH is in the range of 0–14 pH units;

(iii) Achieve method detection limits according to the procedures in Appendix B of Part 136 of this title as follows:

(A) Lead: 0.001 mg/l; or

(iv) Be currently approved by EPA or the State to perform analyses to the specifications described in paragraph (a)(5) of this section.

(5) States have the authority to allow the use of previously collected monitoring data for purposes of compliance monitoring, if the data were collected and analyzed in accordance with the requirements of this section.

(6) All lead levels measured between the PQL of 0.005 mg/l and the MDL of 0.001 mg/l must be averaged as reported. All levels below the MDL of 0.001 mg/l must be reported as zero and average as such. Lead levels reported below an MDL larger than 0.001 mg/l must be reported as the MDL and averaged as such.

(b) *Phased-in monitoring program.* Systems must begin monitoring to determine compliance with the MCLs specified in § 141.82(a) of this part, and to determine wheter the no-action levels specified in § 141.83(b)(1) of this part are met, according to the following schedule:

System size (# of persons served)	Monitoring to being no later than	Monitoring to conclude no later than
>3,300	[enter date 3 months after publication of final rule]	[enter date 15 months after publication of final rule]
500-3,300	[enter date 15 months after publication of final rule]	[enter date 27 months after publication of final rule]
>500	[enter date 27 months after publication of final rule]	[enter date 39 months after publication of final rule]

(c) *Monitoring provisions for lead and copper MCLs.* (1) Samples must be collected at every entry point to the water distribution system, except when multiple wells draw from a single aquifer and there is no treatment, in which case, the State may designate one or more representative wells for monitoring. When multiple samples are required under this paragraph, states may allow up to 5 samples to be composited for analysis. If the lead or copper level in the composited sample exceeds one-fifth the lead or copper MCL specified in § 141.82 of this part, each of the entry points represented in the composite sample must be resampled individually for whichever contaminant exceeded one-fifth the MCL. This means that for lead, the laboratory must be able to measure levels down to 0.001 mg/l for compositing to be allowed. A composited sample that contains less than or equal to 0.001 mg/l of lead would be deemed in compliance with the MCL without sampling each well represented in the composited sample.

(2) Non-transient non-community water systems must sample water for lead and copper in at least one sample per entry point (except as specified in paragraph (c)(1) of this section) every five years. Non-transient non-community water systems are not eligible for reduced monitoring frequency.

(3) Community water systems must sample water for lead and copper in at least one sample per entry point as follows:

System size (persons served)	Minimum # Samples per Entry Point/ Monitoring Period
>500	1/Year.
>500 using ground water	1/Year.
>500 using surface water or a combination of surface water and ground water.	1/Quarter.

(4) For community water systems, if no violation of the MCL has occurred within the most recent 2 years of monitoring, the State may reduce the monitoring frequency to no less than the following:

System size (persons served)	Minimum number samples/entry point/ monitoring period
>500	1/year, every 5 years.
>500 using ground water	1/year, every 5 years.
>500 using surface water or a combination of surface water and ground water.	1/quarter for 1year, every 5 years.

(5) If the result of an analysis performed under paragraph (c) of this section indicates that the level of copper or lead at any sampling point exceeds the MCL specified in § 141.82(a) of this part, the State may allow the system to obtain and analyze one additional sample at the same sampling point within 2 weeks of the original sample.

(6) When the only analysis, or the average of the two analyses, as appropriate, made pursuant to paragraph (c)(5) of this section exceeds the MCL at any sampling point, the system is in violation of the MCL and must notify the State pursuant to § 141.31 of this part and give notice to the public pursuant to § 141.32 of this part. The system must perform increased monitoring at this sampling point at a frequency determined by the State until: (i) The MCL has not been exceeded in two successive monitoring periods of the increased monitoring program; or (ii) a monitoring schedule imposed as a condition of a variance, exemption, or enforcement action becomes effective.

(d) *Monitoring provisions for corrosion control treatment technique requirements for community water systems.*—(1) *Materials evaluation and identification of sampling group.* (i) By the applicable data specified in paragraph (b) of this section, each community water system must complete a materials evaluation in the community adequate to identify a group of residences from which samples required by this section must be taken. Systems are to select single-family houses, except that they may include apartments and other multiple-family housing where such housing constitutes more than 20 percent of the housing served by the community. This group of residences must be served by the ends of the distribution system and have plumbing systems that either contain lead solder that is less than 5 years old or have lead service connections or interior lead pipes. To the extent possible, the group of residences shall have an equal number of residences from each of these two categories. To identify these residences, systems must use the information collected by pursuant to § 141.42(d) of this part. As necessary, systems must also review the following:

(A) Plumbing codes, permits, and records in the files of the community building department that indicate the plumbing materials installed within residences;

(B) Inspections and records of the distribution system that indicate the material composition of the distribution lines, service lines, and connections;

(C) Existing water quality information, including results of prior analyses of water in the system or individual residences, indicating residences in which the lead level of the water may be of concern; and

(D) Design plans of the distribution system indicating residences that are served by the ends of the distribution system.

(ii) The number of residences in the sampling group must be no less than 50 percent greater than the number of sample points required for compliance with this section. If, based on the materials evaluation, a community water system cannot identify a sufficient number of residences with the specified characteristics, the system must demonstrate this to the State by:

(A) Submitting a report on the materials evaluation documenting that lead pipe was never used for service lines, goosenecks, pigtails, or interior plumbing pipes or that all such plumbing has been replaced, in those portions of the community that are served by the ends of the distribution system; and/or

(B) Demonstrating that the community has had in effect and successfully enforced for a minimum of five years a ban on lead solder use or that no lead solder was used in the construction of residences in those portions of the community served by the ends of the distribution system.

(iii) A system that meets either of the conditions in paragraph (d)(1)(ii) of this section must add to the sampling group, as appropriate, depending upon which of the conditions in paragraph (d)(1)(ii) of this section is met, residences located elsewhere within the distribution system that either:

(A) Are served by lead service connections; or

(B) Contain lead solder that is less than five years old. If the community water system still cannot establish a sampling group sufficiently large to meet the monitoring requirements of this section, the system must add to the sampling group the number of residences with lead solder served by the ends of the distribution system, irrespective of the lead content of the system and the age of lead solder in plumbing of the residences, that will increase the size of the sampling group sufficiently to meet the monitoring requirements of this section.

(iv) States may disapprove proposed monitoring plans. Systems with disapproved plans must revise the plans and obtain State approval before monitoring commences. A system with a disapproved monitoring plan is in violation of this section until the State approves a revised plan.

(2) *Sample collection.* Community water systems must obtain a one-liter sample of water from the cold-water kitchen tap of each residence monitored in the sampling group each monitoring period. In residences selected because they have new lead solder, the system must collect a morning first draw sample. In residences selected because they have lead service connections, the system must collect a service connection sample. The service connection sample consists of a sample from:

(i) The tap after the morning first draw water changes temperature;

(ii) The tap after flushing the water in the household plumbing (calculated based on pipe diameter and length to the tap from the connection); or

(iii) Directly from the service line itself.

In residences with both new lead solder and a lead service connection, the system may take a morning first draw sample and a service connection sample and count it as two residences in its pool. Systems must take subsequent samples from the same residences that were sampled during the initial monitoring period, except that, to the extent this is not possible, systems may, with State concurrence, take a sample from another residence remaining in the sampling group with the same characteristics as the initial site. Systems collecting only one set of samples annually must collect all samples during the months of July, August, or September.

(3) *Frequency of monitoring.* By the applicable date specified in paragraph (b) of this section, each community water system must begin monitoring in accordance with paragraph (a) of this section to determine whether its water meets the no-action levels specified in § 141.83(b)(1) of this part. Community water systems must monitor the sampling group at the following minimum frequency:

System size (persons served)	Minimum number samples/monitoring period
>100,000	50/Quarter.
10,001 to 100,000	30/Quarter.
3,301 to 10,000	20/Quarter.
500 to 3,300	10/Year, Every Other Year.
<500	10/Year, Every Five Years.

(4) *Reduced frequency of monitoring.* If, throughout the most recent four quarters, a community water system serving more than 3,300 persons has met the no-action levels specified in § 141.83(b)(1) of this part or has not departed from the operating parameters specified by the State after implementation of a State-approved treatment plan under § 141.84 of this part, the State may reduce the monitoring frequency required by this section to no less than the following minimum frequency:

System size (persons served)	Minimum number samples per monitoring period
>100,000	50/Year.
10,001 to 100,000	30/Year.
3,301 to 10,000	20/Year.

(5) Systems monitoring once per year under this schedule must do so during the months of July, August, or September.

(e) *Monitoring provisions for corrosion control treatment technique requirements for non-transient non-community water systems.*—(1) *Identification of sampling group.* By the applicable date specified in paragraph (b) of this section, each nontransient non-community water system must identify all buildings served by the system. Such buildings will comprise the sampling group.

(2) *Sample collection.* Non-transient non-community water systems must obtain a one-liter morning first draw sample from the tap or a service connection sample (if the building has a lead service connection) in each building typically used to draw water for human consumption. The service connection samples may be drawn by any of the three methods specified in paragraph (d)(2) of this section. At least one sample must be taken from every building in the sampling group each monitoring period.

(3) *Frequency of monitoring.* By the applicable date specified in paragraph (b) of this section, each non-transient non-community water system must begin monitoring in accordance with paragraph (a) of this section to determine whether its water meets the no-action levels specified in §141.83(b)(1) of this part. Non-transient non-community water systems must monitor the sampling group at least annually, during the months of July, August, or September.

(4) *Reduced frequency of monitoring.* Non-transient non-community water systems are not eligible for reduced monitoring frequency.

(f) Only samples collected in compliance with section 141.86(d)(1)(i) of this part can be used to determine whether no-action levels described in § 141.83 of this part have been met.

§ 141.87 Reporting and recordkeeping.

(a) All systems that serve more than 500 persons must report to the State the results of all monitoring required by this subpart within 10 days of the end of

each calendar quarter the system is in operation for any period of time. Systems that serve 500 or fewer persons must report such results to the State within 10 days of the end of each calendar year such system is in operation for any period of time. All systems must certify that the information submitted under this section is accurate. To the extent systems perform more monitoring in conformance with § 141.86(a) of this part than required under § 141.86 of this subpart, systems must include the results of the additional monitoring in their reports to the State.

(b) Reporting under this section must include the identification and location of sampling sites monitored under § 141.86(d) of this part and, the first time a site is sampled, the rationale for choosing the site.

(c) Systems operating under a State approved treatment plan to install or improve corrosion control must, according to a schedule established by the State in the treatment plan, report to the State the system's progress in completing the treatment plan's interim steps (see §141.84(a)(2) of this part).

(d) Systems operating under an approved treatment plan containing a public education program must detail the system's progress in completing the public education program requirements in the reports submitted to the State under paragraph (c) of this section, this report must include. As specified in § 141.85(f) of this part, this report must include data to the State that indicate that, as a result of the public education program, the users' knowledge about lead in drinking water enables them to alter voluntarily their water use patterns to reduce consumption of lead-contaminated water.

(e) EPA may require a system to establish and maintain such records, reports, or information as the Administrator deems necessary to determine whether the system has acted or is acting in compliance with this subpart.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority for Part 142 continues to read as follows:

Authority: 42 U.S.C. 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, and 300j-9.

2. Section 142.14 is amended by revising paragraphs (a)(1)(iii) and (d)(2), reserving paragraphs (d)(4), (5), and (6), adding paragraphs (d)(7), (d)(8), (d)(9), and (d)(10) to read as follows:

§ 142.14 Records kept by States.

(a) * * *

(1) * * *

(iii) The analytical results, set forth in a form that makes possible comparison with the limits specified in §§ 141.14, §141.71, §141.72, §141.73, § 141.82, and no-actions levels in § 141.83 of this chapter.

* * * * *

(d) * * *

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(2) Records of any State approvals, including approvals of treatment plans required by § 141.83 of this chapter, and the grounds for such approvals;

(3) * * *

(4) [Reserved]—(6)

(7) Records of any reductions in monitoring frequency authorized by § 141.86(c)(4) or § 141.86(d)(4) of this chapter, specifying the new frequency;

(8) Records of any requirements to perform increased monitoring, as required by § 141.86(c)(6) the frequency of such monitoring;

(9) Records of any determination under § 141.84 of this chapter that a system has minimized the corrosivity of its water, the evidence supporting this determination, and the final approved operating parameters.

(10) Records of a system's evaluation of its public education program, as required by § 141.85(f) of this chapter, and of any State determination that the system must modify subsequent public education efforts.

3. Section 142.15 is amended by reserving paragraphs (b) (3) and (4) and adding paragraphs (b)(5), (b)(6), (b)(7), (b)(8), (b)(9), (b)(10), and (b)(11) to read as follows:

§ 142.15 Reports by States.

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(b) * * *

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(3)—(4) [Reserved.]

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(5) A list, including system identification numbers, of systems that have been authorized to reduce their monitoring frequencies in accordance with § 141.86(c)(4) and/or § 141.86(d)(4) of this chapter and the new monitoring frequencies;

(6) a list, including system identification numbers, of systems that are required to perform increased monitoring under § 141.86(c)(6) of this chapter and the new monitoring frequency.

(7) A list, including system identification numbers, of systems that have demonstrated to the State that an insufficient number of residences were available for sampling, as specificed by § 141.86(d)(1) of this chapter;

(8) A list, including system identification numbers, of systems that exceed one or more no-action levels and the level(s) exceeded.

(9) A list, including the system identification numbers, of systems serving 3,300 or more persons that have received State approval for their treatment plans, as specified in § 141.84 of this chapter and a list, including system identification numbers, of the system serving fewer than 3,300 persons which have received treatment plans from the State, or have recevied State approval for treatment plans submitted by the system;

(10) A list, including system identification numbers, of systems that have demonstrated that they have minimized the corrosivity of their water as required by § 141.84 of this chapter. The report must also contain for each system the new operating parameters with which the system must comply.

(11) A report of the results of the evaluations of public education programs required by § 141.85(f) of this chapter and of any State determination that the system must modify subsequent public education efforts.

4. Section 142.17 is added to read as follows:

§ 142.17 Special primacy requirements.

(a)—(b) [Reserved.]

(c) *Special primacy requirements for States to adopt 40 CFR Part 141, Subpart I, Control of Lead and Copper.* An application for approval of a State program revision that adopts 40 CFR Part 141, Subpart I, Control of Lead and Copper, must contain:

(1) The text of the State statute or regulations containing the procedures or criteria for determining increased monitoring frequency (in accordance with § 141.86(c)(4) and/or § 141.86(d)(4) of this chapter) including a procedure for notifying the system of the new monitoring requirements.

(2) The text of the State statute or regulations requiring community water systems to conduct a materials evaluation and specifying the procedures for demonstrating to the State that sufficient residence with the required characteristics are not available (in accordance with § 141.86(d)(1) of this chapter). The regulations shall include the criteria the State will use to evaluate the community water system's demonstration. Such criteria must be the same or more stringent than those specified in § 141.86(d)(1) of this chapter.

(3) The text of the State statute or regulations specifying enforceable design and operating criteria for treatment techniques designed to control the corrosivity of water. These techniques include pH adjustment, alkalinity adjustment, and the addition of corrosion inhibitors. In addition, the regulations must contain a procedure (e.g., a permit or certification system) to ensure that the design and operating criteria are met on a continuous basis.

(4) The text of the State statute or regulations specifying the procedures and criteria the State will use to evaluate and approve a treatment plan submitted for approval by systems serving more than 3,300 persons (in accordance with § 141.84 of this chapter); the criteria the State will use to determine that corrosivity has been minimized (including the data the system must submit to show that water corrosivity has been minimized) and select approved operating parameters and a method for informing the system of its approved operating parameters.

(5) Text of the State statute or regulations specifying procedures and criteria the State will use to issue or approve treatment plans for systems serving 3,300 or fewer persons, including procedures the system must follow to request a plan, the criteria the state will use to determine that corrosivity has been minimized, and the procedures the State will use to inform the system of its new operating parameters.

(6) Procedures and criteria the State will use in evaluating the data submitted by the system on the effectiveness of its public education program and in determining if the system must modify subsequent public education efforts.

5. A new § 142.63 is added to read as follows:

§ 142.63 Variances from the maximum contaminant levels for lead and copper.

(a) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for lead and copper: Coagulation/filtration; ion exchange; lime softening; reverse osmosis.

(b) A state shall require community water systems and non-transient, non-community water systems (hereinafter referred to as "systems") to install and/or use any treatment method identified in paragraph (a) of this section as a condition for granting a variance. If, after the system's installation of the treatment method, the system cannot meet the requirements of § 141.82(a) of this chapter, that system shall not be eligible for a variance under the provisions of section 1415(a)(1)(A) of the Act unless the system demonstrates to the State that lead levels or copper levels, as appropriate, would not pose an unreasonable risk to health.

(c) The State may require a system to provide bottled water or point-of-use devices or other means as a condition of granting a variance from the requirements of § 141.82(a) of this chapter to avoid an unreasonable risk to health.

(d) Systems that use bottled water as a condition of receiving a variance from the requirements of §141.82(a) of this chapter must meet the requirements in either paragraph (d)(1) or (d)(2) of this section in addition to the requirements in paragraph (d)(3) of this section:

(1) The State must require and approve a monitoring program for bottled water. The system must develop and implement a monitoring program that provides reasonable assurances that the bottled water meets all MCLs. The system must analyze a representative sample of the bottled water for all contaminants for which MCLS are promulgated under Part 141 of this chapter during the first quarter it supplies the bottled water to the public and annually thereafter. The system must provide results of the monitoring program to the State annually.

(2) The system must receive a certification from the provider of bottled water that the bottled water supplied has been taken from an "approved source" as defined in 21 CFR 129.3(a); the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g)(1) through (3); and the bottled water does not exceed any MCLs or quality limits as set out in 21 CFR 103.35, 110, and 129. The system shall provide the certification to the State the first quarter after it supplies bottled water and annually thereafter.

(3) The system is fully responsible for the provision of sufficient quantities of bottled water, for consumption but not washing purposes, to every customer of the system via door-to-door bottled water delivery.

(e) Systems that use point-of-use devices as a condition for obtaining a variance from the MCLs for lead or copper must meet the following requirements:

(1) It is the responsibility of the system to operate and maintain the point-of-use treatment device.

(2) The system must develop a monitoring plan and obtain State approval for the plan before point-of-use devices are installed for compliance. This monitoring plan must provide health protection at least equivalent to a monitoring plan for central water treatment.

(3) The system must properly apply effective technology under a plan approved by the State and must maintain the microbiological safety of the water.

(4) The system must meet all State requirements regarding adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of the point-of-use devices.

(5) The design and application of the point-of-use devices must consider the tendency for increases in heterotrophic bacteria concentrations in water treated with activiated carbon. It may be necessary to use frequent backwashing, post-contactor disinfection, and heterotrophic plate count monitoring to ensure that the microbiological safety of the water is not compromised. The system must obtain any necessary right-of-entry to enable the State and EPA to inspect point-of-use devices.

(6) The system must protect all users. Every building connected to the system must have a point-of-use device installed, maintained, and adequately monitored. The system must subject every building to treatment and monitoring, and must ensure that the rights and responsibilities of the system customer convey with title upon sale of property.

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August 18, 1988

Part VI

Department of Education

34 CFR Part 74 et al.

Education Department General Administrative Regulations; Notice of Proposed Rulemaking

DEPARTMENT OF EDUCATION

34 CFR Parts 74, 75, 76, 77, 237, 263, 300, 356, 562, 630, 653, and 762

Education Department General Administrative Regulations

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the Education Department General Administration Regulations (EDGAR) to reduce burden by deleting unnecessary requirements and provisions; remove sections already contained in other Department of Education (Department) regulations; update financial reporting requirements and payment methods to comply with the Treasury Department's mandate to eliminate the Federal Reserve Bank letter-of-credit and reduce dependence on paper checks; and include provisions for the award and administration of cooperative agreements under 31 U.S.C. Chapter 63. The Secretary also proposes to add regulations making financial aid recipients who are not current in the repayment of debts owed to the Federal government ineligible for discretionary grants and other forms of assistance from the Department of Education.

Certain EDGAR provisions relating to preapplications would be transferred to the program regulations for the only program which currently uses preapplications; other EDGAR provisions, relating to State complaint procedures, would be transferred to the program regulations of the program from which they were derived originally, Assistance to States for Education of Handicapped Children.

Finally, the cost principles in Part 74 would be amended in order to ensure the Department's conformity with the requirements of the revised Office of Management and Budget (OMB) Circulars A-21 and A-110.

DATES: Comments must be received on or before November 16, 1988.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Mary Hughes, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, SW. (Room 3122, Regional Office Building No. 3), Washington, DC 20202.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Mary Hughes. Telephone: (202) 732-7400.

SUPPLEMENTARY INFORMATION: In a continuing effort to improve the administration of Department programs and service to the public, and in order to reduce regulatory burden, the Secretary has identified certain provisions of EDGAR that should be revised or removed. These provisions are in addition to those published as final regulations in the **Federal Register** of July 24, 1987 (52 FR 27801).

As with the earlier publication, the Secretary has identified opportunities to remove sections that are obsolete or not required by law. In addition, the Secretary proposes amendments to reflect the most efficient and cost-effective method of making payments to grantees, in accordance with Treasury Circular 1075 (31 CFR Part 205) and the Treasury Department mandate to replace letter of credit and Treasury check payments with more efficient electronic funds transfers. The Secretary also proposes to make changes in the financial reporting requirements to reduce burden on grantees.

Finally, the Secretary, recognizing the increase in the number of cooperative agreements used by the Department and consistent with the rulemaking requirements of the General Education Provisions Act (GEPA) section 431, proposes to revise sections of EDGAR to establish requirements for the award and use of cooperative agreements under 31 U.S.C. Chapter 63.

The Secretary is open to further suggestions for the deregulation of EDGAR and is particularly interested in public comment on the award and administration of cooperative agreements.

The specific parts and sections proposed for revision are as follows:

Section 74.3—The Secretary proposes to continue using general grant-making procedures to enter into cooperative agreements rather than establish an entirely new selection process for cooperative agreements. The Secretary proposes to amend the definition of "grant" in § 74.3 to include, specifically, cooperative agreements rather than relying on the fact that the current definition of "grant" covers all types of assistance relationships. However, the Secretary believes that some additional procedures are necessary for the administration of cooperative agreements. Therefore, the Secretary proposes to add requirements for cooperative agreements in appropriate places throughout the regulations.

Section 74.47—The Secretary proposes to amend this section to reflect the codification of the Intergovernmental Cooperation Act of 1968 into Title 31 of the U.S. Code, Chapter 65, and to reflect amendments to OMB Circular A-110 regarding income on advances made to grantees. Under the amendments to the Circular a grantee, other than a State as defined in 31 U.S.C. 6501, is required to hold advances in an interest-bearing account. Any interest over $100 per year must be paid to the Department. The exception in § 74.47(b) regarding interest earned by States does not apply to programs subject to section 487 of the Higher Education Act of 1965, as amended (20 U.S.C. 1094).

Sections 74.73, 74.74, 74.75, 74.76, 74.91, 74.93 and 74.96—The Secretary proposes to revise these sections to reflect current procedures for financial reporting and to describe the most efficient and cost-effective method of making payments to grantees, in accordance with Treasury Circular 1075 (31 CFR Part 205) and other guidance provided by the Treasury Department. For example, the amendment to § 74.91 would change the definition of "advance by Treasury check" to "advance" to reflect the Secretary's discretion to make advances through other methods authorized by the Treasury Circular. The current regulations do not fully describe the kind of payment methods the Secretary may use to implement the requirements of the Treasury Circular.

Section 74.94—The Secretary proposes to remove this section because it is redundant with § 74.93 as revised. Proposed § 74.93 would now cover payment methods for both construction and non-construction grants.

Section 74.172—The Secretary proposes to revise this section because it is outdated. Currently, educational institutions follow the cost principles found in EDGAR, Part 74, Appendix D; these cost principles implement OMB Circular A-21, Cost Principles for Educational Institutions. However, in 1979 and again in 1982, OMB revised Circular A-21. The Department has not yet implemented these changes in EDGAR. Additionally, OMB revised Circular A-21 on June 9, 1986, at 51 FR 20908, and on December 2, 1986, at 51 FR 43487, to establish a fixed overhead allowance for the administration of federally sponsored grants and contracts at educational institutions. The fixed allowance will equal 3.6 percent of modified total direct costs, and no faculty reporting will be required to support the allowance. These regulations amend EDGAR by revising

Appendix D of Part 74 to include the current provisions of OMB Circular A-21. These changes will permit the Department to ensure consistency with the government-wide requirements of Circular A-21.

Section 74.174—In recent years Congress has passed laws that make for-profit organizations eligible for grants under some programs administered by the Secretary. The Department has no regulations that specify what cost principles apply to these organizations when they receive grants. Therefore, the Secretary proposes to apply the cost principles for commercial organizations when the Secretary makes a grant to a for-profit organization. These principles already apply, under the Federal Acquisition Regulations, to for-profit organizations that enter into contracts with the Federal government (48 CFR Part 31). The underlying principle that the Federal government should pay only for costs to assist a grant activity is not changed simply because for-profit organizations are made eligible. Thus, to ensure that the Department does not pay for costs that inure to the owners of a for-profit grantee, the proposed regulations would provide that no fee or other element above actual costs may be paid to a for-profit organization that receives a grant from the Department.

Section 74.175—The Secretary proposes to revise this section to update references that are obsolete due to legislative and regulatory changes.

Sections 75.3 and 76.3—The Education Department General Administrative Regulations in 34 CFR Part 74 are referenced in each set of applicable program regulations. Thus, it is unnecessary to include the reference again in Parts 75 and 76 of EDGAR. Therefore, the Secretary proposes to remove these two sections.

Section 75.4—The Secretary proposes to revise this section by updating the cross-reference to the regulations for contracts that will appear in Title 48 of the Code of Federal Regulations.

Sections 75.60 through 75.62—Consistent with the requirements of OMB Circular A-129, Managing Federal Credit Programs, dated May 9, 1985, the Secretary proposes to add regulations making persons who are not current in repaying debts owed to the Federal government ineligible to receive a fellowship, scholarship, or discretionary grant from the Department. In order to demonstrate the concern of the Secretary regarding the need for individuals to meet their responsibilities under the programs of this Department, § 75.60 lists the current ED programs under which an individual might owe a debt to the Department. The Department already has provisions in the regulations implementing the student financial assistance provisions of Title IV of the Higher Education Act of 1965 (Title IV), as amended, that prohibit a student whose account under certain Title IV programs is not current from receiving further financial assistance from the Department. While these procedures do not fully implement Circular A-129, they do reach a substantial portion of the debt owed to the Department. The requirement for eligibility proposed in § 75.60 would increase the Department's ability to ensure that individuals repay debts incurred under those Title IV programs and the other programs listed in that section. The Secretary believes that an essential condition for an individual receiving a fellowship, scholarship, or discretionary grant is that the individual keep his or her account current as required under prior loan or grant conditions.

This Department and twenty-six other agencies have published final and interim final Nonprocurement Debarment and Suspension regulations. These regulations permit debarment of an individual or organization that failed to pay a single substantial debt, or a number of outstanding debts, owed to any Federal agency or instrumentality, provided the debt is uncontested by the debtor or, if contested, provided that the debtor's legal and administrative remedies have been exhausted. Thus, the Department does not intend to make awards to individuals debarred or suspended under Debarment and Suspension regulations.

Section 75.61 requires an applicant for a fellowship, scholarship, or direct grant to certify that he or she is eligible under § 75.60, and not debarred or suspended under regulations established under Exective Order 12549. The fact that an award is made to an individual who has provided a certification required by § 75.61 does not mean that the Secretary has concluded that the individual is eligible under § 75.60. If an individual is not current in repaying debts owed to this Department or any other Federal agency, or has been debarred or suspended by this Department or any other Federal agency, and fails to certify to those facts, the Secretary may proceed with a civil action to recover the funds made available and may take other legal actions aganst the individual.

The Secretary directly administers a number of fellowship and scholarship programs and a few programs where discretionary grants may be made to individuals. However, not all fellowship and scholarship programs are administered directly by the Secretary. In some cases an institution of higher education may make fellowships. Under other programs, a State or State educational Agency may make awards after receiving funds on a formula or other basis. Sometimes the Secretary awards a grant to the institution or organization making the awards; in other cases, the Secretary enters into an agreement with the institution or organization. Whatever the nature of the programs involving an institution of higher education, State educational agency, or other intermediate entity, § 75.62 is intended to apply to the entity, imposing minimal requirements to ensure that a fellowship or scholarship is not provided to an individual who fails to keep his or her prior commitments. Section 75.62 requires that an entity to which the section applies obtain a certification from each individual who applies for a fellowship or scholarship. The certification, made under penalty of perjury, would state that the individual is eligible under § 75.60, and not debarred or suspended under regulations established under Executive Order 12549. If an applicant failed to provide the certification or the entity is informed by the Secretary that the applicant is ineligible, the entity would be prohibited from giving the applicant a fellowship or scholarship. Section 75.62 also permits the Secretary to require that an entity subject to § 75.62 submit a list of proposed or actual fellowship or scholarship recipients to the Secretary so the Secretary may verify the eligibility of these individuals. If the Secretary determines that an individual has provided a false certification, the Secretary may take appropriate legal action, including recovery of any funds made available to the individual.

The Secretary is interested in receiving comments on whether the Secretary should also apply the § 75.60 eligibility provisions to programs where the Secretary or an intermediate entity provides stipends to individuals.

Finally, as a technical matter, the Secretary intends to have these regulations apply to all fellowship and scholarship programs of the Department. However, some of the fellowship and scholarship programs do not apply Part 75 to the program. Therefore, the Secretary is proposing in this document to amend the program regulations of those programs that do not apply Part 75 to include a direct reference to these proposed new sections. The program regulations that are being amended for this purpose are the Christa McAuliffe Fellowship Program (Part 237), the Indian Fellowship Program (Part 263),

Handicapped Research: Research Fellowships (Part 356), Bilingual Education: Fellowship Program (Part 562), the Paul Douglas Teacher Scholarship Program (Part 653), and the Office of Educational Research and Improvement Fellows Program (Part 762).

Section 75.105(c)—The Secretary proposes to revise this section by adding language to paragraph (c)(3) that clarifies how the competitive process works when the Secretary announces absolute preference priorities.

Sections 75.107, 75.108, 75.110, 75.111, 75.113, 75.114, 75.115, 75.116, and the note following § 75.118—The Secretary proposes to remove these sections as burdensome and unnecessary. Section 75.110 is proposed for removal because it duplicates provisions in standard forms required by OMB. Sections 75.111 and 75.113–75.116 are proposed for removal because they require applicants under direct formula grant programs to provide information not essential to determine funding under a formula grant program. OMB circulars and regulations of OMB under the Paperwork Reduction Act of 1980 limit a Federal agency to collecting only that information which has practical utility to the agency in carrying out one of its functions or which is required by law. See 5 CFR 1320.4 (b) and (c). Sections 75.107 and 75.108 are proposed for removal as technical conforming amendments. The note following § 75.118 is proposed for removal because it contains a list of sections which are outdated.

Sections 75.130 through 75.134—The Secretary proposes to remove these sections, which cover how the Secretary treats preapplications, and to place them in the program regulations of the program to which they now apply—the Fund for the Improvement of Postsecondary Education (FIPSE).

Sections 75.150 through 75.154—The Secretary proposes to remove these sections as unnecessary because, at this time, there is no Department program that contains a requirement that a State must approve applications submitted to the program.

Section 75.155—Under Executive Order 12372, the Department has established regulations in Part 79 that allow States to comment on Department programs and activities. Sections 75.156–75.158, which pre-date the Executive Order, also provided a procedure for States to comment on Department programs. The procedure was designed for use by Department programs that required State input either by statute or by regulation. The Secretary proposes to revise § 75.155 to limit the applicability of §§ 75.156–75.158 to those programs that require State input by statute, and to add a cross-reference regarding 34 CFR Part 79.

Section 75.160—The Secretary proposes to remove this section as a conforming amendment to the removal of §§ 75.151 and 75.153.

Section 75.200—The Federal Grant and Cooperative Act, now codified in Title 31 of the U.S. Code, sections 6301–6309, authorizes the use of cooperative agreements. At the time EDGAR was written, cooperative agreements were not widely used by the Department, but since then the number of program requests for using this award instrument has increased significantly. The proposed change to § 75.200 implements the standards in the Act and OMB guidance, 43 FR 36860, August 18, 1978.

Under the revised § 75.200, the Secretary may decide to use a cooperative agreement if the Department will be substantially involved in the administration of a particular assistance project. The key factor is whether the Secretary can expect agency collaboration or participation in the management of the project.

Section 75.216—The Secretary proposes to revise this section so the Department no longer must return applications that are not evaluated under § 75.217 or § 75.219. The change will reduce the cost to the Department of managing grant competitions. The provision in paragraph (b) of this section, under which the Secretary informs an applicant that its application has not been evaluated, is proposed for consolidation with § 75.218 which provides for notice to unfunded applicants.

Section 75.218—The Secretary proposes to change the requirement in this section that the Department explain reasons why an applicant was not selected after evaluation of its application. The Secretary currently sends a general letter if an applicant is not selected and provides a detailed letter upon the request of the applicant. The Secretary will continue to provide detailed information to applicants upon their request for that information. This policy would also apply to applications that are not evaluated under § 75.216.

Section 75.233—This section describes the factors the Secretary uses to set the amount of a grant. The Secretary proposes to make a technical revision to this section by clarifying that the Federal share of allowable costs is subject to any applicable matching or cost-sharing requirements.

Section 75.234—The Secretary proposes to revise this section, which describes conditions for making a grant, to include conditions required for a high risk grantee, or the explicit nature of Federal involvement in a cooperative agreement.

Section 75.235—The Secretary proposes to revise paragraph (b) of this section to clarify that the Secretary includes in an award document any conditions as necessary under specific program authority or to implement high risk or cooperative agreement requirements.

Section 75.253—The Secretary proposes to clarify and strengthen the criteria for making continuation awards for multi-year projects. The current regulations, among other criteria, require the Secretary to be "satisfied that the grantee will satisfactorily complete the budget period that is about to end." The Secretary strongly believes that recipients of Federal grants should be accountable for making effective use of the funds they receive, just as local school districts should be accountable for the effectiveness of the education they provide. The proposed regulations would require that a grantee either (1) be making substantial progress toward meeting the objectives of its project, or (2) have obtained approval of changes in its project, at no additional cost to the Federal Government, that enable the grantee to meet those objectives in succeeding budget periods. Whether to approve any such proposed changes would be at the discretion of the Secretary. This revised provision should ensure that projects continued in subsequent budget periods will be successful in meeting the goals of the affected Federal programs.

Sections 75.253 and 75.261—The Secretary proposes to revise these sections to describe more fully the situations in which the Secretary has discretion to extend budget periods and project periods. Under § 75.703, a grantee may only obligate funds during the grant period. That period includes one or more approved budget periods within an authorized project period. However, if a grantee fails to receive a continuation award, the grant period ends with the last funded budget period. Thus, the grantee, in many cases, will not have obligated funds during that last budget period to prepare a final evaluation of the grant or to prepare closeout reports. The amendment to § 75.253 would permit the grantee to obligate funds for these purposes during an extension of the last budget period.

This section is also amended to clarify the procedures the Secretary uses to make a continuation award. Section 75.261 is proposed for amendment to make clear the Secretary's discretion to

extend project periods in cases where the need for the extension is not predicated on facts pertinent solely to an individual grantee. For example, Congress may not authorize funds for a particular program until sometime after the start of the fiscal year. In such a case, a group of grantees might have to delay the start of a project or cease operations temporarily, delaying the expected completion date for the grants. In this case, the Secretary may decide to extend the project periods of these projects without receiving an individual request from each grantee.

Section 75.262—This section is added to specify the Secretary's authority to convert a grant to a cooperative agreement, or to convert a cooperative agreement to a grant, after considering the necessity to do so. The decision to make a change in the type of award would be made after considering the factors in proposed § 75.200(b) (4) and (5). This assessment would dictate the type of award necessary to complete the project.

Section 75.510—The Secretary proposes to remove this section, governing the use of project directors, to reduce the intrusion of Federal regulations in day-to-day management of the Department's grants. Given the fact that, in general, discretionary grant programs base selection of a grantee, in part, on the quality of key personnel and that any change in key personnel must be approved by ED, the Department has sufficient assurances that the concerns addressed in this section are adequately met.

Section 75.518—This section is a general reference to Federal laws that may establish the minimum wage. The Secretary proposes to remove this section because it it merely informative and has not substantive effect.

Section 75.560(a)—The Secretary proposes to revise this section to update references that are obsolete. Paragraph (a) of this section is revised to refer to the cost principles in Parts 74 and 80 which describe the differences between direct costs and indirect costs, and which include principles for determining the general indirect cost rate that a grantee may use for grants under most programs.

Section 75.563 and 76.563—These sections currently provide illustrative lists of programs that have a statutory requirement not to use Federal funds to supplant non-Federal funds. The Secretary has found that these lists have not been helpful in informing potential recipients about these statutory requirements. Therefore, the Secretary proposes to remove the lists and will inform recipients under direct grant programs through the grant approval process, including the specification of restricted indirect cost rates in approved budgets. The Secretary will inform recipients under State-administered programs through approved State plans.

Sections 75.580, 75.581, 76.580, and 76.581—The Secretary proposes to remove these sections in their entirety. Paragraphs (b) and (c) of §§ 75.580 and 76.580 were based on statutory requirements that are not obsolete. Furthermore, coordination with other activities in the same geographic area served by the project is not necessary in all types of programs and, therefore, should not be a general requirement in EDGAR.

Section 75.590—The Secretary proposes to remove the examples of persons being served by the project given in paragraph (c) of the current regulations. The grantee continues to be responsible for evaluating the effect of the project on all participants.

Section 75.608—The Secretary proposes to change the word "shall" to "may" to permit a grantee discretion in the use of its facilities.

Section 75.616—The Secretary proposes to revise the current standards for energy efficiency to incorporate the most recent standards of the American Society of Heating, Refrigerating, and Air Conditioning Engineers. This incorporation by reference was approved by the Director of the **Federal Register** pursuant to the Director's authority under 5 U.S.C. 552(a).

Section 75.617—The Secretary proposes to add a section to implement his regulatory authority as required under the Coastal Barriers Resource Act.

Section 75.622—The Secretary proposes to make a technical correction.

Section 75.625—The cross-reference preceding this section refers to regulations that specify the Department's policy on inventions and patents. The content of § 75.625, which is also a cross-reference, would be incorporated into the existing cross-reference, and § 75.625 would be removed.

Section 75.626—Paragraph (b) of this section contains a reference to regulations that no longer exist. The Secretary proposes to remove paragraph (b) of this section to be consistent with OMB Circular A-124, Patents—Small Business Firms and Nonprofit Organizations. The Department no longer has an interest, as a general matter, in retaining rights to inventions and patents of grantees of the Department. In specific cases where the Department needs to protect its rights to inventions and patents, it may do so in the grant award document.

Sections 75.681 and 76.681—The Secretary proposes to remove the cross-reference following these sections. The cross-reference refers to regulations of the Department of Health and Human Services regarding the protection of human research subjects. These regulations do not apply to Department of Education programs except as specifically provided in appropriate program regulations. Also, there is currently underway an initiative to establish government-wide regulatory guidelines regarding the protection of human research subjects. The Department will promulgate appropriate regulations after the general government-wide policy is established. See 51 FR 20204, June 1986.

Sections 75.684 and 76.684—These sections on day-care services were originally included in EDGAR as requirements of the former Department of Health, Education, and Welfare. However, the sections were used primarily to impose requirements in welfare programs where funds were used specifically to establish day care centers. The Secretary proposes to remove these sections because they are not needed under the types of programs funded by the Department.

Sections 75.690 and 76.690—These requirements regarding the inclusion of educational components on energy conservation awareness are not required by E.O. 12185. The Secretary proposes to remove these sections as a part of the Administration's regulatory burden-reduction effort. However, a grantee remains free to include these components, as appropriate, if desired under the grantee's own policies.

Sections 75.707(h) and 76.707(h)—The Secretary proposed to update these sections to refer to the sections in 34 CFR Part 74 that impose the appropriate cost principles on grantees of the Department. The Secretary also notes his intention to address, in a future rulemaking document, issues regarding the accountability of funds under section 437 of GEPA as those issues relate to this section and certain other sections of EDGAR.

Sections 75.720 and 76.720—The Secretary proposes to limit the applicability of these sections to the financial status report required under § 74.73 and performance reports required under Subpart J of Part 74. Under §§ 75.720 and 76.720, as they currently stand, the Secretary may only request financial and performance reports on an annual basis. Prior to 1980, when EDGAR became effective, the

Department exercised discretion to require both performance and financial reports on a quarterly basis. At the time EDGAR was drafted, a general policy decision was made to limit performance reports and certain financial reports (such as the financial status report) to an annual reporting cycle. However, there was no intent to limit collection of the Federal Cash Transactions Report to an annual basis. For more than a decade, this report has been collected by this Department and its predecessor agencies on a quarterly, or more frequent, basis in order to prevent excessive drawdowns by grantees. In order to clarify the Department's authority to collect these reports when necessary, the Secretary proposes to limit the applicability of §§ 75.720 and 76.720 to the financial status reports and performance reports.

Sections 75.740 and 76.740—The Secretary proposes to amend these sections to include references to the regulations protecting student rights in research, experimental programs, and testing. The requirements referenced in these sections are codified at 34 CFR Part 98 and 99.

Sections 75.750 through 75.755—The Secretary proposes to remove these sections because the Paperwork Reduction Act of 1980 changed the nature of review under the paperwork control requirements in section 400A of the GEPA. As a result, this Department currently screens documents under OMB regulations at 5 CFR Part 1320 before final review and approval by OMB.

Section 76.102—This section of EDGAR lists those documents to which the provisions governing State plans in Part 76 of EDGAR apply. Since the list in § 76.1, which contains the programs and their statutory authorities to which Part 76 applies, has been removed (52 FR 27801, July 24, 1987), the Secretary proposes to revise § 76.102 by removing the cross-reference to § 76.1 at the end of the section and, as an aid to readers, by adding a reference to the statutory authority for each covered program. The Secretary also proposes to remove obsolete programs from the list and to add new programs to the list.

Section 76.125—The table following this section is outdated. The Secretary proposes to revise and update the table to reflect the programs administered by the Department that the Secretary has determined are eligible for inclusion in the consolidated grant application process. Programs that are not presently funded are not included in this list.

Sections 76.300 and 76.305—The Secretary proposes to remove § 76.305 because it restricts the discretion of the States to establish simpler procedures for amending a subgrant than were required for the approval of the subgrant. Section 76.300 is revised to reflect this greater discretion.

Section 76.401—The Secretary proposes to revise this section to reflect more accurately the programs under which a State agency hearing is required before disapproval of an application.

Section 76.560—The Secretary proposes to make technical corrections.

Section 76.591—The Secretary proposes to make a technical correction.

Sections 76.770 and 76.771—These sections currently contain detailed instructions to the States on how to administer the programs subject to Part 76, particularly with respect to subgrantees under those programs. The Secretary proposes to simplify and consolidate these sections into a revised § 76.770, which would provide that a State must have procedures, for the administration of these programs, that are designed to ensure compliance with applicable statutes and regulations. It is not expected that the requirement being retained would impose any significant burden, since the States should already have these procedures in place for administering the programs involved.

Section 76.772—This section applies to the programs under Title IV of the Elementary and Secondary Education Act. The Title IV authority has been repealed. Therefore, the Secretary proposes to remove this section.

Sections 76.780–76.782—The Secretary proposes to remove these sections because they either do not apply to or have not been used under most programs of the Department. Most of these provisions were derived from the regulations for the State-administered program under Part B of the Education of the Handicapped Act (EHA). Those provisions of the State complaint procedure that were derived from the regulations under the EHA are proposed for transfer back to that program, which has shown the greatest need for the complaint procedure.

This action is not intended to implement the Augustus F. Hawkins—Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988, Pub. L. 100–297. The conference report for that legislation states Congress' intent that the Department apply the EDGAR complaint procedures to the Chapter 1 program under Title I of the Elementary and Secondary Education Act of 1965, as amended by Pub. L. 100–297. The regulations for the Chapter 1 program are being developed at this time and will separately address the issue concerning inclusion of complaint procedures for that program.

Part 77—The Secretary proposes to amend the definitions Part of EDGAR to include cooperative agreements within the definition of "award."

Part 300—The Secretary proposes to amend the EHA Part B regulations to include the State complaint procedures that are proposed for removal from EDGAR.

Part 630—The Secretary proposes to revise Part 630 to include modified provisions from the current § 75.130–§ 75.134 regarding preapplications. The Fund for the Improvement of Postsecondary Education is the only Department program that uses these preapplication procedures.

Executive Order 12291

The proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classifed as major because they do not meet the criteria for major regulations established in the Order.

Regulatory Flexibility Act

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. None of the proposed changes will place undue burden on small entities submitting applications. Many of the proposed changes are technical and will remove obsolete material from the regulations. Some of the proposed changes will reduce burden imposed by existing regulations. These changes, while not economically significant for individual entities, will be beneficial for all applicants.

Paperwork Reduction Act of 1980

Sections 74.73, 74.74, 75.261, and 75.720 contain information collection requirements. The Department of Education will submit a copy of these proposed regulations to the Office of Management and Budget for its review under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511). Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 3002, New Executive Office Building, Washington, DC 20503; Attention: James D. Houser.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection during

and after the comment period in Room 3122, Regional Office Building No. 3, Seventh and D Streets, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and its overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burden found in these proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects

34 CFR Part 74

Administrative practice and procedure, Education Department, Grant programs—education, Grants administration.

34 CFR Part 75

Education Department, Grant programs—education, Grants administration.

34 CFR Part 76

Education Department, Grant programs—education, Grants administration, Intergovernmental relations, State-administered programs.

34 CFR Part 77

Definitions.

34 CFR Part 237

Colleges and universities, Education, Elementary and secondary education, Scholarships and fellowships, Teachers.

34 CFR Part 263

Business and industry, Colleges and universities, Education, Engineers, Health professions, Indians—education, Law, Medical and dental schools, Natural resources, Scholarships and fellowships, Teachers.

34 CFR Part 300

Administrative practice and procedure, Education, Education of handicapped, Equal educational opportunity, Grant programs—education, Privacy, Private schools.

34 CFR Part 356

Education, Educational research, Fellowships.

34 CFR Part 562

Bilingual education, Education, Elementary and secondary education, Grant programs—education, Reporting and recordkeeping requirements, Scholarships and fellowships.

34 CFR Part 630

Colleges and universities, Education, Government contracts, Grant programs—education, Reports and recordkeeping requirements.

34 CFR Part 653

Education, Grant programs, State-administered, Student aid.

34 CFR Part 762

Education, Educational research, Fellowships, Teachers.

(Catalog of Federal Domestic Assistance number does not apply.)

Dated: July 21, 1988.

William J. Bennett,

Secretary of Education.

The Secretary proposes to amend Parts 74, 75, 76, 77, 237, 263, 300, 356, 562, 630, 653, and 762 of Title 34 of the Code of Federal Regulations as follows:

PART 74—ADMINISTRATION OF GRANTS

1. The authority citation for Part 75 is revised to read as follows:

Authority: 20 U.S.C. 1221e–3(a)(1) and 3474, OMB Circular A–110, unless otherwise noted.

2. An authority citation is added following each section of Part 74 that does not already have such an authority citation, to read as follows:

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474, OMB Circular A–110)

3. Section 74.3 is amended by revising the definition of "grant" to read as follows:

§ 74.3 Definitions.

* * * * *

"Grant" means an award of financial assistance in the form of money, or property in lieu of money, by the Federal government to an eligible recipient. The term includes a cooperative agreement except where otherwise provided by regulation. The term does not include any Federal procurement subject to the Federal Acquisition Regulation in 48 CFR, nor does it include technical assistance, which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct appropriations. Also, the term does not include assistance, such as a fellowship or other lump sum award, for which the recipient is not required to account on an actual cost basis.

* * * * *

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474, OMB Circular A–110)

4. Section 74.47 is revised to read as follows:

§ 74.47 Interest earned on advances of grant funds.

(a) Unless exempted by Federal statute (see paragraph (b) of this section for the principal exemption)—

(1) Recipients shall maintain advances of Federal funds in interest-bearing accounts;

(2) Interest earned on Federal advances deposited in those accounts must be remitted promptly, but at least quarterly, to the Department; and

(3) A recipient may retain interest income up to $100 per year to assist in the recoupment of administrative expenses.

(b) In accordance with 31 U.S.C. 6503, States are not accountable to the Federal government for interest earned by the State itself, or by its subgrantees, if this income is earned on an advance of funds made under a Department grant.

(c) Recipients are subject to the provisions in § 74.61(e) for minimizing the time between the transfer of advances and their disbursement. Those provisions apply even if there is no accountability to the Federal government for interest or other investment income earned on the advances.

(d) The following definitions apply to this section:

(1) "Interest" includes any interest or investment income earned by grantees, subgrantees, and cost-type contractors on advances of Department grant funds to the grantee.

(2) "State" includes any agency or instrumentality of a State but does not include any local government in a State.

(3) Notwithstanding the definition of "grant" in § 74.3, the word "grant" has the meaning given in 31 U.S.C. 6501.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474, 31 U.S.C. Chapter 65, OMB Circular A–110)

5. In § 74.73, paragraphs (a) and (b) are revised to read as follows:

§ 74.73 Accounting basis for reports; the financial status report.

(a) Each grantee shall report program outlays and program income on the same accounting basis, i.e., cash or

accrued expenditure (accrual), that it uses in its accounting system.

(b) The Secretary may require a grantee to use Standard Form 269, Financial Status Report, to report the status of funds for nonconstruction grants.

* * * * *

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circular A-110)

6. In § 74.74, paragraphs (a), (c), and (d) are revised to read as follows:

§ 74.74 Federal cash transactions report.

(a) *Reporting payments.* (1) The Secretary may require a grantee to submit Standard Form 272 to report payments under a grant.

(2) This report is used by the Secretary to monitor cash advanced to the grantee and to obtain disbursement or outlay information for each grant. The Secretary may also use this form to determine the status of funds for a nonconstruction grant.

* * * * *

(c) *Cash in hands of secondary recipients.* If the submission of a report is considered necessary and feasible by the Secretary, the Secretary may require a grantee to report the amount of cash subadvances in excess of three days' need in the hands of its subgrantees or contractors and to provide short narrative explanations of actions taken by the grantee to reduce the excess balances.

(d) *Frequency and due date.* A grantee shall submit the report on a quarterly basis. If a Department grant authorizes advances at an annualized rate of one million dollars or more, the Secretary may require submission of the report on a monthly basis.

(Authority: 20 U.S.C. 1221-3(a)(1) and 3474, OMB Circular A-110)

7. Section 74.75 is amended by revising paragraph (a), redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b), to read as follows:

§ 74.75 Request for advance or reimbursement.

(a) The Secretary includes in the terms and conditions of a grant—

(1) Whether the grantee will be paid by advance or reimbursement; and

(2) Instructions regarding how the grantee must request advances or reimbursements under the grant.

(b) Pursuant to any applicable regulations, the Secretary may change, at any time, the method of making payments to a grantee.

* * * * *

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circular A-110)

§ 74.76 [Amended]

8. Section 74.76(c) is amended by removing "by 74.73(b)" and adding in its place "by 74.73(a)".

9. Section 74.91 is amended by removing the definition "Advance by Treasury check" and by adding a definition of "Advance" in its place, to read as follows:

§ 74.91 Definitions.

* * * * *

"Advance" is a payment made by the Department to a grantee, upon its periodic request or through the use of predetermined payment schedules, before outstanding obligations are liquidated by the grantee.

* * * * *

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circular A-110)

10. Section 74.93 is revised to read as follows:

§ 74.93 Payment methods under Department grants.

The Department makes payments to a grantee using the most efficient and cost-effective method available in accordance with Treasury Circular 1075 (31 CFR Part 205) and any supplementary instructions prescribed by the Department of the Treasury.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circular A-110)

§ 74.94 [Removed]

11. Section 74.94 is removed.

12. Section 74.96 is revised to read as follows:

§ 74.96 Establishing frequency of payments.

The Secretary establishes, in the terms and conditions of a grant, the frequency of the grantee's request for payments.

(Authority): 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circular A-110)

13. Section 74.172 is revised to read as follows:

§ 74.172 Institutions of higher education.

Institutions of higher education shall comply with the cost principles stated in Appendix D to this Part.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, OMB Circulars A-110, A-21)

14. Section 74.175 is revised to read as follows:

§ 74.175 Subgrants to commercial organizations

(a) The cost principles applicable to a subgrantee or cost-type contractor under a grant are not necessarily the same as those applicable to the grantee. For example, if a State government awards a subgrant or cost-type contract to an institution of higher education, OMB Circular A-21, as specified in § 74.172, applies to the costs incurred by the institution of higher education, even though OMB Circular A-87 applies to the costs incurred by the State.

(b) If the Secretary makes a grant to a for-profit organization, the Secretary uses the cost principles in the Federal Acquisition Regulation, 48 CFR Part 31, to determine the allowability of costs. In making a grant to such an organization, the Secretary does not pay any fee or other element above actual costs that may inure to the benefit of the owners of the organizations.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474 OMB Circular A-110)

15. Appendix D is revised to read as follows:

Appendix D—Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements With Educational Institutions

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A. Purpose and Scope

1. *Objective.* This Attachment provides principles for determining the costs applicable to research and development, training, and other sponsored work performed by colleges and universities under grants, contracts, and other agreements with the Federal Government. These agreements are referred to as sponsored agreements.

2. *Policy guides.* The successful application of these cost accounting principles requires development of mutual understanding between representatives of universities and of the Federal Government as to their scope, implementation, and interpretation. It is recognized that—

a. The arrangements for Federal agency and institutional participation in the financing of a research, training, or other project are properly subject to negotiation between the agency and the institution concerned, in accordance with such Government-wide criteria or legal requirements as may be applicable.

b. Each institution, possessing its own unique combination of staff, facilities, and experience, should be encouraged to conduct research and educational activities in a manner consonant with its own academic philosophies and institutional objectives.

c. The dual role of students engaged in research and the resulting benefits to sponsored agreements are fundamental to the research effort and shall be recognized in the application of these principles.

d. Each institution, in the fulfillment of its obligations, should employ sound management practices.

e. The application of these cost accounting principles should require no significant changes in the generally accepted accounting practices of colleges and universities. However, the accounting practices of individual colleges and universities must support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to sponsored agreements.

f. Cognizant Federal agencies involved in negotiating indirect cost rates and auditing should assure that institutions are generally applying these cost accounting principles on a consistent basis. Where wide variations exist in the treatment of a given cost item among institutions, the reasonableness and equitableness of such treatments should be fully considered during the rate negotiations and audit.

3. *Application.* These principles shall be used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles shall also be used in determining the costs of work performed by such institutions under subgrants, cost-reimbursement subcontracts, and other awards made to them under sponsored agreements. They also shall be used as a guide in the pricing of fixed-price contracts and subcontracts where costs are used in determining the appropriate price. The principles do not apply to:

a. Arrangements under which Federal financing is in the form of loans, scholarships, fellowships, traineeships, or other fixed amounts based on such items as education allowance or published tuition rates and fees of an institution.

b. Capitation awards.

c. Other awards under which the institution is not required to account to the Government for actual costs incurred.

B. *Definition of Terms.*

1. *Major functions of an institution* refers to instruction, organized research, other sponsored activities, and other institutional activities as defined below:

a. *Instruction* means the teaching and training activities of an institution. Except for research training as provided in c. below, this term includes all teaching and training activities, whether they are offered for credits toward a degree or certificate or on a noncredit basis, and whether they are offered through regular academic departments or separate divisions, such as a summer school division or an extension division. Also considered part of this major function are departmental research, and, where agreed to, university research.

(1) *Sponsored instruction and training* means specific instructional or training activity established by grant, contract, or cooperative agreement. For purposes of the cost principles, this activity may be considered a major function even though an institution's accounting treatment may include it in the instruction function.

(2) *Departmental research* means research development and scholarly activities that are not organized research and, consequently, are not separately budgeted and accounted for. Departmental research, for purposes of this document, is not considered as a major function, but as a part of the instruction function of the institution.

b. *Organized research* means all research and development activities of an institution that are separately budgeted and accounted for. It includes:

(1) *Sponsored research* means all research and development activities that are sponsored by Federal and non-Federal agencies and organizations. This term includes activities involving the training of individuals in research techniques (commonly called research training) where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.

(2) University research means all research and devlopment activities that are separately budgeted by the institution under an internal application of institutional funds. University research, for purposes of this document, may be considered a part of the instruction function, or may be combined with sponsored research under the function, of organized research, or may be treated as a separate major function, as agreed to with the cognizant agency.

c. *Other sponsored activities* means programs and projects financed by Federal and non-Federal agencies and organizations which involve the performance of work other than instruction and organized research. Examples of such programs and projects are health service projects, and community service programs. However, when any of these activities are undertaken by the institution without outside support, they may be classified as other institutional activities.

d. *Other institutional activities* means all activities of an institution except: (1) instruction, departmental research, organized research, and other sponsored activities, as

defined above; (2) indirect cost activities indentified in Section F, and (3) specialized service facilities described in Section J38. Other institutional activities include operation of residence halls, dining halls, hospitals and clinics, student unions, intercollegiate athletics, bookstores, faculty housing, student apartment, guest houses, chapels, theaters, public museums, and other similar auxiliary enterprises. This definition also includes any other categories of activities, costs of which are "unallowable" to sponsored agreements, unless otherwise indicated in the agreements.

d. *Other institutional activities* means all activities of an institution except: (1) instruction, departmental research, organized research, and other sponsored activities, as defined above; (2) indirect cost activities indentified in Section F, and (3) specialized service facilities described in Section J38. Other institutional activities include operation of residence halls, dining halls, hospitals and clinics, student unions, intercollegiate athletics, bookstores, faculty housing, student apartment, guest houses, chapels, theaters, public museums, and other similar auxiliary enterprises. This definition also includes any other categories of activities, costs of which are "unallowable" to sponsored agreements, unless otherwise indicated in the agreements.

2. *Sponsored agreement*, for purposes of this circular, means any grant, contract, or other agreement between the institution and the Federal Government.

3. *Allocation* means the process of assigning a cost, or a group of costs, to one or more cost objectives, in reasonable and realistic proportion to the benefit provided or other equitable relationship. A cost objective may be a major function of the institution, a particular service or project, a sponsored agreement, or an indirect cost activity, as described in Section F. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate costs objectives.

C. Basic Considerations

1. *Composition of total costs.* The cost of a sponsored agreement is comprised of the allowable direct costs incident to its performance, plus the allocable portion of the allowable indirect costs of the institution, less applicable credits as described in 5 below.

2. *Factors affecting allowability of costs.* The tests of allowability of costs under these principles are: (a) they must be reasonable; (b) they must allocable to sponsored agreements under the principles and methods provided herein; (c) they must be given consistent treatment through application of those generally accepted accounting principles appropriate to the circumstances; and (d) they must conform to any limitations or exclusions set forth in these principles or in the sponsored agreement as to types and amounts or costs items.

3. *Reasonable costs.* A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount involved therefor, reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. Major considerations involved in the determination of the reasonableness of a cost are: (a) whether or not the cost is of a type generally recognized as necessary for the operation of the institution of the performance of the sponsored agreement; (b) the restraints or requirements imposed by such factors as arm's-length bargaining, Federal and State laws and regulations, and sponsored agreement terms and conditions; (c) whether or not the individuals concerned acted with due prudence in the circumstances, considering their responsibilities to the institution, it employees, its students, the Government, and the public at large; and (d) the extent to which the actions taken with respect to the incurrence of the cost are consistent with established institutional policies and practices applicable to the work of the institution generally, including sponsored agreements.

4. *Allocable costs.*

a. A cost is allocable to a particular cost objective (i.e, a specific function, project, sponsored agreement, department, or the like) if the goods or services involved are chargeable or assignable to such cost objective in accordance with relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a sponsored agreement if (1) it is incurred solely to advance the work under the sponsored agreement; (2) its benefits both the sponsored agreement and other work of the institution, in proportions that can be approximated through use of reasonable methods, or (3) it is necessary to the overall operation of the institution and, in light of the principles provided in this Circular, is deemed to be assignable in part to sponsored projects. Where the purchase of equipment or other capital items is specifically authorized under a sponsored agreement, the amounts thus authorized for such purchases are assignable to the sponsored agreement regardless of the use that may subsequently be made of the equipment or other capital items involved.

b. Any costs allocable to a particular sponsored agreement under the standards provided in this Circular may not be shifted to other sponsored agreements in order to meet deficiencies caused by overruns or other fund considerations, to avoid restrictions imposed by law or by terms of the sponsored agreement, or for other reasons of convenience.

5. *Applicable credits.*

a. The term applicable credits refers to those receipts or negative expenditures that operate to offset or reduce direct or indirect cost items. Typical examples of such transactions are: purchase discounts, rebates, or allowances; recoveries or indemnites on losses; and adjustments of overpayments or erroneous charges. This term also includes "educational discounts" on products or services provided specifically to educational institutions, such as discounts on computer equipment, except where the arrangement is clearly and explicitly identified as a gift by the vendor.

b. In some instances, the amounts received from the Federal Government to finance institutional activities or service operations should be treated as applicable credits. Specifically, the concept of netting such credit items against related expenditures should be applied by the institution in determining the rates or amounts to be charged to sponsored agreements for services rendered whenever the facilities or other resources used in providing such services have been financed directly, in whole or in part, by Federal funds. (See Sections F8, J9a, and J38 for areas of potential application in the matter of direct Federal financing.)

6. *Costs incurred by State and local governments.* Costs incurred or paid by State or local governments on behalf of their colleges and universities for fringe benefit programs such as pension costs and FICA and any other costs specifically incurred on behalf of, and in direct benefit to, the institutions are allowable costs of such institutions whether or not these costs are recorded in the accounting records of the institutions, subject to the following:

a. The costs meet the requirements of C1 through 5 above.

b. The costs are properly supported by cost allocation plans in accordance with applicable Federal cost accounting principles

c. The costs are not otherwise borne directly or indirectly by the Federal Government.

7. *Limitations on allowance of costs.* Sponsored agreements may be subject to statutory requirements that limit the allowance of costs. When the maximum amount allowable under a limitation is less than the total amount determined in accordance with the principles in this Circular, the amount not recoverable under a sponsored agreement may not be charged to other sponsored agreements.

D. Direct Costs

1. *General.* Direct costs are those costs that can be identified specifically with a particular sponsored project, and instructional activity, or any other institutional activity; or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

2. *Application to sponsored agreements.* Identification with the sponsored work rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect costs of sponsored agreements. Typical costs charged directly to a sponsored agreement are the compensation of employees for performance of work under the sponsored agreement, including related fringe benefit costs to the extent they are consistently treated, in like circumstances, by the institution as direct rather than indirect costs; the costs of materials consumed or expended in the performance of the work; and other items of expense incurred for the sponsored agreement, including extraordinary utility consumption. The cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations may be included as direct costs of sponsored agreements, provided such items are consistently treated, in like circumstances, by the institution as direct rather than indirect costs, and are charged under a recognized method of computing

actual costs, and conform to generally accepted cost accounting practices consistently followed by the institution.

E. Indirect Costs

1. *General.* Indirect costs are those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, and instructional activity, or any other institutional activity. At educational institutions such costs normally are classified under the following indirect cost categories: depreciation and use allowances, general administration expenses, sponsored projects administration expenses, operation and maintenance expenses, library expenses, departmental administration expenses, and student administration and services.

2. *Criteria for distribution.*

3. *Base period.* A base period for distribution of indirect costs is the period during which the costs are incurred. The base period normally should coincide with the fiscal year established by the institution, but in any event the base period should be so selected as to avoid inequities in the distribution of costs.

b. *Need for cost groupings.* The overall objective of the indirect cost allocation process is to distribute the indirect costs described in Section F to the major functions of the institution in proportions reasonably consistent with the nature and extent of their use of the institution's resources. In order to achieve this objective, it may be necessary to provide for selective distribution by establishing separate groupings of cost within one or more of the indirect cost categories referred to in E1 above. In general, the cost groupings established within a category should constitute, in each case, a pool of those items of expense that are considered to be of like nature in terms of their relative contribution to (or degree of remoteness from) the particular cost objectives to which distribution is appropriate. Cost groupings should be established considering the general guides provided in c below. Each such pool or cost grouping should then be distributed individually to the related cost objectives, used the distribution base or method most appropriate in the light of the guides set forth in d below.

c. *General considerations on cost groupings.* The extent to which separate cost groupings and selective distribution would be appropriate at an institution is a matter of judgment to be determined on a case-by-case basis. Typical situations which may warrant the establishment of two or more separate cost groupings (based on account classification or analysis) within an indirect cost category include but are not limited to the following:

(1) Where certain items or categories of expense relate solely to one of the major functions of the institution or to less than all functions, such expenses should be set aside as a separate cost grouping for direct assignment or selective allocation in accordance with the guides provided in E2b and d.

(2) Where any types of expense ordinarily treated as general administration or departmental administration are charged to sponsored agreements as direct costs, expenses applicable to other activities of the institution when incurred for the same purposes in like circumstances must, through separate cost groupings, be excluded from the indirect costs allocable to those sponsored agreements and included in the direct cost of other activities for cost allocation purposes.

(3) Where it is determined that certain expenses are for the support of a service unit or facility whose output is susceptible of measurement on a workload or other quantitative basis, such expenses should be set aside as a separate cost grouping for distribution on such basis to organized research, instructional, and other activities at the institution or within the department.

(4) Where activities provide their own purchasing, personnel administration, building maintenance or similar service, the distribution of general administration and general expenses, or operation and maintenance expenses to such activities should be accomplished through cost groupings which include only that portion of central indirect costs (such as for overall management) which are properly allocable to such activities.

(5) Where the institution elects to treat fringe benefits as indirect charges, such costs should be set aside as a separate cost grouping for selective distribution to related cost objectives.

(6) The number of separate cost groupings within a category should be held within practical limits, after taking into consideration the materiality of the amounts involved and the degree of precision attainable through less selective methods of distribution.

d. *Selection of distribution method.*

(1) Actual conditions must be taken into account in selecting the method or base to be used in distributing individual cost groupings. The essential consideration in selecting a base is that it be the one best suited for assigning the pool of costs to cost objectives in accordance with benefits derived; a traceable cause and effect relationship; or logic and reason, where neither benefit nor cause and effect relationship is determinable.

(2) Where a cost grouping can be identified directly with the cost objective benefited, it should be assigned to that cost objective.

(3) Where the expenses in a cost grouping are more general in nature, the distribution may be based on a cost analysis study which results in an equitable distribution of the costs. Such cost analysis studies may take into consideration weighting factors, population, or space occupied if appropriate. Cost analysis studies, however, must (a) be appropriately documented in sufficient detail for subsequent review by the cognizant Federal agency, (b) distribute the costs to the related cost objectives in accordance with the relative benefits derived, (c) be statistically sound, (d) be performed specifically at the institution at which the results are to be used, and (e) be reviewed periodically, but not less frequently than every two years, updated if necessary, and used consistently. Any assumptions made in the study must be stated and explained. The use of cost analysis studies and periodic changes in the method of cost distribution must be fully justified.

(4) If a cost analysis study is not performed, or if the study does not result in an equitable distribution of the costs, the distribution shall be made in accordance with the appropriate base cited in Section F., unless one of the following conditions is met: (a) it can be demonstrated that the use of a different base would result in a more equitable allocation of the costs, or that a more readily available base would not increase the costs charged to sponsored agreements, or (b) the institution qualifies for, and elects to use, the simplified method for computing indirect cost rates described in Section H.

e. *Order of Distribution.*

(1) Indirect cost categories consist of depreciation and use allowance, operation and maintenance, general administration and general expenses, departmental administration, sponsored projects administration, library, and student administration and services, as described in Section F.

(2) Depreciation and use allowances, operation and maintenance expenses, and general administrative and general expenses should be allocated in that order to the remaining indirect cost categories as well as to the major functions and specialized service facilities of the institution. Other cost categories may be allocated in the order determined to be most appropriate by the institutions. When cross allocation of costs is made as provided in (3) below, this order of allocation does not apply.

(3) Normally an indirect cost category will be considered closed once it has been allocated to their cost objectives, and costs may not be subsequently allocated to it. However, a cross allocation of costs between two or more indirect cost categories may be used if such allocation will result in a more equitable allocation of costs. If a cross allocation is used, an appropriate modification to the composition of the indirect cost categories described in Section F is required.

F. Identification and Assignment of Indirect Costs

1. *Depreciation and use allowances.*

a. The expenses under this heading are the portion of the costs of the institution's buildings, capital improvements to land and buildings, and equipment which are computed in accordance with Section J9.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be allocated in the following manner:

(1) Depreciation or use allowances on buildings used exclusively in the conduct of a single function, and on capital improvements and equipment used in such buildings, shall be assigned to that function.

(2) Depreciation or use allowances on buildings, used for more than one function, and on capital improvements and equipment used in such buildings, shall be allocated to the individual functions performed in each building on the bais of usable square feet of space, excluding common areas such as hallways, stairwells, and restrooms.

(3) Depreciation or use allowances on buildings and capital improvements where

space is used jointly, and on equipment used jointly, shall be allocated to benefiting functions in proportion to the total salaries and wages applicable to the joint functions.

(4) Depreciation or use allowances on buildings, capital improvements, and equipment used predominantly for one function and only incidentally for other(s), may be assigned to the function in which it is used predominantly.

(5) Depreciation or use allowances on certain capital improvements to land, such as paved parking areas, fences, sidewalks, and the like, not included in the cost of buildings, shall be allocated to user categories of students and employees on a full-time equivalent basis. The amount allocated to the student category shall be assigned to the instruction functions of the institution. The amount allocated to the employee category shall be further allocated to the major functions of the institution in proportion to the salaries and wages of all employees applicable to those functions.

2. *Operation and maintenance expenses.*

a. The expenses under this heading are those that have been incurred by a central service organization or at the departmental level for the administration, supervision, operation, maintenance, preservation, and protection of the institution's physical plant. They include expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and equipment; and care of grounds and maintenance and operation of buildings and other plant facilities. The operation and maintenance expenses category should also include the fringe benefit costs applicable to the salaries and wages included therein, and depreciation and use allowance.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be allocated in the same manner as described in Section F1b for depreciation and use allowances.

3. *General administration and general expenses.*

a. The expenses under this heading are those that have been incurred for the general executive and administrative offices of educational institutions and other expenses of a general character which do not relate solely to any major function of the institution; i.e., solely to (1) instruction, (2) organized research, (3) other sponsored activities, or (4) other institutional activities. The general administration and general expense category should also include the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of operation and maintenance expense, and depreciation and use allowances.

General administration and general expenses shall not include expenses incurred within nonuniversity-wide deans' offices, academic departments, organized research units, or similar organizational units. (See section F.4., departmental administration expenses.)

Federal agencies may authorize reimbursement of additional costs for department heads and faculty only in exceptional cases where an institution can demonstrate undue hardship or detriment to project performance.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be grouped first, according to common major functions of the institution to which they render services or provide benefits. The aggregate expenses of each group shall then be allocated to serviced or benefited functions on the modified total cost basis. Modified total costs consist of salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to $25,000 each. When an activity included in this indirect cost category provides a service or product to another institution or organization, and appropriate adjustment must be made to either the expenses or the basis of allocation or both, to assure a proper allocation of costs.

4. *Departmental administration expenses.*

a. The expenses under this heading are those that have been incurred for administrative and supporting services that benefit common or joint departmental activities or objectives in academic deans' offices, academic departments and divisions, and organized research institutes, study centers, and research centers. Departmental administration expenses are subject to the following limitations.

(1) Academic deans' offices. Salaries and operating expenses are limited to those attributable to administrative functions.

(2) Academic departments:

(a) Salaries and fringe benefits attributable to the administrative work (including bid and proposal preparation) of faculty (including departmental heads), and other professional personnel conducting research and/or instruction, shall be allowed at a rate of 3.6 percent of modified total direct costs. This category does not include professional business or professional administrative officers. This allowance shall be added to the computation of the indirect cost rate for major functions in section G; the expenses covered by the allowance shall be excluded from the departmental administration cost pool. No documentation is required to support this allowance.

(b) Other administrative and supporting expenses incurred within academic departments are allowable provided they are treated consistently in like circumstances. This would include expenses such as the salaries of secretarial and clerical staffs, the salaries of administrative officers and assistants, travel, office supplies, stockrooms, and the like.

(3) Other fringe benefit costs applicable to the salaries and wages included in (1) and (2) above are allowable, as well as an appropriate share of general administration and general expenses, operation and maintenance expenses, and depreciation and/or use allowances.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be allocated as follows:

(1) The administrative expenses of the dean's office of each college and school shall be allocated to the academic departments within that college or school on the modified total cost basis.

(2) The administrative expenses of each academic department, and the department's share of the expenses allocated in (1) above shall be allocated to the appropriate functions of the department on the modified total cost basis.

5. *Sponsored projects administration.*

(a) The expenses under this heading are limited to those incurred by a separate organization(s) established primarily to administer sponsored projects, including such functions as grant and contract administration (Federal and non-Federal) special security, purchasing, personnel administration, and editing and publishing of research and other reports. They include the salaries and expenses of the head of such organization, assistants, and immediate staff, together with the salaries and expenses of personnel engaged in supporting activities maintained by the organization, such as stock rooms, stenographic pools and the like. This category also includes an allocable share of fringe benefit costs, general administration and general expenses, operation and maintenance expenses, and depreciation/use allowances. Appropriate adjustments will be made for services provided to other functions or organizations.

Federal agencies may authorize reimbursement of additional costs for department heads and faculty only in exceptional cases where an institution can demonstrate undue hardship or detriment to project performance.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be allocated to the major functions of the institution under which the sponsored projects are conducted on the basis of the modified total cost of sponsored projects.

c. An appropriate adjustment shall be made to eliminate any duplicate charges to sponsored agreements when this category includes similar or identical activities as those included in the general administration and general expense category or other indirect cost items, such as accounting, procurement, or personnel administration.

6. *Library expenses.*

a. The expenses under this heading are those that have been incurred for the operation of the library, including the cost of books and library materials purchased for the library, less any items of library income that qualify as applicable credits under Section C5. The library expense category should also include the fringe benefits applicable to the salaries and wages included therein, an appropriate share of general administration and general expense, operation and maintenance expense, and depreciation and use allowances. Costs incurred in the purchases of rare books (museum-type books) with no value to sponsored agreements should not be allocated to them.

b. In the absence of the alternatives provided for in Section E2d, the expenses included in this category shall be allocated first on the basis of primary categories of users, including students, professional employees, and other users.

(1) The student category shall consist of full-time equivalent students enrolled at the institution, regardless of whether they earn credits toward a degree or certificate.

(2) The professional employee category shall consist of all faculty members and other professional employees of the institution, on a full-time equivalent basis.

(3) The other users category shall consist of all other users of library facilities.

c. Amounts allocated in b above shall be assigned further as follows: (1) The amount in the student category shall be assigned to the instruction function of the institution.

(2) The amount in the professional employee category shall be assigned to the major functions of the institution in proportion to the salaries and wages of all faculty members and other professional employees applicable to those functions.

(3) The amount in the other users category shall be assigned to the other institutional activities function of the institution.

7. *Student administration and services.*

a. The expenses under this heading are those that have been incurred for the administration of student affairs and for services to students, including expenses of such activities as deans of students, admissions, registrar, counseling and placement services, student advisers, student health and infirmary services, catalogs, and commencements and convocations.

The salaries of members of the academic staff whose responsibilities to the institution require administrative work that benefits sponsored projects may also be included to the extent that the portion charged to Student Administration is determined in accordance with Section J.6. This expense category also includes the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of general administration and general expenses, operation and maintenance, and use allowances and/or depreciation.

b. In the absence of the alternatives provided for in Section E2d, the expenses in this category shall be allocated to the instruction function, and subsequently to sponsored agreements in that function.

8. *Offset for indirect expenses otherwise provided for by the Government.*

a. The items to be accumulated under this heading are the reimbursements and other payments from the Federal Government which are made to the institution to support solely, specifically, and directly, in whole or in part, any of the administrative or service activities described in F1 through 7 above.

b. The items in this group shall be treated as a credit to the affected individual indirect cost category before that category is allocated to benefiting functions.

G. Determination and Application of Indirect Cost Rate or Rates

1. *Indirect cost pools.*

a. Subject to b below, the separate categories of indirect costs allocated to each major function of the institution as prescribed in Section f shall be aggregated and treated as a common pool for that function. The amount in each pool shall be divided by the distribution base described in G2 below to arrive at a single indirect cost rate for each function. The rate for each function is used to distribute indirect costs to individual sponsored agreements of that function. Since a common pool established for each major function of the institution, a separate indirect cost rate would be established for each of the major functions described in Section B1 under which sponsored agreements are carried out.

b. In some instances a single rate basis for use across the board on all work within a major function at an institution may not be appropriate. A single rate for research, for example, might not take into account those different environmental factors and other conditions which may affect substantially the indirect costs applicable to a particular segment of research at the institution. A particular segment of research may be that performed under a single sponsored agreement or it may consist of research under a group or sponsored agreement performed in a common environment. The environmental factors are not limited to the physical location of the work. Other important factors are the level of the administrative support required, the nature of the facilities or other resources employed, the scientific disciplines or technical skills involved, the organizational arrangements used, or any combination thereof. Where a particular segment of a sponsored agreement is performed within an environment which appears to generate a significantly different level of indirect costs, provision should be made for a separate indirect cost pool applicable to such work. The separate indirect cost pool should be developed during the regular course of the rate determination process and the separate indirect cost rate resulting therefrom should be utilized; provided it is determined that (1) such indirect cost rate differs significantly from that which would have been obtained under a. above, and (2) the volume of work to which such rate would apply is material in relation to other sponsored agreements at the institution.

2. *The distribution basis.* Indirect costs shall be distributed to applicable sponsored agreements on the basis of modified total direct costs, consisting of salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to $25,000 each. For this purpose, an indirect cost rate should be determined for each of the separate indirect cost pools developed pursuant to G1, above. The rate in each case should be stated as the percentage which the amount of the particular indirect cost pool is of the modified total direct costs identified with such pool. Other bases may be used where it can be demonstrated that they produce more equitable results.

3. *Negotiated lump sum for indirect costs.* A negotiated fixed amount in lieu of indirect costs may be appropriate for self-contained, off-campus, or primarily subcontracted activities where the benefits derived from an institution's indirect services cannot be readily determined. Such negotiated indirect costs will be treated as an offset before allocation to instruction, organized research, other sponsored activities, and other institutional activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

4. *Predetermined fixed rates for indirect costs.* Public Law 87–638 (76 Stat. 437) authorizes the use of predetermined fixed rates in determining the indirect costs applicable under research agreements with educational institutions. The stated objectives of the law are to simplify the administration of cost-type research and development contracts (including grants) with educational institutions, to facilitate the preparation of their budgets, and to permit more expeditious closeout of such contracts when the work is completed. In view of the potential advantages offered by this procedure, consideration should be given to the negotiation of predetermined fixed rates for indirect costs in those situations where the cost experience and other pertinent facts available are deemed sufficient to enable the parties involved to reach an informed judgment as to the probable level of indirect costs during the ensuing accounting period.

5. *Negotiated fixed rates and carry-forward provisions.* When a fixed rate is negotiated in advance for a fiscal year (or other time period), the over- or under-recovery for that year may be included as an adjustment to the indirect cost for the next rate negotiation. When the rate is negotiated before the carry-forward adjustment is determined, the carry-forward amount may be applied to the next subsequent rate negotiation. When such adjustments are to be made, each fixed rate negotiated in advance for a given period will be computed by applying the expected indirect costs allocable to sponsored agreements for the forecast period plus or minus the carry-forward adjustment (over- or under-recovery) from the prior period, to the forecast distribution base. Unrecovered amounts under lump-sum agreements or cost-sharing provisions or prior years shall not be carried forward for consideration in the new rate negotiation. There must, however, be an advance understanding in each case between the institution and the cognizant Federal agency as to whether these differences will be considered in the rate negotiation rather than making the determination after the differences are known. Further, institutions electing to use this carry-forward provision may not subsequently change without prior approval of the cognizant Federal agency. In the event that an institution returns to a postdetermined rate, any over- or under-recovery during the period in which negotiated fixed rates and carry-forward provisions were followed will be included in the subsequent postdetermined rates. Where multiple rates are used, the same procedure will be applicable for determining each rate.

H. Simplified Method for Small Institutions

1. *General.*

a. Where the total direct cost of work covered by this Circular at an institution does not exceed $3,000,000 in a fiscal year, the use of the simplified procedure described in 2, below, may be used in determining allowable indirect costs. Under this simplified procedure, the institution's most recent annual financial report and immediately available supporting information with salaries and wages segregated from other costs, will be utilized as a basis for determining the indirect cost rate applicable to all sponsored agreements.

b. The simplified procedure should not be used where it produces results which appear

inequitable to the Government or the institution. In any such case, indirect costs should be determined through use of the regular procedure.

2. *Simplified procedure.*

a. Establish the total amount of salaries and wages paid to all employees of the institution.

b. Establish an indirect cost pool consisting of the expenditures (exclusive of capital items and other costs specifically identified as unallowable) which customarily are classified under the following titles or their equivalents:

(1) General administration and general expenses (exclusive of cost of student administration and services, student activities, student aid, and scholarships).

(2) Operation and maintenance of physical plant; and depreciation and use allowances; after appropriate adjustment for costs applicable to other institutional activities.

(3) Library.

(4) Department administration expenses, which will be computed as 20 percent of the salaries and expenses of deans and heads of departments.

In those cases where expenditures classified under (1) above have previously been allocated to other institutional activities, they may be included in the indirect cost pool. The total amount of salaries and wages included in the indirect cost pool must be separately identified.

c. Establish a salary and wage distribution base, determined by deducting from the total of salaries and wages as established in a above the amount of salaries and wages included under b above.

d. Establish the indirect cost rate, determined by dividing the amount in the indirect cost pool, b above, by the amount of the distribution base, c above.

e. Apply the indirect cost rate to direct salaries and wages for individual agreements to determine the amount of indirect costs allocable to such agreements.

J. General Provisions for Selected Items of Cost

Sections 1 through 44 below provide principles to be applied in establishing the allowability of certain items involved in determining cost. These principles should apply irrespective of whether a particular item of cost is properly treated as direct cost or indirect cost. Failure to mention a particular item of cost is not intended to imply that it is either allowable or unallowable; rather determination as to allowability in each case should be based on the treatment provided for similar or related items of cost. In case of a discrepancy between the provisions of a specific sponsored agreement and the provisions below, the agreement should govern.

1. *Advertising costs.*

a. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television programs, direct mail, exhibits, and the like.

b. The only advertising costs allowable are those which are solely for (1) the recruitment of personnel required for the performance by the institution of obligations arising under the sponsored agreement, when considered in conjunction with all other recruitment costs, as set forth in Section J32; (2) the procurement of goods and services for the performance of the sponsored agreement; (3) the disposal of scrap or surplus materials acquired in the performance of the sponsored agreement except when institutions are reimbursed for disposal costs at a predetermined amount in accordance with Attachment N, OMB Circular No. A–110; or (4) other specific purposes necessary to meet the requirements of the sponsored agreement.

c. Costs of this nature, if incurred for more than one sponsored agreement or for both sponsored work and other work of the institution, are allowable to the extent that the principles in Sections D and E are observed.

2. *Bad debts.* Any losses, whether actual or estimated, arising from uncollectible accounts and other claims, related collections costs, and related legal costs, are unallowable.

3. *Civil defense costs.* Civil defense costs are those incurred in planning for, and the protection of life and property against, the possible effects of enemy attack. Reasonable costs of civil defense measures (including costs in excess of normal plant protection costs, first-aid training and supplies, firefighting training, posting of additional exit notices and directions, and other approved civil defense measures) undertaken on the institutions' premises pursuant to suggestions or requirements of civil defense authorities are allowable when distributed to all activities of the institution. Capital expenditures for civil defense purposes will not be allowed, but a use allowance or depreciation may be permitted in accordance with provisions set forth in Section J9. Costs of local civil defense projects not on the institution's premises are unallowable.

4. *Commencement and convocation costs.* Costs incurred for commencements and convocations are unallowable, except as provided for in Section F7.

5. *Communication costs.* Costs incurred for telephone services, local and long distance telephone calls, telegrams radiograms, postage and the like, are allowable.

6. Compensation for personal services

a. *General.* Compensation for personal services covers all amounts paid currently or accrued by the institution for services of employees rendered during the period of performance under sponsored agreements. Such amounts include salaries, wages, and fringe benefits (See Section J15.). These costs are allowable to the extent that the total compensation to individual employees conforms to the established policies of the institution, consistently applied, and provided that the charges for work performed directly on sponsored agreements and for other work allocable as indirect costs are determined and supported as provided below. Charges to sponsored agreements may include reasonable amounts for activities contributing and intimately related to work under the agreements, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences. Incidental work (that in excess of normal for the individual), for which supplemental compensation is paid by an institution under institutional policy, need not be included in the payroll distribution systems described below, provided such work and compensation are separately identified and documented in the financial management system of the institution.

b.(1) *General Principles.* (a) The distribution of salaries and wages whether treated as direct or indirect costs, will be based on payrolls documented in accordance with the generally accepted practices of colleges and universities. Institutions may include in a residual category all activities that are not directly charged to sponsored agreements, and that need not be distributed to more than one activity for purposes of identifying indirect costs and the functions to which they are allocable. The components of the residual category are not required to be separately documented.

(b) The apportionment of employee's salaries and wages which are chargeable to more than one sponsored agreement or other cost objective will be accomplished by methods which will (1) be in accordance with Sections A–2 and C above, (2) produce an equitable distribution of charges for employee's activities, and (3) distinguish the employees' direct activities from their indirect activities.

(c) In the use of any methods for apportioning salaries, it is recognized that, in an academic setting, teaching, research, service, and administration are often inextricably intermingled. A precise assessment of factors that contribute to costs is not always feasible, nor is it expected. Reliance, therefore, is placed on estimates in which a degree of tolerance is appropriate.

(d) There is no single best method for documenting the distribution of charges for personal services. Methods for apportioning salaries and wages, however, must meet the criteria specified in J.6.b.(2) below. Examples of acceptable methods are contained in J.6.c. below. Other methods which meet the criteria specified in J.6.b.(2) below also shall be deemed acceptable, if a mutually satisfactory alternative agreement is reached.

(2) *Criteria for Acceptable Methods.* (a) The payroll distribution system will (i) be incorporated into the official records of the institution, (ii) reasonably reflect the activity for which the employee is compensated by the institution, and (iii) encompass both sponsored and all other activities on an integrated basis, but may include the use of subsidiary records. (Compensation for incidental work described in J.6.a. need not be included.)

(b) The method must recognize the principle of after-the-fact confirmation or determination so that costs distributed represent actual costs, unless a mutually satisfactory alternative agreement is reached. Direct cost activities and indirect cost activities may be confirmed by responsible persons with suitable means of verification that the work was performed. Confirmation by the employee is not a requirement for either direct or indirect cost activities if other

responsible persons make appropriate confirmations.

(c) The payroll distribution system will allow confirmation of activity allocable to each sponsored agreement and each of the categories of activity needed to identify indirect costs and the functions to which they are allocable. The activities chargeable to indirect cost categories or the major functions of the institution for employees whose salaries must be apportioned (see J.6.b.1.(b) above), if not initially identified as separate categories, may be subsequently distributed by any reasonable method mutally agreed to, including, but not limited to, suitably conducted surveys, statistical sampling procedures, or the application of negotiated fixed rates.

(d) Practices vary among institutions and within institutions as to the activity constituting a full workload. Therefore, the payroll distribution system may reflect categories of activities expressed as a percentage distribution of total activities.

(e) Direct and indirect charges may be made initially to sponsored agreements on the basis of estimates made before services are performed. When such estimates are used, significant changes in the corresponding work activity must be identified and entered into the payroll distribution system. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term, such as an academic period.

(f) The system will provide for independent internal evaluations to ensure the system's effectiveness and compliance with the above standards.

(g) For systems which meet these standards, the institution will not be required to provide additional support or documentation for the effort actually performed.

c. *Examples of Acceptable Methods for Payroll Distribution:*

(1) *Plan—Confirmation:* Under this method, the distribution of salaries and wages of professorial or professional staff applicable to sponsored agreements is based on budgeted, planned, or assigned work activity, updated to reflect any significant changes in work distribution. A plan-confirmation system used for salaries and wages charged directly or indirectly to sponsored agreements will meet the following standards:

(a) A system of budgeted, planned, or assigned work activity will be incorporated into the official records of the institution and encompass both sponsored and all other activities on an integrated basis. The system may include the use of subsidiary records.

(b) The system will reasonably reflect only the activity for which the employee is compensated by the institution (compensation for incidental work described in J.6.a. need not be included). Practices vary among institutions and within institutions as to the activity constituting a full workload. Hence, the system will reflect categories of activities expressed as a percentage distribution of total activities. (But see Section H for treatment of indirect costs under the simplified method for small institutions.)

(c) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify indirect costs and the functions to which they are allocable. The system may treat indirect cost activities initially within a residual category and subsequently determine them by alternate methods as discussed in J.6.b.(2)(c).

(d) The system will provide for modification of an individual's salary or salary distribution commensurate with an significant change in the employee's work activity. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term such as an academic period. Whenever it is apparent that a significant change in work activity which is directly or indirectly charged to sponsored agreements will occur or has occurred, the change will be documented over the signature of a responsible official and entered into the system.

(e) At least annually a statement will be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification that the work was performed, stating that salaries and wages charged to sponsored agreements as direct charges, and to residual, indirect cost or other categories are reasonable in relation to work performed.

(f) The system will provide for independent internal evaluation to ensure the system's integrity and compliance with the above standards.

(g) In the use of this method, an institution shall not be required to provide additional support or documentation for the effort actually performed.

(2) *After-the-fact Activity Records:* Under this system the distribution of salaries and wages by the institution will be supported by activity reports as prescribed below.

(a) Activity reports will reflect the distribution of activity expended by employees covered by the system (compensation for incidental work as described in J.6.a. need not be included).

(b) These reports will reflect an after-the-fact reporting of the percentage distribution of activity of employees. Charges may be made initially on the basis of estimates made before the services are performed, provided that such charges are promptly adjusted if significant differences are indicated by activity records.

(c) Reports will reasonably reflect the activities for which employees are compensated by the institution. To confirm that the distribution of activity represents a reasonable estimate of the work performed by the employee during the period, the reports will be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification that the work was performed.

(d) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify indirect costs and the functions to which they are allocable. The system may treat indirect cost activities initially within a residual category and subsequently determine them by alternate methods as discussed in J.6.b.(2)(c).

(e) For professorial and professional staff, the reports will be prepared each academic term, but no less frequently than every six months. For other employees, unless alternate arrangements are agreed to, the reports will be prepared no less frequently than monthly and will coincide with one or more pay periods.

(f) Where the institution uses time cards or other forms of after-the-fact payroll documents as original documentation for payroll and payroll charges, such documents shall qualify as records for this purpose provided that they meet the requirements in (a) through (e) above.

(3) *Multiple Confirmation Records:* Under this system the distribution of salaries and wages of professorial and professional staff will be supported by records which certify separately for direct and indirect cost activities as prescribed below.

(a) For employees covered by the system, there will be direct cost records to reflect the distribution of that activity expended which is to be allocable as direct cost to each sponsored agreement. There will also be indirect cost records to reflect the distribution of that activity to indirect costs. These records may be kept jointly or separately (but are to be certified separately, see below).

(b) Salary and wage charges may be made initially on the basis of estimates made before the services are performed provided that such charges are promptly adjusted if significant differences occur.

(c) Institutional records will reasonably reflect only the activity fo which employees are compensated by the institution (compensation for incidental work as described in J.6.a. need not be included).

(d) The system will reflect activity applicable to each sponsored agreement and to each category needed to identify indirect costs and the functions to which they are allocable.

(e) To confirm that distribution of activity represents a reasonable estimate of the work performed by the employee during the period the record for each employee will include:

(1) The signature of the employee or of a person having direct knowledge of the work, confirming that the record of activities allocable as direct costs of each sponsored agreement is appropriate.

(2) The record of indirect costs will include the signature of responsible person(s) who use suitable means of verification that the work was performed and is consistent with the overall distribution of the employee's compensated activities.

These signatures may all be on the same document.

(f) The reports will be prepared each academic term, but no less frequently than every six months.

(g) Where the institution uses time cards or other forms of after-the-fact payroll documents as original documentation for payroll and payroll charges, such documents shall qualify as records for this purpose provided they meet the requirements in (a) through (f) above.

d. *Salary rates for faculty members.*

(1) *Salary rates for academic year.* Charges for work performed on sponsored agreements by faculty members during the academic year will be based on the individual faculty member's regular compensation for the continuous period which, under the policy of the institution concerned, constitutes the basis of his salary. Charges for work performed on sponsored agreements during all or any portion of such period are allowable at the base salary rate. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period. This principle applies to all members of the faculty at an institution. Since intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full-time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement conducted by another faculty member of the same institution. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency.

(2) *Periods outside the academic year.*

(a) Except as otherwise specified for teaching activity in (b) below, charges for work performed by faculty members on sponsored agreements during the summer months or other period not included in the base salary period will be determined for each faculty member at a rate not in excess of the base salary divided by the period to which the base salary relates, and will be limited to charges made in accordance with other parts of this section. The base salary period used in computing charges for work performed during the summer months will be the number of months covered by the faculty member's official academic year appointment.

(b) Charges for teaching activities performed by faculty members on sponsored agreements during the summer months or other periods not included in the base salary period will be based on the normal policy of the institution governing compensation to faculty members for teaching assignments during such periods.

(3) *Part-time faculty.* Charges for work performed on sponsored agreements by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for the part-time assignments; e.g., an institution pays $5,000 to a faculty member for half-time teaching during the academic year. He devoted one-half of his remaining time to a sponsored agreement. Thus, his additional compensation, chargeable by the institution to the agreement, would be one-half of $5,000, or $2,500.

e. *Noninstitutional professional activities.* Unless an arrangement is specifically authorized by a Federal sponsoring agency, an institution must follow its institution-wide policies and practices concerning the permissible extent of professional services that can be provided outside the institution for noninstitutional compensation. Where such institution-wide policies do not exist or do not adequately define the permissible extent of consulting or other noninstitutional activities undertaken for extra outside pay, the Government may require that the effort of professional staff working on sponsored agreements be allocated between (1) institutional activities, and (2) noninstitutional professional activities. If the sponsoring agency considers the extent of noninstitutional professional effort excessive, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.

7. *Contingency provisions.* Contributions to a contingency reserve or any similar provision made for events, the occurrence of which cannot be foretold with certainty as to time, intensity, or with an assurance of their happening, are unallowable. (But see also Section J16c.)

8. *Deans of faculty and graduate schools.* The salaries and expenses of deans of faculty and graduate schools, or their equivalents, and their staffs, are allowable.

9. *Depreciation and use allowances.* Institutions may be compensated for the use of their buildings, capital improvements, and equipment; provided that they are used, needed in the institutions' activities, and properly allocable to sponsored agreements. Such compensation shall be made by computing either depreciation or use allowance. Use allowances are the means of providing such compensation when depreciation or other equivalent costs are not computed. The allocation for depreciation or use allowance shall be made in accordance with Section F1. Depreciation and use allowances are computed applying the following rules:

a. The computation of depreciation or use allowances shall be based on the acquisition cost of the assets involved. For this purpose, the acquisition cost will exclude (1) the cost of land; (2) any portion of the cost of buildings and equipment borne by or donated by the Government, irrespective of where title was originally vested or where it is presently located; and (3) any portion of the cost of buildings and equipment contributed by or for the institution where law or agreement prohibit recovery. For an asset donated to the institution by a third party, its fair market value at the time of the donation shall be considered as the acquisition cost.

b. In the use of the depreciation method, the following shall be observed:

(1) The period of useful service or useful life established in each case for usable capital assets must take into consideration such factors as type of construction, nature of the equipment, technological developments in the particular area, and the renewal and replacement policies followed for the individual items or classes of assets involved.

(2) The depreciation method used to charge the cost of an asset (or group of assets) to accounting periods shall reflect the pattern of consumption of the asset during its useful life. In the absence of clear evidence indicating that the expected consumption of the asset will be significantly greater in the early portions than in the later portions of its useful life, the straightline method shall be presumed to be the appropriate method. Depreciation methods once used shall not be changed unless appoved in advance by the cognizant Federal agency.

(3) Where the depreciation method is introduced for application to assets for which use allowance was previously charged, the aggregate amount of use allowances and depreciation applicable to such assets must not exceed the total acquisition cost of the assets.

(4) When the depreciation method is used for buildings, a building "shell" may be treated separately from other building components, such as plumbing system and heating and air conditioning system. Each component item may then be depreciated over its estimated useful life. On the other hand, the entire building, including the shell and all components, may be treated as a single asset and depreciated over a single useful life.

(5) Where the depreciation method is used for a particular class of assets, no depreciation may be allowed on any such assets that have outlived their depreciable lives. (But see also c(3), below.)

c. Under the use allowance method, the following shall be observed:

(1) The use allowance for buildings and improvements (including improvements such as paved parking areas, fences, and sidewalks) will be computed at an annual rate not exceeding two percent of acquisition cost. The use allowance for equipment will be computed at an annual rate not exceeding six and two-thirds percent of acquisition cost.

(2) In contrast to the depreciation method, the entire building must be treated as a single asset without separating its "shell" from other building components under the use allowance method. The entire building must be treated as a single asset, and the two-percent use allowance limitation must be applied to all parts of the building. The two-percent limitation, however, need not be applied to equipment or other assets that are merely attached or fastened to the building but not permanently fixed and are used as furnishings, decorations or for specialized purposes (e.g., dentist chairs and dental treatment units, counters, laboratory benches bolted to the floor, dishwashers, and carpeting). Such equipment and assets will be considered as not being permanently fixed to the building if they can be removed without the need for costly or extensive alterations or repairs to the building to make the space usable for other purposes. Equipment and assets which meet these criteria will be subject to the six and two-thirds percent equipment use allowance.

(3) A reasonable use allowance may be negotiated for any assets that are considered to be fully depreciated, after taking into consideration the amount of depreciation previously charged to the Government, the estimated useful life remaining at the time of negotiation, the effect of any increased maintenance charges, decreased efficiency due to age, and any other factors pertinent to

the utilization of the asset for the purpose contemplated.

d. Except as otherwise provided in b and c above, a combination of the depreciation and use allowance methods may not be used, in like circumstances, for a single class of assets (e.g., buildings, office equipment, and computer equipment).

e. Charges for use allowances or depreciation must be supported by adequate property records, and physical inventories must be taken at least once every two years to ensure that the assets exist and are usable, used, and needed. Statistical sampling techniques may be used in taking these inventories. In addition, when the depreciation method is used, adequate depreciation records showing the amount of depreciation taken each period must also be maintained.

10. *Donated services and property.* The value of donated services and property are not allowable either as a direct or indirect cost, except that depreciation or use allowances on donated assets are permitted in accordance with Section J9a. The value of donated services and property may be used to meet cost sharing or matching requirements, in accordance with OMB Circular No. A-110.

11. *Employee morale, health, and welfare costs and credits.* The costs of house publications, health or first-aid clinics and/or infirmaries, recreational activities, employees, counseling services, and other expenses incurred in accordance with the institution's established practice or custom for the improvement of working conditions, employer-employee relations, employee morale, and employee performance, are allowable. Income generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably set over to employee welfare organizations.

12. *Entertainment costs.* Costs incurred for amusement, social activities, entertainment, and any items relating thereto, such as meals, lodging, rentals, transportation, and gratuities, are unallowable.

13. *Equipment and other capital expenditures.*

a. For purposes of this paragraph, the following definitions apply:

(1) *Equipment* means an article of nonexpendable tangible personal property having a useful life of more than two years, and an acquisition cost of $500 or more per unit. However, consistent with institutional policy, lower limits may be established.

(2) *Capital expenditure* means the cost of the asset including the cost to put it in place. Capital expenditure for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective intransit insurance, freight, and installation may be included in, or excluded from, capital expenditure cost in accordance with the institution's regular accounting practices.

(3) *Special purpose equipment* means equipment which is used only for research, medical, scientific, or other technical activities.

(4) *General purpose equipment* means equipment, the use of which is not limited only to research, medical, scientific or other technical activities. Examples of general purpose equipment include office equipment and furnishings, air conditioning equipment, reproduction and printing equipment, motor vehicles, and automatic data processing equipment.

b. The following rules of allowability shall apply to equipment and other capital expenditures:

(1) Capital expenditures for general purpose equipment, buildings, and the land are unallowable as direct charges, except where approved in advance by the sponsoring agency.

(2) Capital expenditures for special purpose equipment are allowable as direct charges, provided that the acquisition of items having a unit cost of $1,000 or more is approved in advance by the sponsoring agency.

(3) Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as direct charges, except where approved in advance by the sponsoring agency.

(4) Capital expenditures are unallowable as indirect costs. But see Section J9 for allowability of depreciation or use allowance on buildings, capital improvements, and equipment. Also see Section J33 for allowability of rental costs on land, buildings, and equipment.

14. *Fines and penalties.* Costs resulting from violations of, or failure of the institution to comply with Federal, State, and local laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the sponsoring agreement, or instructions in writing from the contracting officer or equivalent.

15. *Fringe benefits.*

a. Fringe benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, sick leave, military leave, and the like, are allowable, provided such costs are distributed to all institutional activities in proportion to the relative amount of time or effort actually devoted by the employees. see Section J35 for treatment of sabbatical leave.

b. Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workmen's compensation insurance, tuition or remission of tuition for individual employees or their families and the like are allowable, provided such benefits are granted in accordance with established institutional policies, and are distributed to all institutional activities on an equitable basis. See Section J36b for treatment of tuition remission provided to students.

c. Rules for pension plan costs are as follows:

(1) Costs of the institution's pension plan which are incurred in accordance with the established policies of the institution are allowable, provided (a) such policies meet the test of reasonableness; (b) the methods of cost allocation are equitable for all activities; (c) the amount of pension cost assigned to each fiscal year is determined in accordance with (2) below; and (d) the cost assigned to a given fiscal year is paid or funded for all plan participants within six months after the end of that year.

(2) The amount of pension cost assigned to each fiscal year shall be determined in accordance with generally accepted accounting principles. Institutions may elect to follow the "Cost Accounting Standard for Composition and Measurement of Pension Cost" (4 CFR Part 412).

(3) Premiums paid for pension plan termination insurance pursuant to the Employee Retirement Income Security Act of 1974 (Public Law 93-406) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and prohibited transactions of pension plan fiduciaries imposed under the Employee Retirement Income Security Act are also unallowable.

d. Fringe benefit may be assigned to cost objectives by identifying specific benefits to specific individual employees or by allocating on the basis of the salaries and wages of the employees receiving the benefits. When the allocation method is used, separate allocations must be made to selective groupings of employees, if the costs in relationship to salaries and wages differ significantly for different groups of employees. Also fringe benefits related to institutional salaries and wages treated as direct costs may be treated as direct costs.

16. *Insurance and indemnification.*

a. Costs of insurance required or approve, and maintained, pursuant to the sponsored agreement, are allowable.

b. Costs of other insurance maintained by the institution in connection with the general conduct of its activities, are allowable subject to the following limitations: (1) types and extent and cost of coverage must be in accordance with sound institutional practice; (2) costs of insurance or of any contributions to any reserve covering the risk of loss of or damage to Government-owned property are unallowable, except to the extent that the Government has specifically required or approved such costs; and (3) costs of insurance on the lives of officers or trustees are unallowable except where such insurance is part of an employee plan which is not unduly restricted.

c. Contributions to a reserve for a self-insurance program are allowable, to the extent that the types of coverage, extent of coverage, and the rates and premiums would have been allowed had insurance been purchased to cover the risks.

d. Actual losses which could have been covered by permissible insurance (whether through purchased insurance or self-insurance) are unallowable, unless expressly provided for in the sponsored agreement, except that costs incurred because of losses not covered under existing deductible clauses for insurance coverage provided in keeping with sound management practice as well as minor losses not covered by insurance, such as spoilage, breakage and disappearance of small hand tools, which occur in the ordinary course of operations, are allowable.

e. Indemnification includes securing the institution against liabilities to third persons and other losses not compensated by insurance or otherwise. The Government is obligated to indemnify the institution only to the extent expressly provided for in the sponsored agreement, except as provided in d above.

17. *Interest, fund raising, and investment management costs.*

a. Costs incurred for interest on borrowed capital or temporary use of endowment funds, however represented, are unallowable, except as indicated in e below.

b. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions, are unallowable.

c. Cost of investment counsel and staff and similar expenses incurred solely to enhance income from investments are unallowable.

d. Costs related to the physical custody and control of monies and securities are allowable.

e. The cost of interest paid to an external party is allowable where associated with the following assets, provided the assets are used in support of sponsored agreements, and the total cost (including depreciation or use allowances, operation and maintenance costs, interest etc.,) does not exceed the rental cost of comparable assets in the same locality.

(1) Buildings acquired or completed on or after July 1, 1982.

(2) Major reconstruction and remodeling of existing buildings completed on or after July 1, 1982.

(3) Acquisition or fabrication of capital equipment (as defined in paragraph J.13, "Equipment and other capital expenditures") completed on or after July 1, 1982, costing $10,000 or more, if agreed to by the Government.

18. *Labor relations costs.* Costs incurred in maintaining satisfactory relations between the institution and its employees, including cost of labor management committees, employees' publications, and other related activities, are allowable.

19. *Losses on other sponsored agreements or contracts.* Any excess of costs over income under any other sponsored agreement or contract of any nature is unallowable. This includes, but is not limited to, the institution's contribution portion by reason of cost-sharing agreements or any under-recoveries through negotiation of flat amounts for indirect costs.

20. *Maintenance and repair costs.* Costs incurred for necessary maintenance, repair or upkeep of property (including Government property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life but keep it in an efficient operating condition, are allowable.

21. *Material costs.* Costs incurred for purchased materials, supplies, and fabricated parts directly or indirectly related to the sponsored agreements, are allowable. Purchases made specifically for the sponsored agreement should be charged thereto at their actual prices after deducting all cash discounts, trade discounts, rebates, and allowances received by the institution. Withdrawals from general stores or stockrooms should be charged at their cost under any recognized method of pricing stores withdrawals conforming to sound accounting practices consistently followed by the institution. Incoming transportation charges are a proper part of material cost. Direct material cost should include only the materials and supplies actually used for the performance of the sponsored agreement, and due credit should be given for any excess materials retained, or returned to vendors. Due credit should be given for all proceeds or value received for any scrap resulting from work under the sponsored agreement. Where Goverment-donated or furnished material is used in performing the sponsored agreement such material will be used without charge.

22. *Memberships, subscriptions and professional activity costs.*

a. Costs of the institution's membership in civic, business, technical and professional organizations are allowable.

b. Costs of the institution's subscriptions to civic, business, professional, and technical periodicals are allowable.

c. Costs of meetings and conferences, when the primary purpose is the dissemination of technical information, are allowable. This includes costs of meals, transportation, rental of facilities, and other items incidental to such meetings or conferences.

23. *Patent costs.* Costs of preparing disclosures, reports, and other documents required by the sponsored agreement, and of searching the art to the extent necessary to make such invention disclosures, are allowable. In accordance with the clauses of the sponsored agreement relating to patents, costs of preparing documents and any other patent costs, in connection with the filing of a patent application where title is conveyed to the Government, are allowable. (See also Section J34.)

24. *Plant security costs.* Necessary expenses incurred to comply with security requirements, including wages, uniforms and equipment of personnel engaged in plant protection, are allowable.

25. *Preagreement costs.* Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless approved by the sponsoring agency.

26. *Professional service costs.*

a. Costs of professional services rendered by the members of a particular profession who are not employees of the institution are allowable, subject to b and c below, when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Government. Retainer fees to be allowable must be reasonably supported by evidence of services rendered.

b. Factors to be considered in determining the allowability of costs in a particular case include (1) the past pattern of such costs, particularly in the years prior to the award of sponsored agreements; (2) the impact of sponsored agreements on the institution's total activity; (3) the nature and scope of managerial services expected of the institution's own organizations; and (4) whether the proportion of Government work to the institution's total activity is such as to influence the institution in favor of incurring the costs, particularly where the services rendered are not of a continuing nature and have little relationship to work under sponsored agreements.

c. Costs of legal, accounting, and consulting services, and related costs, incurred in connection with the prosecution of claims against the Government, are unallowable. Costs of legal, accounting and consulting services, and related costs, incurred in connection with patent infringement litigation, are unallowable unless otherwise provided for in the sponsored agreements.

27. *Profits and losses on disposition of plant equipment or other capital assets.* Profits or losses arising from the sale or exchange of plant, facilities, equipment or other capital assets, including sale or exchange of either short-term or long-term investments, shall not be considered in computing the costs of sponsored agreements except for pension plans as provided in Section J15c. When assets acquired with Federal funds, in part or wholly, are disposed of, the distribution of the proceeds shall be made in accordance with Attachment N, OMB Circular No. A–110.

28. *Proposal costs.* Proposal costs are the costs of preparing bids or proposals on potential Government and nongovernment sponsored agreements or projects, including the development of data necessary to support the institution's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect costs and allocated currently to all activities of the institution, and no proposal costs of past accounting periods will be allocable to the current period. However, the institution's established practices may be to treat proposal costs by some other recognized method. Regardless of the method used, the results obtained may be accepted only if found to be reasonable and equitable.

29. *Public information services costs.* Cost of news releases pertaining to specific research or scientific accomplishment are allowable, when they result from performance of sponsored agreements.

30. *Rearrangement and alteration costs.* Cost incurred for ordinary or normal rearrangement and alteration of facilities are allowable. Special arrangement and alteration costs incurred specifically for the project are allowable when such work has been approved in advance by the sponsoring agency.

31. *Reconversion costs.* Costs incurred in the restoration or rehabilitation of the institution's facilities to approximately the same condition existing immediately prior to commencement of a sponsored agreement, fair wear and tear excepted, are allowable.

32. *Recruiting costs.*

a. Subject to b, c, and d below, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of "help wanted" advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating

an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to a well managed recruitment program. Where the institution uses employment agencies, costs not in excess of standard commerical rates for such services are allowable.

b. In publications, costs of help wanted advertising that includes color, includes advertising material for other than recruitment purposes, or is excessive in size (taking into consideration recruitment purposes for which intended and normal institutional practices in this respect), are unallowable.

c. Costs of help wanted advertising, special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel from other institutions that do not meet the test of reasonableness or do not conform with the established practices of the institution, are unallowable.

d. Where relocation costs incurred incident to recruitment of a new employee have been allowed either as an allocable direct or indirect cost, and the newly hired employee resigns for reasons within his control within twelve months after hire, the institution will be required to refund or credit such relocation costs to the Government.

33. *Rental cost of buildings and equipment.*

a. Rental costs of buildings or equipment are allowable to the extent that the decision to rent or lease is in accord with Section C-3. Rental arrangements should be reviewed periodically to determine if circumstances have changed and other options are available.

b. Rental costs under "sale and lease back" arrangements are allowable only up to the amount that would be allowed if the institution continued to own the property.

c. Rental costs under "less-than-arms-length" leases are allowable only up to the amount that would be allowed if the institution owned the property. For this purpose, a "less-than-arms-length" lease is one under which one party to the lease agreement is able to control or substantially influence the actions of the other.

d. Where significant rental costs are incurred under leases which create a material equity in the leased property, they are allowable only up to the amount that would be allowed if the institution purchased the property on the date the lease agreement was executed. For this purpose, a material equity in the property exists when the lease:

(1) is noncancelable or is cancelable only upon the occurrence of some remote contingency, and

(2) has one or more of the following characteristics:

(a) Title to the property passes to the institution at some time during or after the lease period.

(b) The term of the lease corresponds substantially to the estimated useful life of the property (i.e., the period of economic usefulness to the legal owner of the property).

(c) The initial term is less than the useful life of the property and the institution has the option to renew the lease for the remaining useful life at substantially less than fair rental value.

(d) The property was acquired by the leasor to meet the special needs of the institution and will probably be usable only for that purpose and only by the institution.

(e) The institution has the right, during or at the expiration of the lease, to purchase the property at a price which at the inception of the lease appears to be substantially less that the probable fair market value at the time it is permitted to purchase the property (commonly called a lease with a bargan purchase option), except for any discount normally given to educational institutions.

34. *Royalties and other costs for use of patents.* Royalties on a patent or amortization of the cost of acquiring a patent or invention or rights thereto, necessary for the proper performance of the sponsored agreement and applicable to tasks or processes thereunder, are allowable unless the Government has a license or the right to free use of the patent, the patent has been adjudicated to be invalid or has been administratively determined to be invalid, the patent is considered to be unenforceable, or the patent has expired.

35. *Sabbatical leave costs.* Costs of leave of absence by employees for performance of graduate work or sabbatical study, travel, or research are allowable provided the institution has a uniform policy on sabbatical leave for persons engaged in instruction and persons engaged in research. Such costs will be allocated on an equitable basis among all related activities of the institution. Where sabbatical leave is included in fringe benefits for which a cost is determined for assessment as a direct charge, the aggregate amount of such assessments applicable to all work of the institution during the base period must be reasonable in relation to the institution's actual experience under its sabbatical leave policy.

36. *Scholarships and student aid costs.*

a. Costs of scholarships, fellowships, and other programs of student aid are allowable only when the purpose of the sponsored agreement is to provide training to selected participants and the charge is approved by the sponsoring agency. However, tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work are allowable provided that (1) there is a bonafide employer-employee relationship between the student and the institution for the work performed, (2) the tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work, and (3) it is the institution's practice to similarly compensate students in nonsponsored as well as sponsored activities.

b. Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages shall be subject to the reporting requirements stipulated in Section J6, and shall be treated as direct or indirect cost in accordance with the actual work being performed. Tuition remission may be charged on an average rate basis.

37. *Severance pay.*

a. Severance pay is compensation in addition to regular salary and wages which is paid by an institution to employees whose services are being terminated. Costs of severance pay are allowable only to the extent that such payments are required by law, by employer-employee agreement, by established policy that constitutes in effect an implied agreement on the institution's part, or by circumstances of the particular employment.

b. Severance payments that are due to normal recurring turnover and which otherwise meet the conditions of a above may be allowed provided the actual costs of such severance payments are regarded as expenses applicable to the current fiscal year and are equitably distributed among the institution's activities during that period.

c. Severance payments that are due to abnormal or mass terminations are of such conjectural nature that allowability must be determined on a case-by-case basis. However, the Government recognizes its obligation to participate, to the extent of its fair share, in any specific payment.

38. *Specialized service facilities.*

a. The costs of institutional services involving the use of highly complex or specialized facilities such as electronic computers, wind tunnels, and reactors are allowable, provided the charge for the service meets the conditions of b through d below.

b. The cost of each service normally shall consist of both its direct costs and its allocable share of indirect costs with deductions for appropriate income or Federal financing as describing in Section C5.

c. The cost of such institutional services when material in amount will be charged directly to users, including sponsored agreements based on actual use of the services and a schedule of rates that does not discriminate between federally and nonfederally supported activities of the institution, including use by the institution for internal purposes. Charges for the use of specialized facilities should be designed to recover not more than the aggregate cost of the services over a long-term period agreed to by the institution and the cognizant Federal agency. Accordingly, it is not necessary that the rates charged for services be equal to the cost of providing those services during any one fiscal year as long as rates are reviewed periodically for consistency with the longterm plan and adjusted if necessary.

d. Where the costs incurred for such institutional services are not material, they may be allocated as indirect costs. Such arrangements must be agreed to by the institution and the congnizant Federal agency.

e. Where it is in the best interest of the Government and the institution to establish alternative costing arrangements, such arrangements may be worked out with the cognizant Federal agency.

39. *Special services costs.* Costs incurred for general public relations activities, alumni activities, and similar services, are unallowable.

40. *Student activity costs.* Costs incurred for intramural activities, student publications, student clubs, and other student activities, are unallowable, unless specifically provided for in the sponsored agreements

41. *Taxes.*

a. In general taxes which the institution is required to pay and which are paid or accrued in accordance with generally accepted accounting principles are allowable. Payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for (1) taxes from which exemptions are available to the institution directly or which are available to the institution based on an exemption afforded the Government, and in the latter case when the sponsoring agency makes available the necessary exemption certificates; and (2) special assessments on land which represent capital improvements.

b. Any refund of taxes, interest, or penalties, and any payment to the institution of interest thereon, attributable to taxes, interest, or penalties which were allowed as sponsored agreement costs, will be credited or paid to the Government in the manner directed by the Government. However, any interest actually paid or credited to an institution incident to a refund of tax, interest, and penalty will be paid or credited to the Government only to the extent that such interest accrued over the period during which the institution had been reimbursed by the Government for the taxes, interest, and penalties.

42. *Transportation costs.* Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such casts can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation costs may be charged to the appropriate indirect cost accounts if the institution follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms of the sponsored agreement, should be treated as a direct cost.

43. *Travel costs.*

a. Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the institution. Such costs may be charged on an actual basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two, provided the method used is applied to an entire trip and not to selected days of the trip, and results in charges consistent with those normally allowed by the institution in its regular operations.

b. Travel costs are allowable subject to c, d, e, and f below, when they are directly attributable to specific work under a sponsored agreement or are incurred in the normal course of administration of the institution or a department or program thereof.

c. The difference in cost between first-class air accommodations and less than first-class air accommodations is unallowable except when less than first-class air accommodations are not reasonably available to meet necessary mission requirements, such as where less than first-class accommodations would (1) require circuitous routing, (2) require travel during unreasonable hours, (3) greatly increase the duration of the flight, (4) result in additional costs which would offset the transportation savings, or (5) offer accommodations which are not reasonably adequate for the medical needs of the traveler.

d. Costs of personnel movements of a special or mass nature are allowable only when authorized or approved in writing by the sponsoring agency or its authorized representative.

e. Foreign travel costs are allowable only when the travel has received specific prior approval. Each separate foreign trip must be specifically approved. For purposes of this provision, foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country.

f. Domestic travel costs are allowable when permitted by the sponsored agreement. Expenditures for such travel will not be allowed if they exceed the amount specified by more than 25% or $500, whichever is greater, except with an advanced approval of the sponsoring agency.

44. *Termination costs applicable to sponsored agreements.*

a. Termination of sponsored agreements generally gives rise to the incurrence of costs or to the need for special treatment of costs, which would not have arisen had the agreement not been terminated. Items peculiar to termination are set forth below. They are to be used in conjunction with all other provisions of this Circular in the case of termination.

b. The cost of common items of material reasonably usable on the institution's other work will not be allowable unless the institution submits evidence that it could not retain such items at cost without sustaining a loss. In deciding whether such items are reasonably usable on other work of the institution, consideration should be given to the institution's plans and orders for current and scheduled work. Contemporaneous purchases of common items by the institution will be regarded as evidence that such items are reasonably usable on the institution's other work. Any acceptance of common items as allowable to the terminated portion of the agreement should be limited to the extent that the quantities of such items on hand, in transit, and on order are in excess of the reasonable quantitative requirements of other work.

c. If in a particular case, despite all reasonable efforts by the institution, certain costs cannot be discontinued immediately after the effective date of termination, such costs are generally allowable within the limitations set forth in this Circular, except that any such costs continuing after termination due to the negligent or willful failure of the institution to discontinue such costs will be considered unacceptable.

d. Loss of useful value of special tooling, and special machinery and equipment is generally allowable, provided (1) such special tooling, machinery, or equipment is not reasonably capable of use in the other work of the institution; (2) the interest of the Government is protected by transfer of title or by other means deemed appropriate by the contracting officer or equivalent; and (3) the loss of useful value as to any one terminated agreement is limited to that portion of the acquisition cost which bears the same ratio to the total acquisition cost as the terminated portion of the agreement bears to the entire terminated agreement and other Government agreements for which the special tooling, special machinery, or equipment was acquired.

e. Rental costs under unexpired leases are generally allowable where clearly shown to have been reasonably necessary for the performance of the terminated agreement, less the residual value of such leases, if (1) the amount of such rental claimed does not exceed the reasonable use value of the property leased for the period of the agreement and such further period as may be reasonable; and (2) the institution makes all reasonable efforts to terminate, assign, settle, or otherwise reduce the cost of such lease. There also may be included the cost of alterations of such leased property, provided such alterations were necessary for the performance of the agreement, and of reasonable restoration required by the provisions of the lease.

f. Settlement expenses including the following are generally allowable: (1) accounting, legal, clerical, and similar costs reasonably necessary for the preparation and presentation to contracting officers or equivalent of settlement claims and supporting data with respect to the terminated portion of the agreement, and the termination and settlement of subagreements; and (2) reasonable costs for the storage, transportation, protection, and disposition of property provided by the Government or acquired or produced by the institution for the agreement, except when the institution is reimbursed for disposals at a predetermined amount in accordance with the provisions of Circular No. A–110.

g. Claims under subagreements, including the allocable portion of claims which are common to the agreement and to other work of the institution, are generally allowable.

K. Certification of Charges

To assure that expenditures for sponsored agreements are proper and in accordance with the agreement documents and approved project budgets, the annual and/or final fiscal reports or vouchers requesting payment under the agreements will include a certification, signed by an authorized official of the university, which reads essentially as follows: "I certify that all expenditures reported (or payment requested) are for appropriate purposes and in accordance with the provisions of the application and award documents."

PART 75—DIRECT GRANT PROGRAMS

16. The authority citation for Part 75 is revised to read as follows:

Authority: 20 U.S.C. 1221e-3(a)(l) and 3474, unless otherwise noted.

§ 75.3 [Removed]

17. Section 75.3 is removed.

18. Section 75.4(a)(1) is revised to read as follows:

§ 75.4 Department contracts.

(a) A Federal contract made by the Department is governed by—

(1) Chapters 1 and 34 of Title 48 of the Code of Federal Regulations (Federal Acquisition Regulation and Education Department Acquisition Regulation).

* * * * *

19. New §§ 75.60–75.62 are added and a new center heading is added preceding these sections, to read as follows:

Ineligibility of Certain Individuals To Receive Assistance

§ 75.60 Individuals ineligible to receive assistance.

(a) An individual is ineligible to receive a fellowship, scholarship, or discretionary grant funded by the Department if the individual—

(1) Is not current in repaying a debt owed—

(i) Under a program listed in paragraph (b) of this section; or

(ii) To the Federal government under a nonprocurement transaction; and

(2) Has not made satisfactory arrangements to repay the debt.

(b) An individual who is not current in repaying a debt under a discretionary grant, scholarship, fellowship, or loan program as included in the following list is ineligible under paragraph (a) of this section:

(1) A grant awarded under the Pell Grant (20 U.S.C. 1070a, *et seq.*), Supplemental Educational Opportunity Grant (SEOG) (20 U.S.C. 1070b, *et seq.*), or State Student Incentive Grant (SSIG) 20 U.S.C. 1070c, *et seq.*) program, or a scholarship awarded under the Robert C. Byrd Honors Scholarship Program (20 U.S.C. 1070d–31, *et seq.*), a fellowship awarded under the Jacob K. Javits Fellows Program (20 U.S.C. 1134h–1134k), or a fellowship awarded under the Patricia Roberts Harris Fellowship Program (20 U.S.C. 1134d–1134f).

(2) A fellowship awarded under the Christa McAuliffe Fellowship Program (20 U.S.C. 1113–1113e), the Bilingual Education Fellowship Program (20 U.S.C. 3221–3262), or the Rehabilitation Long-Term Training Program (29 U.S.C. 774(b)), or on a repayment obligation incurred under the Paul Douglas Teacher Scholarship Program (20 U.S.C. 1111, *et seq.*).

(3) A loan made under the Perkins Loan Program (20 U.S.C. 1087aa, *et seq.*), the Income Contingent Direct Loan Demonstration Project (20 U.S.C. 1087a, *et seq.*), the Guaranteed Student Loan (GSL), Supplemental Loans for Students (SLS), PLUS, or Consolidation Loan Program (20 U.S.C. 1071, *et seq.*), or the Cuban Student Loan Program (22 U.S.C. 2601, *et seq.*).

(4) A grant, or a loan, made under the Law Enforcement Education Program (42 U.S.C. 3775).

(5) A stipend awarded under the Indian Fellowship Program (29 U.S.C. 774(b)).

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§ 75.61 Certification of eligibility; effect of ineligibility.

(a) An individual who applies for a fellowship, scholarship, or discretionary grant from the Department shall provide with his or her application a certification under the penalty of perjury—

(1) That the individual is eligible under § 75.60;

(2) That the individual has not been debarred or suspended by—

(i) This Department under the procedures in Part 85 of this title; or

(ii) Another Federal agency under procedures established under Executive Order 12549.

(b) The Secretary specifies the form of the certification required under paragraph (a) of this section.

(c) The Secretary does not award a fellowship, scholarship, or discretionary grant to an individual who—

(1) Fails to provide the certification required under paragraph (a) of this section; or

(2) Is ineligible, based on information available to the Secretary at the time the award is made.

(d) If a fellowship, scholarship, or discretionary grant is made to an individual who provided a false certification under paragraph (a) of this section, the individual is liable for recovery of the funds made available under the certification, for civil damages or penalties imposed for false representation, and for criminal prosecution under 18 U.S.C. 1001.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3473)

§ 75.62 Requirements applicable to entities making certain awards.

(a) An entity that provides a fellowship, scholarship, or discretionary grant to an individual under a grant from, or an agreement with, the Secretary shall require the individual that applies for such an award to provide with his or her application a certification under the penalty of perjury—

(1) That the individual is eligible under § 75.60;

(2) That the individual has not been debarred or suspended by—

(i) This Department under the procedures in Part 85 of this title; or

(ii) Another Federal agency under procedures established under Executive Order 12549.

(b) An entity subject to this section may not award a fellowship, scholarship, or discretionary grant to an individual if—

(1) The individual fails to provide the certification required under paragraph (a) of this section; or

(2) The Secretary informs the entity that the individual is ineligible under § 76.60.

(c) If a fellowship, scholarship, or discretionary grant is made to an individual who provided a false certification under paragraph (a) of this section, the individual is liable for recovery of the funds made available under the certification, for civil damages or penalties imposed for false representation, and for criminal prosecution under 18 U.S.C. 1001.

(d) The Secretary may require an entity subject to this section to provide a list of the individuals to whom fellowship, scholarship, or discretionary grant awards have been made or are proposed to be made by the entity.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

20. Section 75.105(c)(3) is revised to read as follows:

§ 75.105 Annual priorities.

* * * * *

(c) * * *

(3) *Absolute preference.* The Secretary may give an absolute preference to applications that meet a priority. The Secretary establishes a separate competition for applications that meet the priority and reserves all or part of a program's funds solely for that competition. The Secretary may adjust the amount reserved for the priority after determining the number of high quality applications received.

* * * * *

§§ 75.107, 75.108, 75.110, 75.111, 75.113, 74.114, 75.115, and 75.116 [Removed]

21. Sections 75.107, 75.108, 75.110, 75.111, 75.113, 75.114, 75.115, and 75.116 are removed.

§ 75.118 [Amended]

22. The note following § 75.118 is removed.

§§ 75.130 through 75.134 [Removed]

23. Sections 75.130 through 75.134, and the center heading "PREAPPLICATIONS", are removed.

§§ 75.150 through 75.154 [Removed]

24. Sections 75.150 through 75.154, and the center heading "STATE APPROVAL PROCEDURES", are removed.

25. Section 75.155 is revised and a cross-reference is added following the section to read as follows:

§ 75.155 Review procedures if State may comment on applications: purpose of §§ 75.156–75.158.

If the authorizing statute for a program requires that a specific State agency be given an opportunity to comment on each application, the State and the applicant shall use the procedures in §§ 75.156–75.158.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

Cross-reference: See 34 CFR Part 79 (Intergovernmental Review of Department of Education Programs and Activities) for the regulations implementing the application review procedures that States may use under E.O. 12372.

§ 75.160 [Removed]

26. Section 75.160 is removed.

27. Section 75.200 is amended by revising the title and adding paragraphs (b)(4) and (5) to read as follows:

§ 75.200 How applications for new grants and cooperative agreements are selected for funding; standards for use of cooperative agreements.

* * * * *

(b) * * *

(4) The Secretary may award a cooperative agreement instead of a grant if the Secretary determines that substantial involvement between the Department and the recipient is necessary to carry out a collaborative project.

(5) The Secretary uses the selection procedures in this subpart to select recipients of cooperative agreements.

* * * * *

28. Section 75.216 is revised to read as follows:

§ 75.216 Applications not evaluated for funding.

The Secretary does not evaluate an application if—

(a) The applicant is not eligible;

(b) The applicant does not comply with all of the procedural rules that govern the submission of the application;

(c) The application does not contain the information required under the program; or

(d) The proposed project cannot be funded under the authorizing statute or implementing regulations for the program.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

29. Section 75.218 is revised to read as follows:

§ 75.218 Applications not evaluated or selected for funding.

The Secretary informs an applicant if its application—

(a) Is not evaluated; or

(b) Is not selected for funding.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

30. Section 75.233 is revised to read as follows:

§ 75.233 Setting the amount of the grant.

(a) Subject to any applicable matching or cost-sharing requirements, the Secretary may fund up to 100 percent of the allowable costs in the applicant's budget.

(b) In deciding what percentage of the allowable costs to fund, the Secretary may consider any other financial resources available to the applicant.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

31. Section 75.234 is revised to read as follows:

§ 75.234 The conditions of the grant.

(a) The Secretary makes a grant to an applicant only after determining—

(1) The approved costs; and

(2) Any special conditions necessary for a high risk grantee subject to 34 CFR 74.7 or 80.12.

(b) In awarding a cooperative agreement, the Secretary includes conditions that state the explicit nature, character, and extent of anticipated Federal involvement.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

32. Section 75.235 is amended by revising paragraph (b) to read as follows:

§ 75.235 The notification of grant award.

* * * * *

(b) The notification of grant award sets the amount of the grant award and establishes other specific conditions, if any.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

33. Section 75.253 is amended by revising paragraph (a)(2), redesignating paragraph (d) as paragraph (e), and adding a new paragraph (d) to read as follows:

§ 75.253 Continuation of a multi-year project after the first budget period.

(a) * * *

(2) The grantee has either—

(i) Made substantial progress toward meeting the objectives in its approved application; or

(ii) Obtained the Secretary's approval of changes in the project that—

(A) Do not increase the cost of the grant; and

(B) Enable the grantee to meet those objectives in succeeding budget periods;

* * * * *

(d)(1) If the Secretary decides, under this section, not to make a continuation award, the Secretary may authorize a no-cost extension of the last budget period of the grant in order to provide for the orderly closeout of the grant.

(2) If the Secretary makes a continuation award under this section—

(i) The Secretary makes the award under §§ 75.231–75.236; and

(ii) The new budget period begins on the day after the previous budget period ends.

* * * * *

34. Section 75.261 is revised to read as follows:

§ 75.261 Extension of a project period.

The Secretary may extend a project period if—(a) The extension does not violate any statute or regulations;

(b) The extension does not involve the obligation of additional Federal funds;

(c) The extension is to carry out the activities in the approved application; and

(d)(1)(i) Special or unusual circumstances would delay completion of the project;

(ii) The grantee requests an extension of the project at least 45 days before the end of the project period; and

(iii) The grantee provides a written statement before the end of the project period giving the reasons why the extension is appropriate under paragraph (d)(1)(i) of this section; or

(2) The Secretary determines that, due to special or unusual circumstances applicable to a class of grantees, the project periods for the grantees should be extended.

(Authority: 20 U.S.C. 1221e–3(a)(1) and 3474)

35. A new § 75.262 is added to read as follows:

§ 75.262 Conversion of a grant or a cooperative agreement.

(a)(1) The Secretary may convert a grant to a cooperative agreement or a cooperative agreement to a grant at the time a continuation award is made under § 75.253.

(2) In deciding whether to convert a grant to a cooperative agreement or a cooperative agreement to a grant, the Secretary considers the factors included in § 75.200(b) (4) and (5).

(b) The Secretary and a recipient may agree at any time to convert a grant to a

cooperative agreement or a cooperative agreement to a grant, subject to the factors included in § 75.200(b) (4) and (5).

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§ 75.510 [Removed]

36. Section 75.510 is removed.

§ 75.518 [Removed]

37. Section 75.518 is removed.

38. In § 75.534, the introductory text and paragraph (a) are revised to read as follows:

§ 75.534 Automatic increases for additional dependents.

The Secretary may increase a grant to cover the cost of additional dependents not specified in the notice of award under § 75.235 if—

(a) Allowances for dependents are authorized by the program statute and are allowable under the grant; and

* * * * *

39. Section 75.560(a) is revised to read as follows:

§ 75.560 General indirect cost rates; exceptions.

(a) The differences between direct and indirect costs and the principles for determining the general indirect cost rate that a grantee may use for grants under most programs are specified in the cost principles for—

(1) Institutions of higher education, at 34 CFR 74.172;

(2) Hospitals, at 34 CFR 74.173;

(3) Other nonprofit organizations, at 34 CFR 74.174;

(4) Commercial organizations, at 34 CFR 74.175; and

(5) State and local governments and Federally-recognized Indian tribal organizations, at 34 CFR 80.22.

* * * * *

40. Section 75.563 is revised to read as follows:

§ 75.563 Restricted indirect cost rate—programs covered.

Sections 75.564–75.568 apply to each program that has a statutory requirements not to use Federal funds to supplant non-Federal funds.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§§ 75.580 and 75.581 [Removed]

41. Sections 75.580 and 75.581, and the center heading "COORDINATION", are removed.

42. Section 75.590 is amended by revising paragraph (c) to read as follows:

§ 75.590 Evaluation by the grantee.

* * * * *

(c) The effect of the project on participants being served by the project.

* * * * *

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

43. Section 75.608 is revised to read as follows:

§ 75.608 Areas in the facilities for cultural activities.

A grantee may make reasonable provision, consistent with the other uses to be made of the facilities, for areas in the facilities that are adaptable for artistic and other cultural activities.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

44. Section 75.616 is revised to read as follows:

§ 75.616 Energy conservation.

(a) To the extent feasible, a grantee shall design and construct facilities to maximize the efficient use of energy.

(b) The following standards of the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) are incorporated by reference in this section:

(1) ASHRAE—90 A-1980 (Sections 1–9).

(2) ASHRAE—90 B-1975 (Sections 10–11).

(3) ASHRAE—90 C-1977 (Section 12).

Note: Incorporation by reference of these provisions has been approved by the Director of the Office of the Federal Register pursuant to the Director's authority under 5 U.S.C. 552(a). The incorporated document is on file at the Office of the Federal Register. These standards may be obtained from the publication sales department at the American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc., 1791 Tullie Circle, NE., Atlanta, Georgia 30329.

(c) A grantee shall comply with ASHRAE standards listed in paragraph (b) of this section in designing and constructing facilities built with project funds.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, 42 U.S.C. 8373(b); E.O. 12185)

45. A new § 75.617 is added to read as follows:

§ 75.617 Compliance with the Coastal Barrier Resources Act.

A recipient may not use, within the Coastal Barrier Resources System, funds made available under a program administered by the Secretary for any purpose prohibited by 31 U.S.C. Chapter 55 (§§ 3501–3510).

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, 31 U.S.C. 3504, 3505)

46. Section 75.621 is amended by revising the section heading, removing paragraph (b), and removing the paragraph designation "(a)", to read as follows:

§ 75.621 Copyright policy for grantees.

* * * * *

47. Section 75.622 is revised to read as follows:

§ 75.622 Definition of "project materials."

As used in §§ 75.620–75.621, "project materials" means a copyrightable work developed with funds from a grant of the Department.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§ 75.625 [Removed]

48. Section 75.625 is removed and the cross-reference preceding this section is revised to read as follows:

Cross-Reference: See 34 CFR 74.45, Program income—royalties or equivalent income earned from patents or from inventions; and 34 CFR Part 6, INVENTIONS AND PATENTS (GENERAL).

§ 75.626 [Amended]

49. Section 75.626 is revised by removing paragraph (b) and the paragraph designation "(a)".

§ 75.681 [Amended]

50. Section 75.681 is revised by removing the cross-reference following that section.

§ 75.684 [Removed]

51. Section 75.684 is removed.

§ 75.690 [Removed]

52. Section 75.690 is removed.

53. In § 75.707, Column I, paragraph (h) in the Table is revised to read as follows:

§ 75.707 When obligations are made.

* * * * *

(h) A preagreement cost that was properly approved by the Secretary under the cost principles identified in 34 CFR Part 74, Subpart Q.

* * * * *

54. Section 75.720 is revised to read as follows:

§ 75.720 Financial and performance reports.

(a) This section applies to the reports required under 34 CFR 74.73 (Financial Status Report) and 34 CFR Part 74, Subpart J (Monitoring and Reporting of Program Performance).

(b) A grantee shall submit these reports annually, unless the Secretary allows less frequent reporting. However, the Secretary may require a grantee of a grant made under 34 CFR Part 700, 706, 707 (certain programs of the Office for Educational Research and Improvement)

to submit performance reports more often than annually.

(c) The Secretary may, under 34 CFR 74.7 (Special grant or subgrant conditions) or 34 CFR 74.72(e) (regarding grantee accounting systems), require a grantee to report more frequently than annually.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

55. Section 75.740 is amended by revising the title, designating the existing text as paragraph (a) and adding a new paragraph (b), to read as follows:

§ 75.740 Protection of and access to student records; student rights in research, experimental programs, and testing.

* * * * *

(b) Under most programs administered by the Secretary, research, experimentation, and testing are subject to the requirements of section 439 of GEPA and its implementing regulations at 34 CFR Part 98.

(Authority: 20 U.S.C. 1221e-3(a)(1), 1232g, 1232h, 3474)

§§ 75.750 through 75.755 [Removed]

56. Section 75.750 through 75.755, the center heading "DATA COLLECTION BY A GRANTEE", and the cross-reference following § 75.750 are removed.

PART 76—STATE-ADMINISTERED PROGRAMS

57. The authority citation for Part 76 is revised to read as follows:

Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, unless otherwise noted.

§ 76.3 [Removed]

58. Section 76.3 is removed.

59. Section 76.102 is revised to read as follows:

§ 76.102 Definition of "State plan" for Part 76.

As used in this part, "State plan" means any of the following documents:

Document	Program	Authorizing statute
State plan	Assistance to States for Education of Handicapped Children.	Part B (except section 619), Education of the Handicapped Act (20 U.S.C. 1411-1420).
Application	Preschool Grants	Section 619, Education of the Handicapped Act (20 U.S.C. 1419).
Application	Handicapped Infants and Toddlers	Part H, Education of the Handicapped Act (20 U.S.C. 1471-1485).
State plan	State Vocational Education Program	Title I, Part B, Carl D. Perkins Vocational Education Act (20 U.S.C. 2321-2325).
State plan and application	State-Administered Adult Education Program	Section 341, Adult Education Act (20 U.S.C. 1206).
Application	State Student Incentive Grant Program	Section 415C, Higher Education Act of 1965 (20 U.S.C. 1070c-2).
Basic State plan, long-range program, and annual program.	The Library Services and Construction Act State-Administered Program.	Library Services and Construction Act (20 U.S.C. 351-355e-3).
Application/written request for assistance.	Client Assistance Program	Section 112, Rehabilitation Act of 1973 (29 U.S.C. 732).
Application	Removal of Architectural Barriers to the Handicapped Program.	Section 607, Education of the Handicapped Act (20 U.S.C. 1406).
Application	Emergency Immigrant Education Program	Emergency Immigrant Education Act (20 U.S.C. 3121-3130).
Application	Transition Program for Refugee Children	Section 412(d) Immigration and Naturalization Act (8 U.S.C. 1522 (d)).
State Application	State Grants for Strengthening Instruction in Mathematics and Science.	Title II, Part A, Elementary Education Act of 1965, as amended (20 U.S.C. 2981).
Application	Paul Douglas Teacher Scholarship Program	Section 553, Higher Education Act of 1965 (20 U.S.C. 1111b).
State plan	State Vocational Rehabilitation Services Program.	Title I, Parts A-C, Rehabilitation Act of 1973 (29 U.S.C. 720-741).
State plan supplement	State Supported Employment Services Program	Title VI, Part C, Rehabilitation Act of 1973 (29 U.S.C. 795j-795r).
State plan	State Independent Living Services Program	Title VII, Part A, Rehabilitation Act of 1973 (29 U.S.C. 796-796d).
Any document that the authorizing statute for a State-administered program requires a State to submit to receive funds.	Any State-administered program without implementing regulations.	Section 408(a)(1), General Education Provisions Act and Section 414, Department of Education Organization Act (20 U.S.C. 1221e-3(a)(1) and 3474).

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

60. The table following § 76.125 is revised to read as follows:

§ 76.125 What is the purpose of these regulations?

* * * * *

CFDA No. and name of program	Authorizing statute	Implementing regulations Title 34 CFR Part
	Library Programs	
84.034 Library Services	Title I, Library Services and Construction Act (20 U.S.C. 351-354).	770
84.035 Interlibrary Cooperation and Resource Sharing	Title III, Library Services and Construction Act (20 U.S.C. 351-351f; 355e-355e-3).	770
84.154 Public Library Construction	Title II, Library Services and Construction Act (20 U.S.C. 351-351f; 355a-355c).	770
	Postsecondary Education Programs	
84.069 State Student Incentive Grants	Title IV, Part A, subpart 3, Higher Education Act of 1965 (20 U.S.C. 1070c-1070c-4).	692
84.185 Robert C. Byrd Honors Scholarships	Title IV, Part A, subpart 6, Higher Education Act of 1965 (20 U.S.C. 1070d-31-1070d-41).	654
84.173 Paul Douglas Teacher Scholarship Program	Title V, Part D, subpart 1, Higher Education Act of 1965 (20 U.S.C. 1111-1111h).	653

CFDA No. and name of program	Authorizing statute	Implementing regulations Title 34 CFR Part
	Vocational and Adult Education Programs	
84.002 Adult Education—State-Administered Programs	Adult Education Act, (20 U.S.C. 1201 *et seq.*)	425, 426
84.048 Vocational Education—Basic Grants to States	Title II, Carl D. Perkins Vocational Education Act (20 U.S.C. 2331-2342).	400, 401
84.049 Vocational Education—Consumer and Homemaking Education.	Title III, Part B, Carl D. Perkins Vocational Education Act (20 U.S.C. 2361-2363).	400, 401
84.053 Vocational Education—State Councils	Section 112, Carl D. Perkins Vocational Education Act (20 U.S.C. 2322).	400, 401
84.174 Vocational Education—Community-Based Organizations.	Title III, Part A, Carl D. Perkins Vocational Education Act (20 U.S.C. 2351-2352).	400, 401
* State Vocational Education—Adult Training, Retraining, and Employment Development Program.	Title III, Part C, Carl D. Perkins Vocational Education Act (20 U.S.C. 2371-2373).	400, 401
* State Vocational Education—Comprehensive Career Guidance and Counseling Program.	Title III, Part D, Carl D. Perkins Vocational Education Act (20 U.S.C. 2381-2383).	400, 401
* State Vocational Education—Industry—Education Partnership for Training in High Technology Occupations.	Title III, Part E, Carl D. Perkins Vocational Education Act (20 U.S.C. 2391-2393).	400, 401
	Education for the Handicapped Programs	
84.009 Program for Education of Handicapped Children in State Operated or Supported Schools.	Subpart 2, Part D, Chapter 1, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2791-2796).	302
84.027 Handicapped Preschool and School Programs—State Grant Programs.	Part B (except section 619), Education of the Handicapped Act (20 U.S.C. 1411-1418 and 1420).	300
84.027 Handicapped Preschool and School Programs—Incentive Grants.	Section 619, Education of the Handicapped Act (20 U.S.C. 1419).	301
84.155 Removal of Architectural Barriers to the Handicapped.	Section 607, Education of the Handicapped Act (20 U.S.C. 1406).	304
	Other Elementary and Secondary Programs	
84.010 Educationally Deprived Children—Local Educational Agencies.	Part A, Chapter 1, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2701 *et seq.*).	200
84.011 Migrant Education Programs—State Formula Grant Program.	Subpart 1, Part D, Chapter 1, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2781-2783).	201
84.012 Educationally Deprived Children—State Administration.	Chapter 1, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2701 *et seq.*).	200
84.013 Educationally Deprived Children in State Administered Institutions Serving Neglected and Delinquent Children.	Subpart 3, Part D, Chapter 1, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2801-2804).	203
84.146 Transition Program for Refugee Children	Section 412(d), Immigration and Naturalization Act (8 U.S.C. 1522(d)).	538
84.151 Federal, State, and Local Partnership for Educational Improvement.	Chapter 2, Title I, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2911 *et seq.*)	298
84.162 Emergency Immigrant Education Program	Emergency Immigrant Education Act (20 U.S.C. 3121-3130).	581
84.164 State Grants for Strengthening Instruction in Mathematics and Science.	Part A, Title II, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2981-2993).	208
84.186 Drug Free Schools—State and local programs	Title V, Part B, Elementary and Secondary Education Act of 1965, as amended, Sections 5121-5127 (20 U.S.C. 3191-3197).	N/A

* No CFDA Number.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

61. Section 76.300 is revised to read as follows:

§ 76.300 Contact the State for procedures to follow.

The State agency that administers a program may establish procedures that an applicant for a subgrant must follow to obtain the subgrant.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§ 76.305 [Removed]

62. Section 76.305 is removed.

63. Section 76.401(a) is revised to read as follows:

§ 76.401 Disapproval of an application—opportunity for a hearing.

(a) *State agency hearing before disapproval.* Under the programs listed in the chart below, the State agency that administers the program shall provide an applicant with notice and an opportunity for a hearing before it may disapprove the application.

Program	Authorizing statute	Implementing regulations Title 34 CFR Part
State Grants for Strengthening Instruction in Mathematics and Science	Part A, Title II, Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 2981-2993).	208
Assistance to States for Education of Handicapped Children	Part B, Education of the Handicapped Act (except Section 619) (20 U.S.C. 1411-1420).	300
Preschool Grants	Section 619, Education of the Handicapped Act (20 U.S.C. 1419)	301
Transition Program for Refugee Children	Section 412(d), Immigration and Naturalization Act (8 U.S.C. 1522(d))	538

Program	Authorizing statute	Implementing regulations Title 34 CFR Part
Emergency Immigrant Education Program	Emergency Immigrant Education Act (20 U.S.C. 3121-3130)	581
Financial Assistance for Construction, Reconstruction, or Renovation of Higher Education Facilities.	Section 711, Higher Education Act of 1965 (20 U.S.C. 1132b)	617

* * * * *

64. Section 76.560 is revised to read as follows:

§ 76.560 General indirect cost rates; exceptions.

(a) The differences between direct and indirect costs and the principles for determining the general indirect cost rate that a grantee may use for grants under most programs are specified in the cost principles for—

(1) Institutions of higher education, at 34 CFR 74.172;

(2) Hospitals, at 34 CFR 74.173;

(3) Other nonprofit organizations, at 34 CFR 74.174;

(4) Commercial organizations, at 34 CFR 74.175; and

(5) State and local governments and Federally-recognized Indian tribal organizations, at 34 CFR 80.22.

(b) Section 76.563 provides restrictions on indirect cost rates under certain programs.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

65. Section 76.563 is revised to read as follows:

§ 76.563 Restricted indirect cost rate—programs covered.

A State and a subgrantee shall use a restricted indirect cost rate, computed under 34 CFR 75.564–75.568, for each program that has a statutory requirement not to use Federal funds to supplant non-Federal funds.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§§ 76.580 and 76.581 [Removed]

66. Sections 76.580 and 76.581 and the center heading "COORDINATION" are removed.

§ 76.591 [Corrected]

67. In § 76.591, "75.591" is corrected to read "76.591".

§ 76.600 [Amended]

68. In § 76.600, paragraph (a), "75.615" is revised to read "75.617".

§ 76.681 [Amended]

69. Section 76.681 is amended by removing the cross-reference following that section.

§ 76.684 [Removed]

70. Section 76.684 is removed.

§ 76.690 [Removed]

71. Section 76.690 is removed.

72. In § 76.707, Column I, paragraph (h) in the Table is revised to read as follows:

§ 76.707 When obligations are made.

* * * * *

(h) A preagreement cost that was properly approved by the State under the cost principles identified in 34 CFR Part 74, Subpart Q.

* * * * *

73. Section 76.720 is revised to read as follows:

§ 76.720 Financial and performance reports by a State.

(a) This section applies to a State's reports required under 34 CFR 74.73 (Financial Status Report) and 34 CFR Part 74, Subpart J (Monitoring and Reporting of Program Performance).

(b) A State shall submit these reports annually, unless the Secretary allows less frequent reporting.

(c) However, the Secretary may, under 34 CFR 74.7 (Special grant or subgrant conditions) or 34 CFR 74.72(e) (regarding grantee accounting systems), require a State to report more frequently than annually.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

74. Section 76.740 is amended by revising the title, designating the existing paragraph as paragraph (a) and adding a new paragraph (b), to read as follows:

§ 76.740 Protection of and access to student records; student rights in research, experimental programs, and testing.

* * * * *

(b) Under most programs administered by the Secretary, research, experimentation, and testing are subject to the requirements of section 439 and GEPA and its implementing regulations at 34 CFR Part 98.

(Authority: 20 U.S.C. 1221e-3(a)(1), 1232g, 1232h, 3474)

75. Section 76.770 is revised to read as follows:

§ 76.770 A State shall have procedures to ensure compliance.

Each State shall have procedures for reviewing and approving applications for subgrants and amendments to those applications, for providing technical assistance, for monitoring and evaluating projects, and for performing other administrative responsibilities, designed to ensure compliance with applicable statutes and regulations.

(Authority: 20 U.S.C. 1221e-3(a)(1) and 3474)

§ 76.771 [Removed]

76. Section 76.771 is removed.

§ 76.772 [Removed]

77. Section 76.772 and the cross-reference following that section are removed.

§§ 76.780 through 76.782 [Removed]

78. The center heading preceding § 76.780 is removed and §§ 76.780–76.782 are removed.

PART 77—DEFINITIONS THAT APPLY TO DEPARTMENT REGULATIONS

79. The authority citation for Part 77 is revised to read as follows:

Authority: 20 U.S.C. 1221e-3(a)(1) and 3474, unless otherwise noted.

80. Paragraph (c) of § 77.1 is amended by revising the definition of "award" to read as follows:

§ 77.1 Definitions that apply to all Department programs.

* * * * *

(c) * * *

"Award" means an amount of funds that the Department provides under a contract, grant, or cooperative agreement.

* * * * *

PART 237—CHRISTA MCAULIFFE FELLOWSHIP PROGRAM

81. The authority citation for Part 237 continues to read as follows:

Authority: 20 U.S.C. 1113–1113e, unless otherwise noted.

82. Section 237.2 is amended by removing "and" at the end of paragraph (a)(4), substituting "; and" for the period at the end of paragraph (b), and adding a new paragraph (c) to read as follows:

§ 237.2 Who is eligible to apply under the Christa McAuliffe Fellowship Program?

* * * * *

(c) Is eligible for a fellowship under 34 CFR 75.60.

* * * * *

83. Section 237.7 is amended by revising paragraph (a), to read as follows:

§ 237.7 What regulations apply?

* * * * *

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR 75.60 and 75.61 (regarding the ineligibility of certain individuals to receive assistance) and Part 77 (Definitions that Apply to Department Regulations).

* * * * *

PART 263—INDIAN FELLOWSHIP PROGRAM

84. The authority citation for Part 263 is revised to read as follows:

Authority: 20 U.S.C. 3385b, unless otherwise noted.

85. Section 263.2 is amended by adding a new paragraph (d), to read as follows:

§ 263.2 Who is eligible to apply under the Indian Fellowship Program?

* * * * *

(d) An applicant must be eligible under 34 CFR 75.60.

* * * * *

86. A new § 263.10 is added to read as follows:

§ 263.10 Application contents: Evidence of eligibility under 34 CFR 75.60.

An applicant shall submit the certification required under 34 CFR 75.61.

(Authority: 20 U.S.C. 3385b)

PART 300—ASSISTANCE TO STATES FOR EDUCATION OF HANDICAPPED CHILDREN

87. The authority citation for Part 300 continues to read as follows:

Authority: 20 U.S.C. 1411–1420, unless otherwise noted.

88. Part 300 is amended by adding a center heading after § 300.653 and by adding new §§ 300.670–300.672, to read as follows:

Complaint Procedures of the State

§ 300.670 A State shall adopt complaint procedures.

A State shall adopt written complaint procedures for—

(a) Receiving and resolving any complaint that any public agency is violating a requirement in the Act or in this part;

(b) Reviewing an appeal from a decision of a public agency with respect to a complaint; and

(c) Conducting an independent on-site investigation of a complaint if the State determines that an on-site investigation is necessary.

(Authority: 20 U.S.C. 1412(6))

§ 300.671 Minimum complaint procedures.

A State shall include the following in its complaint procedures—

(a) A time limit of 60 calendar days after the State receives a complaint—

(1) If necessary, to carry out an independent on-site investigation; and

(2) To resolve the complaint.

(b) An extension of the time limit under (a) of this section only if exceptional circumstances exist with respect to a particular complaint.

(Authority: 20 U.S.C. 1412(6))

§ 300.672 An organization or individual may file a complaint.

An organization or individual may file a written signed complaint with a State. The complaint must include—

(a) A statement that a public agency has violated a requirement in the Act or in this part; and

(b) The facts on which the statement is based.

(Authority: 20 U.S.C. 1412(6))

PART 356—HANDICAPPED RESEARCH: RESEARCH FELLOWSHIPS

89. The authority citation for Part 356 is revised to read as follows:

Authority: 29 U.S.C. 760–762, unless otherwise noted.

90. Section 356.2 is amended by adding a new paragraph (d), to read as follows:

§ 356.2 Who is eligible for assistance under this program?

* * * * *

(d) An applicant for a fellowship under this program must be eligible under 34 CFR 75.60.

* * * * *

91. Section 356.3 is amended by removing "and" at the end of paragraph (b), removing the period at the end of paragraph (c), adding "; and" at the end of paragraph (c), and adding a new paragraph (d), to read as follows:

§ 356.3 What regulations apply to this program?

* * * * *

(d) The regulations in 34 CFR 75.60–75.61 (regarding the ineligibility of certain individuals to receive assistance).

* * * * *

PART 562—BILINGUAL EDUCATION: FELLOWSHIP PROGRAM

92. The authority citation for Part 562 is revise to read as follows:

Authority: 20 U.S.C. 3221–3262, unless otherwise noted.)

93. Section 562.2 is amended by removing "and" after the semicolon in paragraph (b)(1)(iii), substituting "; and" for the period at the end of paragraph (b)(2), and adding a new paragraph (b)(3) to read as follows:

§ 562.2 Who is eligible to apply for assistance under the fellowship program?

* * * * *

(3) Is eligible for a fellowship under 34 CFR 75.60.

* * * * *

94. Section 562.3 is amended by adding a new paragraph (c), to read as follows:

§ 562.3 What regulations apply to the Fellowship Program?

* * * * *

(c) The regulations in 34 CFR 75.60–75.62 (regarding the ineligibility of certain individuals to receive assistance).

PART 630—FUND FOR THE IMPROVEMENT OF POSTSECONDARY EDUCATION

95. The authority citation for Part 630 is revised to read as follows:

Authority: 20 U.S.C. 1135, *et seq.*, unless otherwise noted.

96. Section 630.11 is amended by revising the parenthetical phrase in the introductory text to read as follows:

§ 630.11 Types of competitions.

* * * * *

(See § 630.22)

* * * * *

97. New §§ 630.22 and 630.23 are added to read as follows:

§ 630.22 Preapplications.

The Secretary considers a preapplication under the procedures in §§ 630.21 and 630.23.

(Authority: 20 U.S.C. 1135)

§ 630.23 Consideration of a preapplication.

(a) The Secretary considers a preapplication if—

(1) The applicant complies with the procedural rules that govern submission of the preapplication; and

(2) The preapplication is submitted in response to an application notice that requires preapplications.

Cross-Reference: See Subpart N of 34 CFR Part 74.

(b) If the Secretary requires preapplications and an applicant does not preapply, the applicant may not apply for a grant.

(c) If an applicant submits a preapplication, the Secretary—

(1) Informs the applicant that it is eligible and encourages it to apply for a grant;

(2) Informs the applicant that it is eligible but does not encourage it to apply for a grant; or

(3) Informs the applicant that it is ineligible for assistance, and explains why the applicant is ineligible.

(d) An applicant may apply for a grant if the Secretary does not encourage it to apply.

(Authority: 20 U.S.C. 1135)

PART 653—PAUL DOUGLAS TEACHER SCHOLARSHIP PROGRAM

98. The authority citation for Part 653 continues to read as follows:

Authority: 20 U.S.C. 1111–1111h, unless otherwise noted.

99. Section 653.2 is amended by adding a new paragraph (c), to read as follows:

§ 653.2 Who is eligible to participate in this program?

* * * * *

(c) A high school graduate who applies for a scholarship under this program must be eligible under 34 CFR 75.60.

* * * * *

§ 653.3 [Amended]

100. Section 653.3 is amended by adding "§§ 75.60–75.62 (regarding the ineligiblity of certain individuals to receive assistance)," after "(Administration of Grants)," in paragraph (b).

PART 762—OFFICE OF EDUCATIONAL RESEARCH AND IMPROVEMENT FELLOWS PROGRAM

101. The authority citation for Part 762 continues to read as follows:

Authority: 20 U.S.C. 1221e, unless otherwise noted.

102. Section 762.2 is amended by adding a new paragraph (d), to read as follows:

§ 762.2 Who is eligible for fellowship?

(d) An individual who applies for a fellowship under the program must be eligible under 34 CFR 75.60.

* * * * *

103. Section 762.4 is amended by designating the existing text paragraph (a) and adding a new paragraph (b), to read as follows:

§ 762.4 What regulations apply?

* * * * *

(b) The regulations in 34 CFR 75.60–75.61 (regarding the ineligibility of certain individuals to receive assistance) also apply this to this program.

* * * * *

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