

ICD-9 code	Cancer description
189 .....	Malignant neoplasm of kidney and other and unspecified urinary organs.
190 .....	Malignant neoplasm of eye.
191 .....	Malignant neoplasm of brain.
192 .....	Malignant neoplasm of other and unspecified parts of nervous system.
193 .....	Malignant neoplasm of thyroid gland.
194 .....	Malignant neoplasm of other endocrine glands and related structures.
195 .....	Malignant neoplasm of other and ill-defined sites.
196 .....	Secondary and unspecified malignant neoplasm of the lymph nodes.
197 .....	Secondary malignant neoplasm of the respiratory and digestive organs.
198 .....	Secondary malignant neoplasm of other tissue and organs.
199 .....	Malignant neoplasm without specification of site.
200 .....	Lymphosarcoma and reticulosarcoma.
201 .....	Hodgkin's disease.
202 .....	Other malignant neoplasms of lymphoid and histiocytic tissue.
203 .....	Multiple myeloma and other immunoproliferative neoplasms.
204 .....	Lymphoid leukemia.
205 .....	Myeloid leukemia.
206 .....	Monocytic leukemia.
207 .....	Other specified leukemia.
208 .....	Leukemia of unspecified cell type.

<sup>1</sup> The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91-1260, U.S. Government Printing Office, Washington, DC.

Dated: September 21, 2001.

**Tommy G. Thompson,**

Secretary, Department of Health and Human Services.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 82

RIN 0920-ZA00

#### Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Interim Final Rule With Request for Comments

**AGENCY:** Department of Health and Human Services.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** This rule implements select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA" or "Act"). The Act requires the promulgation of methods, in the form of regulations, for estimating the dose levels of ionizing radiation incurred by workers in the performance of duty for nuclear weapons production programs of the Department of Energy and its predecessor agencies. These "dose reconstruction" methods will be applied by the National Institute for Occupational Safety and Health, which is responsible for producing the radiation dose estimates that the U.S. Department of Labor will use in adjudicating certain cancer claims under the Act.

**DATES: Effective Date:** This interim final rule is effective October 5, 2001.

**Compliance Dates:** Affected parties are not required to comply with the information collection requirements in § 82.10 until the Department of Health and Human Services publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB) to these information collection requirements. Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

**Comments:** The Department invites written comments on the interim final rule from interested parties. Comments on the rule must be received by November 5, 2001. Comments on the collection of information requirements should be received by October 22, 2001.

**ADDRESSES:** Address written comments on the interim final rule to the NIOSH Docket Officer. Submit comments electronically by e-mail to NIOCINDOCKET@CDC.GOV. See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing. Alternatively, submit printed comments to the following address: NIOSH Docket Office, Robert A. Taft Laboratories; M/S C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Written comments on the collection of information requirements should be sent to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333.

**FOR FURTHER INFORMATION CONTACT:** Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational

Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone 513-841-4498 (this is not a toll-free number). Information requests may also be submitted by e-mail to OCAS@CDC.GOV.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Comments Invited**

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this rulemaking. Some generic topics for comment include the following questions:

(1) Does the interim rule make appropriate use of current science for conducting dose reconstructions to be used in an occupational illness compensation program?

(2) Does the interim rule appropriately balance the potential precision of dose reconstructions and the necessary efficiency of the dose reconstruction process?

(3) Does the interim rule implement an appropriate process for involving the claimant in the dose reconstruction?

Comments should identify the author(s), return address, and phone number, in case clarification is needed. Comments can be submitted by e-mail to: NIOCINDOCKET@CDC.GOV. If submitting comments by e-mail, they should be provided as a Microsoft Word or Word Perfect file attachment. Printed comments can be submitted to the NIOSH Docket Office at the address above. The Secretary will consider all communications received on or before the closing date for comments before taking action on the interim final rule. All comments submitted will be available for examination in the Rule Docket both before and after the closing date for comments. A report summarizing each substantive public contact with personnel involved in this rulemaking will be filed in the docket. An electronic docket containing all comments submitted by e-mail will be available over the Internet from the National Institute for Occupational Safety and Health (NIOSH) homepage at [www.cdc.gov/niosh](http://www.cdc.gov/niosh).

##### **II. Final Rule**

The Department of Health and Human Services ("HHS") expects to issue a final rule within six months of publication of this interim final rule. Upon publication of the final rule, dose reconstructions completed under this interim final rule will be reviewed and revised, as necessary, to conform with any substantive changes that might be included in the final rule.

### III. Background

#### A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA"), Public Law 106-398, 114 Stat. 1654, 1654A-1231 (October 30, 2000), was enacted as Title XXXVI of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001. EEOICPA established a compensation program to provide a lump sum payment of \$150,000 and medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy and certain of its vendors, contractors, and subcontractors. This law also provided for payment of compensation to certain survivors of covered employees.

EEOICPA instructed the President to designate one or more federal agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179, titled Providing Compensation to America's Nuclear Weapons Workers, which assigned primary responsibility for administering the compensation program to the Department of Labor ("DOL"). 65 FR 77487 (Dec. 7, 2000). DOL published an interim final rule governing DOL's administration of EEOICPA on May 25, 2001 (see 66 FR 28948).

The executive order directed HHS to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop methods to estimate radiation doses ("dose reconstruction") for certain individuals with cancer applying for benefits under the DOL program. These methods are the subject of this rule. HHS is also to apply these methods to conduct the program of dose reconstructions required by EEOICPA. This program will be delegated to the National Institute for Occupational Safety and Health ("NIOSH"), an institute of the Centers for Disease Control and Prevention.

(2) HHS is also to develop guidelines to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or atomic weapons facility. These guidelines are being published simultaneously with this interim final rule as a notice of proposed rulemaking under 42 CFR part 81 in this issue of the **Federal Register**.

(3) HHS is to staff the Advisory Board on Radiation and Worker Health and provide it with administrative and other necessary support services. The Board, a federal advisory committee, will advise HHS in implementing its roles under EEOICPA described here.

(4) Finally, HHS is to develop and apply procedures for considering petitions by classes of employees to be added to the *Special Exposure Cohort* established under EEOICPA. Employees included in the *Special Exposure Cohort* who have a specified cancer and meet other conditions, as defined by DOL regulations (66 FR 28948), qualify for compensation under EEOICPA. HHS procedures for considering *Special Exposure Cohort* petitions are under development. HHS expects to issue these procedures within the next six months.

As provided for under section 3625 of EEOICPA, HHS is implementing its responsibilities with the assistance of NIOSH.

#### B. What Legal Requirements Are Specified by EEOICPA for Dose Reconstruction?

Section 3623(d) of EEOICPA requires that HHS establish, by regulation, methods for arriving at reasonable estimates of the radiation doses incurred by covered employees seeking compensation for cancer, other than as members of the *Special Exposure Cohort* seeking compensation for a *specified cancer*. These methods will be applied to estimate radiation doses for the following covered employees seeking compensation for cancer under EEOICPA: (1) An employee who was not monitored for exposure to radiation at a DOE or Atomic Weapons Employer facility; (2) an employee who was monitored inadequately for exposure to radiation at such a facility; or (3) an employee whose records of exposure to radiation at such facility are missing or incomplete.

EEOICPA requires the Advisory Board on Radiation and Worker Health to independently review the methods established by this rule and to verify a reasonable sample of dose reconstructions established under these methods. The Advisory Board is a federal advisory committee established and appointed by the President to advise HHS on its major responsibilities under EEOICPA.

Sections 3623(e) and 3626(c) of EEOICPA require that DOE provide HHS with relevant information on worker radiation exposures necessary for dose reconstructions and require DOE to inform covered employees with cancer of the results of their dose

reconstructions. NIOSH, which will be conducting the dose reconstructions, will inform covered employees of the results of these dose reconstructions on behalf of DOE.

Subject to provisions of the Privacy Act (5 U.S.C. 552a), HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses, as required by Section 3623(e)(2) of EEOICPA.

Finally, HHS notes that EEOICPA does not authorize the establishment of new radiation protection standards through the promulgation of these methods, and these methods do not constitute such new standards.

#### C. What Is the Purpose of Dose Reconstruction?

Dose reconstructions are used to estimate the radiation doses to which individual workers or groups of workers have been exposed, particularly when radiation monitoring is unavailable, incomplete, or of poor quality. Originally dose reconstructions were conducted for research on the health effects of exposure to radiation. In recent decades, dose reconstruction has become an integral component of radiation illness compensation programs in the United States and internationally.

#### D. How Are Radiation Doses Reconstructed?

The procedures and level of effort involved in dose reconstructions depend in part on the quantity and quality of available dose monitoring information, the conditions under which radiation exposure arose, and the forms of radiation to which the individual was exposed. If individuals for whom dose estimates are needed were monitored using present day technology and received only external radiation doses, dose reconstruction could be very simple. It might only require summing the radiation doses recorded from radiation badges and adding estimated potential "missed" doses resulting from the limits of detection of monitoring badges.

Dose reconstruction can require extensive research and analysis. Such work is required if radiation doses were not monitored or there is uncertainty about the monitoring methods involved; if there was potential for internal doses through the ingestion, inhalation or absorption of radioactive materials; or if the processes and circumstances involved in the radiation exposures were complex. For the most complex dose reconstructions, research and analyses may include determining or

assuming specific characteristics of the monitoring procedures; identifying events or processes that were unmonitored; identifying the types and quantities of radioactive materials involved; evaluating production processes and safety procedures employed; identifying the locations and activities of exposed persons; identifying comparable exposure circumstances for which data is available to make assumptions; and conducting a variety of complex analyses to interpret the data compiled or estimated.

#### *E. How is Dose Reconstruction Conducted in a Compensation Program?*

An additional, critical factor affecting how doses are reconstructed is the amount of time available. For health research studies dose reconstructions may take from months to years to complete. In compensation programs, however, a balance must be struck between efficiency and precision. Section 3611 of EEOICPA specifically states that one of the purposes of the compensation program is to provide for "timely" compensation. As applied under EEOICPA, dose reconstruction must rely on information that can be developed on a timely basis and on carefully developed assumptions.

When conducting dose reconstruction for a compensation program, our primary concern will be to ensure the assumptions used to estimate doses are fair, consistent, and well grounded in the best available science. To address fairness, the Defense Threat Reduction Agency ("DTRA"), which conducts dose reconstructions for veterans and Department of Defense civilian personnel who participated in U.S. atmospheric nuclear testing and in the occupation forces of Hiroshima and Nagasaki, applies certain assumptions that err reasonably on the side of overestimating exposures (see 32 CFR part 218). These assumptions substitute for more detailed information that would be time-consuming and costly to develop. HHS will take an approach similar to that of DTRA by using reasonable, fair, and scientifically based assumptions as substitutes for additional research and analysis to achieve an efficient dose reconstruction process.

#### *F. How Will Dose Reconstruction Methods Under EEOICPA Differ From Dose Reconstruction for Veterans?*

The major differences for the HHS methods for dose reconstructions arise from characteristics that distinguish the radiation exposure experiences of nuclear weapons production workers

from those of veterans. Whereas veterans were primarily exposed to external sources of radiation over brief periods in acute doses, employees covered by EEOICPA frequently may have received both acute and chronic exposures to internal and external radiation over periods as long as three to four decades. Further, nuclear weapons production workers experienced more diverse exposures and circumstances of exposure, on an individual basis and as a group than did veterans. As a result, many HHS dose reconstructions will be more complex than those conducted by DTRA, making it necessary that HHS place a high premium on any efficiencies that can be achieved.

Addressing the need for efficiency, HHS is establishing a dose reconstruction process that limits the work performed in cases where it is evident the outcome of the compensation claim will be unaffected. HHS will rely on less detailed or precise estimates for claims for which compensation would clearly be due based on the more limited dose reconstruction, and for claims for which additional work clearly would not result in compensation. In the former case, if it is evident from limited dose reconstruction that the estimated cumulative dose is sufficient to qualify the claimant for compensation, no additional work will be performed. In the latter case, limited dose reconstructions will be conducted only for claims for which it is evident that further research and dose reconstruction is extremely unlikely to produce a compensable level of radiation dose, because the use of worst-case assumptions does not produce a compensable level of radiation dose. In these latter cases, the decisive factors that result in NIOSH deciding to limit the dose reconstruction process will be clearly set forth in the draft of the dose reconstruction results reported to the claimant under § 82.25, and in the dose reconstruction results reported to the claimant under § 82.26.

A second important aspect of the HHS dose reconstruction process is that it will involve interaction with the covered employee or survivor. NIOSH will use information provided by the claimant to evaluate the completeness and adequacy of dose information available, to locate additional exposure or dose-related information, and to estimate unmonitored doses.

#### *G. How Will HHS Incorporate Scientific Methods Established by the Radiation Safety Scientific Community in Internal Dose Estimation Under EEOICPA?*

The methods for calculating internal dose in this rule use current models published by the International Commission on Radiological Protection (ICRP). Specifically, NIOSH will use the new ICRP respiratory tract model for assessing doses due to inhalation of radioactive particles.<sup>1</sup> In addition, NIOSH will use the new biokinetic models for the radionuclides contained in publications 56,<sup>2</sup> 67<sup>3</sup> and 69<sup>4</sup> in place of those described in previous ICRP publications. These models provide the most widely accepted methods for mathematically describing the uptake, transport and retention of radionuclides in the body.

#### *H. What Elements Underlying the Dose Reconstruction Process Are Expected to Change With Scientific Progress?*

ICRP periodically updates the models used to evaluate internal doses, based on new research on the metabolic properties of radioactive materials (radionuclides). These ICRP updates reflect the current state of scientific knowledge on the uptake, transport, and retention of radionuclides in the human body.

In addition, technological advances in the areas of retrospective detection of radiation exposure or radiation exposure and dose biomarkers (detectable changes in human tissues and/or physiologic processes resulting from radiation exposure) may make it possible to add new analyses to the dose reconstruction process in the future.

As outlined below, NIOSH will address the need to update the scientific elements underlying dose reconstructions in a process that permits input from the public.

<sup>1</sup> International Commission on Radiological Protection (ICRP). 1994. Human Respiratory Model for Radiological Protection. ICRP Publication 66, Annals of the ICRP 24(1-4). Elsevier Scientific Ltd., Oxford.

<sup>2</sup> International Commission on Radiological Protection (ICRP). 1989. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 1. ICRP Publication 56, Annals of the ICRP 20(2). Pergamon Press, Oxford.

<sup>3</sup> International Commission on Radiological Protection (ICRP). 1993. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 2. ICRP Publication 67, Annals of the ICRP 23(2/3). Pergamon Press, Oxford.

<sup>4</sup> International Commission on Radiological Protection (ICRP). 1995. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 3: Ingestion Dose Coefficients. ICRP Publication 69, Annals of the ICRP 25(1). Elsevier Scientific Ltd., Oxford.

*I. How Will NIOSH Inform the Public of Any Plans to Change Scientific Elements Underlying the Dose Reconstruction Process to Maintain Methods Reasonably Current With Scientific Progress?*

Periodically, NIOSH will publish a notice in the **Federal Register** notifying the public of plans to change scientific elements underlying the dose reconstruction process under EEOICPA to reflect scientific progress. Notice will include a summary of the planned changes and the expected completion date for such changes.

*J. How Can the Public Recommend Changes to Scientific Elements Underlying the Dose Reconstruction Process, as Scientific Progress Makes Substantive Improvements in Methods Possible?*

At any time, the public can submit written recommendations to NIOSH for changes to scientific elements underlying the dose reconstruction process, based on relevant new research findings and technological advances. Recommendations will be provided to the Advisory Board on Radiation and Worker Health and may be addressed at a public meeting of the Advisory Board, with notification provided to the source of the recommendations. Recommendations should be addressed to: Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, Ohio 45226.

The public can also submit recommendations by e-mail. Instructions will be provided on the NIOSH Internet homepage at [www.cdc.gov/niosh](http://www.cdc.gov/niosh).

*K. How Will NIOSH Make Changes in Scientific Elements Underlying the Dose Reconstruction Process, Based on Scientific Progress?*

Proposed changes will be presented to the Advisory Board on Radiation and Worker Health prior to implementation. These proposed changes will be summarized in the notice of the board meeting published in the **Federal Register**. The public will have the opportunity to comment on proposed changes at the meeting of the Advisory Board and/or in written comments submitted for this purpose. NIOSH will fully consider the comments of the Advisory Board and of the public before deciding upon any changes.

*L. How Will NIOSH Inform the Public of Changes to the Scientific Elements Underlying the Dose Reconstruction Process?*

NIOSH will publish a notice in the **Federal Register** informing the public of changes and the rationale for the changes. This notice will also provide a summary of the recommendations and comments received from the Advisory Board and the public, as well as responses to the comments.

#### **IV. History of Rule Development**

*A. What Experience Does HHS Have in Dose Reconstruction?*

NIOSH, an Institute of the Centers for Disease Control and Prevention, has conducted a program of federally sponsored health research on DOE employees since 1991. Dose reconstructions are an integral element of this research. In fact, NIOSH will draw substantially on records it has developed through its research on DOE employees in conducting the program of dose reconstructions under EEOICPA.

*B. Did HHS Consult With Outside Experts and Interested Parties During the Development of This Notice of Proposed Rulemaking?*

HHS consulted individually with a wide variety of experts and interested parties to help ensure the quality and practicality of these methods. Reports on these consultations are available in the regulatory docket for public review. While these consultations provided less opportunity for initial public input than generally desired for rulemaking, they served the purpose of ensuring that this interim final rule was developed with reasonable information on the points of view of individual experts and members of public directly affected by the rule. HHS will fully consider comments from the public and from the Advisory Board on Radiation and Worker Health in producing a final rule.

#### **V. Summary of the Interim Rule**

Congress, in enacting EEOICPA, created a new Energy Employees Occupational Illness Compensation Program to ensure an efficient, uniform, and adequate compensation system for certain employees. Under Executive Order 13179, the President assigned primary responsibility for administering the program to DOL. The President assigned various technical responsibilities for policymaking and assistance to HHS. Included among these is promulgation of this rule to establish methods NIOSH will apply to conduct dose reconstructions for covered employees seeking

compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. NIOSH dose reconstructions will be used by DOL to estimate the probability that the cancers of these covered employees were related to radiation exposures at covered facilities.

#### *Introduction*

Sections 82.0 and 82.1 briefly describe how these regulations relate to DOL authorities under EEOICPA and the assignment of authority for these regulations to HHS. In § 82.2, HHS provides a general introduction to dose reconstruction and describes the hierarchy of information to be relied upon for dose reconstructions. This hierarchy gives preference to individual radiation monitoring data, if complete and adequate, and provides for use of information on the workplace environment and radiation exposures for interpretation and as a secondary source of data, and provides for use of reasonable and scientific assumptions in lieu of certain data when the workplace environment cannot be fully characterized. HHS believes this approach would give due weight to the potentially most precise data, but would take into account the limitations of such data and its availability.

Section 82.3 summarizes the specific provisions of EEOICPA directing HHS in the development of this regulation and NIOSH in the conduct of dose reconstructions under this regulation. Section 82.4 describes how DOL will use the results of NIOSH dose reconstructions for the adjudication of claims.

#### *Definitions*

Section 82.5 defines the principal terms used in this part. It includes terms specifically defined in EEOICPA that, for the convenience of the reader of this part, are repeated in this section. It clarifies the definition of radiation. Section 3621(16) of EEOICPA defines radiation as ionizing radiation in the form of alpha or beta particles, neutrons, gamma rays, or accelerated ions or subatomic particles from accelerator machines. The rule elaborates upon this definition, specifically including x rays, protons and other particles capable of producing ions in the body, which are components of ionizing radiation exposures experienced by nuclear weapons production workers. In addition, for clarity the definition in this rule explicitly excludes non-ionizing forms of radiation, such as radio-frequency radiation and microwaves.

### *Dose Reconstruction Process*

Section 82.10 provides an overview of the major elements of the dose reconstruction process that NIOSH will implement under EEOICPA. It describes the steps in the process, the sources and types of information that will be collected and analyzed, the role of the claimants in developing a factual basis for dose reconstruction, the types of analyses, and criteria that will direct NIOSH to ensure dose reconstructions produce reasonable dose estimates and serve claimants efficiently.

NIOSH will obtain available monitoring data and information on the workplace environment and practices from DOE and other sources. NIOSH will interview the claimant to obtain information and to report to the claimant on dose reconstruction results and the methods and data used to produce the results. NIOSH will take measures to produce results as efficiently as possible, so that adjudication of the claim by DOL can be resumed and completed in a timely fashion. These measures include limiting the dose reconstruction process to use less detailed or precise estimates for claims for which it is evident that further research and analysis will not affect the outcome of the claim.

For example, under these proposed regulations, if it is evident from the record of external radiation dose alone that an employee incurred a sufficiently high level of dose to have the claim accepted by DOL for compensation (a dose that would result in a probability of causation of 50% or higher), NIOSH would conclude the process without continuing with time consuming research and analysis to estimate internal dose. Instead, NIOSH would immediately report the limited dose estimate, based on external dose only, to the claimant and DOL, along with an explanation of the reason for limiting the dose reconstruction process.

Similarly, if, for example, records and information establish that an employee incurred radiation doses evidently below a level that could result in compensation, NIOSH would substitute worst-case assumptions for additional research and analysis, to complete and report on the dose reconstruction without delay.

This approach will provide more timely compensation for claims for which it is evident the claimant will qualify for compensation, and more timely results and adjudication for claims for which it is evident further research and analysis is extremely unlikely to produce a compensable level of radiation dose. The Department seeks

public comment on all aspects of this process.

Section 82.11 defines the subset of claimants under EEOICPA for whom NIOSH will conduct dose reconstructions. NIOSH will attempt to conduct dose reconstructions for all claims forwarded to NIOSH from DOL. This includes all covered employees seeking compensation for cancer, other than as members of the *Special Exposure Cohort* seeking compensation for a specified cancer, as determined by DOL.

Section 82.12 describes NIOSH procedures for notifying any claimants for whom a dose reconstruction cannot be completed because of insufficient information to reasonably estimate the dose potentially incurred by the covered employee. NIOSH will notify the claimant and DOL that a dose reconstruction cannot be completed and describe the basis for this finding. In these cases, the claimant would have the opportunity to seek administrative review of this result after DOL produces a recommended decision to deny the claim, based on the report from NIOSH that there is insufficient evidence to complete a dose reconstruction. For a claim in which the employee has a specified cancer, the claimant might still be eligible for compensation under EEOICPA. Classes of covered employees have the option to petition HHS to be added to the Special Exposure Cohort. HHS will establish procedures to consider such petitions, as required under section 3626 of EEOICPA and § 2(b) of E.O. 13179. HHS expects to establish the procedures within six months of publication of this rule.

Sections 82.13 and 82.14 describe in detail the sources and examples of the types of information NIOSH will use in dose reconstructions. DOE and claimants will be the primary sources of information. Information types include: Subject and employment information, worker monitoring data, monitoring program data, workplace monitoring data, workplace characterization data, and process descriptions for each work location. The actual use of this wide range of information will be determined for each claim individually, based on the types of information available and necessary.

Sections 82.15–82.17 describe how NIOSH will evaluate the completeness and adequacy of monitoring data and how NIOSH would remedy limitations, applying the general approach described in § 82.2 and making use of the data sources and types described in §§ 82.13 and 82.14. NIOSH will evaluate the completeness and adequacy of monitoring data by various means, such

as evaluating associated information on the workplace environment and practices, evaluating the monitoring technology, and evaluating other sources of information. NIOSH will remedy data limitations using established dose reconstruction practices, such as interpolating from recorded doses to estimate unrecorded doses, and substituting monitoring data from comparably exposed workers. HHS seeks public comments suggesting alternative approaches that NIOSH should consider.

Sections 82.18–82.19 describe how NIOSH will address salient technical issues of calculating internal dose and taking into account uncertainty with respect to dose information. Internal dose is the radiation dose received by radioactive materials taken into the body, such as by inhalation or ingestion. It is important because it accumulates year after year, increasing the risk of certain cancers over time. NIOSH will use current ICRP models for calculating internal dose, and will accompany dose estimates with uncertainty distributions. DOL will use these distributions with appropriate statistical methods to take into account uncertainty about the dose when calculating probability of causation for a claim.

### *Reporting and Review of Dose Reconstruction Results*

Sections 82.25 and 82.26 describe in detail NIOSH procedures for reporting the results of dose reconstructions to claimants and DOL, specifying the timing, content, and form of the dose reconstruction reports.

Section 82.27 describes how and when claimants can obtain reviews of NIOSH dose reconstructions. NIOSH will review dose reconstructions upon request by DOL under DOL procedures for claimants seeking review of dose reconstructions. These procedures also allow for DOL to request reviews of dose reconstruction upon its own initiative; for example, to request review of previously completed dose reconstructions to reflect updated scientific methods.

## **VI. Regulatory Procedures**

The Department of Health and Human Services (HHS) follows the Administrative Procedure Act (“APA”) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. In most circumstances, the APA requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule having the effect of law. However, the APA provides for exceptions to its notice and

comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In the case of this interim final rule, HHS has determined that under 5 U.S.C. 553(b)(B), good cause exists for waiving the notice and comment procedures. For these same reasons, HHS has also determined good cause exists under 5 U.S.C. 553(d)(3) for these interim rules to become effective immediately.

A number of courts have considered the circumstances under which an agency can conclude that good cause exists for issuing regulations without prior notice and comment. In *American Transfer & Storage Co., et al v. Interstate Commerce Commission*, 719 F.2d 1283, 1295 (5th Cir. 1983), the Fifth Circuit described the impracticability test as requiring "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." Similarly, the Seventh Circuit noted that the "legislative history of the impracticability standard reveals that Congress intended this exemption to operate when the regular course of rulemaking procedure would interfere with the agency's ability to perform its functions with the time constraints imposed by Congress." *United States Steel Corporation v. United States Environmental Protection Agency*, 605 F.2d 283, 287 (7th Cir. 1979). Courts have also recognized that while strict deadlines alone do not justify dispensing with notice and comment, "deviation from APA requirements has been permitted where congressional deadlines are very tight and the statute is particularly complicated." *Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1236 (D.C. Cir. 1994).

Precisely such an "analysis in practical terms" demonstrates that in this case, as with respect to changes in the Aid to Families with Dependent Children program at issue in *Philadelphia Citizens in Action v. Schweiker*, 669 F.2d 887, 894 (3rd Cir. 1982), "Congress, by setting an effective date so close to the date of enactment, expressed its belief that implementation \* \* \* was urgent." Legislation enacting EEOICPA was signed by the President on October 30, 2000, and responsibility for implementing EEOICPA was assigned to specific agencies by Executive Order on December 7, 2000. In sections 3628 and 3629 of EEOICPA, however, Congress authorized the Secretary of Labor to begin providing compensation to qualified claimants on July 31 2001. To ensure qualified

claimants who have cancer or survive employees who had cancer caused by exposure to radiation in their employment by DOE or its contractors or subcontractors receive the compensation to which they are entitled as soon as possible after July 31, 2001, HHS has determined it is necessary to implement the dose reconstruction methods set forth here on an interim final basis.

Under Executive Order 13179, the President assigned HHS three primary responsibilities in assisting the Department of Labor to make determinations on claims for cancer. First, HHS must promulgate methods for estimating the radiation doses incurred in the performance of duty by covered employees who submit claims or are the subject of claims submitted by their survivors. Second, pursuant to the methods established by this interim final regulation, HHS must perform individual dose reconstructions to determine the radiation dose incurred by each covered employee for whom a claim is made. Third, HHS must promulgate guidelines for DOL to use in determining whether the cancers presented by the employees were "as least as likely as not" caused by the radiation doses they incurred. HHS is publishing these probability of causation guidelines simultaneously with this interim final rule as a notice of proposed rulemaking (NPRM) in this issue of the **Federal Register**.

Completion of HHS work on dose reconstructions is a prerequisite for DOL to begin using the HHS probability of causation guidelines to make individual determinations. HHS has determined to publish the methods for dose reconstruction as an interim final rule so that HHS can initiate the lengthy process of dose reconstructions for individual claimants. HHS must identify and gather relevant records, evaluate their adequacy, and interact with the claimant in completing each dose reconstruction. By publishing the dose reconstruction methods as an interim final rule, HHS will be able to complete dose reconstruction work to allow DOL to complete the adjudication of claims as soon as possible after the HHS probability of causation guidelines are published as final rules.

If HHS were to issue an NPRM proposing dose reconstruction methods, HHS would be delayed in processing dose reconstructions for individual claimants by at least 150 days, until a final regulation could be issued.

HHS believes good cause exists to waive the notice and comment procedures under the APA for the promulgation of these interim final

rules. There is a strong public interest in the expeditious adjudication of claims that these workers, who served in this nation's nuclear weapons programs, were harmed in the performance of their duties. This public interest is clearly reflected in the mandate given by Congress to swiftly initiate this program. Moreover, qualified claimants should be given the opportunity to obtain their benefits, including medical benefits, as soon as possible. This is especially material given that many of the covered workers eligible to make claims under this Act are elderly and ill. An undue delay in the processing of their claims would result in real harm to these claimants.

With the publication of this interim final rule, HHS can begin the labor intensive process of reconstructing the radiation doses of employees covered by these claims. Once the probability of causation guidelines are finalized, DOL will be able to expeditiously adjudicate cancer claims requiring dose reconstructions.

Although HHS is adopting these dose reconstruction rules on an interim final basis, it requests public comment on this rule. After full consideration of public comments, HHS will publish a final rule with any necessary changes. HHS expects to issue a final rule within six months of the publication of this interim final rule, at the same time as it expects to issue final guidelines regarding the probability of causation. Since dose reconstructions completed under the interim final rule cannot be used to finally adjudicate claims until those guidelines are issued in final form, HHS will be able to review and revise dose reconstructions completed under this interim final rule, as necessary, to conform with any substantive changes that might be included in the final dose reconstruction rule before any final action is taken on a particular claim. By issuing the dose reconstruction regulation as an interim final regulation, however, substantial time can be saved and many more claims can be timely adjudicated, based on the final regulation and guidelines, enabling covered employees or their survivors to receive benefits to which they may be entitled as expeditiously as possible.

## VII. Significant Regulatory Action (Executive Order 12866)

This rule is being treated as a "significant regulatory action" within the meaning of Executive Order (E.O.) 12866 because it raises novel or legal policy issues arising out of the legal mandate established by EEOICPA. The rule is designed to establish practical

methods, grounded in current science, to fairly and efficiently assist claimants and support DOL in the adjudication of applicable claims seeking compensation for cancer under EEOICPA. NIOSH will apply the methods to produce reasonable, scientifically supported estimates of the radiation doses incurred by covered employees subject to the claims, as permitted by available data and information. The financial cost to the federal government of producing these estimates is expected to be several thousand dollars per claim, on average.

The rule carefully explains the manner in which the regulatory action is consistent with the mandate for this action under § 3623(d) of EEOICPA and implements the detailed requirements concerning this action under this section of EEOICPA. The rule does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in section 3(f)(1) of the Executive Order 12866. It has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR parts 1 and 30. DOL has determined that its rule fulfills the requirements of Executive Order 12866 and provides estimates of the aggregate cost of benefits and administrative expenses of implementing EEOICPA under its rule (see FR 28948, May 25, 2001). OMB has reviewed this rule for consistency with the President's priorities and the principles set forth in E.O. 12866.

#### VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. This rule affects only DOL, DOE, HHS, and some individuals filing compensation claims under EEOICPA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

#### IX. What Are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under This Rule, and How Are Comments Submitted?

Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The Paperwork Reduction Act is applicable to the data collection aspects of this rule.

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of projects. To request more information on this project or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer at (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

NIOSH is requesting an emergency clearance from the Office of Management and Budget (OMB) to collect data under EEOICPA. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 14 days of this notice. OMB is expected to act on the request of HHS within 21 days of publication of this notice.

In performance of its dose reconstruction responsibilities under

the Act, NIOSH will interview claimants individually and provide them with the opportunity, through a structured interview, to assist NIOSH in documenting the work history of the employee (characterizing the actual work tasks performed), identifying incidents that may have resulted in undocumented radiation exposures, characterizing radiation protection and monitoring practices, and identifying co-workers, radiation protection management and staff, line managers, and other witnesses, if NIOSH determines this is necessary, to confirm undocumented information. In this process, NIOSH will use a computer assisted telephone interview (CATI) system, which will allow interviews to be conducted more efficiently and quickly than would be the case with a paper-based interview instrument.

NIOSH will use the data collected in this process to complete an individual dose reconstruction that accounts for radiation dose, including unmonitored or inadequately monitored dose, incurred by the employee in the performance of duty for DOE nuclear weapons production programs. After dose reconstruction, NIOSH will provide a draft of the dose reconstruction report to the claimant and perform a brief follow-up interview with the claimant to explain the results and to allow the claimant to confirm or question the record NIOSH has compiled. This will also be the final opportunity for the claimant to supplement the dose reconstruction record.

At the conclusion of the dose reconstruction process, the claimant will be requested to submit to NIOSH a form (OCAS-1) to confirm that the claimant has completed providing information to NIOSH for the dose reconstruction. The form will notify the claimant that signing the form allows NIOSH to provide a final dose reconstruction report to DOL and closes the record on data to be used for the dose reconstruction. DOL will use data from the dose reconstruction report to determine the probability that the cancer(s) of the covered employee may have been caused by radiation doses incurred in the performance of duty at a DOE or AWE facility.

There will be no cost to respondents for this data collection. This is a new data collection. The estimated burden of this data collection is described in the table below.

Respondents	Number of respondents	Number of responses	Avg. burden per response (hrs.)	Total hours
Initial interview .....	22,500	1	60/60	22,500
Conclusion form .....	22,500	1	5/60	1,875
Total .....				24,375

### X. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report to Congress promulgation of this rule prior to its effective date. The report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more. However, this rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR parts 1 and 30. DOL has determined that its rule is a "major rule" because it will likely result in an annual effect on the economy of \$100 million or more.

### XI. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector, "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$ 100 million by State, local or tribal governments in the aggregate, or by the private sector.

### XII. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the Federal court system. Dose reconstruction may be an element in reviews of DOL adverse decisions in the United States District Courts pursuant to the Administrative Procedure Act. However, DOL has attempted to minimize that burden by providing claimants an opportunity to seek administrative review of adverse decisions, including those involving dose reconstruction. This rule provides a clear legal standard for HHS and DOL

to apply regarding dose reconstruction. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

### XIII. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

### XIV. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. The agency has determined that the rule will not affect children.

### XV. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that this rule is not likely to have a significant adverse effect on them.

### List of Subjects in 42 CFR Part 82

Cancer, Dose reconstruction, Government employees, Occupational safety and health, Nuclear materials, Radiation protection, Radioactive materials, Workers' compensation.

### Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR to add Part 82 to read as follows:

### PART 82—METHODS FOR CONDUCTING DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

#### Subpart A—Introduction

Sec.

- 82.0 Background Information on this Rule.  
 82.1 What is the purpose of this rule?  
 82.2 What are the basics of dose reconstruction?  
 82.3 What are the requirements for dose reconstruction under EEOICPA?  
 82.4 How will DOL use the results of the NIOSH dose reconstructions?

#### Subpart B—Definitions

- 82.5 Definition of Terms Used in this Rule.

#### Subpart C—Dose Reconstruction Process

- 82.10 Overview of the Dose Reconstruction Process.  
 82.11 For which claims under EEOICPA will NIOSH conduct a dose reconstruction?  
 82.12 Will it be possible to conduct dose reconstructions for all claims?  
 82.13 What sources of information may be used for dose reconstructions?  
 82.14 What types of information could be used in dose reconstructions?  
 82.15 How will NIOSH evaluate the completeness and adequacy of individual monitoring data?  
 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?  
 82.17 What types of information could be used to supplement or substitute for individual monitoring data?  
 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?  
 82.19 How will NIOSH address uncertainty about dose levels?

#### Subpart D—Reporting and Review of Dose Reconstruction Results

- 82.25 When will NIOSH report dose reconstruction results, and to whom?  
 82.26 How will NIOSH report dose reconstruction results?  
 82.27 How can claimants obtain reviews of their dose reconstruction results by NIOSH?  
 82.28 Who can review NIOSH dose reconstruction files on individual claimants?

**Authority:** 42 U.S.C. 7384n; E.O. 13179, 65 FR 77487.

## Subpart A—Introduction

### § 82.0 Background Information on this Rule.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), Public Law 106–398, provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under (a) of this section.

(a) One category is employees with cancer for whom a dose reconstruction must be conducted, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 and 30.213 that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 3626 of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

### § 82.1 What is the purpose of this rule?

The purpose of this rule is to provide methods for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction. These methods will be applied by the National Institute for Occupational Safety and Health (NIOSH) in a dose reconstruction program serving claimants under EEOICPA, as identified under § 82.0.

### § 82.2 What are the basics of dose reconstruction?

The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer

occurring among the workers. A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure conditions and the type, quality, and completeness of data available to characterize the environment.

(a) If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure. These monitoring data are interpreted using additional data characterizing the workplace radiation exposures. If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer.

(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.

(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model. For internal exposures, this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion.

### § 82.3 What are the requirements for dose reconstruction under EEOICPA?

(a) Dose reconstructions are to be conducted for the following covered employees with cancer seeking compensation under EEOICPA: An employee who was not monitored for exposure to radiation at Department of Energy (DOE) or Atomic Weapons Employer (AWE) facilities; an employee who was monitored inadequately for exposure to radiation at such facilities;

or an employee whose records of exposure to radiation at such facility are missing or incomplete. Technical limitations of radiation monitoring technology and procedures will require HHS to evaluate each employee's recorded dose. In most, if not all cases, monitoring limitations will result in possibly undetected or unrecorded doses, which are estimated using commonly practiced dose reconstruction methods and would have to be added to the dose record.

(b) Section 3623(e) of EEOICPA requires the reporting of radiation dose information resulting from dose reconstructions to the covered employees for whom claims are being adjudicated. DOE is specifically charged with this responsibility but the Department of Health and Human Services (HHS), which will be producing the dose reconstruction information, will implement this reporting responsibility on behalf of DOE. HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses, as required by EEOICPA.

### § 82.4 How will DOL use the results of the NIOSH dose reconstructions?

Under 42 CFR part 81, DOL will apply dose reconstruction results together with information on cancer diagnosis and other personal information provided to DOL by the claimant to calculate an estimated probability of causation. This estimate is the probability that the cancer of the covered employee was caused by radiation exposure at a covered facility of DOE or an Atomic Weapons Employer (AWE).

## Subpart B—Definitions

### § 82.5 Definition of Terms Used in this Rule.

(a) *Atomic weapons employer (AWE)* means any entity, other than the United States, that:

(1) Processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and,

(2) Is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(b) *Bioassay* means the determination of the kinds, quantities, or concentrations, and in some cases, locations of radioactive material in the human body, whether by direct measurement or by analysis, and

evaluation of radioactive material excreted or eliminated by the body.

(c) *Claimant* means the individual who has filed with the Department of Labor for compensation under EEOICPA.

(d) *Covered employee* means, for the purposes of this rule, an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(e) *Covered facility* means any building, structure, or premises, including the grounds upon which such building, structure, or premise is located:

(1) In which operations are, or have been, conducted by, or on behalf of, the DOE (except for buildings, structures, premises, grounds, or operations covered by Executive Order 12344, dated February 1, 1982, pertaining to the Naval Nuclear Propulsion Program); and

(2) With regard to which the DOE has or had:

(i) A proprietary interest; or,

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services; or

(3) A facility owned by an entity designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA that is or was used to process or produce, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining or milling.

(f) *DOE*: The U.S. Department of Energy, includes predecessor agencies of DOE, including the Manhattan Engineering District.

(g) *DOL*: The U.S. Department of Labor.

(h) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, Public Law 106-398, as amended.

(i) *Equivalent dose* is the absorbed dose in a tissue multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(j) *External dose* means that portion of the equivalent dose that is received from radiation sources outside of the body.

(k) *Internal dose* means that portion of the equivalent dose that is received from radioactive materials taken into the body.

(l) *NIOSH*: the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S.

Department of Health and Human Services.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) resulting in tumors at other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure. This concept is further explained under 42 CFR part 81, which provides guidelines by which DOL will determine probability of causation under EEOICPA.

(o) *Radiation* means ionizing radiation, including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body. For purposes of this rule, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(p) *Specified cancer* is a term defined in section 3621(17) of EEOICPA and 20 CFR part 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis), and bone. Pursuant to section 2403 of Public Law 107-20, this definition will include renal cancer.

(q) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(r) *Worst-case assumption* is a term used to describe a type of assumption used in certain instances for certain dose reconstructions conducted under this rule. It assigns the highest reasonably possible value, based on reliable science, documented experience, and relevant data, to a radiation dose of a covered employee.

## Subpart C—Dose Reconstruction Process

### § 82.10 Overview of the Dose Reconstruction Process.

(a) Upon receipt of a claims package from the Department of Labor, as provided under 20 CFR part 30, NIOSH will request from the Department of Energy (DOE) records on radiation dose monitoring and radiation exposures associated with the employment history of the covered employee. Additionally, NIOSH may compile data, and information from NIOSH records that may contribute to the dose reconstruction. For each dose reconstruction, NIOSH will include records relevant to internal and external exposures to ionizing radiation, including exposures from medical screening x rays that were required as a condition of employment.

(b) NIOSH will evaluate the initial radiation exposure record compiled to: Reconcile the exposure record with the reported employment history, as necessary; complete preliminary calculations of dose, based upon this initial record, and prepare to consult with the claimant. Any discrepancies in the employment history information will be reconciled with the assistance of DOE, as necessary.

(c) NIOSH will interview the claimant. The purpose of the interview is to:

(1) Explain the dose reconstruction process;

(2) Confirm elements of the employment history transmitted to NIOSH by DOL;

(3) Identify any relevant information on employment history that may have been omitted;

(4) Confirm or supplement monitoring information included in the initial radiation exposure record;

(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary;

(6) Identify co-workers and other witnesses with information relevant to the radiation exposures of the covered worker to supplement or confirm information on work experiences, as necessary.

(d) NIOSH will provide a report to the claimant summarizing the findings of the interview, titled: "NIOSH Claimant Interview under EEOICPA." The report will also notify the claimant of the opportunity to contact NIOSH if necessary, by a specified date, to make any written corrections or additions to

information provided by the claimant during the interview process.

(e) Information provided by the claimant will be accepted and used for dose reconstruction, providing it is reasonable, supported by substantial evidence, and is not refuted by other evidence. In assessing whether the information provided by the claimant is supported by substantial evidence, NIOSH will consider:

(1) Consistency of the information with other information in the possession of NIOSH, from radiation safety programs, research, medical screening programs, labor union documents, worksite investigations, dose reconstructions conducted by NIOSH under EEOICPA, or other reports relating to the circumstances at issue;

(2) Consistency of the information with medical records provided by the claimant;

(3) Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant; and,

(4) Confirmation of information by co-workers or other witnesses.

(f) NIOSH will seek to confirm information provided by the claimant through review of available records and records requested from DOE.

(g) As necessary, NIOSH will request additional records from DOE to characterize processes and tasks potentially involving radiation exposure for which dose and exposure monitoring data is incomplete or insufficient for dose reconstruction.

(h) NIOSH will review the adequacy of monitoring data and completeness of records provided by DOE. NIOSH will request certification from DOE that record searches requested by NIOSH have been completed.

(i) As necessary, NIOSH will characterize the internal and external exposure environments for parameters known to influence the dose. For internal exposures, examples of these parameters include the mode of intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type. When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science. For external exposures, the radiation type (gamma, x-ray, neutron, beta, or other charged particle) and radiation energy spectrum will be evaluated. When possible, the effect of non-uniformity and geometry of the radiation exposure will be assessed.

(j) For individual monitoring records that are incomplete, doses may be

imputed using techniques discussed in § 82.16. Once the resulting data set has been evaluated and validated, an occupational exposure matrix will be constructed, using the general hierarchical approach discussed in § 82.2. This matrix will contain the estimated annual equivalent dose(s) to the relevant organ(s) or tissue(s), for the period from the initial date of potential exposure at a covered facility until the date the cancer was diagnosed. The equivalent dose(s) will be calculated using the current, standard radiation weighting factors from the International Commission on Radiological Protection (ICRP, Publication 60),<sup>1</sup> indicated in Table 1.

TABLE 1.—RADIATION WEIGHTING FACTORS

Radiation type and energy range	Radiation weighting factor, $w_R$
Photons, all energies .....	1
Electrons and muons, all energies .....	1
Neutrons, energy <10 keV .....	5
10 keV to 100 keV .....	10
>100 keV to 2 MeV .....	20
>2 MeV to 20 MeV .....	10
>20 MeV .....	5
Protons, other than recoil protons, energy >2 MeV .....	5
Alpha particles, fission fragments and heavy nuclei .....	20

(k)(1) At any point during steps in paragraphs (f)–(j) of this section of dose reconstruction, NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met:

(i) From acquired experience, it is evident the estimated cumulative dose is sufficient to qualify the claimant for compensation (i.e., the dose produces a probability of causation of 50% or greater);

(ii) Dose is determined using worst-case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,

(iii) Research and analysis indicated under steps in paragraphs (f)–(j) of this section have been completed.

(2) Worst-case assumptions will be employed under condition in paragraph (k)(1)(ii) of this section to limit further research and analysis only for claims for which it is evident that further research and analysis will be extremely unlikely

<sup>1</sup> International Commission on Radiological Protection (ICRP) 60: "1990 Recommendations of the International Commission on Radiological Protection." Ann. ICRP 21(1–3): 6.

to produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because even using worst-case assumptions it cannot be determined that the employee may have incurred a compensable level of radiation dose. For all claims in which worst-case assumptions are employed under condition in paragraph (k)(1)(ii) of this section, the reasoning that resulted in the determination to limit further research and analysis will be clearly described in the draft of the dose reconstruction results reported to the claimant under § 82.25 and in the dose reconstruction results reported to the claimant under § 82.26.

(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant to review the dose reconstruction results and the basis upon which the results were calculated. This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction.

(m) Subject to any additional information provided by the claimant under § 82.10(l), the claimant is required to return form OCAS–1 to NIOSH, certifying that the claimant has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form and completion of any changes in the dose reconstruction resulting from new information provided under § 82.10(l), NIOSH will forward a final dose reconstruction report to DOL and to the claimant.

(n) NIOSH will not forward the dose reconstruction report to DOL for adjudication without receipt of form OCAS–1 signed by the claimant or a representative of the claimant authorized pursuant to 20 CFR 30.600. If the claimant or the authorized representative of the claimant fails to sign and return form OCAS–1 within 60 days, after notifying the claimant or the authorized representative, NIOSH may administratively close the dose reconstruction and notify DOL of this action. Upon receiving this notification by NIOSH, DOL may administratively close the claim.

(o) Once actions under § 82.10(m) are completed, the record for dose reconstruction shall be closed unless reopened at the request of DOL under 20 CFR part 30.

**§ 82.11 For which claims under EEOICPA will NIOSH conduct a dose reconstruction?**

NIOSH will conduct a dose reconstruction for each claim determined by DOL to be a claim for a covered employee with cancer under DOL regulations at 20 CFR 30.210(b), subject to the limitation and exception noted in § 82.12. Claims for covered employees who are members of the Special Exposure Cohort seeking compensation for a specified cancer, as determined by DOL under 20 CFR 30.210(a), do not require and will not receive a dose reconstruction under this rule.

**§ 82.12 Will it be possible to conduct dose reconstructions for all claims?**

It is uncertain whether adequate information of the types outlined under § 82.14 will be available to complete a dose reconstruction for every claim eligible under § 82.11.

(a) NIOSH will notify in writing any claimants for whom a dose reconstruction cannot be completed once that determination is made, as well as in the closing interview provided for under § 82.10(l).

(b) Notification will describe the basis for finding a dose reconstruction cannot be completed, including the following:

(1) A summary of the information obtained from DOE and other sources; and,

(2) A summary of necessary information found to be unavailable from DOE and other sources.

(c) NIOSH will notify DOL when it is unable to complete a dose reconstruction for the claimant. This will result in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH under this rule.

(d) A claimant for whom a dose reconstruction cannot be completed, as indicated under this section, may have recourse to seek compensation under provisions of the Special Exposure Cohort (see 20 CFR part 30). Pursuant to section 3626 of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

**§ 82.13 What sources of information may be used for dose reconstructions?**

NIOSH will use the following sources of information for dose reconstructions, as necessary:

(a) DOE and its contractors, including Atomic Weapons Employers and the former worker medical screening program;

(b) NIOSH and other records from health research on DOE worker populations;

(c) Interviews and records provided by claimants;

(d) Co-workers of covered employees, or other witnesses with information relevant to the covered employee's exposure, that the claimant identified during the initial interview with NIOSH;

(e) Labor union records from unions representing employees at covered facilities of DOE or AWEs; and,

(f) Any other relevant information.

**§ 82.14 What types of information could be used in dose reconstructions?**

NIOSH will obtain the types of information described in this section for dose reconstructions, as necessary and available:

(a) *Subject and employment information*, including:

(1) Gender;

(2) Date of birth; and,

(3) DOE and/or AWE employment history, including: job title held by year, and work location(s): Including site name(s), building number(s), technical area(s), and duration of relevant employment or tasks.

(b) *Worker monitoring data*, including:

(1) External dosimetry data, including external dosimeter readings (film badge, TLD, neutron dosimeters); and,

(2) Pocket ionization chamber data.

(c) *Internal dosimetry data*, including:

(1) Urinalysis results;

(2) Fecal sample results;

(3) In Vivo measurement results;

(4) Incident investigation reports;

(5) Breath radon and/or thoron results;

(6) Nasal smear results; and,

(7) External contamination measurements.

(d) *Monitoring program data*, including:

(1) Analytical methods used for bioassay analyses;

(2) Performance characteristics of dosimeters for different radiation types;

(3) Historical detection limits for bioassay samples and dosimeter badges;

(4) Bioassay sample and dosimeter collection/exchange frequencies; and,

(5) Documentation of record keeping practices used to record data and/or administratively assign dose.

(e) *Workplace monitoring data*, including:

(1) Surface contamination surveys;

(2) General area air sampling results;

(3) Breathing zone air sampling results;

(4) Radon and/or thoron monitoring results;

(5) Area radiation survey measurements (beta, gamma and neutron); and,

(6) Fixed location dosimeter results (beta, gamma and neutron).

(f) *Workplace characterization data*, including:

(1) Information on the external exposure environment, including: Radiation type (gamma, x-ray, neutron, beta, other charged particle); radiation energy spectrum; uniformity of exposure (whole body vs partial body exposure); irradiation geometry; and work-required medical screening x rays.

(2) [Reserved]

(g) *Information characterizing internal exposures*, including:

(1) Radionuclide(s) and associated chemical forms;

(2) Results of particle size distribution studies; and,

(3) Respiratory protection practices.

(h) *Process descriptions for each work location*, including:

(1) General description of the process;

(2) Characterization of the source term (i.e., the radionuclide and its quantity);

(3) Extent of encapsulation;

(4) Methods of containment;

(5) Other information to assess potential for airborne dispersion.

**§ 82.15 How will NIOSH evaluate the completeness and adequacy of individual monitoring data?**

(a) NIOSH will evaluate the completeness of an individual's monitoring data provided by DOE through one or more possible measures including, but not limited to:

(1) Comparisons with information provided by claimants, co-workers, and other witnesses;

(2) Comparisons with available information on area monitoring, production processes, and radiologic protection programs;

(3) Comparisons with information documented in the records of unions representing covered employees;

(4) Comparisons with data available on co-workers; and

(5) Reviews of DOE contractor record systems.

(b) NIOSH will evaluate the instruments and procedures used to collect individual monitoring data to determine whether they adequately characterized the radiation environments in which the covered employee worked, (adequately for the purpose of dose reconstruction,) based on present-day scientific understanding. For external dosimeter measurements, this includes an evaluation of the dosimeter response to the radiation types (gamma, x-ray, neutron, beta, or other charged particle) and the

associated energy spectrum. For internal exposure, the methods used to analyze bioassay samples will be reviewed to determine their ability to detect the radionuclides present in the work environment. An analysis of the monitoring or exchange frequencies for the monitoring programs will also be conducted to determine the potential for undetected dose.

**§ 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?**

(a) For external dosimeter results that are incomplete due to historical record keeping practices, NIOSH will use commonly practiced techniques, such as those described in the NIOSH Research Issues Workshop,<sup>2</sup> to estimate the missing component of dose and to add this to the total dose estimate. For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation, using available monitoring results from other time periods close to the period in question, or based on monitoring data on other workers engaged in similar tasks.

(b) NIOSH will review historical bioassay sample detection limits and monitoring frequencies to determine, when possible, the minimum detectable dose for routine internal dose monitoring programs. This "missed dose" will establish the upper limit of internal dose that a worker could have received for periods when bioassay sample analysis results were below the detection limit. Using ICRP biokinetic models, NIOSH will estimate the internal dose and include an associated uncertainty distribution.

**§ 82.17 What types of information could be used to supplement or substitute for individual monitoring data?**

Three types of information could be used:

(a) Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment; or,

(b) A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area

radiation survey results, air sampling data; or,

(c) A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices.

**§ 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?**

(a) The calculation of dose from ingested, inhaled or absorbed radioactivity involves the determination of the types and quantities of radionuclides that entered the body. NIOSH will use the results of all available bioassay monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program. If bioassay monitoring data are unavailable, the dose reconstruction will rely on the results of air sampling measurements.

(b) NIOSH will calculate the dose to the organ or tissue of concern using metabolic models published by ICRP. Using data available to NIOSH, the models will be based on exposure conditions representative of the work environment. When NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration.

(c) Internal doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.

**§ 82.19 How will NIOSH address uncertainty about dose levels?**

The estimate of each annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate. This information will be used by DOL in the calculation of probability of causation, under HHS guidelines for calculating probability of causation estimates at 42 CFR part 81. In this way, claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH.

**Subpart D—Reporting and Review of Dose Reconstruction Results**

**§ 82.25 When will NIOSH report dose reconstruction results, and to whom?**

NIOSH will report dose reconstruction results to DOL and to the claimant, as provided for under § 82.10. Draft results will be reported to the claimant upon tentative completion of the dose reconstruction. Final results

will be reported to the claimant and DOL after NIOSH receives certification from the claimant that the claimant has completed providing information to NIOSH for the dose reconstruction (Form OCAS-1).

**§ 82.26 How will NIOSH report dose reconstruction results?**

(a) NIOSH will provide dose reconstruction results to the claimant and DOL in a report: "NIOSH Report of Dose Reconstruction under EEOICPA." The report itself will not provide information on probability of causation, which DOL must calculate to determine a recommended decision on the claim.

(b) The report will include the following information, as relevant:

(1) Annual dose estimates (or a fraction thereof) related to covered employment for each year from the date of initial radiation exposure at a covered facility to the date of cancer diagnosis;

(2) Separate dose estimates for acute and chronic exposures, different types of ionizing radiation, and internal and external doses, providing dose information for the organ or tissue relevant to the primary cancer site(s) established in the claim;

(3) Uncertainty distributions associated with each dose estimated, as necessary;

(4) Explanation of each type of dose estimate included in terms of its relevance for estimating probability of causation;

(5) Identification of any information provided by the claimant relevant to dose estimation that NIOSH decided to omit from the basis for dose reconstruction, justification for the decision, and if possible, a quantitative estimate of the effect of the omission on the dose reconstruction results; and

(6) A summary and explanation of information and methods applied to produce the dose reconstruction estimates, including any factual findings and the evidence upon which those findings are based.

(c) As provided under § 82.10(l), NIOSH staff will conduct a closing interview with claimants to explain the dose reconstruction report.

**§ 82.27 How can claimants obtain reviews of their dose reconstruction results by NIOSH?**

Claimants can seek reviews of their dose reconstruction through the processes established by DOL under 20 CFR part 30. DOL will request NIOSH to review dose reconstructions under the following conditions, as provided under 20 CFR 30.318:

(a) DOL may determine that factual findings of the dose reconstruction do

<sup>2</sup> NIOSH (1995). NIOSH research issues workshop: Epidemiologic use of nondetectable values in radiation exposure measurements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 224647 (NTIS-PB 95189601).

not appear to be supported by substantial evidence; or,

(b) Although the methodology established by HHS under this Part is binding on DOL, DOL may determine that arguments concerning the application of this methodology should be considered by NIOSH.

**§ 82.28 Who can review NIOSH dose reconstruction files on individual claimants?**

(a) Claimants and DOL will be provided individual dose reconstruction files, upon request. Claimants should note, however, that a complete summary of the data and methods used in a dose reconstruction will be included in the "NIOSH Report of Dose Reconstruction under EEOICPA".

(b) Researchers and the public will be provided limited access to NIOSH dose reconstruction files, subject to provisions and restrictions of the Privacy Act for the protection of confidential information on individuals. Researchers will not receive names of claimants or covered employees associated with dose reconstructions.

Dated: September 21, 2001.

**Tommy G. Thompson,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 01-24879 Filed 10-4-01; 8:45 am]

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**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 73**

[MM Docket No. 01-235; FCC 01-262]

RIN 4207

**Cross-Ownership of Broadcast Stations and Newspapers**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document initiates a proceeding to consider whether to eliminate, modify, or retain the Commission's newspaper/broadcast cross-ownership rule and/or related waiver policies. The takes this action in part because it committed to do so in its first biennial review of its broadcast ownership rules. The intended effect is the harmonization of the Commission's competition and diversity goals with the current realities of the local media marketplace.

**DATES:** Comments are due December 3, 2001; reply comments are due January 7, 2002.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Eric J. Bash, (202) 418-2130 or ebash@fcc.gov.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the *Notice of Proposed Rule Making* ("NPRM") in MM Docket No. 01-235, FCC 01-262, adopted September 13, 2001, and released September 20, 2000. The complete text of this NPRM is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY-A257, 445 12th Street, SW., Washington, DC and may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street SW, Room CY-B-402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via email [qualexint@aol.com](mailto:qualexint@aol.com). The NPRM is also available on the Internet at the Commission's website: <http://www.fcc.gov>.

**Introduction**

1. In this proceeding, the Commission seeks comment on whether and to what extent it should revise the newspaper/broadcast cross-ownership rule, which prohibits common ownership of a broadcast station and a newspaper in the same geographic area. The rule rests on the "twin goals" of diversity of viewpoints and economic competition. The Commission adopted the rule in 1975. The local multimedia marketplace in which broadcast stations and newspapers operate has changed significantly since that time. This proceeding seeks comment on the relevance of these changes to the newspaper/broadcast cross-ownership rule.

**Background**

2. The newspaper/broadcast cross-ownership rule prohibit common ownership of a full-service broadcast station and a daily newspaper when the broadcast station's service contour (2mV/m contour for AM, 1 mV/m contour for FM, Grade A for TV) fully encompasses the newspaper's city of publication. When adopting the rule in 1975, the Commission not only prohibited future newspaper/broadcast combinations, but also required existing combinations in highly concentrated markets to divest holdings to come into compliance within five years. The Commission grandfathered combinations in other markets, so long as the parties to the combination remained the same. The Commission, however, contemplated waiving the

rule, for existing or future combinations, if: (1) A combination could not sell a station except at an artificially depressed price; (2) a combination could not sell a station except at an artificially depressed price; (3) separate ownership and operation of a newspaper and a station could not be supported in a locality; or (4) for whatever reason, the purposes of the rule would be disserved. The Supreme Court has reviewed the rule and the Commission's related waiver policies, and upheld them in their entirety. The Commission has granted only four permanent waivers in the twenty-six years since it adopted the rule.

3. In February 1996, the Telecommunications Act of 1996 also became law. Section 202(h) of the 1996 Act instructs the Commission to review each of its ownership rules biennially, to determine whether the rule is "necessary in the public interest as a result of competition" and repeal or modify any rule it finds is no longer in the public interest. As required by section 202(h) of the 1996 Act, the Commission examined the newspaper/broadcast cross-ownership policies in its first biennial review on broadcast ownership rules. The Commission concluded that the newspaper/broadcast cross-ownership rule continues to serve the public interest because it furthers diversity, and therefore should be retained. However, the Commission also noted that the rule might not be necessary to achieve its intended public interest benefits under certain circumstances. Thus, the Commission committed to undertaking a rulemaking proceeding to tailor the rule accordingly.

**Discussion**

4. Since the Commission adopted the newspaper/broadcast cross-ownership rule over twenty-five years ago, the local media marketplace has changed dramatically. In this proceeding, we seek to examine our newspaper/broadcast cross-ownership policies in the context of these changes in the local media marketplace, taking into account section 202(h) of the Telecommunications Act of 1996, and our diversity and competition goals.

5. *Current Status of the Media Marketplace.* The number of local media outlets has grown substantially since 1975. A significant portion of this growth has occurred within the broadcast industry itself. A total of 7,785 radio stations were on the air as of January 1, 1975; as of June 30, 2001, the Commission had licensed 12,932 radio stations. A total of 952 TV stations were on the air on January 1, 1975; as of June 30, 2001, the Commission had