PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

Paragraph 1. The authority citation for part 20 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 20.6081–1 also issued under 26 U.S.C. 6081(a). * * *

Par. 2. Section 20.6075–1 is revised to read as follows:

§ 20.6075–1 Returns; time for filing estate tax return.

The estate tax return required by section 6018 must be filed on or before the due date. The due date is the date on or before which the return is required to be filed in accordance with the provisions of section 6075(a) or the last day of the period covered by an extension of time as provided in § 20.6081–1. The due date, for a decedent dying after December 31, 1970, is, unless an extension of time for filing has been obtained, the day of the ninth calendar month after the decedent's death numerically corresponding to the day of the calendar month on which death occurred, except that, if there is no numerically corresponding day in such ninth month, the last day of the ninth month is the due date. For example, if the decedent dies on July 31, 2000, the estate tax return and tax payment must be made on or before April 30, 2001. When the due date falls on Saturday, Sunday, or a legal holiday, the due date for filing the return is the next succeeding day that is not Saturday, Sunday, or a legal holiday. For the definition of a legal holiday, see section 7503 and § 301.7503–1 of this chapter. As to additions to the tax in the case of failure to file the return or pay the tax within the prescribed time, see section 6651 and § 301.6651–1 of this chapter. For rules with respect to the right to elect to have the property valued as of a date or dates subsequent to the decedent's death, see section 2032 and § 20.2032–1, and section 7502 and § 301.7502–1 of this chapter. This section applies to estates of decedents dying after August 16, 1954.

Par. 3. Section 20.6081–1 is revised to read as follows:

§ 20.6081–1 Extension of time for filing the return.

(a) *Extensions of time for good cause shown.* Where it is impossible or impracticable to file a reasonably complete return within the time prescribed by statute, the person required to file the return may request an extension of time for filing. Except as provided in paragraph (b) of this section, an extension of time for filing an estate tax return is not automatic and is within the discretion of the Internal Revenue Service. Unless the person required to file the return is abroad, an extension may not be granted for more than 6 months from the filing date prescribed by statute. Requests for an extension of time for filing are made by submitting Form 4768, ''Application for Extension of Time To File a Return and/or Pay U.S. Estate (and Generation-Skipping Transfer) Taxes.'' The application must contain a full recital of the causes for the delay. It should be filed with the Internal Revenue Service office designated in the application's instructions (except as provided in § 301.6091–1(b) of this chapter for hand-carried documents). The application should, where possible, be filed sufficiently early to permit the Internal Revenue Service time to consider the matter and reply before what otherwise would be the due date of the return. Failure to file the application before the expiration of the time within which the return otherwise must be filed may indicate negligence and constitute sufficient cause for denial of the extension.

(b) *Automatic extension*—(1) *Application for extension.* Executors who are required to file Form 706, ''United States Estate (and Generation-Skipping Transfer) Tax Return,'' may request an automatic 6-month extension of time beyond the date prescribed in section 6075(a) for filing the return by submitting Form 4768, ''Application for Extension of Time To File a Return and/or Pay U. S. Estate (and Generation-Skipping Transfer) Taxes.'' An automatic extension will be allowed if—

(i) The application is filed on or before the date prescribed in section 6075(a) for filing the return;

(ii) The application is filed with the Internal Revenue Service office designated in the application's instructions (except as provided in § 301.6091–1(b) of this chapter for hand-carried documents); and

(iii) The application includes an estimate of the amount of estate and generation-skipping transfer tax liability with respect to the estate.

(2) *Executors who are abroad.* If an executor who is abroad has received an automatic 6-month extension, the executor may request an additional extension of time by following the procedures in paragraph (a) of this section.

(c) *Filing the return.* A return as complete as possible must be filed before the expiration of the extension period. The return thus filed will be the return required by section 6018(a), and any tax shown on the return will be the amount determined by the executor as the tax referred to in section 6161(a)(2), or the amount shown as the tax by the taxpayer upon the taxpayer's return referred to in section 6211(a)(1)(A). The return cannot be amended after the expiration of the extension period although supplemental information may subsequently be filed that may result in a finally determined tax different from the amount shown as the tax on the return.

(d) *Payment of the tax.* An extension of time for filing a return does not operate to extend the time for payment of the tax. See § 20.6151–1 for the time for payment of the tax, and §§ 20.6161–1 and 20.6163–1 for extensions of time for payment of the tax.

(e) *Effective date.* This section applies to estates of decedents dying after August 16, 1954, except for paragraph (b) of this section which applies to estate tax returns due after the date these regulations are published as a final regulation in the **Federal Register**.

Robert E. Wenzel,
Deputy Commissioner of Internal Revenue.

[FR Doc. 00–26942 Filed 10–19–00; 8:45 am]
BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–6888–8]

RIN 2040–AB75

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: The Environmental Protection Agency (EPA) proposed regulations for arsenic in drinking water on June 22, 2000 (65 FR 38888), and comments on that action were due on September 20, 2000. Since that time, EPA has received new risk information which the Agency is considering during the development of the final regulation. This document summarizes the new risk information received and analyzed by the Agency. In addition, this document makes available the cost curves used to develop the costs published in the proposal. This information does not change the overall technical approach for the proposal. EPA is requesting comments on EPA's

use of the new risk analysis and development of cost estimates for the final rule and any comments on other parts of the proposal which would change because of the information provided today.

DATES: Your comments on this document must be submitted to EPA in writing and should be postmarked or received November 20, 2000.

ADDRESSES: Send written comments to the W–99–16 NODA Arsenic Comments Clerk, Water Docket (MC–4101); U.S. Environmental Protection Agency; 1200 Pennsylvania Ave., NW., Washington, DC 20460. Comments may be hand-delivered to the Water Docket, U.S. Environmental Protection Agency; 401 M Street, SW; East Tower Basement, room EB–57; Washington, DC 20460; (202) 260–3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. Comments may be submitted electronically, marked docket number W–99–16 NODA, to *ow-docket@epa.gov*. Please refer to the information under the headings ''Additional Information for Commenters'' and ''Availability of Docket'' in **SUPPLEMENTARY INFORMATION** for detailed information about filing and docket review.

FOR FURTHER INFORMATION CONTACT: For technical inquiries about risk and benefits discussed in this notice, contact Dr. John B. Bennett, (202) 260–0446, email: *bennett.johnb@epa.gov*, and for technical inquiries about treatment and cost discussed in this notice, contact Jeff Kempic, (202) 260–9567, email: *kempic.jeffrey@epa.gov*. For general information about this notice, contact Irene Dooley, (202) 260–9531, email: *dooley.irene@epa.gov*.

SUPPLEMENTARY INFORMATION:

Regulated Entities

A public water system, as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or other constructed conveyances, if such system has ''at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year.'' A public water system is either a community water system (CWS) or a non-community water system (NCWS). A community water system, as defined in § 141.2, is ''a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents.'' The definition in § 141.2 for a non-transient, non-community water system [NTNCWS] is ''a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year.'' EPA has an inventory totaling over 54,000 community water systems and approximately 20,000 non-transient, non-community water systems nationwide. Entities potentially regulated by this action are community water systems and non-transient, non-community water systems. The following table provides examples of the regulated entities under this rule.

TABLE OF REGULATED ENTITIES

Category	Examples of potentially regulated entities
Industry	Privately owned/operated community water supply systems using ground water or mixed ground water and surface water.
State, Tribal, and Local Government	State, Tribal, or local government-owned/operated water supply systems using ground water or mixed ground water and surface water.
Federal Government	Federally owned/operated community water supply systems using ground water or mixed ground water and surface water.

The table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.11 and 141.62 of the rule. If you have any questions regarding the applicability of this action to a particular entity, consult the general information person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Additional Information for Commenters

Please submit an original and three copies of your comments and enclosures (including references) and identify your submission by the docket number W–99–16 NODA. To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that comments cite, where possible, the paragraph(s) or sections in the document or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed. If you are submitting your comments electronically and mailing hard copies, please indicate on your electronic submission that hard copies are being sent separately. Electronic comments must be submitted as a WordPerfect 5.1, WP6.1 or WP8 file or as an ASCII file avoiding the use of special characters. Comments and data will also be accepted on disks in WP 5.1, WP6.1 or WP8, or ASCII file format. Electronic comments on this document may be filed online at many Federal Depository Libraries. Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

Availability of Docket

The docket for this document has been established under number W–99–16–II, and includes supporting documentation as well as printed, paper versions of electronic comments. The docket is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, at the Water Docket; EB 57; in the East Tower basement of U.S. EPA; 401 M Street, SW; Washington, DC. For access to docket materials, please call (202) 260–3027 to schedule an appointment.

Abbreviations Used

%—percent
AIC—Akaike information criterion
CWS—community water system
EB—East Tower Basement
ED_{01}—Effective dose which results in 1% excess lifetime risk
EPA—U.S. Environmental Protection Agency
et al.—et alibi, Latin for ''and others''
FR—**Federal Register**
i.e.—id est, Latin for ''that is''
kg—kilograms, 2.2 pounds
L—Liter, also referred to as lower case ''l'' in older citations
LED_{01}—a 95% lower confidence limit for ED_{01}
MDBP—microbial/disinfection by-product
MCL—maximum contaminant level

mg—milligrams—one thousandth of a gram, 1 milligram = 1,000 micrograms
microgram (µg)—One-millionth of gram (3.5×10^{-8} oz., 0.000000035 oz.)
µg/L—micrograms per liter
MOE_{01}—margin of exposure, ratio of ED_{01} to MCL
NAS—National Academy of Sciences
NODA—Notice of Data Availability
NRC—National Research Council, operating agency of NAS
NRC—National Research Council, the operating arm of NAS
O&M—operation and maintenance
ppb—Parts per billion. Also, µg/L or micrograms per liter
RIA—Regulatory Impact Analysis
U.S.—United States
VSL—Value of a statistical life
WTP—Willingness to pay

How Does This Document Relate to the June 22, 2000 Proposal?

In the Thursday, June 22, 2000, **Federal Register** the U.S. Environmental Protection Agency (EPA) proposed regulations for arsenic and clarifications to compliance and new source contaminants monitoring (65 FR 38888). This document applies only to the arsenic part of the proposal. Specifically, EPA noted that ''Further work on the risk assessment will also be done before the final rule is issued to analyze the risks of internal cancers (65 FR 38888 at 38899).'' This document discusses new risk information and EPA's subsequent risk analysis.

On page 39835 of the June 22, 2000, arsenic proposal, EPA noted that the unit cost curves are in the November 1999 ''Technologies and Costs for the Removal of Arsenic from Drinking Water.'' It has come to EPA's attention that the cost curves used to develop the costs that are included in the proposal and supporting Regulatory Impact Analysis (RIA) are in an earlier version of this document dated April 1999. This document announces the availability of the April 1999 version, with curves that more accurately reflect the analysis in the preamble and the RIA. The overall approach to cost estimation in the proposed rule and the proposed Maximum Contaminant Level (MCL) remain unchanged.

What New Risk Data Has EPA Analyzed?

In the proposal we calculated bladder cancer benefits and risks using the bladder cancer risk analysis from the 1999 National Research Council (NRC) report, *Arsenic in Drinking Water.* We also estimated lung cancer benefits in a ''What If'' analysis based on a qualitative statement about lung cancer deaths from the 1999 NRC report. At that time we noted that a peer-reviewed lung cancer risk study would probably become available before the final rule came out (65 FR 38888 at 38944). This Spring, we received a copy of a peer-reviewed article by Morales *et al.* (2000). This article presented additional analyses of bladder cancer risks as well as estimates of lung and liver cancer risks for the same Taiwanese population analyzed in the NRC report. This document makes available for public comment the Morales *et al.* (2000) information and the Agency's analysis of the bladder and lung cancer risks from that paper.

What Is in the Article by Morales et al.?

The article ''Risk of Internal Cancer from Arsenic in Drinking Water'' (Morales *et al.,* 2000) presents an assessment of the magnitude of risk for cancers of the bladder, liver and lung from exposure to arsenic in water, based on data from 42 villages in an arseniasis endemic region of Taiwan. The authors calculated excess lifetime risk estimates using several Poisson regression models and a multistage-Weibull model. (Excess lifetime risk is the additional probability of disease or death due to the given cause over the course of a lifetime.) Risk estimates are expressed as ED_{01}, the concentration at which 1% additional lifetime risk of death is incurred; LED_{01}, a 95% lower confidence limit for ED_{01}; and $MOE_{01}(50)$, the ''margin of exposure,'' or the ratio of ED_{01} to the current MCL of 50 µg/L. The authors found that risk estimates are sensitive to the choice of model, to whether a comparison population is used to define the unexposed disease mortality rates, and whether the comparison population is all of Taiwan or just an unexposed portion of the population in the study area. The authors noted that some of the factors that may affect the magnitude of risk could not be evaluated quantitatively: The ecological nature of the data, the nutritional status of the study population, and the dietary intake of arsenic. Despite all these sources of uncertainty, however, the analysis suggests that the current standard of 50 µg/L is associated with a substantial increased risk of cancer and thus is not suffciently protective of public health. (The authors state that ''the risk associated with a concentration of 50 µg/L is approximately 1 in 300, based on linear extrapolation from the point of departure. * * * This is an extremely high value.'')

The Morales *et al.* (2000) article uses several statistical models to estimate bladder, lung, and liver cancer risk from arsenic exposure. It also presents the combined risk of all three cancers. The risk assessments are based on a study from Taiwan published by Chen *et al.* (1985), with the data grouped at the village level. These data are also used for the bladder cancer risk analysis in the 1999 NRC report. Morales *et al.* (2000) examine issues of dose-response modeling for the generalized linear model. The authors identify several Poisson and multistage-Weibull models which fit the data about equally well. They prefer the Poisson models, in part because the fit of the Weibull models is more sensitive to the omission of subsets of individual villages. The models are based on mortality data from Taiwan, and model results are transferred to the United States (U.S.) without adjustment for differences in mortality-to-incidence ratios for the various illnesses. The authors adjusted the risk analyses to reflect differences in average population weight and in the consumption of drinking water between the U.S. and Taiwan (assuming a representative person in the U.S. weighs 70 kg and drinks 2 liters of water per day vs. a Taiwanese weighing 55 kg and drinking 3.5 liters). Two comparison populations, one from all of Taiwan and one from southwestern Taiwan, were used in the modeling to estimate background levels of risk.

The various model results present considerable variability in cancer risk estimates for arsenic. The authors propose several reasons for the variability, including the large variability of exposure among people within each village and use of a comparison population in the analysis. The authors also suggest that a variety of factors for which data were not available, including the dietary intake of inorganic arsenic, could influence or even confound these models. They observe that ''* * * this is an ecological study wherein only relatively simple exposure and population characteristics could be measured. It will be important to consider this and other sources of uncertainty when interpreting the results (Morales *et al*., 2000).'' The authors conclude, however, that it seems likely that arsenic is contributing to excess cancer mortality in the U.S. based on their evaluation of combined risks of bladder, lung, and liver cancer: ''Despite the considerable variation in estimated ED_{01}, the results are sobering and indicate that current standards are not adequately protective against cancer (Morales *et al*., 2000).''

What Models Did EPA Choose To Use for Additional Analysis?

Ten risk models were presented in Morales *et al.* (2000). Following Dr. Louise Ryan's presentation to the SAB

Drinking Water Committee (SAB, 2000), and after additional consultation with the primary authors (Morales and Ryan), EPA chose Model 1 with no comparison population for further analysis. In Model 1 the dose effect is assumed to follow a linear function and the age effect is assumed to follow a quadratic function.

EPA believes, after consultation with the authors, that the models in Morales *et al.* (2000) with a comparison population are less reliable than those without a comparison population. With no comparison population, the arsenic dose-response curve is estimated only from the study population. Models with a comparison population include mortality data from a similar population (in this case either all of Taiwan or part of southwestern Taiwan), whose exposure is assumed to be zero. Most of the models with comparison populations resulted in dose-response curves that were supralinear (higher than a linear dose-response) at low doses. The curves were forced down at zero dose because the comparison population consists of a large number of people with low risk and assumed zero exposure. EPA believes, based on discussions with the authors, that these models are less reliable, for two reasons. First, there is no basis in data on arsenic's carcinogenic mode of action to consider a supralinear curve to be biologically plausible. The conclusion of the NRC panel (NRC, 1999) was that the mode of action data led one to expect dose responses that would be either linear or less than linear at low dose. However, the NRC indicated that available data are inconclusive and ''* * * do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity.'' Second, models which include comparison populations assume that the exposure of the comparison population is zero, and that the study and comparison populations are the same in all important ways except for arsenic exposure. Neither of these comparison populations assumptions may be correct: NRC (1999) notes that ''the Taiwanese-wide data do not clearly represent a population with zero exposure to arsenic in drinking water''; and Morales *et al.* (2000) agree that ''[t]here is reason to believe that the urban Taiwanese population is not a comparable population for the poor rural population used in this study.'' Moreover, because of the large amount of data in the comparison populations, the model results are relatively sensitive to assumptions about this group. For these reasons, EPA believes that the models without comparison populations are more reliable than those with them.

Of the models that did not include a comparison population, EPA believes Model 1 fits the data best, based on the Akaike information criterion (AIC), a standard criterion of model fit, applied to the Poisson models. EPA did not consider the multi-stage Weibull model for additional analysis, because of its greater sensitivity to the omission of individual villages (Morales *et al.*, 2000) and to the grouping of responses by village (NRC, 1999), as occurs in the Taiwanese data.

The Poisson regression model (Model 1), without a comparison population, gave results for lifetime excess risk of bladder cancer for males from arsenic ingestion (about 1.3 in a 1000 at an arsenic level of 50 μg/L) which were approximately the same as those risks found by the NRC (approximately 1 in a 1000 at an arsenic level of 50 μg/L). Among females, lifetime excess risk of bladder cancer is estimated to be 2.0 in 1000 at 50 μg/L. We also considered estimates using this model for excess risks for lung and liver cancer due to arsenic. The lung cancer risk estimates, which were comparable to the bladder cancer risk estimates, were of special interest to the Agency, as the NRC report did not provide a statistical analysis of these risks.

However, EPA did not further consider the Taiwan liver cancer estimates for U.S. liver cancer risks. Angiosarcoma liver cancer (cancer in the liver's blood vessels) has been linked to arsenic exposure in Germany (Roth, 1957, as reported in Smith *et al.*, 1992), Chile (Zaldivar *et al.*, 1981, as reported in Smith *et al.*, 1992), and the U.S. (Falk *et al.*, 1981, as reported in Smith *et al.*, 1992). However, most liver cancers in Taiwan were hepatocellular (*i.e.*, liver cell) carcinomas linked to hepatitis (Chen *et al.*, 1985 & 1986), rather than angiosarcoma cancer, and are extremely rare in the U.S.

How Will the New Data Affect EPA's Risk Analysis?

This section describes EPA's risk analysis in the June 22, 2000, proposed arsenic rulemaking, then extends the analysis to incorporate new information from Morales *et al.* (2000).

The June 22, 2000, proposed arsenic rulemaking contained an analysis of the excess exposed population risks associated with arsenic consumption for bladder cancer. This analysis was based on the 1999 National Research Council (NRC) report, in which the NRC examined risk distributions for male bladder cancer in 42 villages in Taiwan. This population was exposed to drinking water with arsenic ranging from 10 to 934 μg/L; arsenic exposure estimates were grouped by village. To monetize bladder cancer benefits, EPA calculated the number of cases potentially avoided, based on the NRC bladder cancer risk analyses, for populations exposed to MCL options of 3 μg/L, 5 μg/L, 10 μg/L, and 20 μg/L. The proposal's analytic approach included five components. First, EPA used data from the recent EPA water consumption study (US EPA, 2000a). Second, we used Monte Carlo simulations to develop a distribution of ''relative exposure factors,'' which account for individual variations in risk due to water consumption and body weight. Third, arsenic occurrence estimates (US EPA, 2000c) were used to identify the population exposed to levels above 3 μg/L. We assumed drinking water exposure reflected treatment to 80% of the MCL level, because water systems tend to treat below the MCL level in order to provide a margin of safety. Fourth, EPA chose four NRC risk distributions (NRC, 1999, from Tables 10–11 and 10–12) for the analysis, that used Poisson-model derived risk estimates, with and without baseline comparison data. Fifth, EPA used Monte Carlo simulations to develop estimates of the risks faced by the exposed population, using the relative exposure factors, occurrence, and the NRC risk distributions. These components of the analysis are described in the proposed rulemaking (US EPA, 2000d, section X.A). EPA also monetized the potential benefits of avoided lung cancer, using a ''What If'' analysis based on statements in the NRC report.

Table 1 shows the mean and 90th percentile bladder cancer incidence risks summarized from Tables X–4A, X–4B, X–2A, and X–2B in the June 22, 2000, arsenic proposed rulemaking (65 FR 38888), after treatment, for the U.S. population currently exposed at or above 3 μg/L, 5 μg/L, 10 μg/L, and 20 μg/L. These risk distributions are based on bladder cancer mortality data in Taiwan, in a section of Taiwan where arsenic concentrations in the water are very high by comparison to those in the U.S. It is also an area of low incomes (NRC, 1999, pg. 292) and poor diet (NRC, 1999, pg. 295), and the availability and quality of medical care is not of high quality, by U.S. standards. In its estimate of bladder cancer risk, the Agency assumed that within the Taiwanese study area at the time of the study, the risk of contracting bladder cancer was relatively close to the risk of dying from bladder cancer (that is, that the bladder cancer incidence rate was equal to the bladder cancer mortality rate). Survival rates for bladder cancer in the U.S. have been improving from 1973 to 1996 (*i.e.*, U.S. bladder cancer mortality rates decreased overall 24% to 26%). Recent bladder cancer survival rates in developing countries range from 23.5% to 66.1%, and are currently 45% for bladder cancer in Taiwan, as discussed in the proposed rulemaking (65 FR 38888 at 38942). At most, the Agency concluded that bladder cancer incidence could be no more than 2 times bladder cancer mortality; and that an 80% mortality rate would be plausible. The benefits analysis included estimates using an assumed mortality rate ranging from 80% to 100%.

TABLE 1.—BLADDER CANCER RISKS FROM THE JUNE 22, 2000 PROPOSAL: MEAN (FROM TABLES X–4A AND X–4B) AND 90TH PERCENTILE (FROM TABLES X–2A AND X–2B) LIFETIME INCIDENCE RISKS,[1] FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT[2] (LOWER BOUNDS: LOW NRC RISK, CWS WATER CONSUMPTION; UPPER BOUNDS: HIGH NRC RISK, TOTAL WATER CONSUMPTION)

MCL µg/L	Mean exposed population risk	90th percentile exposed population risk
3	$2.1-4.5 \times 10^{-5}$	$4-7 \times 10^{-5}$
5	$3.6-7.5 \times 10^{-5}$	$6-12 \times 10^{-5}$
10	$5.5-11.4 \times 10^{-5}$	$1-2 \times 10^{-4}$
20	$6.9-13.9 \times 10^{-5}$	$1.4-2.8 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate.
[2] The risk analysis assumed exposure at 80% of the MCL level, because water systems tend to treat below the MCL level in order to provide a margin of safety.

The Morales *et al.* (2000) article provided a new analysis of bladder cancer risk. Although the data used were the same as used by the NRC to analyze bladder cancer risk in their 1999 publication, Morales *et al.* (2000) consider more dose-response models and evaluate how well they fit the Taiwanese data. Therefore the Agency decided to examine the implications of the new bladder cancer risk assessment from Morales *et al.* (2000), as well as the lung cancer risk assessment. Using the same analytical approach as in the arsenic proposed rule (with Monte Carlo simulations combining relative exposure factors, occurrence estimates, and risk distributions), the Agency recalculated the mean bladder cancer risks for U.S. populations, based on the risk estimates from Morales *et al.* (2000), derived from Model 1 with no comparison population. The results are shown in Table 2, along with the bladder cancer risks remaining, after treatment, for the 90th percentile U.S. population.

TABLE 2.—BLADDER CANCER: MEAN AND 90TH PERCENTILE LIFETIME INCIDENCE RISKS,[1] FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT[2] (MORALES RISK, LOW WATER CONSUMPTION FOR LOWER BOUND, HIGH WATER CONSUMPTION FOR UPPER BOUND)

MCL µg/L	Mean exposed population risk	90th percentile population risk
3	$4.9-6.0 \times 10^{-5}$	$1-1.2 \times 10^{-4}$
5	$8.4-10.2 \times 10^{-5}$	$1.8-2.0 \times 10^{-4}$
10	$1.2-1.47 \times 10^{-4}$	$2.6-3.1 \times 10^{-4}$
20	$1.55-1.89 \times 10^{-4}$	$3.5-4.1 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate.
[2] The risk analysis assumed exposure at 80% of the MCL level, because water systems tend to treat below the MCL level in order to provide a margin of safety.

The Agency also estimated the mean and 90th percentile lung cancer risks for U.S. populations, using the same analytical approach and the risk estimates from Morales *et al.* (2000), derived from Model 1 with no comparison population. The results are shown in Table 3.

TABLE 3.—LUNG CANCER: MEAN LIFETIME INCIDENCE RISKS,[1] FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT[2] (MORALES RISK, LOW WATER CONSUMPTION FOR LOWER BOUND, HIGH WATER CONSUMPTION FOR UPPER BOUND)

MCL µg/L	Mean exposed population risk	90th percentile population risk
3	$4.9-6.1 \times 10^{-5}$	$1.0-1.2 \times 10^{-4}$
5	$8.2-10.5 \times 10^{-5}$	$1.7-2.1 \times 10^{-4}$
10	$1.21-1.46 \times 10^{-4}$	$2.7-3.1 \times 10^{-4}$
20	$1.52-1.87 \times 10^{-4}$	$3.4-4.3 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate.
[2] The risk analysis assumed exposure at 80% of the MCL level, because water systems tend to treat below the MCL level in order to provide a margin of safety.

EPA believes, based upon this most recent risk information, that the combined risk of excess cases of lung and bladder cancer attributable to arsenic in drinking water could be at least twice that of bladder cancer alone. However, EPA will need to conduct additional analyses of this risk information, together with additional analyses of the various uncertainties associated with the underlying data, and of comments submitted in response to the proposed rule, to develop its best estimate of the overall risk in support of a final rulemaking.

How Did EPA Analyze the Lower Bound of its Risk Estimates?

The Agency performed a sensitivity analysis of the lower bound risk estimates, considering the effect on risk estimates of exposure to arsenic through water used in preparing food in Taiwan. The 1988 EPA ''Special Report on Ingested Inorganic Arsenic'' contained the following discussion:

> For the studied population, rice and sweet potatoes were the main staple and might account for as much as 80% of food intake per meal. For the purpose of discussion we will assume that a man in the study population ate one cup of dry rice and two pounds of potatoes per day and that the amount of water required to cook the rice and potatoes was about 1 L. Under this assumption, the risk calculated before is overestimated by about 30% (1 L/ 3.5 L). This calculation considers only the water used for cooking; the arsenic content in the rice and potatoes that might have been absorbed from soil arsenic is not considered because of the lack of information.

The Taiwanese staple foods were dried sweet potatoes and rice (Wu *et al.,* 1989). Both the 1988 EPA report and the 1999 NRC report assumed that an average Taiwanese male weighed 55 kg and drank 3.5 liters of water daily, and that an average Taiwanese female weighed 50 kg and drank 2 L of water daily. Using these assumptions, along with an assumption that Taiwanese men and women ate one cup of dry rice and two pounds of sweet potatoes a day, the Agency re-estimated risks for bladder and lung cancer, using one additional liter water consumption for food preparation (*i.e.,* the water absorbed by hydration during cooking). The food consumed in Taiwan contains more arsenic than in the U.S.: on average, about 50 µg/day in Taiwan, versus about 10 µg/day in the U.S. (NRC, 1999, pp. 50–51). Thus our analysis may still overstate the risk to the U.S. population, when the total consumption of inorganic arsenic (from food preparation and drinking water) is considered. Results of the EPA analysis considering water used in cooking are shown in Table 4, using the NRC bladder cancer risk, the Morales *et al.* (2000) bladder cancer risk, and the Morales *et al.* (2000) lung cancer risk estimates utilized earlier in this Document. Table 5 shows the cancer risks remaining, after treatment to 80% MCL options, for high percentile U.S. populations, providing a sensitivity analysis for the lower bound risk taking into account the arsenic intake from water used in cooking dried foods.

TABLE 4.—SENSITIVITY ANALYSIS OF MEAN LOWER BOUND INCIDENCE RISK ESTIMATES,[1, 2] RISKS ADJUSTED FOR WATER USED IN COOKING (CWS WATER CONSUMPTION DATA)

MCL (µg/L)	Bladder (NRC)	Bladder (Morales)	Lung (Morales)
3	1.7×10^{-5}	3.5×10^{-5}	3.6×10^{-5}
5	2.9×10^{-5}	5.7×10^{-5}	5.7×10^{-5}
10	4.1×10^{-5}	8.4×10^{-5}	8.4×10^{-5}
20	5.1×10^{-5}	1.01×10^{-5}	1.06×10^{-5}

[1] Risks are adjusted under assumption that Taiwanese males and females consume one additional liter of water in rehydrating dried rice and sweet potatoes.
[2] The bladder cancer risks presented in this table provide ''best'' estimates. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate.

TABLE 5.—SENSITIVITY ANALYSIS OF 90TH PERCENTILE LOWER BOUND INCIDENCE RISK ESTIMATES,[1,2] RISKS ADJUSTED FOR WATER USED IN COOKING (CWS WATER CONSUMPTION DATA)

MCL (μg/L)	Bladder (NRC)	Bladder (Morales)	Lung (Morales)
3	3.5×10^{-5}	7.5×10^{-5}	7.2×10^{-5}
5	5.9×10^{-5}	1.2×10^{-4}	1.2×10^{-4}
10	9.0×10^{-5}	1.8×10^{-4}	1.8×10^{-4}
20	1.1×10^{-4}	2.3×10^{-4}	2.4×10^{-4}

[1] Risks are adjusted under assumption that Taiwanese males and females consume one additional liter of water in rehydrating dried rice and sweet potatoes.

[2] The bladder cancer risks presented in this table provide ''best'' estimates. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate.

How Will EPA Evaluate Benefits in the Final Rule?

The benefits of a regulatory option depend primarily on the number of cases of an illness avoided due to the reduction in risk resulting from the implementation of the option. For the arsenic proposed rule and following established Agency practices, EPA estimated the number of cases of bladder cancer avoided using mean exposed population incidence risk estimates at various MCL levels (these mean exposed population incidence risks are shown in Table 1). We converted lifetime risk estimates to annual risk factors, and applied these to the exposed population to determine the number of cases avoided (both fatal and non-fatal). We adjusted the upper bound bladder cancer number of cases estimates by assuming an 80% mortality rate in Taiwan, which is a plausible mortality rate for the area of Taiwan during the Chen study. The lower bound estimates assumed a 100% mortality rate from bladder cancer in Taiwan. For the benefits assessment, EPA used U.S. mortality information to divide the number of cases into fatal and non-fatal cases avoided. Benefits are assumed to begin to accrue on the effective date of the arsenic rule (65 FR 38888 at 38946).

The avoided cases of fatal bladder cancer are valued by what is known as the ''value of a statistical life'' (VSL), currently estimated at $6.1 million (in 1999 dollars).[1] VSL does not refer to the value of an identifiable life, but instead to the value of small reductions in mortality risks in a population. We used the central tendency estimate of $604,000 (1999 dollars) [2] of the willingness to pay (WTP) to avoid a case of chronic bronchitis to monetize the benefits of avoiding non-fatal bladder cancers (Viscusi *et al.,* 1991). WTP data for avoiding chronic bronchitis has been used before by EPA (the microbial/disinfection by-product (MDBP) rulemaking) as a surrogate for the WTP to avoid non-fatal bladder cancer. EPA summed the monetized benefits for fatal and non-fatal bladder cancer cases avoided to obtain total monetized benefits for avoided bladder cancer cases (shown in Tables X–7 and XI–1 of the proposed rule preamble, in 1999 dollars).

In the arsenic proposed rule, EPA also estimated the number of lung cancer cases avoided, for the various options considered, using a ''What If'' analysis, and monetized these cases using the same process that was used to monetize the benefits of avoided bladder cancer cases. The ''What If'' analysis examined possible benefits from avoided lung cancer cases if the number of those cases in the U.S. which were fatal in outcome was 2–5 times the number of fatal bladder cancer cases (the implicit risk for lung cancer ranged from about half to about twice that of the risk for bladder cancer).

EPA plans to use the benefits evaluation process described in this section for the final rule, using the data and analysis of the bladder and lung cancer risks described in this document instead of the ''What If'' lung cancer analysis included in the proposal. These more definitive benefits estimates will be derived from the new risk calculations that will accompany the final rule (based upon further consideration of additive risk analyses) and other pertinent information. Background information on the economic concepts that provide the foundation for benefits valuation, and the methods that are typically used by economists to monetize the value of risk reductions, such as wage-risk, cost of illness, and contingent valuation studies are provided in the arsenic RIA.

EPA Benefits Summary and Conclusions

Morales *et al.* (2000) assess the risks of lung and bladder cancer associated with arsenic consumption in water, based on data from Taiwan, using several statistical models. Although the data used were the same as used by the NRC (1999). Morales *et al.* consider more dose-response models, providing a more exhaustive treatment of model fit. They also discuss additional factors, for which data were not available, which might influence or confound the analysis. Dose-response risk estimate for both bladder and lung cancer, derived from the best-fitting model, were analyzed further by the Agency. The Agency calculated new risk estimates for the U.S. exposed population, for the various MICL options under consideration. The resulting risk estimates for bladder cancer are higher than those examined in detail in the proposal, and the new lung cancer risks are approximately equal to the new bladder cancer risks. As noted earlier, EPA believes that the combined risk of excess cases from lung and bladder cancer could be at least twice that of bladder cancer alone and will be refining its overall risk estimate in support of the final rule based on a number of factors, with a particular focus on the additive risks of lung and bladder cancer. Monetized benefits from avoided cases overall are expected to fall within the ranges presented in the June 22 Proposed Rule, because of the implicit assumptions of lung cancer risk in the ''What If'' analysis. However, the lung cancer monetized benefits would be more certain, and removed from the ''What If'' categorization. In addition, the Agency performed a lower bound sensitivity analysis of risk estimates given a variation in the assumption about water used for cooking in Taiwan.

What Technologies and Costs Document Is Being Made Available?

In the June 22, 2000, **Federal Register**, the EPA presented national cost

[1] The June 20, 2000, proposal (65 FR 38888) cited the central tendency estimate of the VSL as $5.8 million in 1997 $ in the preamble text. However, the analyses presented in the proposal's tables reflect 1999 $ values, as noted.

[2] The June 20, 2000, proposal (65 FR 38888) cited the central tendency estimate of the WTP as $536,000 in 1997 $ in the preamble text. However, the analyses presented in the proposal's tables reflect 1999 $ values, as noted.

estimates of the proposed arsenic rule (65 FR 38888). In several tables [3] in the preamble EPA presented annualized national cost estimates for four MCL options (3, 5, 10 and 20 µL). The methodology and data used to develop these estimates are described in the Regulatory Impact Analysis (RIA) (EPA 2000b). This document is making available for public comment additional information on the costs of treatment technologies EPA: ''Technologies and Costs for the Removal of Arsenic From Drinking Water,'' April 1999, which has been placed in the docket, and will be made available on EPA's website. EPA used this April 1999 document to develop the national estimates presented in the proposed rule.

The RIA describes the model (SafeWaterXL) that was used by EPA to estimate national costs. The model uses data on arsenic occurrence, compliance decision trees, unit treatment technology train costs and other relevant data to generate national cost estimates. All of these inputs are described in the RIA. The treatment trains that were used in the national cost estimation are given in Exhibit 6–1 of the RIA. The RIA provides information on treatment technology costs by system size in Exhibit 6–2. The exhibit has cost estimates on treatment capital, treatment operation and maintenance (O&M), waste disposal capital, and waste disposal O&M costs for each treatment train.

Today's document is advising the public about the availability in the docket of ''Technologies and Costs for the Removal of Arsenic from Drinking Water,'' April 1999, which provides the unit cost curves (regressions) that were used to generate Exhibit 6–1 of the RIA. The April 1999 technology and cost document contains curves for several removal efficiencies, including the ones corresponding to the removal efficiencies identified in Exhibit 6–1 of the RIA.

The unit cost treatment curves for each technology can be found in the April 1999 technology and cost document. The unit cost waste disposal curves can be derived from Table 4–1, ''Summary of Residuals Characteristics,'' in the technology and cost document. Those interested in reproducing the waste disposal curves should consult the ''Small Water System Byproducts Treatment and Disposal Cost'' (EPA 1993a) document and the ''Water System Byproducts Treatment and Disposal Cost'' (EPA 1993b) document. The former is for small water systems, and the latter is for larger ones. An electronic copy of the treatment technology and waste disposal equations used in the development of the RIA can also be found in the docket.

Why Does the Docket Have a Copy of a Newer Version of the Technologies & Costs for Comment?

The EPA has continued to refine and update cost estimates of the treatment technologies discussed in the proposed rule. In addition, EPA is following the development of emerging technologies that would be relevant for arsenic removal. An update of the April 1999 document was inadvertently included in the docket: EPA, ''Technologies and Costs for Removal of Arsenic from Drinking Water,'' November 1999. This was not, however, the version used to develop the RIA. The RIA costs were developed using the earlier April 1999 version, which is being provided with this document. This data and information is being made available to those interested in reproducing our national cost estimates.

The differences between the cost curves in the April and November drafts are attributable to the different design criteria assumptions made when running the unit cost models. Three unit cost models were used: ''Very Small Systems'' (for systems between 0.015 to 0.100 mgd), ''Water model'' (for systems between 0.27 and 1.00 mgd), and ''W/W Cost'' (for systems between 10 to 200 mgd). The design criteria assumptions are described prior to the presentation of the cost curves in each document. For example, the design criteria assumptions for coagulation assisted microfiltration are listed on page 3–47 of the November 1999 document and on page 3–60 of the April 1999 document. EPA will continue to refine the cost curves and other cost of compliance information and data based on comments submitted on the proposal.

How Will EPA Use the November 1999 Cost Document?

EPA will carefully consider all comments on the proposed rule and will develop new national cost estimates for the final rule, along with a new supporting treatment technology and cost document, which would update both the April 1999 and November 1999 versions of the treatment technology and cost document. The new version that will be developed will include cost estimates for emerging technologies, and where necessary, updates to the treatment technology cost curves already developed. EPA may also develop an updated decision tree to refine and improve the cost estimates, based on comments received on the proposal. Changes in these inputs to EPA's models for determining the cost of compliance and any changes to the national cost estimates generated by the model will be presented in the final rule.

References

Chen, C. J., Y. C. Chuang, T. M. Lin and H. Y. Wu. 1985. Malignant neoplasms among residents of a Blackfoot disease endemic area in Taiwan: High arsenic well water and cancers. ''Cancer Research'' 45:5895–5899.

Chen, C. J., Y. C. Chuang, T. M. Lin and H. Y. Wu. 1986. A retrospective study on malignant neoplasms of bladder, lung and liver in Blackfoot disease endemic area in Taiwan. ''British Journal of Cancer'' 53:399–405.

Morales, K.H., L. Ryan, K.G. Brown, T–L Kuo, M–M Wu, and C.J. Chen. 2000. Risk of Internal Cancers from Arsenic in Drinking Water. ''Environmental Health Perspectives'' 108:655–661.

National Research Council. 1999. ''Arsenic in Drinking Water.'' Washington, DC. National Academy Press.

Smith, A.H., C. Hopenhayn-Rich, M.N. Bates, H.M. Goeden, I. Hertz-Picciotto, H.M. Duggan, R. Wood, M.J. Kosnett, and M.T. Smith. 1992. Cancer risks from arsenic in drinking water. ''Environmental Health Perspectives'' 97:259–267.

US EPA. 1988. ''Special Report on Ingested Inorganic Arsenic: Skin Cancer; Nutritional Essentiality.'' Risk Assessment Forum. EPA/625/3–87/013. 124 pp. July 1988.

US EPA. 1993a. Small Water System Byproducts Treatment and Disposal Cost Document. April 1993.

US EPA. 1993b. Water System Byproducts Treatment and Disposal Cost Document. April 1993.

US EPA. 1999a. Technologies and Costs for Removal of Arsenic From Drinking Water. EPA–815–R–00–012. Prepared by International Consultants, Inc. and Malcolm Pirnie, Inc. under contract to EPA OGWDW. November 1999.

US EPA. 1999b. Technologies and Costs for the Removal of Arsenic From Drinking Water. Prepared by International

[3] Table VIII–3. Annual Costs of Treatment Trains (Per Household); Table IX–11. National Annual Treatment Costs; Table IX–12. Total Annual Costs Per Household; Table IX–13. Incremental National Annual Costs; Table IX–14. Incremental Annual Costs Per Household; Table X–7. Estimated Costs and Benefits From Reducing Arsenic in Drinking Water; Table XI–1. Estimated Costs and Benefits From Reducing Arsenic in Drinking Water; Table XIII–3. Estimated Costs and Benefits From Reducing Arsenic in Drinking Water; Table XIII–4. Estimated Annualized National Costs of Reducing Arsenic Exposures; Table XIII–5. Estimated Annual Costs Per Household and (Number of Households Affected); Table XIII–6. Summary of the Total Annual National Costs of Compliance with the Proposed Arsenic Rule Across MCL Options; Table XIII–7. Estimates of the Annual Incremental Risk Reduction, Benefits, and Costs of Reducing Arsenic in Drinking Water; Table XIV–2. Average Annual Cost per CWS by Ownership; Table XIV–3. Average Compliance Costs per Household for CWSs Exceeding MCLs; and Table XIV–4. Average Compliance Costs per Household for CWSs Exceeding MCLs as a Percent of Median Household Income.

Consultants, Inc. and Malcolm Pirnie, Inc. under contract 68–C–C6–0039 with EPA OGWDW. April 1999.

US EPA. 2000a. ''Estimated Per Capita Water Ingestion in the United States: Based on Data Collected by the United States Department of Agriculture's (USDA) 1994–1996 Continuing Survey of Food Intakes by Individuals.'' Office of Water, Office of Standards and Technology. EPA–822–00–008. April 2000.

US EPA. 2000b. Proposed Arsenic in Drinking Water Rule: Regulatory Impact Analysis (RIA). Prepared by Abt Associates, Inc. under contract to EPA OGWDW. EPA 815–R–013. June 2000.

US EPA. 2000c. ''Arsenic Occurrence in Public Drinking Water Supplies.'' Public Comment Draft. Office of Water, Washington DC. EPA 815–D–00–001. May 2000.

US EPA. 2000d. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Proposed Rule. **Federal Register**. Vol. 65, No. 121, p. 38888. June 22, 2000.

Viscusi, W.K., W.A. Magat, and J. Huber. 1991. Pricing Environmental Health Risks: Survey Assessments of Risk-Risk and Risk-Dollar Trade-Offs for Chronic Bronchitis. ''Journal of Environmental Economics and Management.'' 21:32–51.

Wu, M.M., T.L. Kuo, Y.H. Hwant, and C.J. Chen. 1989. Dose-response relation between arsenic concentration in well water and mortality from cancers and vascular diseases. American Journal of Epidemiology. 130:1123–1132.

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Dated: October 13, 2000.

J. Charles Fox,

Assistant Administrator for Water.

[FR Doc. 00–27034 Filed 10–19–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1003, 1005 and 1008

RIN 0991–AB09

Medicare and State Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth several revisions and technical corrections to the OIG regulations. This rule proposes revisions or clarifications to the definition of the term ''item or service'', to the reinstatement procedures relating to exclusions resulting from a default on health education or scholarship obligations, and to the limitations period applicable to exclusions. In addition, this rule would make a number of minor technical corrections to the current regulations, and serves to clarify various issues and inadvertent errors appearing in the OIG's existing regulatory authorities in order to achieve greater clarity and consistency.

DATES: To assure consideration, public comments must be mailed and delivered to the address provided below by no later than 5 p.m. November 20, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Department of Health and Human Services, Office of Inspector General, Room 5246, Attention: OIG–62–P, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION: Consistent with existing regulatory authority, the OIG is proposing the following revisions to 42 CFR chapter V, many of which are technical in nature:

• *Limitations Period for Exclusions; § 1001.1 (Scope of Exclusions).*

The purpose of an OIG program exclusion is to protect Medicare, Medicaid and all other Federal health care programs from fraud and abuse, and to protect beneficiaries of those programs from untrustworthy providers. Questions have been raised as to whether a limitations period is applicable to the imposition of OIG program exclusions. The OIG frequently determines that conduct which occurred several years in the past does not warrant an exclusion (other than an exclusion that is mandated by statute). However, there is no statute of limitations specified for exclusions in the Social Security Act (the Act).[1] Moreover, program exclusions are remedial in nature,[2] and it is the OIG's position that if we determine that an exclusion is necessary to protect the programs and beneficiaries from untrustworthy individuals and entities, we are authorized to impose such an exclusion without being subject to a limitations period. To eliminate any confusion on this point, we are clarifying § 1001.1 to indicate that there is no time limitation on the imposition of a program exclusion.

Thus, for example, when a program exclusion imposed under section 1128(b)(7) of the Act is based on violations of another statute, such as the civil money penalty (CMP) statute (section 1128A of the Act), which has a 6 year statute of limitations, the program exclusion is not similarly time limited.

• *Amendment to § 1001.101(c) (Basis for Liability)*

In introductory paragraph (c) of § 1001.101, we propose to add the word ''financial'' before the word ''misconduct.'' This revision would be consistent with the statutory language set forth in section 1128(a)(3) of the Act which specifically uses the word ''financial'' to describe the felony under which the OIG will exclude an individual or entity. The revision to this paragraph is intended to mirror the statutory language.

• *Revisions to §§ 1001.102 and 1001.201 With Respect to Financial Loss and the Threshold Amount*

Currently, §§ 1001.102 and 1001.201 set forth an aggravating factor for lengthening the period of exclusion when an individual's conviction, or similar acts, resulted in financial loss of $1,500 or more. First, we are proposing to revise §§ 1001.102(b)(1) and 1001.201(b)(2)(i) to increase the financial loss considered to be an aggravating factor from $1,500 to $5,000. We believe that this revision would more properly reflect the current economics of health care fraud in the programs and would establish a more reasonable threshold amount as an aggravating factor to be considered as a basis for lengthening a period of exclusion.

In addition, we are proposing to clarify §§ 1001.102(b)(1) and 1001.201(b)(2)(i) to reflect as an aggravating factor both the actual and intended loss to the programs associated with this conduct. We believe that any loss—not just the actual, out-of-pocket loss—that is designed to cause harm to the programs should be taken into consideration. For example, in a situation where an individual intends to commit damage to the programs by filing false cost reports, but whose plans are detected and prevented from reaching fruition by an intermediary who intercepts the damage before it can occur, we believe the intended loss, and not just any actual loss, should also be taken in consideration as a valid measure of the individual's culpability. Accordingly, we would also clarify §§ 1001.102(b)(1) and 1001.201(b)(2)(i)

[1] See section 1128 of the Act; 42 U.S.C. 1320a–7.

[2] See *Manocchio* v. *Kusserow* (961 F.2d 1539 (11th Cir. 1992)), which held that exclusions are remedial.