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

NIOSH Carcinogen Policy

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Public Meeting, December 16, 2013

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
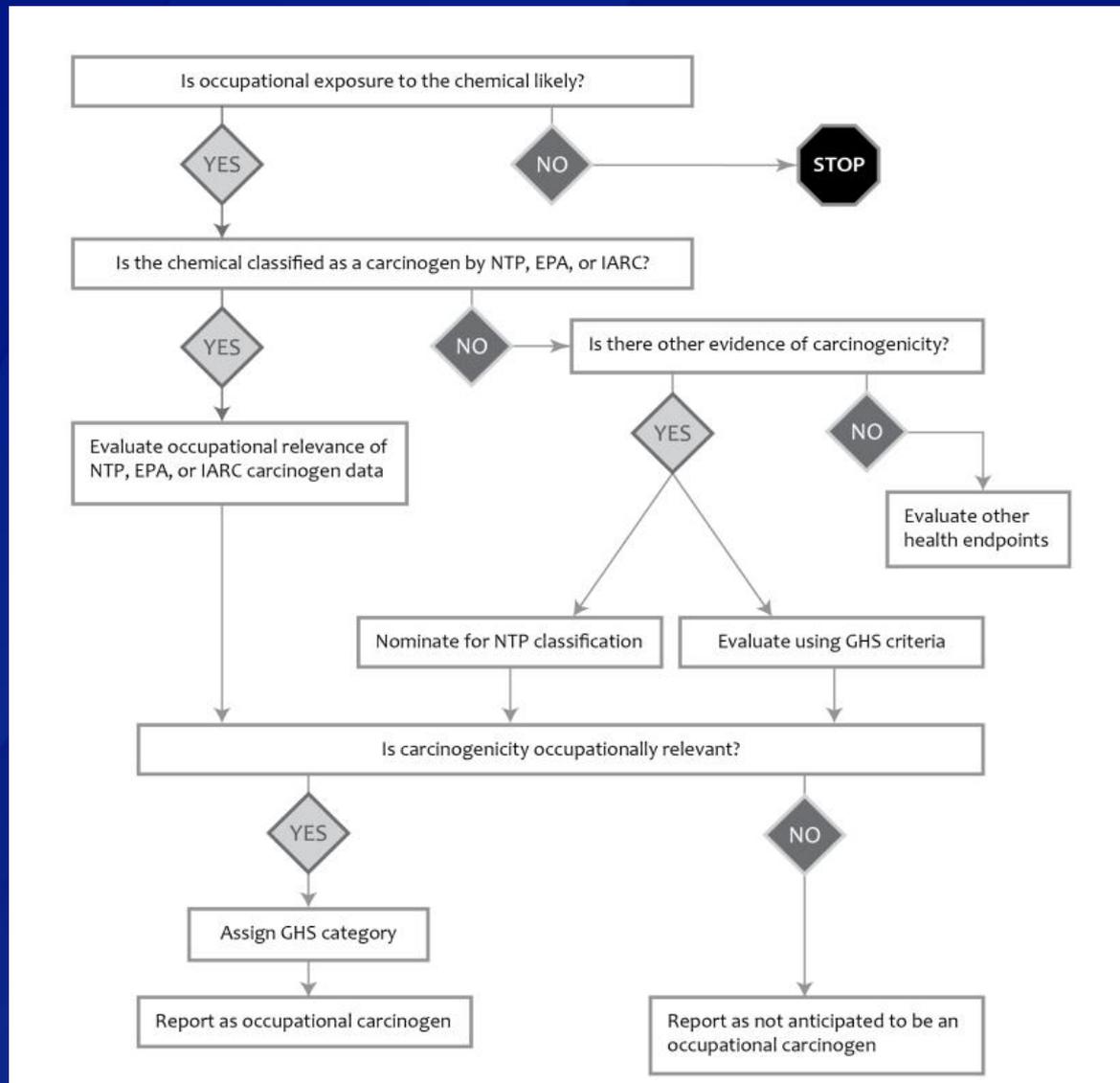
Correspondence of Carcinogen Classification with GHS Carcinogen Categories*

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
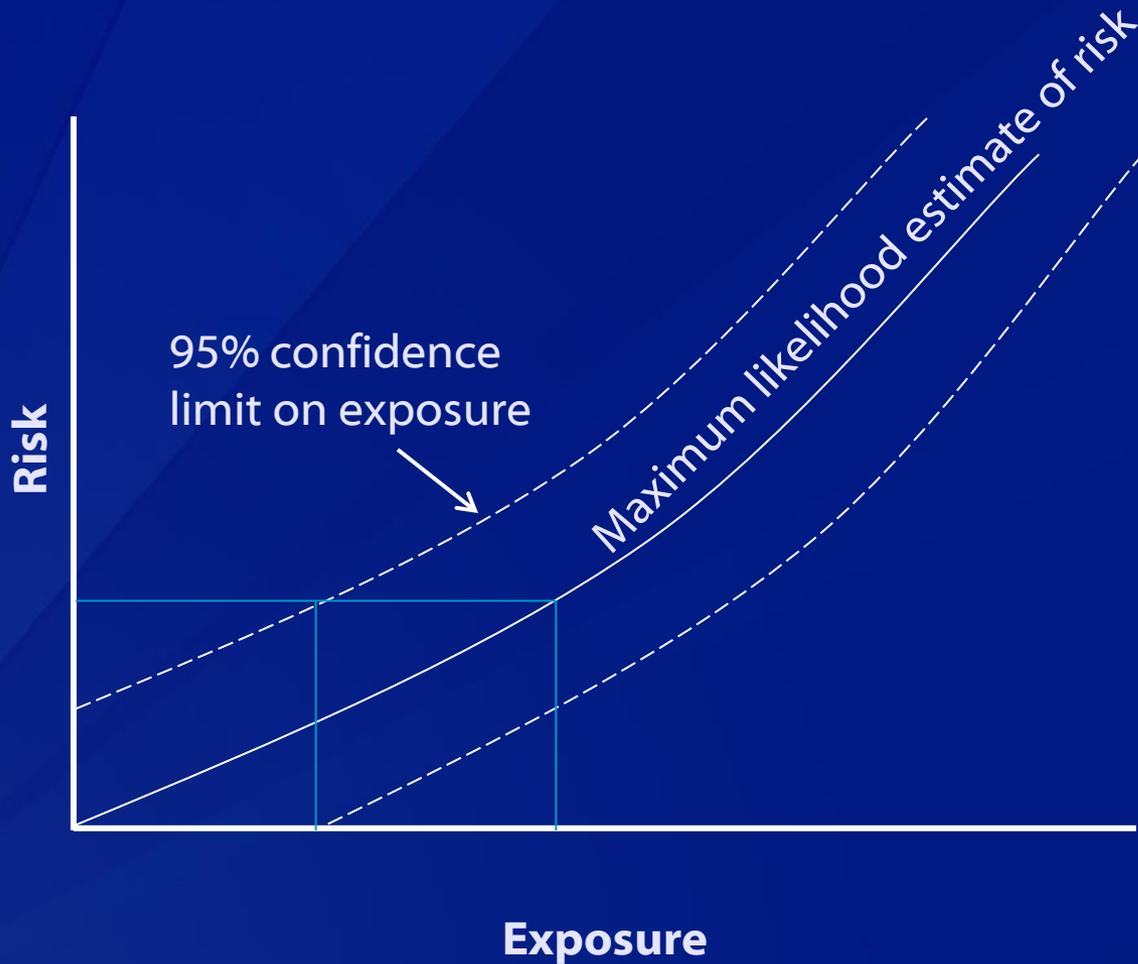
Low Dose Extrapolation
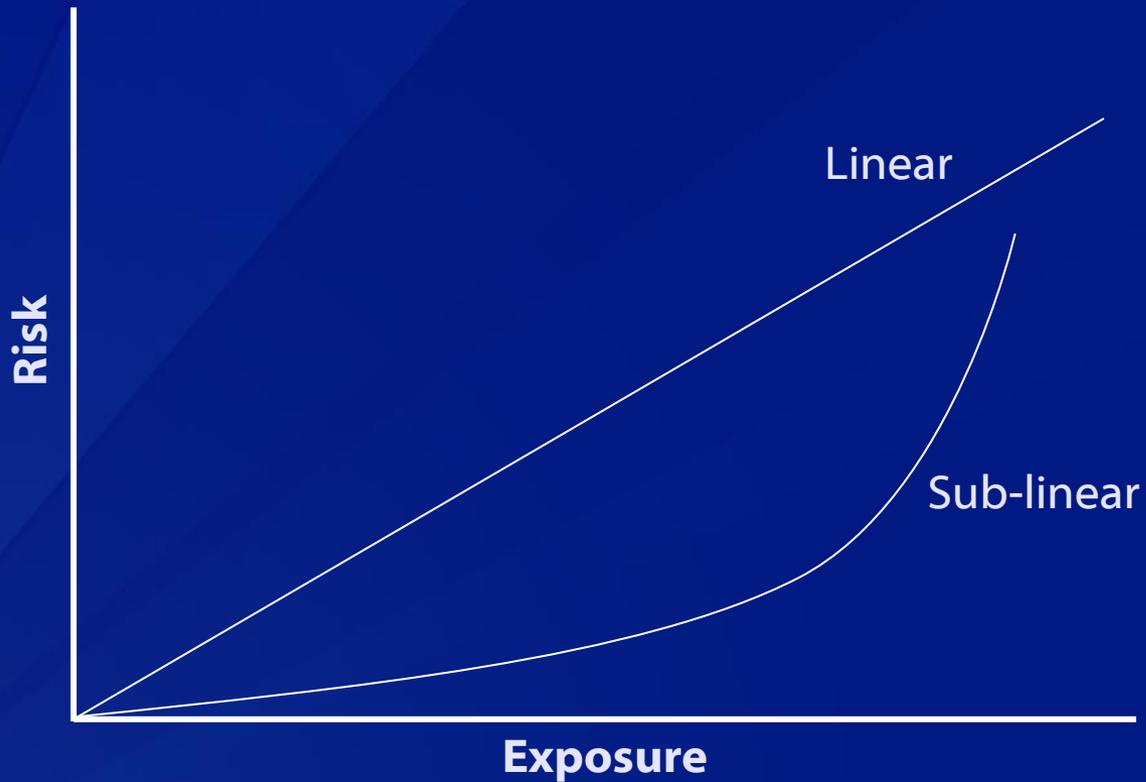
Additional Protections Afforded by Risk Assessment and Related Communications

❑ 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]

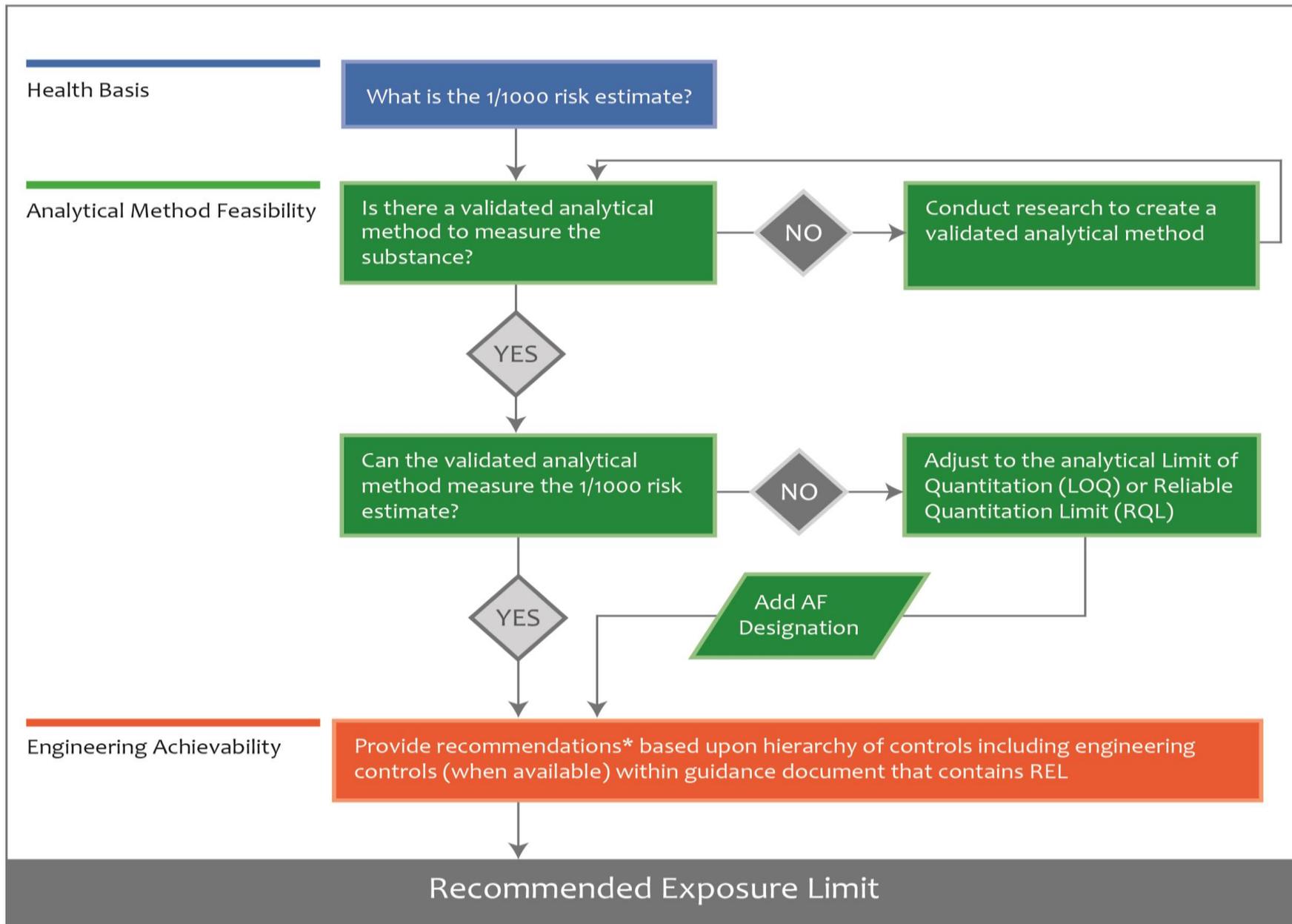# Analytical Feasibility and Engineering Achievability: Issues

❑ 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}

Health Basis

What is the 1/1000 risk estimate?

Analytical Method Feasibility

Is there a validated analytical method to measure the substance? — **NO** → Conduct research to create a validated analytical method

YES

Can the validated analytical method measure the 1/1000 risk estimate? — **NO** → Adjust to the analytical Limit of Quantitation (LOQ) or Reliable Quantitation Limit (RQL)

YES

Add AF Designation

Engineering Achievability

Provide recommendations* based upon hierarchy of controls including engineering controls (when available) within guidance document that contains REL

Recommended Exposure Limit

*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)
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For updates visit the NIOSH Carcinogen Policy web page:

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

Thank you!