\*\*OFFICIAL USE ONLY\*\*
SENSITIVE INTERNAL INFORMATION
LIMITED TO THE NRC UNLESS THE
COMMISSION DETERMINES OTHERWISE



<u>August 13, 2020</u> <u>SECY-20-0074</u>

FOR: The Commissioners

FROM: Margaret M. Doane

**Executive Director for Operations** 

SUBJECT: VALUING NONFATAL CANCER RISKS IN COST-BENEFIT ANALYSIS

### PURPOSE:

The purpose of this paper is to inform the Commission of the staff's planned approach to monetize the value of nonfatal cancer risks due to radiation exposure, as described in the staff-developed "Valuing Morbidity White Paper" (Agencywide Documents Access Management System (ADAMS) Accession No. ML20058C225). Morbidity can be defined as the condition of being ill or diseased, which results in an individual living in a state of reduced health. The staff is exploring options for regulatory treatment of morbidity based on public comments received during post-Fukushima efforts to update the dollar per person-rem conversion factor used by the U.S. Nuclear Regulatory Commission (NRC). The white paper focuses on the reduction of health quality associated with living with a nonfatal illness and does not consider the reduction of life years due to the illness. The staff reviewed current federal and international agency quidance, recent regulatory analyses, and academic viewpoints on this issue to support the development of NRC guidance on the monetary valuation of nonfatal cancers and cancer morbidity risks. The agencies reviewed were those whose primary purpose is to regulate public health and safety, with attention to any agencies that recently issued regulations that value nonfatal cancers or cancer morbidity. In the absence of current estimates of willingness to pay (WTP), the staff plans to develop a monetized quality-adjusted life-year approach for nonfatal cancer risk valuation.

CONTACTS: Amy E. Sharp, RES/DSA

301-415-0960

Pamela S. Noto, NMSS/REFS

301-415-6795

The enclosure transmitted herewith contains Official Use Only - Sensitive Internal Information. When separated from the enclosure this transmittal document is decontrolled.

\*\*OFFICIAL USE ONLY\*\*
SENSITIVE INTERNAL INFORMATION
LIMITED TO THE NRC UNLESS THE
COMMISSION DETERMINES OTHERWISE

#### BACKGROUND:

The NRC develops cost-benefit analyses that often rely on the monetization of averted health detriment risks of radiation exposure when quantifying the benefits associated with proposed safety improvements. As discussed in the draft NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 5, the NRC monetizes health risk reductions in support of regulatory, backfit, and environmental analyses. NUREG/BR-0058 provides guidance to the analyst for the preparation of regulatory and cost-benefit analysis documents for these applications and provides standardized methods on how to estimate the attributes required in these analyses. This guidance points to NUREG-1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor," as providing the basis for selecting a conversion factor to monetize the value of a unit of radiation dose due to accident-related health effects. Currently before the Commission is SECY-17-0017, "Proposed Revision to NUREG-1530 - Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," dated January 30, 2017 (ADAMS Accession No. ML16147A293 (package)), which addresses cancer mortality risks due to radiation exposure. This NUREG does not have a mechanism to value the morbidity component associated with nonfatal cancer risks.

The 2011 accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion of how the NRC's regulatory framework considers the economic consequences caused by a significant radiological release. In response, the staff submitted SECY-12-0110, "Consideration of Economic Consequences Within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated August 14, 2012 (ADAMS Accession No. <a href="ML12173A478">ML12173A478</a> (package)). This paper provided the Commission with information and options to address to what extent the NRC should modify its regulatory framework to consider the economic consequences of an unintended release of licensed nuclear materials to the environment. In the staff requirements memorandum for SECY-12-0110, dated March 20, 2013 (ADAMS Accession No. <a href="ML13079A055">ML13079A055</a>), the Commission approved the staff's plans for updating the existing cost-benefit guidance documents, including NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and the 1995 dollar per person-rem conversion factor in NUREG-1530.

Historically, the dollar per person-rem conversion factor had accounted for morbidity by utilizing the International Commission on Radiological Protection's total health detriment coefficient, which incorporated both fatal cancer risks and nonfatal cancer risks weighted by a judgement of severity. During the public comment period for draft NUREG-1530, Revision 1, issued August 2015, the NRC received a comment suggesting that the NRC revise its method for valuing nonfatal health risks. The final version of NUREG-1530, Revision 1, incorporates the revised cost estimation method for cancer mortality, but it does not provide an approach for quantifying morbidity. The "Valuing Morbidity White Paper" focuses on the risks of nonfatal cancers, which pose the most significant risks from low level chronic exposures. Although radiation could induce hereditary effects, evidence for these effects in direct human studies remains ambiguous.\(^1\) As a result, it is difficult to reliably estimate what the risk coefficient for heritable effects might be. Additionally, established law supports the Commission's interpretation that the Atomic Energy Act (AEA) does not require consideration of psychological

<sup>1</sup> See the U.S. Environmental Protection Agency (EPA) Radiogenic Cancer Risk Models and Projections for the U.S. Population, available at <a href="https://www.epa.gov/radiation/epa-radiogenic-cancer-risk-models-and-projections-us-population">https://www.epa.gov/radiation/epa-radiogenic-cancer-risk-models-and-projections-us-population</a> and the UNSCEAR 2001 Report Annex: "Hereditary effects of radiation," available at <a href="https://www.unscear.org/unscear/en/chernobyl.html#Health">https://www.unscear.org/unscear/en/chernobyl.html#Health</a>.

health effects as part of the NRC's mandate to protect public health and safety against the physical risks associated with radioactivity.<sup>2</sup> As a result of these considerations, the staff chose to focus on the current state of practice for the valuation of cancer morbidity and nonfatal cancer risks and developed the "Valuing Morbidity White Paper" as part of the update to NUREG/BR-0058.

#### **DISCUSSION:**

The staff reviewed current federal agency guidance to examine the theory and methods for valuing nonfatal health risks, as well as the current practices of other federal agencies. The health economics literature, U.S. Governmentwide guidance,<sup>3</sup> and agency-specific guidelines generally agree that the theoretically correct approach to value health risks in cost-benefit analysis is by estimating the individual WTP<sup>4</sup> to avoid these risks. However, because of the lack of economic studies that use direct elicitation to estimate values for WTP for most illnesses, several approaches have been used to estimate this value.

Approaches used to approximate WTP for avoided health risks can be classified broadly into three categories: 1) methods that elicit individual WTP based on either stated preference or revealed preference studies; 2) methods that measure the direct financial and human capital costs of being ill; and 3) proxy methods. The most prevalent proxy method currently in use leverages existing estimates of summary measures of disease outcome known as quality-adjusted life years. These metrics reflect both the quality of life and the longevity associated with a particular health state combined into a single number.

Key observations from the review are summarized below.

Broad Guidance from the Office of Management and Budget

The Governmentwide guidance in Office of Management and Budget (OMB) Circular A-4 gives agencies discretion in their approach to the monetization of nonfatal health effects. The guidance discusses the methods in general but does not prescribe a single approach. For example, while OMB Circular A-4 promotes the WTP measure as the conceptually appropriate measure for monetizing health benefits, it allows for the use of proxy methods when data are not available to support the monetization of a particular health state. With regard to proxy measures, the OMB states that "health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration." This guidance specifically allows for the monetization of quality-adjusted life years to value morbidity when WTP estimates are not available for a particular illness. Reflecting this discretion, agencies have adopted multiple approaches to morbidity valuation.

See SECY-12-0110, page 7 under heading "Metropolitan Edison, the Three Mile Island (TMI) Restart Case" (Discussing D.C. Circuit Court's ruling that upheld the Commission's March 30, 1982, Memorandum and Order regarding the AEA, stating that the Court agreed with the Commission's decision "not to consider psychological stress issues under the AEA." *Metropolitan Edison Co.*, 678 F.2d 222 at 250 (D.C. Cir. 1982).

Office of Management and Budget Circular A-4, "Regulatory Analysis," dated September 17, 2003, gives agencies discretion in their approach to the monetization of nonfatal health effects.

WTP - "Willingness to pay" is the maximum amount of money an individual would be willing to pay rather than do without some health risk reduction. This sum is the amount of money that would make the individual indifferent between the options of paying for and having the improvement and forgoing the improvement while keeping the money to spend on other things (Freeman, A.M., "The Measurement of Environmental and Resource Values," 2003).

## Agency Approaches to Cancer Valuation

The literature review found significant variation across agencies' practices in their approaches to valuing nonfatal health effects. While some agencies have departmentwide guidance for conducting cost-benefit analysis, others do not. For those that do have such guidance, their policies for the monetary valuation of morbidity effects are not prescriptive. The EPA and the Occupational Safety and Health Administration continue to use benefits transfer of WTP estimates where feasible. However, other agencies, including the Food and Drug Administration and the National Highway Traffic Safety Administration, have used monetized quality-adjusted life years in cost-benefit analyses. When considering only those agencies and regulations that have recently monetized cancer risks, two methods have been applied to cancer morbidity: 1) WTP estimates of surrogate illnesses and 2) monetized quality-adjusted life-year changes.

## Staff's Planned Approach

The application of WTP estimates based on either revealed preference or stated preference studies is the preferred method for monetizing changes in health risks in cost-benefit analyses. The literature review found that the most recently applied WTP estimate for nonfatal cancer risk aversion originates from a 1996 study<sup>5</sup> that estimates the WTP value for a single type of nonfatal cancer. However, the OMB guidance allows for the use of proxy measures to approximate WTP when such estimates are unavailable. The staff plans to adopt a monetized quality-adjusted life-year approach that would allow analysts to value cancer types individually because quality-adjusted life-year values exist and are available for many distinct forms of cancer and their various stages.

#### **CONCLUSION:**

The staff plans to develop detailed guidance on monetizing the risks associated with the morbidity from nonfatal cancers using quality-adjusted life years. These quality-adjusted life-year estimates are available for a variety of cancer types and subject populations<sup>6</sup> and can be used in conjunction with the annualized value of a statistical life to approximate WTP. The staff will hold a public meeting to seek public input on this approach prior to developing the guidance. The staff's planned approach would involve the development and publication of an appendix to NUREG/BR-0058 that will provide estimates of the value of nonfatal cancer risks due to radiological exposures for use in cost-benefit analysis. This appendix will detail the assumptions and methodology underlying the development of these estimates and provide guidance to the analyst on the application of these values. The new appendix will be submitted to the Commission for review and approval.

Magat, et al. 1996, estimated the value of a case of nonfatal lymphoma as a fraction of the value of a statistical life using stated preference surveys of risk tradeoffs. (Magat, W.A., Viscusi, W.K., and J. Huber, 1996. "A Reference Lottery Metric for Valuing Health." *Management Science*, Vol. 42, pp. 1118–1130.)

Quality-adjusted life-year estimates are used extensively in medical research and medical decision-making and thus have been estimated for a wide range of illnesses. Tufts Medical Center maintains a Cost-Effectiveness Analysis registry database that collects, reviews, and consolidates this information from newly published studies. Additionally, a vast number of peer-reviewed academic journals publish primary studies where these values are estimated.

## **RESOURCES**:

The enclosure contains the resource estimates for developing the appendix to NUREG/BR-0058.

## **COORDINATION:**

The Office of the General Counsel reviewed this package and has no legal objection to its contents.

The Office of the Chief Financial Officer reviewed this package and determined that it has no financial impact.

Darrell J. Roberts

Digitally signed by Darrell J. Roberts Date: 2020.08.13 13:46:10

-05'00'

/Darrell J. Roberts Acting for/

Margaret M. Doane **Executive Director** for Operations

Enclosure:

Resource Estimates for the Valuing Morbidity Appendix (not publicly available)

SUBJECT: VALUING NONFATAL CANCER RISKS IN COST-BENEFIT ANALYSIS, DATED

AUGUST 13, 2020

# **DISTRIBUTION**:

PNoto, NMSS ASharp, RES FSchofer, NMSS RidsNmssOd RidsResOd RidsOgcMailCenter RidsEdoMailCenter

DATE

07/10/2020

ADAMS Accession Nos.: ML20058C219 (Pkg.) \*Concurrence via e-mail SECY-012

OFFICE	NMSS/REFS/RASB/PM	NMSS/REFS/RASB/TL	RES/DSA/AAB	QTE
NAME	PNoto	FSchofer*	ASharp	JDougherty*
DATE	03/05/2020	03/17/2020	03/18/2020	03/25/2020
OFFICE	RES/DSA/AAB/BC	NMSS/REFS/RASB/BC	RES/DSA/D	NMSS/REFS/DD
NAME	TBloomer	CBladey*	MCase*	KCoyne*
DATE	04/03/2020	04/07/2020	04/11/2020	04/28/2020
OFFICE	RES/DD	OCFO/DOB/DD	OGC (NLO)	NMSS/Tech Ed
NAME	SCoffin*	RAllwein*	CEngland*	LMoorin
DATE	05/05/2020	05/06/2020	05/30/2020	6/8/2020
OFFICE	NMSS/DD	EDO		
NAME	RLewis*	MDoane*		
		(DRoberts for)		

OFFICIAL RECORD COPY

08/13/2020