

Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace

NIOSH Carcinogen Policy

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Why Update the Carcinogen Policy?

- ❑ New scientific advances in risk modeling, biological mode of action, and analytical methods
- ❑ Receive peer and public input on the NIOSH process
- ❑ Increase the transparency of the NIOSH process

Current Intelligence Bulletin

- ❑ Carcinogen classification
- ❑ Target risk level for carcinogen RELs
- ❑ Analytical feasibility and engineering achievability

Carcinogen Classification: History

- ❑ Since 1978 NIOSH used “potential occupational carcinogen” as its highest designation
- ❑ Some dissatisfaction with that terminology
 - Known carcinogens such as asbestos, benzene, and cadmium were mislabeled
- ❑ NIOSH requested public input in 2011
- ❑ Public meeting on issues in December 2011
- ❑ Currently: draft document on web for public/peer review
 - <http://www.cdc.gov/niosh/docket/review/docket240A/pdf/EID-CIB-11052013.pdf>

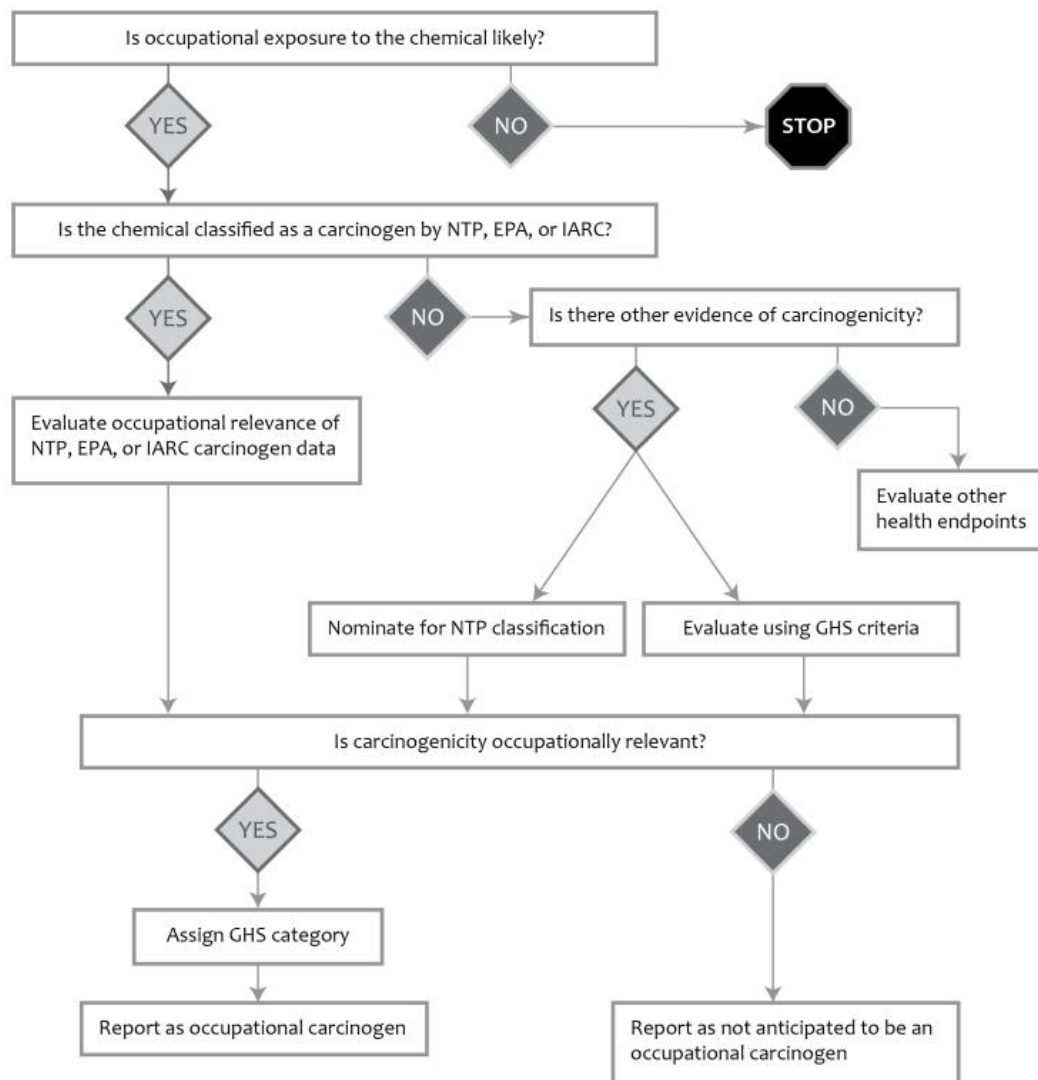
Carcinogen Classification: Features

- ❑ Utilizes NTP, EPA, and IARC cancer classifications for chemicals
- ❑ Evaluates occupational relevance in terms of exposure and applicability of the data
- ❑ Assigns Globally Harmonized System (GHS) category for hazard communication

Occupational Relevance of Carcinogen Classification

- ❑ Potential for worker exposure
- ❑ Applicability of evidence to occupational carcinogenicity
 - Mode of action
 - Route of exposure

NIOSH Chemical Carcinogen Review Process



Correspondence of Carcinogen Classification with GHS Carcinogen Categories*

NTP RoC	IARC	EPA 1986	EPA 2005	GHS Category/ Hazard Phrase
Known to be a human carcinogen	Group 1 Carcinogenic to humans	Group A Human carcinogen	Carcinogenic to humans	Category 1A Known human carcinogen
Reasonably anticipated to be a human carcinogen	Group 2A Probably carcinogenic to humans	Group B1 Probable human carcinogen	Likely to be carcinogenic to humans	Category 1B Presumed human carcinogen
	Group 2B Possibly carcinogenic to humans –adequate in animals; inadequate in humans	Group B2 Probable human carcinogen		
	Group 2B Possibly carcinogenic to humans –limited animal evidence	Group C Possible human carcinogen	Suggestive evidence of carcinogenic potential	Category 2 Suspected carcinogen

*As interpreted by NIOSH

Carcinogen Classification

Sample Determination: Benzene

- ❑ NIOSH occupational carcinogen
- ❑ GHS carcinogen category 1A: known human carcinogen
- ❑ Based on:
 - NTP: known to be carcinogenic to humans
 - EPA: Group A: human carcinogen
 - IARC: Group 1: carcinogenic to humans

Carcinogen Classification

Sample Determination: Heptachlor

- ❑ NIOSH occupational carcinogen
- ❑ GHS carcinogen category 1B: presumed human carcinogen
- ❑ Based on:
 - EPA: Group B2-probable human carcinogen (sufficient data in animals)
 - IARC: Group 2B-possibly carcinogenic to humans (sufficient data in animals)

Target Risk Level for Carcinogen RELs: History

- ❑ Prior to 1995: lowest feasible concentration
 - Determined by employers
 - Employer evaluated technical and economic options
- ❑ In 1995: adopted a quantitative basis for RELs
 - Based on quantitative risk evaluation
 - Use mathematic models to evaluate exposure-response relationships
 - Extrapolate from animals to humans and from high doses to low doses
 - Acknowledged residual risks
 - Inherent in establishing an REL is a target risk level but no such level was specified

Risk Levels in New NIOSH Carcinogen Policy

- ❑ NIOSH affirms scientific knowledge that the only way to eliminate excess risk from carcinogens is to prevent exposure
- ❑ NIOSH advocates using safer alternatives and to substitute noncarcinogen chemicals whenever feasible
- ❑ Removing all carcinogens in commerce is impractical so guidance on reducing carcinogen exposures to workers is needed
- ❑ NIOSH will assess risks using quantitative methods when data are available

Risk Levels in New NIOSH Carcinogen Policy

- ❑ Communicate an array of lifetime cancer risk for exposures from 1/100 to 1/1,000,000
 - Provides useful information to employers and workers to take preventive action
- ❑ NIOSH will identify a minimum level of protection
 - this is 1 in 1000 risk level; to establish a REL a target risk level is needed
- ❑ NIOSH advocates trying to achieve exposures resulting in risks lower than 1 in 1000

Basis for Target Risk Level

- ❑ U.S. Supreme Court “Benzene Decision” characterized a range of risks between 1 in 1000 and 1 in a billion
- ❑ Implied that 1 in 1000 was a significant risk
- ❑ NIOSH will use the 1 in 1000 target risk level because it better relates to OSHA’s work in developing occupational exposure limits
- ❑ NIOSH will use mathematic models for quantitative risk assessment

NIOSH Precedent for Using 1 in 1000 Risk Level*

- 1990** Benzene PEL (Testimony to OSHA)
- 1990** Cadmium PEL (Testimony to OSHA)
- 1991** 1,3-Butadiene PEL (Testimony to OSHA)
- 1995** Coal dust (REL)*
- 1998** Diesel exhaust (Journal article/collaboration with MSHA)*
- 2001** Silica (Journal article-risk assessment)
- 2002** Silica (Journal article-risk assessment) *

*Includes health effects other than cancer

NIOSH Precedent for Using 1 in 1000 Risk Level (cont'd)*

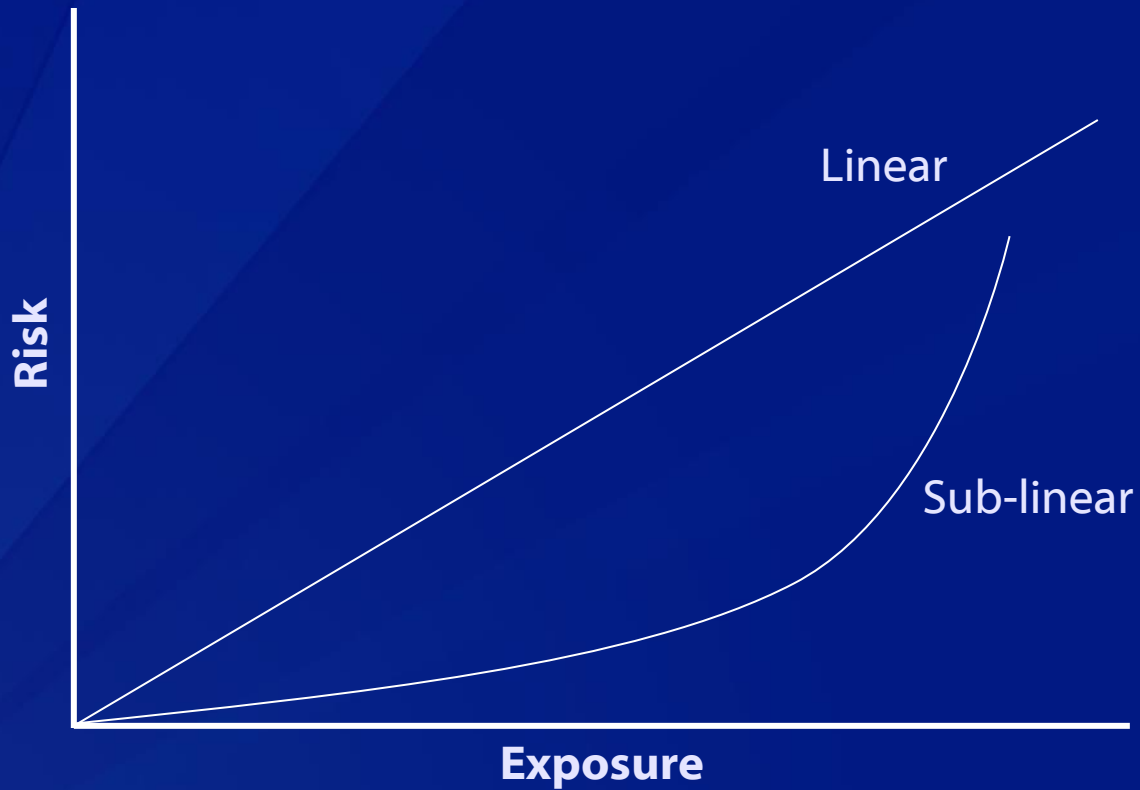
- 2007** Manganese (Journal article-risk assessment)*
- 2011** Titanium dioxide (RELs)
- 2013** Hexavalent chromium (REL)
- 2013** Diacetyl/2,3-Pentanedione (Draft REL)*

*Includes health effects other than cancer

Additional Protections Afforded by Risk Assessment and Related Communications

- ❑ Use of 45-year working lifetime
- ❑ Treats exposure-response as linear at low doses
 - Default assumption
 - In some cases sufficient mode of action data may allow risk estimation based on non-linear dose-response models

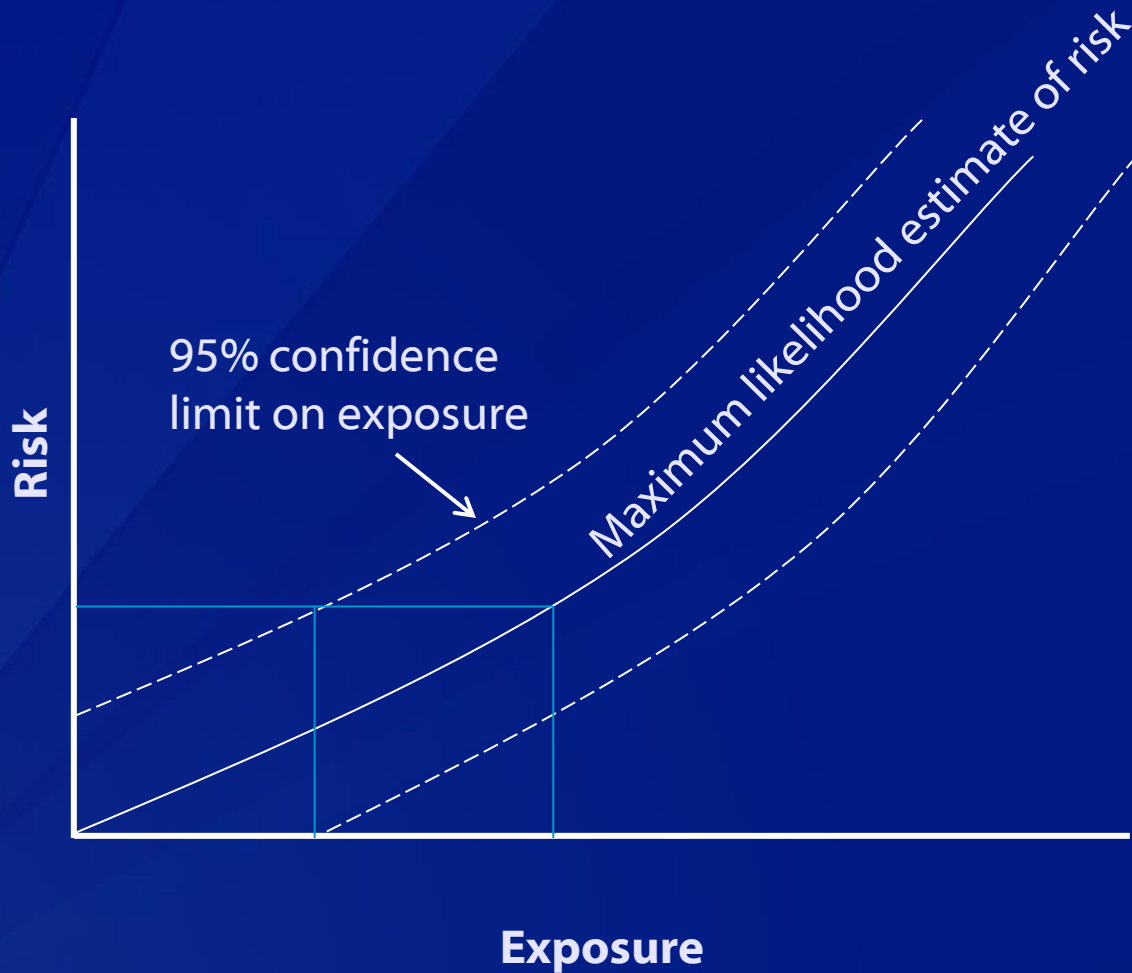
Low Dose Extrapolation



Additional Protections Afforded by Risk Assessment and Related Communications

- ❑ NIOSH REL will be based on 95% lower confidence limit of the exposure corresponding to the target level of risk

Confidence Interval



Additional Protections Afforded by Risk Assessment and Related Communications (cont'd)

- ❑ NIOSH guidance is that risks should be kept well below the REL. Lower exposure lowers the risk.
- ❑ NIOSH recommends alternatives when possible
- ❑ For these reasons the actual risk on which a REL is based will be less than 1/1000

Analytical Feasibility and Engineering Achievability: History

- ❑ "...Engineering controls ...should be used to control occupational exposures **to the fullest extent feasible.**" [1988]
- ❑ "NIOSH RELs will be based upon risk evaluations . ..and on an assessment of what **levels can be feasibly achieved** by engineering controls and measured by analytical techniques." [1995]

Analytical Feasibility and Engineering Achievability: Issues

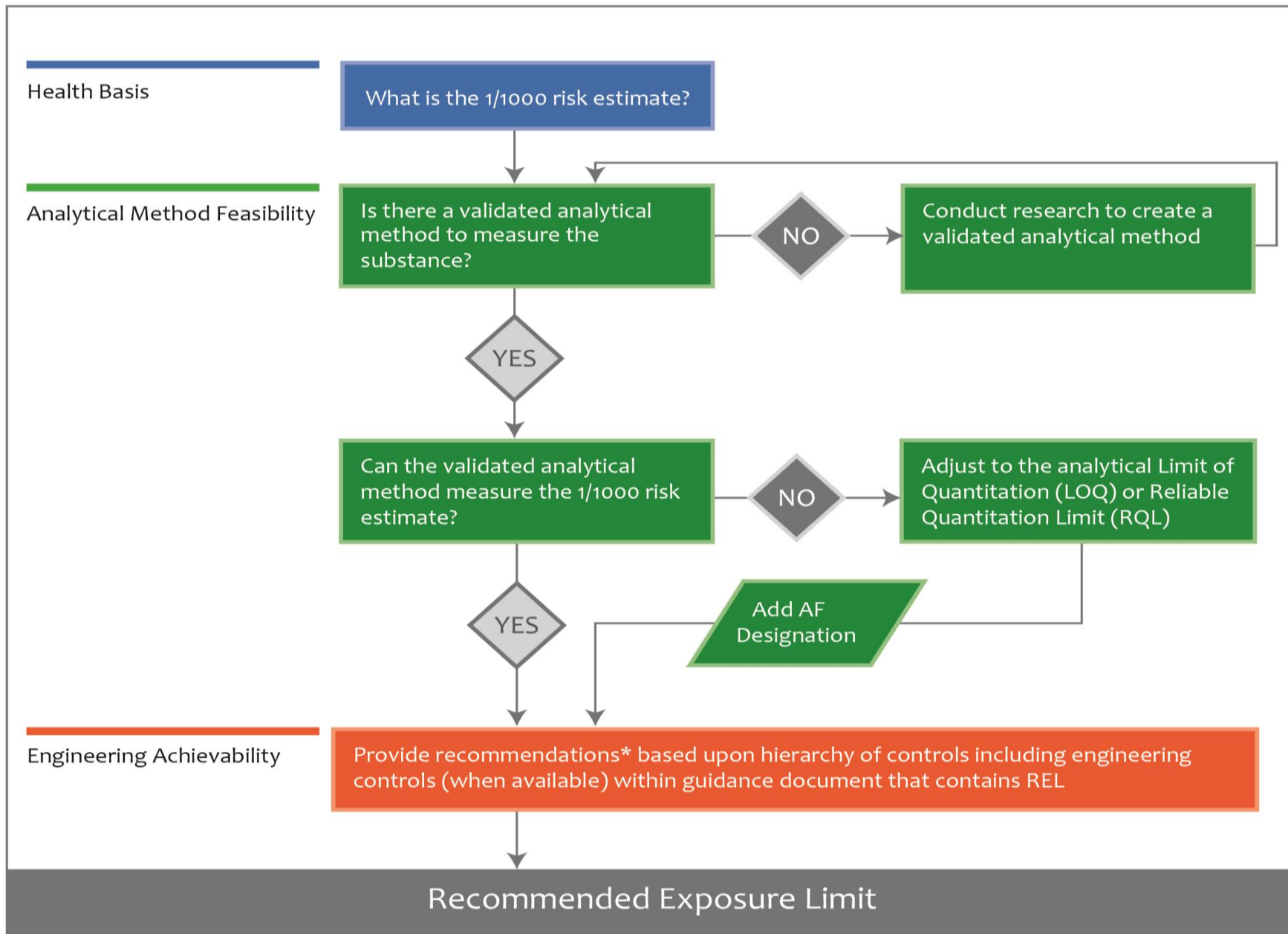
- ❑ Not all NIOSH RELs are health-based
- ❑ Many NIOSH RELs are based on analytical feasibility
- ❑ NIOSH has made some evaluations of engineering feasibility or achievability, but has not routinely conducted quantitative analyses of the technical feasibility of achieving RELs

Analytical Feasibility and Engineering Achievability

- ❑ NIOSH will no longer establish carcinogen RELs relying on an evaluation of engineering controls, but will make an effort to provide control information
- ❑ Basis of NIOSH RELs
 - Health effects (quantitative risk assessment)
 - Analytical feasibility (measurement of chemical in the work environment)

Analytical Feasibility and Engineering Achievability: New RELs Policy

- For new RELs, NIOSH will distinguish between health-based and analytical feasibility-based RELs
 - Health-based RELs = REL
 - RELs based on analytical feasibility = REL_{AF}



*Research on engineering controls will be conducted if such guidance does not yet exist.

Timeline

- ❑ Public meeting (December 16, 2013)
- ❑ Receive all public comments by February 13, 2014
- ❑ Receive all peer review comments by March 14, 2014
- ❑ Anticipate completion of FINAL Cancer Policy in 2014

Carcinogen and RELs Policy Update Committee

- ❑ David Dankovic (EID)
- ❑ John Decker (OD)
- ❑ Charles Geraci (EID)
- ❑ Pius Joseph (HELD)
- ❑ Eileen Kuempel (EID)
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For updates visit the NIOSH Carcinogen Policy web page:

<http://www.cdc.gov/niosh/topics/cancer/policy.html>

Thank you!