Objective of the meeting

and

structure of the ICdA Guidance Document

Patrick de Metz

Objective of the ICdA H&S Committee

- Disseminate the ICdA Guidance document to ICdA member companies and their key personnel
- Dissemination programme is expected to be approx. 10 sessions long. Each session focusing on specific sections of the Guidance:
  - Session 1: H&S Ctee set up, organization and planning
  - Session 2: air quality measurement
  - **TODAY**: Session 3: medical surveillance programme
- Contents:
  - Share on the « WHY » and « WHAT » of each section
  - Exchange on current practice
  - Identify and share best practice

Objectives of the third ICdA H&S Committee

- Getting familiar with the ICdA medical surveillance programme section:
- Understanding the scientific background behind it:
  - Environmental studies
  - Occupational studies
  - Effects
  - Thresholds
- The Swedish programme structure and contents:
  - Bio monitoring; which bio-markers, why, how often?
  - Green zone, Orange zone and Red zone, what are they?
  - What action at what action level?
  - If problem; mandatory removal and recommended removal?
- A few words on the ICdA guidance
- How to move:
  - From where each of us is
  - To the implementation of the Guidance?

Structure of the ICdA Guidance Document

- Chapter ONE gives an overview of cadmium effects to human health in an occupational setting and summarizes the existing knowledge (2005) about thresholds

- Chapter TWO contains four sections which deal with the setting up of a « comprehensive health protection and monitoring programme »:
  - Ensuring plant cleanliness
  - Proper personal protection equipment
  - Ensuring the proper personal and group hygiene habits/procedures are in place
  - **Ensuring that a proper medical supervision programme is in place to detect any possible deviation**

How was the medical surveillance programme section built?

- Construction of medical surveillance programme section of the ICdA Guidance Document was made after a review of existing national regulations with the purpose of selecting one based on:
  - Clarity and formality
  - Experience with one ICdA member with implementation
  - Implementation on a site with a significant workforce size
  - Results of implementation prove effectiveness

- Swedish legislation was selected:
  - With some minor modifications
  - Principles, frequency (of surveillance) and action levels are kept identical
  - Output: « Eurometaux-ICdA 2006 – Management of the Risk Related to Chronic Occupational Exposure to Cadmium and Its Compounds »

- Industry is committed to implement:
  - All members companies of ICdA with operations in the EU have formally declared in writing that they are committed to implementing the Guidance
  - This commitment has been turned into a policy in a unanimous vote of all ICdA members in the last GA of the Association

Role of a medical surveillance programme

- A component of the « comprehensive health protection and monitoring programme »
- Normally unnecessary!
- Because in a « perfect world » risk is managed through:
  - Plant, equipment designed to minimize releases (see 2nd H&S meeting on [Cd-Air])
  - Individual and group hygiene procedures, including training…
- If these components work, medical surveillance programme should be superfluous!
- But since systems fail, and Cd is a cumulative toxic substance:
  - We need to monitor health
  - We need to monitor accumulation
- The medical surveillance programme **is not** a system designed to rotate workers once they have reached « level high » and replace them with fresh (such as in the nuclear industry)!

Review of document package

- Paper binder:
  - Table of contents
  - 1996 Eurometaux – ICdA Guidance document
  - Large format decision/action table
  - Original Swedish legislation (Arbetsmiljöverkets)
  - Translation in EN
  - Translation in FR

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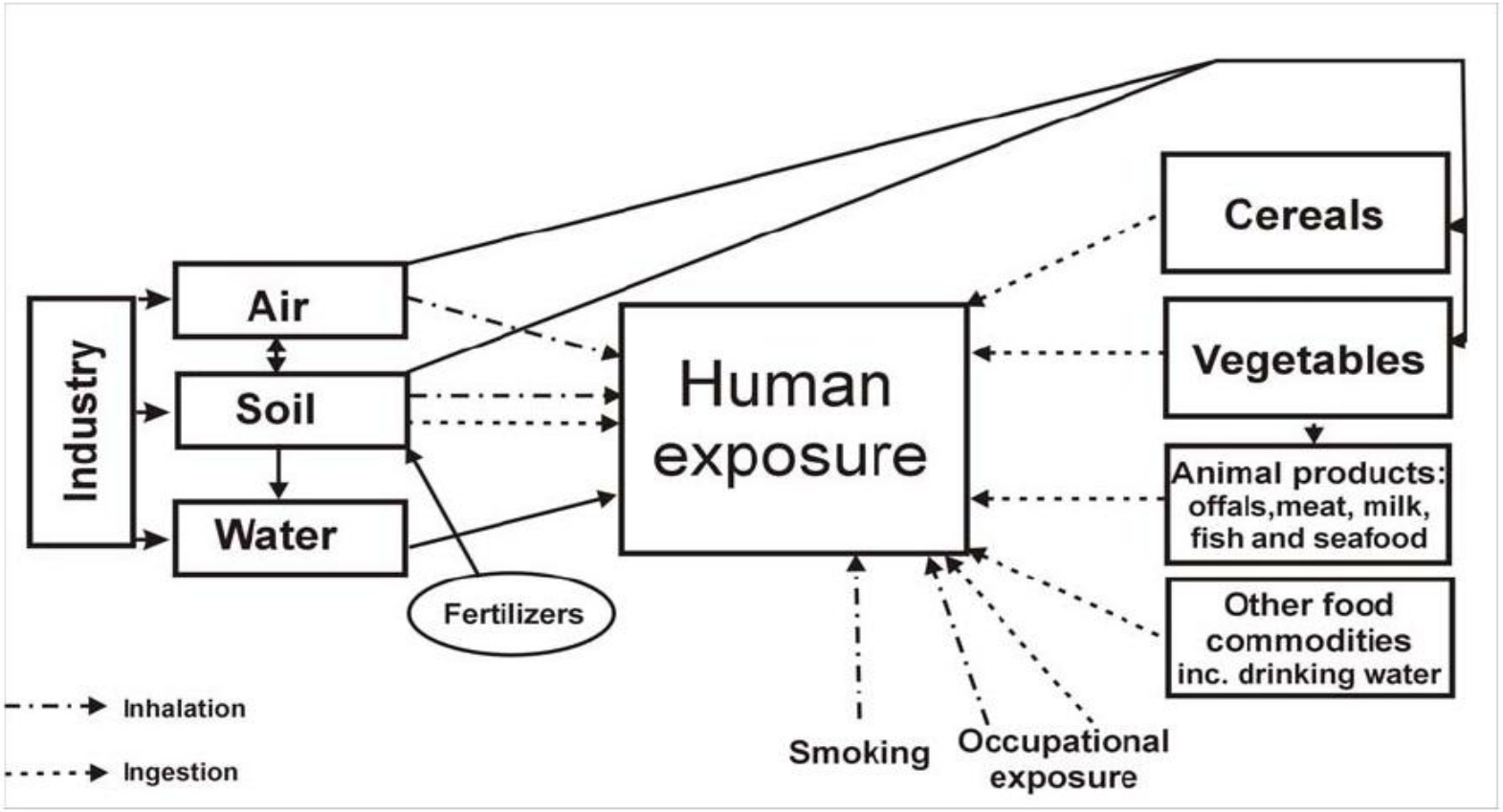
Current status of cadmium in environmental health

ICdA H&S Committee Brussels June 16, 2009

Lars Järup
Imperial College London
Karolinska Institutet, Stockholm

Imperial College London

Exposure sources



From EFSA, 2009

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Exposure pathways

- ✓Inhalation
  - ✓A few percent of daily uptake
  - ✓Occupation
    - ✓Battery workers
    - ✓Smelter workers
    - ✓Solderers
  - ✓Smoking
    - ✓20 cig/day – 1µg Cd absorbed
- ✓Diet
  - ✓Main exposure pathway in non-smoking general population
  - ✓Vegetarians particularly at risk

Exposure trends

- ✓Occupational exposure
  - ✓Since the 1960s, considerable improvements in occupational hygiene have progressively been accomplished. As a result, present day Cd concentrations at the workplace are usually of the order of 10 µg/m³ or lower
- ✓Environmental exposure
  - ✓Based on the relatively few reports on temporal trends, there are no indications of decreasing cadmium exposure in areas without industrial cadmium emissions, while an increasing trend has been reported in some areas during the last decade

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Exposure and dose

- ✓ In general, only airborne total cadmium concentrations are monitored in the working environment; factors influencing respiratory absorption, such as speciation of cadmium are not taken into account and the size distribution of the collected particles is rarely documented
- ✓ Internal dose depends on external exposure and the percentage of the substance that is absorbed (through the respiratory and the gastro-intestinal systems). Absorption through the skin is estimated to be very low when exposure is to particulate Cd and CdO (less than 1%)

Occupational exposure and dose

- ✓For occupationally exposed people, the dominant exposure route is the inhalation route, especially when the occupational exposure is high
- ✓Biomarkers used to assess exposure in occupational settings integrates all sources and routes of exposure (occupational/inhalation + environmental/oral)
- ✓Cigarette smoking adds to occupational Cd exposure via inhalation and this is reflected in the increased (2-5 times) blood Cd level in smokers
- ✓**If the occupational exposure is low, the oral route may become predominant as this is the case in people indirectly exposed to the substance via the environment**

Dose-biomarkers of exposure

- ✓B-Cd
  - ✓Half-life
    - ✓Fast component – 75 to128 days
    - ✓Slow component – 7.4 to16 years
- ✓U-Cd
  - ✓Half-life – 10-20 years

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B-Cd in occupational settings

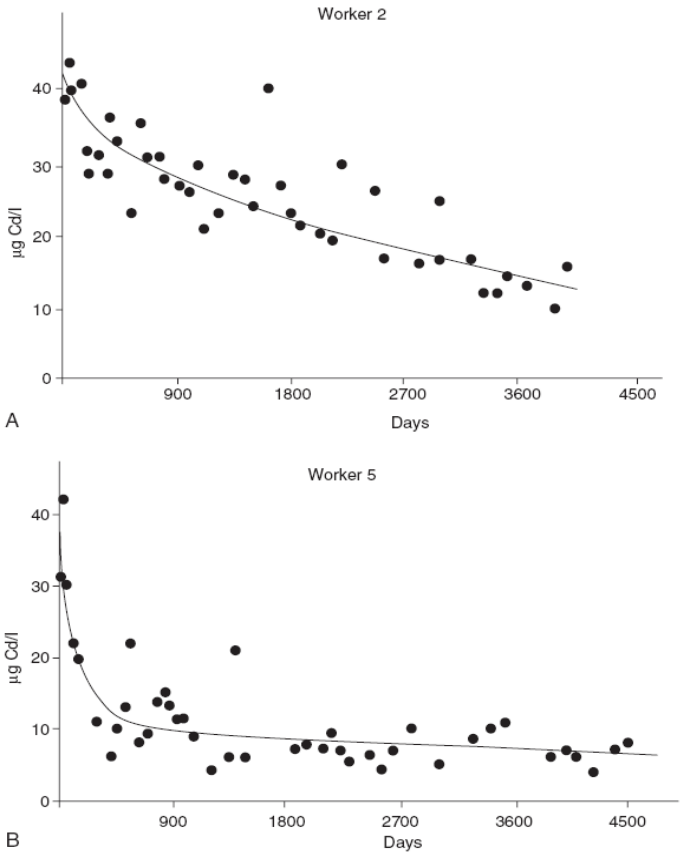

FIGURE 5 Decrease in blood cadmium in two workers after cessation of exposure (1 µg Cd/l=8.9 nmol Cd/l) (From Järup *et al.*, 1983).

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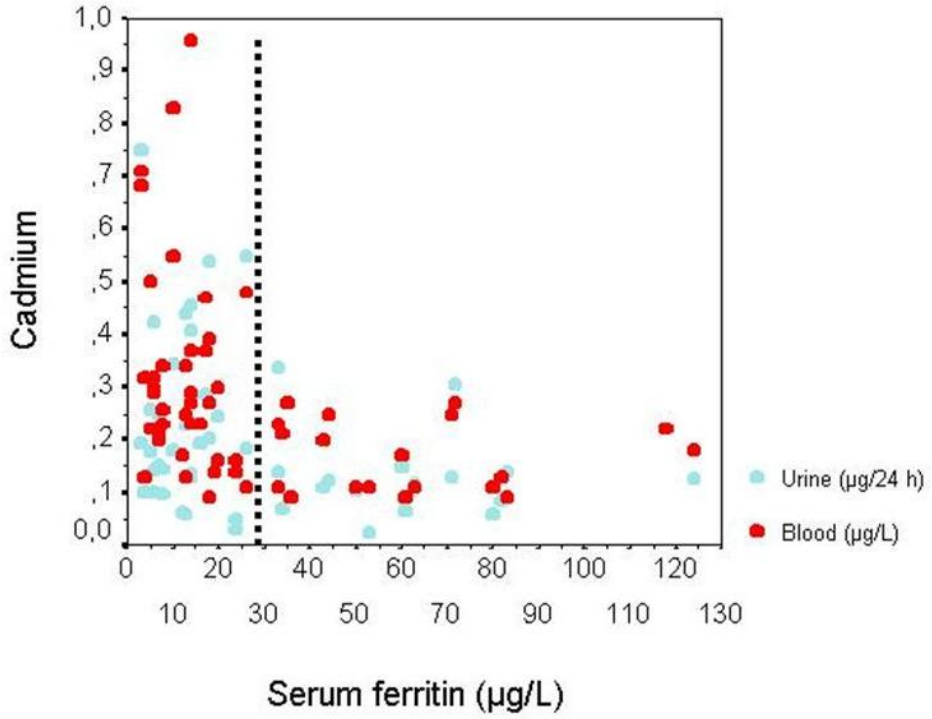
Cadmium absorption and iron stores

✓*Women have higher cadmium body burden than men, reflected as higher concentrations of cadmium in blood, urine and kidney cortex*

✓*The main reason for the higher body burden in women is increased intestinal absorption of dietary cadmium at low iron stores*



Target organs – kidneys and liver

- ✓Cadmium is distributed to most tissues of the body, but tends to concentrate in the liver and the kidney
- ✓Cadmium accumulates throughout life. Hence, the body burden increases due to the continuous exposure
- ✓After long-term low level exposure, about half the body burden of cadmium is localised in the kidneys and liver, a third of the total being in the kidneys with the major portion located in the cortex
- ✓The distribution of Cd in the kidney is of particular importance as this organ is a critical target after exposure to cadmium
- ✓In non-occupationally exposed subjects the cadmium concentration in the kidneys is generally between 10 and 50 ppm (2-5 fold increase in smokers)

Renal effects – tubular damage

- ✓Tubular dysfunction, detected by the occurence of low molecular proteins in the urine, is the first sign of kidney damage
  - ✓Beta-2-microglobulin (BMG)
  - ✓Retinol binding protein (RBP)
  - ✓Alpha-1-microglobulin (AMG; protein HC)
  - ✓N-Acetyl-β-Glucoseaminidase (NAG)
- ✓Such tubular proteinuria may be reversible at low exposure levels, but this is not firmly established
- ✓All studies of tubular proteinuria refer to prevalence of tubular proteinuria, not incidence

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Tubular effects, dose-response studies

Study (population size)	Effect measure/ cut off level for tubular proteinuria (TP)	Probability of adverse response / U-Cd (µg/ g creatinine	Reference
CADMIBEL (n=1,699)	BMG, RBP, NAG/ 95 percentile	10% / 1.8	Buchet et al 1990
OSCAR (n=1,021)	AMG/ 95 percentile	10% / 1.0	Järup et al 2000
China (n=790)	BMG, RBP, NAG/ 95 percentile	$BMDL_5$ / 3 - 4	Jin et al 2004
China (n=245)	BMG, NAG/ 95 percentile	$BMDL_{10}$/ 1.1	Hong et al 2004

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Tubular effects dose-response studies cont.

Study (population size)	Effect measure/ cut off level for tubular proteinuria (TP)	Probability of adverse response / U-Cd (µg/ g creatinine	Reference
Japan (n=828)	BMG, NAG/ 84 percentile	$BMDL_{10}$/ 0.7 – 1.3 (men, women)	Uno et al 2005
Japan (n=6,032)	BMG/ 84 percentile	$BMDL_{10}$/ 2.9 – 3.1 (men, women)	Kobayashi et al 2008
UK (n=180)	NAG/ 97.5 percentile	Relative risk (RR) of TP 0.3-0.5, RR=2.6 0.5+, RR=3.6 p_{trend}=0.045	Thomas et al 2009

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Renal effects – glomerular damage

occupational exposure

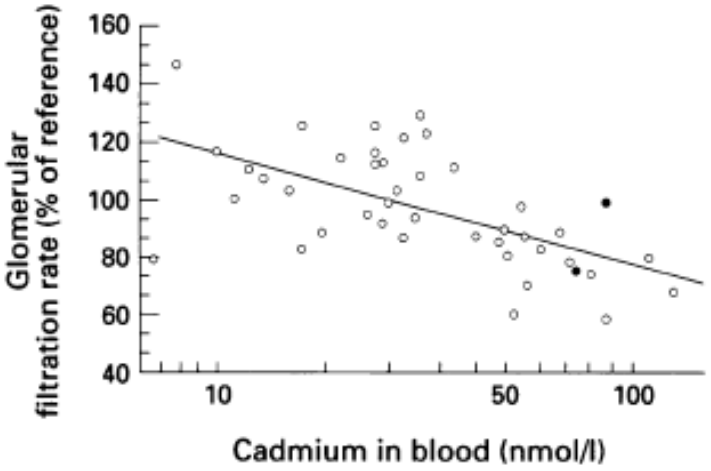

*Figure 3 Glomerular filtration rate (GFR) as a function of blood cadmium. Unfilled circles represent data from the present study. Filled circles represent two workers from the 1989 study that did not participate in the present study. The regression equation is: GFR = 155·0 − 16·7 * ln cadmium in blood, P = 0·000015).*

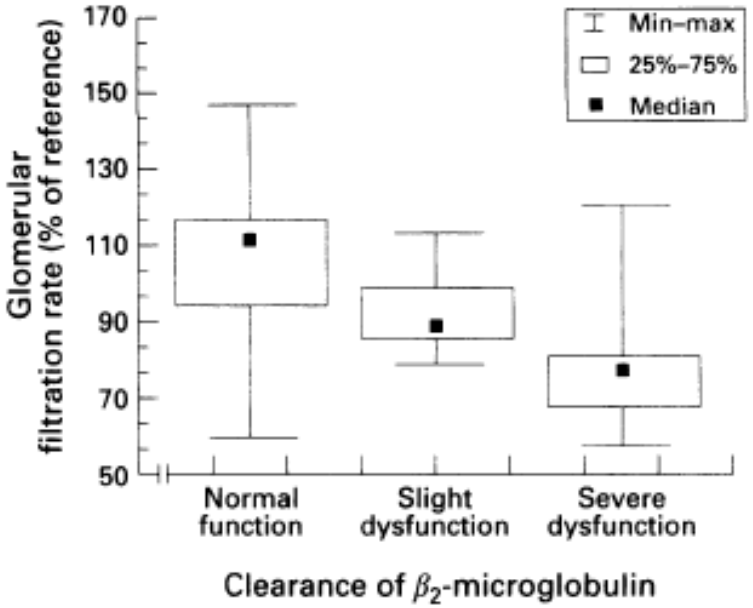

Figure 1 Box plot in three groups of workers. Group 1 includes workers with normal tubular function, group 2 consists of workers with slightly decreased tubular function (β_2-clearance > 0·1 % but < 2·5 %), and group 3 includes workers with severe tubular dysfunction (β_2-clearance > 2·5 %).

From Järup et al 1995
(Cd exposed solderers)

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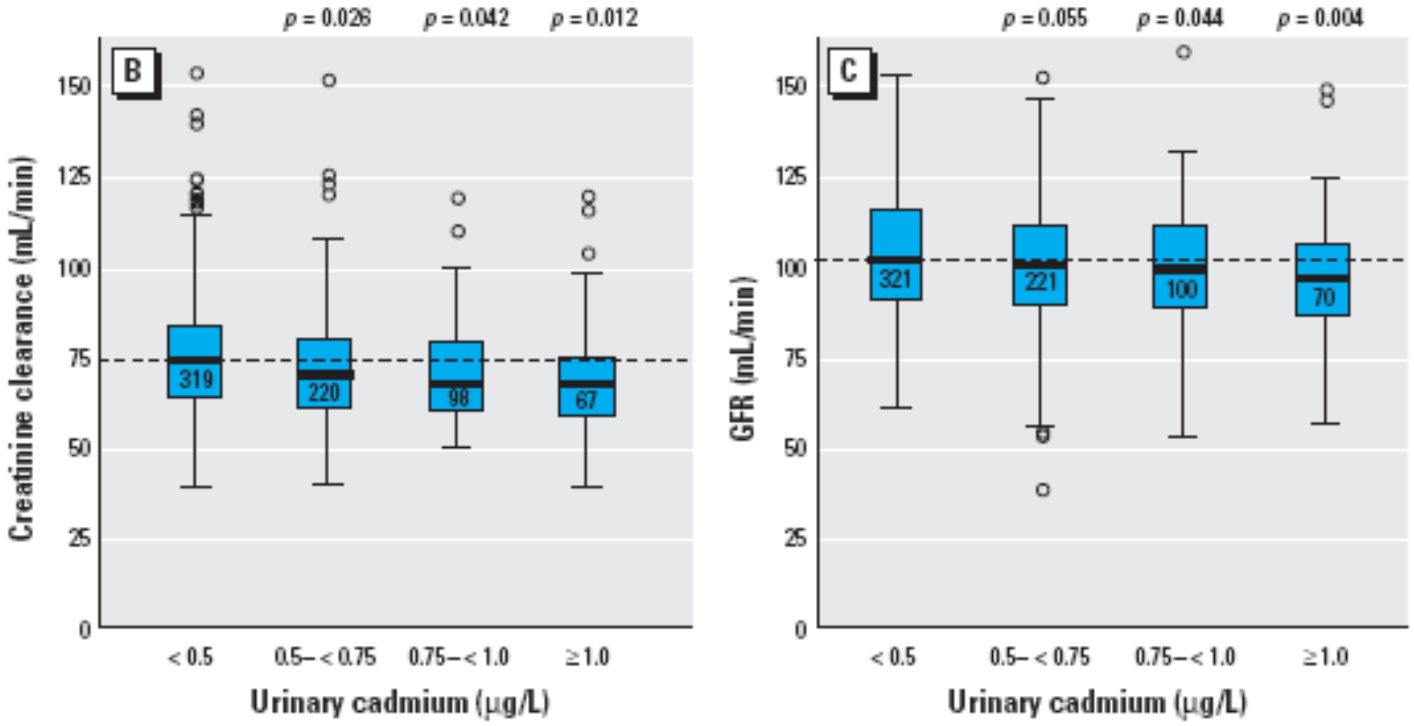
Glomerular damage

environmental exposure



From Åkesson et al 2005 (general population, women only): " We also found associations with markers of glomerular effects: glomerular filtration rate and creatinine clearance. Significant effects were seen already at a mean urinary cadmium level of 0.6 µg/L (0.8 µg/g creatinine)"

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Renal effects – End Stage Renal Disease (ESRD)

Table 3. Incidence of RRT per Million Person-Years and SSRs in Groups Exposed to Different Cadmium Levels Compared With Incidence of RRT in the Unexposed Population Aged 20 to 79 Years in Kalmar County, 1978 to 1995

	Incidence per Million Person-Years			SRR			95% CI		
Exposure by Age (y)	Men	Women	All	Men	Women	All	Men	Women	All
Unexposed									
20–79	157 9	78 8	118 4	(1 0)	(1 0)	(1 0)			
40–79	207 2	99.2	152.2	(1 0)	(1.0)	(1.0)			
Low exposure									
20–79	194 4	95 7	146 6	1 4	1 2	1.4	0 6–2 2	0 2–2 2	0 8–2.0
40–79	301 9	161.9	234 4	1.6	1.5	1 6	0 7–2.6	0 3–2.7	0.9–2.4
Moderate exposure									
20–79	206 9	243 9	226.0	1 3	3 0	1.9	0 7–2 0	1 7–4 4	1 3–2.5
40–79	337 8	255.4	293.6	1 6	2.5	1 9	0 8–2.4	1 2–3.8	1.2–2 6
High exposure									
20–79	458 7	—	344.4	2 1	—	2.3	0 6–5 3		0 6–6.0
40–79	563.6	—	432.4	2.5	—	2.8	0.7–6.5		0.8–7.3

NOTE Test for trend all categories, $P < 0.001$; exposed groups, $P = 0.06$.

From Hellström et al 2001 (workers and general population)
RRT= Renal Replacement Therapy

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Bone effects – osteoporosis and fractures

Study (population size)	Effect measure	U-Cd (µg/ g creatinine) critical dose level	Reference
PheeCad (n= 506	Fractures	RR=1.73 for a 2-fold increase in U-Cd (mean 1.0)	Staessen et al 1999
OSCAR (n=1,064)	Osteoporosis (Z-Score<-1)	RR=1.9 for U-Cd >3.0 vs <0.5	Alfvén et al 2000
OSCAR (n=1,021)	Fractures	RR=8.8 for U-Cd >4.0 vs <0.5	Alfvén et al 2004
China (n=790)	Osteoporosis (T-Score<-2.5)	RR=2.1 for polluted area vs control	Wang et al 2003
Sweden (n=820)	Osteoporosis (T-Score<-2.5)	$BMDL_5/BMDL_{10}$ = 1.0 / 1.6	Åkesson et al 2006
USA (n=4,257)	Osteoporosis (T-Score<-2.5)	RR=1.43 for U-Cd =0.5-1.0 vs <0.5	Gallagher et al 2008

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Bone effects - mechanisms

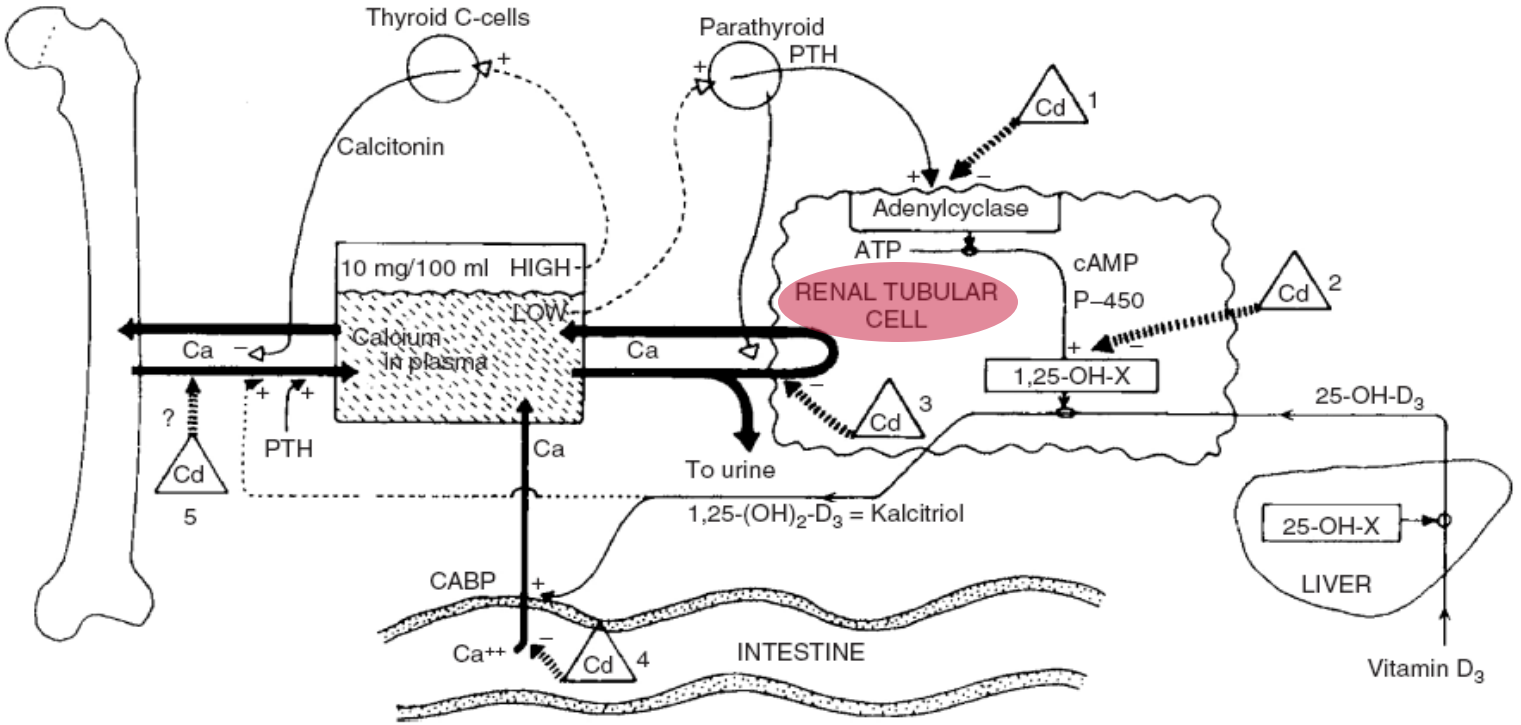

FIGURE 7 Schematic drawing of Vitamin D metabolism and how it may be affected by Cadmium. (1) Cadmium decreases PTH stimulation of adenylcyclase. (2) Cadmium inhibits hydroxylation of 25. OH-D_3. (3) Cadmium increases urinary calcium excretion. (4) Cadmium decreases gastrointestinal calcium absorption. (5) Cadmium affects bone mineralization and bone collagen directly. CABP = calcium binding protein.

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Cancer

✓Lung

- ✓Epidemiological studies on workers was the main basis for IARC's classification of cadmium as a carcinogen (Group 1) (1993)
- ✓More recent studies have shown that co-exposure to arsenic was likely to have influenced the results of these studies (e.g Sorahan and Lancashire 1997)
- ✓EU classifies cadmium as a possible carcinogen
- ✓A recent Belgian study found excess risks in an environmentally exposed population (Nawrot et al 2006)

✓Prostate

- ✓Early studies on workers
- ✓Inconsistent evidence

✓Renal and bladder

- ✓Suggested excess risk, but few studies

✓Breast, endometrium

- ✓Estrogenic effects
- ✓Excess risk of breast cancer (McElroy et al 2006)
- ✓Excess risk of endometrial cancer (Åkesson et al 2008)

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Other health effects / mortality

- ✓**Cardiovascular disease**
  - ✓Myocardial infarction (Everett and Frithsen 2008)
- ✓**Diabetes**
  - ✓Cadmium may potentiate diabetes-induced effects on kidneys
  - ✓Direct causal effect (Schwartz et al 2003, Edwards and Prozialeck 2009)
- ✓**Mortality**
  - ✓Several studies from Japan
    - ✓Increased mortality at low cadmium levels (ca 2 µg/g creatinine)
  - ✓Recent Belgian study (Schutte et al 2008)
    - ✓follow-up of Cadmibel
    - ✓Increased mortality
    - ✓Not directly related to renal dysfunction
    - ✓direct toxic effects

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Risk assessments

- ✓WHO-IPCS 1992
- ✓IARC 1993
- ✓JECFA 1972 –2005
  - ✓Since the main pathway of exposure to cadmium is via food, the position of the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JEFCA) is of particular interest. **JECFA has maintained the Provisional Tolerable Weekly Intake (PTWI) for cadmium at 7 µg/kg body weight throughout its evaluations**
- ✓CDC 2005
- ✓EU 2007

✓Proposed a LOAEL of 2 µg Cd/g creatinine (U-Cd) based on data from the most recent European studies (Buchet et al 1990, Hotz et al 1999 and Järup et al 2000)

✓In an evaluation of the risk assessment document, the EC CSTEE concluded that effects may occur even at lower levels (as low as 0.5 µg/g creatinine) (CSSTE Brussels, 8 Jan 2004). (CSTTEE= Scientific Committee on Toxicity, Ecotoxicity and the Environment)

Risk assessment – ATSDR 2008-9

✓Analysis of the available studies on environmentally as well as occupationally exposed populations estimated the urinary cadmium level that would result in a 10% increase in the prevalence of β2-microglobulin proteinuria (UCD10)

✓The lowest UCD10 (1.34 µg/g creatinine) was estimated from the European *environmental exposure studies* (Buchet et al. 1990; Järup et al. 2000; Suwazono et al. 2006)

✓The UCD10 values from the *occupational exposure studies* were 7.50 µg/g creatinine for the European cohorts (Järup and Elinder 1994; Roels et al. 1993) and 4.58 µg/g creatinine for the Chinese cohort (Chen et al. 2006a, 2006b)

✓The UCD10 from the environmental exposure studies was selected as the basis of the minimal risk level (MRL). **The 95% lower confidence limit on this value (UCDL10) of 0.5 µg/g creatinine was used as the point of departure for the MRL**

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Risk assessment – EFSA 2009

- ✓A meta-analysis was performed on a selected set of studies to evaluate the dose-response relationship between urinary cadmium and urinary beta-2-microglobulin (B2M)
- ✓A Hill model was fitted to the dose-response relationship between urinary cadmium and B2M
- ✓A benchmark dose lower confidence limit for a 5 percent increase of the prevalence of elevated B2M (BMDL5) of 4 µg Cd/g creatinine was derived
- ✓A chemical-specific adjustment factor of 3.9, to account for inter-individual variation of urinary cadmium within the study populations, was applied, leading to a value of **1.0 µg Cd/g creatinine**
- ✓Such a value was also supported by data from occupationally exposed workers and by the results of several individual studies using a variety of biomarkers
- ✓In order to remain below 1 µg Cd/g creatinine in urine in 95 % of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 µg Cd/kg b.w., corresponding to a **weekly dietary intake of 2.5 µg Cd/kg b.w.**

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Conclusions

- ✓Several epidemiological studies using a variety of early markers of kidney damage have identified points of departure for early effects (NOEL and BMDL) between 0.5 and 3 µg Cd/g creatinine
- ✓Recent studies suggest that decreased GFR and creatinine clearance may occur at similar cadmium dose levels
- ✓Adverse effects on bone have been detected at U-Cd levels from 0.5 µg Cd/g creatinine
- ✓In addition, recent studies have indicated increased risk of cancer and mortality at similar, low cadmium dose levels
- ✓A considerable proportion of non-smoking adult populations may have urinary cadmium concentrations of 0.5 µg/g creatinine or higher in 'non-exposed' areas
    - ✓For smokers this proportion is even higher
- ✓This implies no margin of safety between the point of departure and the exposure levels in the general population. Therefore, measures should be put in place to reduce exposure to a minimum

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Reference

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Current status of cadmium as an environmental health problem

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[b] Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden

Abbreviations

- ✓ WHO-IPCS = World Health Organization-International Program on Chemical Safety
- ✓ IARC= International Agency for Research on Cancer (WHO)
- ✓ JECFA= Joint FAO/WHO Expert Committee on Food Additives (FAO=Food and Agriculture Organization)
- ✓ CDC= Centres for Disease Control and Prevention (USA)
- ✓ ATSDR= Agency for Toxic Substances and Disease Registry (US CDC)
- ✓ EFSA= European Food Safety Authority

Medical surveillance of cadmium exposure

ICdA H§S Committee Brussels June 16, 2009

Leif Aringer, MD

Swedish Work Environment Authority (SWEA)

(Revised version)

Medical surveillance in working life, AFS 2005:6

- Valid for employers and their employees
- Medical surveillance is strictly regulated
- Only employees that have undergone medical examinations and have been **certified as fit for work** are allowed to be used for work with cadmium exposure.

Medical surveillance of cadmium exposure; Doctors examination 1

Background data:

-Previous and present diseases - kidney problems?

-Work history - previous exposure to cadmium?

-Smoking habits

Medical surveillance of cadmium exposure; Doctors examination 2

Medical examination:

- General clinical investigation including determination of blood pressure

Laboratory analyses:

- Cadmium in blood (for present exposure)
- Cadmium in urine (accumulated exposure)
- Markers in urine of tubular kidney damage

(α1- microglobulin or NAG are recommended)

Medical surveillance of cadmium exposure; Certificate of fit for work

No signs on:

- high Cd uptake,
- harmfull effects from Cd uptake
- kidney damage not related to Cd exposure
- elevated blood pressure

No other reasons for avoiding Cd exposure

Certificate of fit for work 2

- The worker should not be at a special risk to get hurt by Cd exposure
- The examinating doctor should have special qualifications i.e. a specialization in occupational medicine
- Medical examinations should be repeated every three years

Periodic exposure monitoring

- Determination of Cd in blood at 6 month intervals.
- Depending on the results from Cd anayses certain measures should be taken

Measures based on exposure monitoring (B-Cd nmol/l)

- < 50 12 Month intervals when three consecutive controls are below 50 nmol/l
- > 50 Employer shall investigate work environment and the reason for high uptake and reduce exposure when indicated
- 50-75 6 Month intervals
- > 75 Medical examination. Not allowed to work with Cd until B-Cd < 50 nmol/l

Interpretation of urinary analyses (µmol Cd/mol creatinine)

- <1 ref. value - no occupational exposure
- 1-3 some risk for tubular kidney damage
- 2 should be further investigated
- 5 transfer to non-exposed work should be considered
- Always consult a medical expert in the field in case of elevated values!

Registration of the results

- Name of the investigated person
- What kind of exposure (=Cd)
- Duration of exposure
- Results from biological exposure monitoring
- Doctor´s decision (fit for work?)
- Name of the doctor and date for doctor´s decision

Reports to Swedish Work Environment Authority (SWEA)

- The results from the medical surveillance should be sent to SWEA every 3 months

	Number of investigated persons			
	Males		Females	
	<50	50+	<50	50+ years
B-Cd nmol/l:				
<50				
50-75				
>75				

International Cadmium Association

nyrstar

Analysis of medical monitoring questionnaire responses

Erik Schuurmans

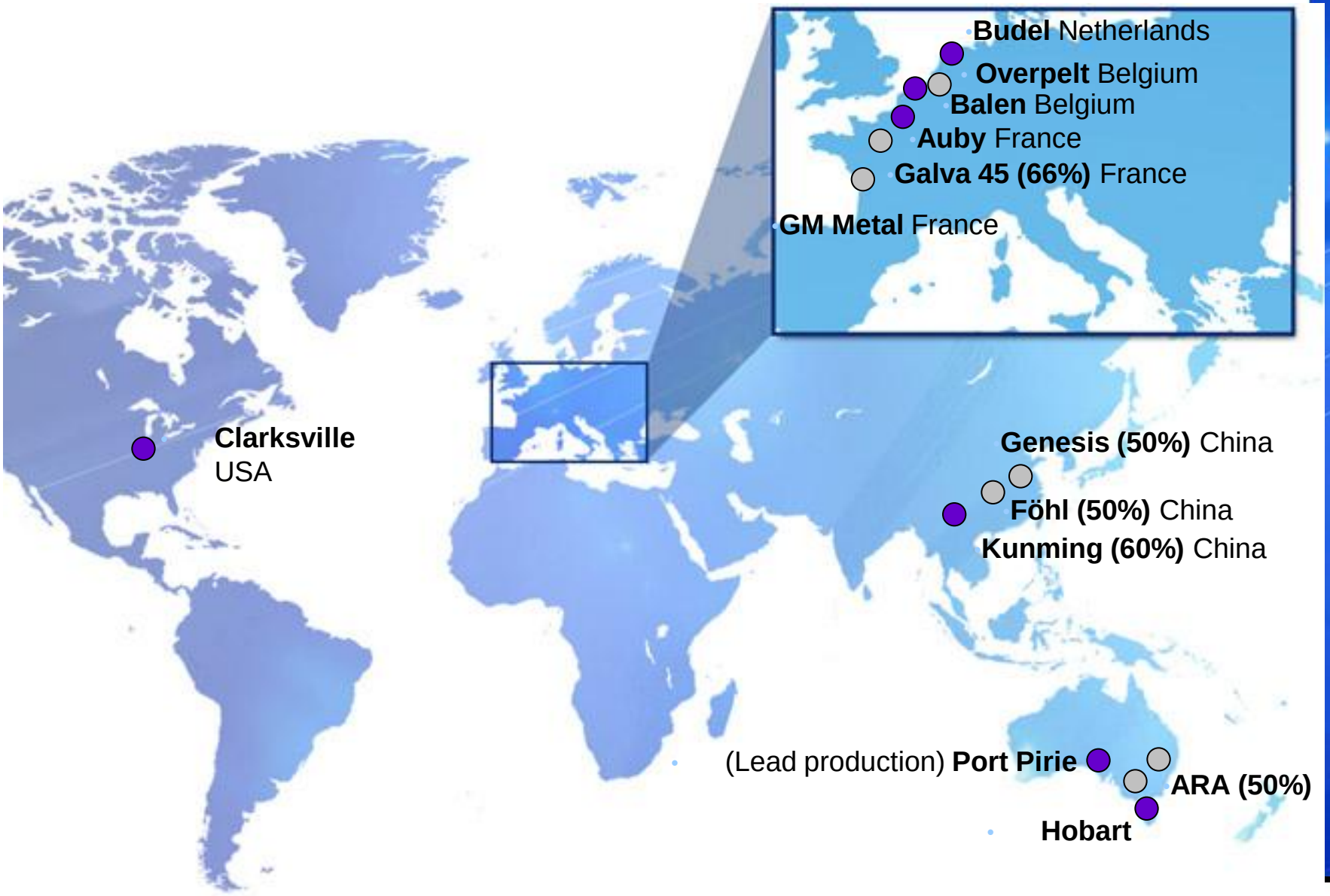
Safety & Health Nyrstar Corporate Office

June 16th 2009

Content presentation

1. Nyrstar
2. Response
3. Structure
4. Operational
5. Quality
6. Other:
   - Recruitment
   - SCOEL
   - ICdA guidance = √

1. Nyrstar smelters



2. Response questionnaire

Countries	Group	Main activity	Nb sites	Complete
BE FR NL	Nyrstar	primary metals	3	Y
NO FI	Boliden	primary metals	2	Y
DE SP	Xstrata	primary metals	2	Y
FR SE CZ	Saft	batteries	4	Y
DE	Hoppecke	batteries	1	Y
DE	GAZ	batteries	1	Y
BE	Floridienne	chemicals	1	Y
FR	SNAM	recycling	1	Y
IT	Portovesme	primary metals	1	
DE	Accurec	recycling	1	Y
UK	James & Brown	pigments	1	Y
UK	Rockwood pigments	pigments	1	Y
PL	ZM SILESIA	chemicals	1	Y
BU	KCM	primary metals /recycling	1	Y
DE	SANYO ?	batteries	1	
PL RO	MIASTECZKO/ BOLESLAW	primary metals	2	

Response 95% = 20 plants answered, 1 did not

3 not member of ICdA HS-committee

FOR FURTHER ANALYSIS ONLY 20 PLANTS INCLUDED

3.Structure programme

- All sites have a medical surveillance programme. √
- Origin programme:
  - 35% Legal （in countries: BE-DE-SP-SE-CZ）
  - 55% Only company doctor
    （sometimes combined with legal/plantmanagement）
  - 10% Only plant management
    （these work with external doctors）

What includes workers in programme?

- Cd air exposure: -> majority of answers
  in general > 5 µg/m^3
  one > TLV BE (2 µg/m^3 resp and 10 µg/m^3 inhalable)

  (one site used > 150 µg/m^3 -> not) ?

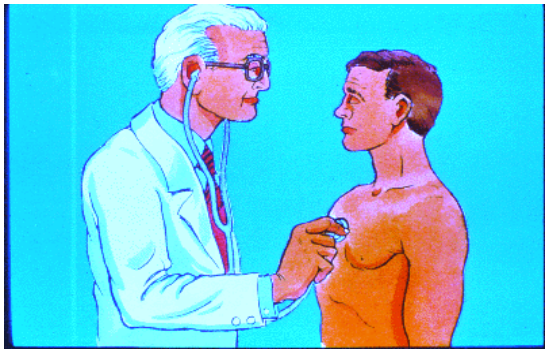
√

- Cd concentration in material:
  0,1%
- Other:
  everybody on site
  decision hygiene authority

  Sometimes sites don't know this exactly

- Number of workers in programme: 2321
  50% Primary metals
  41% Batteries
  9% Pigments, chemicals and recycling

Model programme?



- 35% Fit / Unfit
- 55 % Green / Orange / Red
  = ICdA Guidance
- 10 % Other (legal issue/question not understood)

√

Biomarkers/ BioExposure Indices (BEI's)/ Biological Indicator (BI)

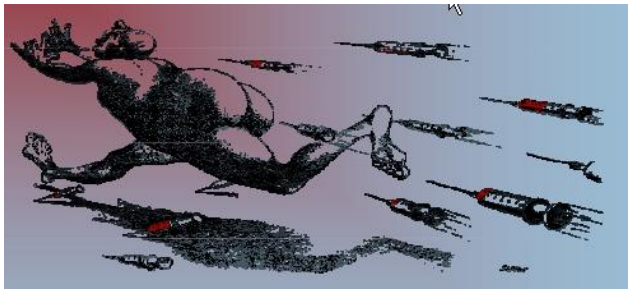
- Primary and secundary decision making tool nearly the same:
  40% CdU ->Half of these measure micro proteins
  40% CdB
  20% CdU+CdB

6x RPB

5x Beta-2-microglobulin

2x Alpha 1

- Secundary marker is for 45% of same importance as the primary.



Biomarkers
Biological Exposure Indices (BI's or BEI's)

- Frequency of testing:
  most plants once a year
  individual frequency increases depending on results

√

- Unit of CdU:
  most plants µg/g creatinine
  rest: different units

- Unit of CdB:
  most plants µg/l
  rest: different units

4.Operational information Exceeding threshold

- 65% Workers is removed from exposure
- **85% Meeting with doctor**
- 30% Meeting with management

Exception CZ: authorities keep records etc

√

Doctor talks about:

- individual result (history)

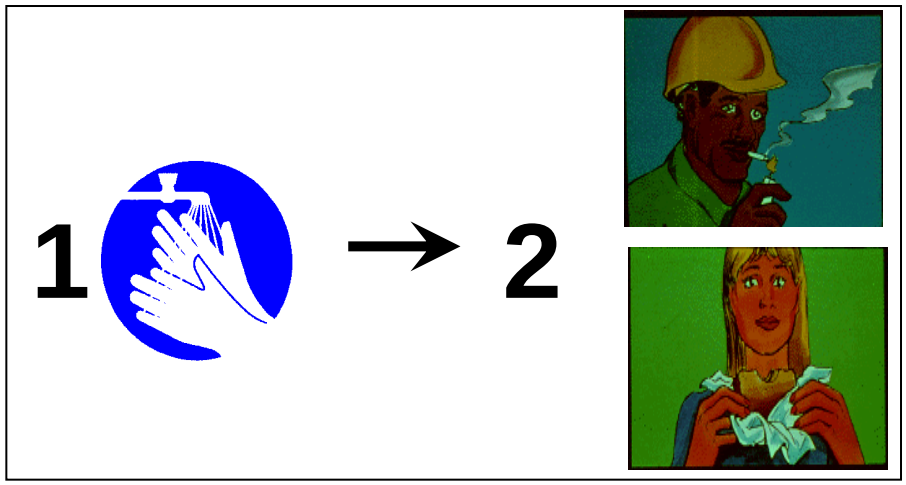
- hygiene rules
  (Hygiene action plan, HAP)

- correct use PPE

- mask fittest

Conversation Doctor

1. Individual results
   last result, trend graph, ..
2. Hygiene rules (Hygiene action plan, HAP)



3. Correct use of dustmask
   Mask fittest

Confirmation results

- 95% always ask confirmation with second sample. √
- 30% does a third sample if second sample is not same as first to get 2 to 1 majority √ √

Feedback

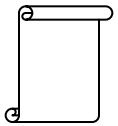
- In all cases: there is feedback to the worker √
  - mostly individual by doctor, less by nurse
  - sometimes by management
- Reporting to management:
  - mostly anonymous grouped by work area
  - sometimes (25%) individual results
  - less as distribution results at plant level

Difficulties to get information about enhanced surveillance or unfit

- 60% it's not a problem to get information
- 25 % it is a problem
- Rest: no answer

- Solution in case of this problem?
  written agreement with employee, limited in time, to limit number of people with access to results in order to manage exposure and individual hygiene habits (SH responsible, shift supervisor)

  * Check if it's legally allowed in your country (UK, NL it is allowed)



Data

- Everybody keeps records. 50% is both on paper (individual dossier) and in databases.
  Excel very popular

- 3 cases in true databases like access, paradox
  2 cases specialized medical data software and
  2 cases who intend to introduce this.
  Kitry EHS/MS former werkamed (BE) and Medtra (SP)

- Records keeping: 10 years – forever
  These records include:

6x = √ ICdA>30 years

Smoking habits 70%	Nail biting 15%	Man with beards 20%	Other records like bad hygiene habits, occupation 10%	None 15%


Any questions till now?

5. Quality samples & testing results

Urine sample method

- 90% spotsampling 10% 24 hour sampling
- Correction spotsampling:
  10% only creatinine √
  50% creatinine with criteria range validity: √
  ICdA guidance doc. > 0,5 g/l

0,3 - 3	0,4 - 2,6	>2	1,5-2 24h sample

  5% only urine density √
  35% no correction

PRECAUTION CONTAMINATION

Urine

Blood

85 % of companies take precautions.
One or more out of the list:

√

- At beginning of shift 50%
- Shower 40%
- Hand washing 15%
- No dirty (work) clothing 15%
- Sterile sampling recipients 15%
- After weekend 5%
- Handling of sample recipients separately 5%
- Washing toilettes 5%

25 - 40%

5 %

Not after holidays 5%

Desinfection of skin with alcohol swab 15%

Quality assurance

- Everybody external labs &
  75% labs have standard for analysis or internal protocol for analysis (25% not known)

- 90% labs quality assurance:
  or **interlaboratory comparison** --> 13 companies
  or **ISO17025 and/or ISO15189** -> 8 companies (3 others not yet)
  or **others** local authority like Finish institute Occ Health, Public Health in Belgium, not specified official license, bioquality certificate GDEA

- 10% not known

6. Recruitment new employees

80% has Cd- hiring policy √ 20%not √

- 30% CdB &CdU
- 15% only CdU
- 15% only CdB
- Others:
  - Smoking status （1: smokers will not be recruited）
  - Asthma and pulmonary diseases
  - Kidney diseases
  - Lung performance test
  - Microproteins in urine

35% will change policy when threshold becomes 2µg/gCr

5. Consequences SCOEL 2µg/gCr

- Problematic. Will lead to significant change of doing business?
  55% of companies or 60%=1392 of total employees
- Problems:

long term employees have higher CdU levels	=>	- will become unfit - dismiss?
5% general population in certain parts of country in Belgium exceeds already this level	=>	will become unfit for recruitment
analytical accuracy is uncertain	=>	Precautions of contamination become very important.
If level will be exceeded, many companies have no possibilities for tempory work with lower exposure	=>	- Dismiss? - Temporary out of work / unemployed ?

Conversion factor Cd 1µg = 8,897 nmol

5. ICdA Guidance

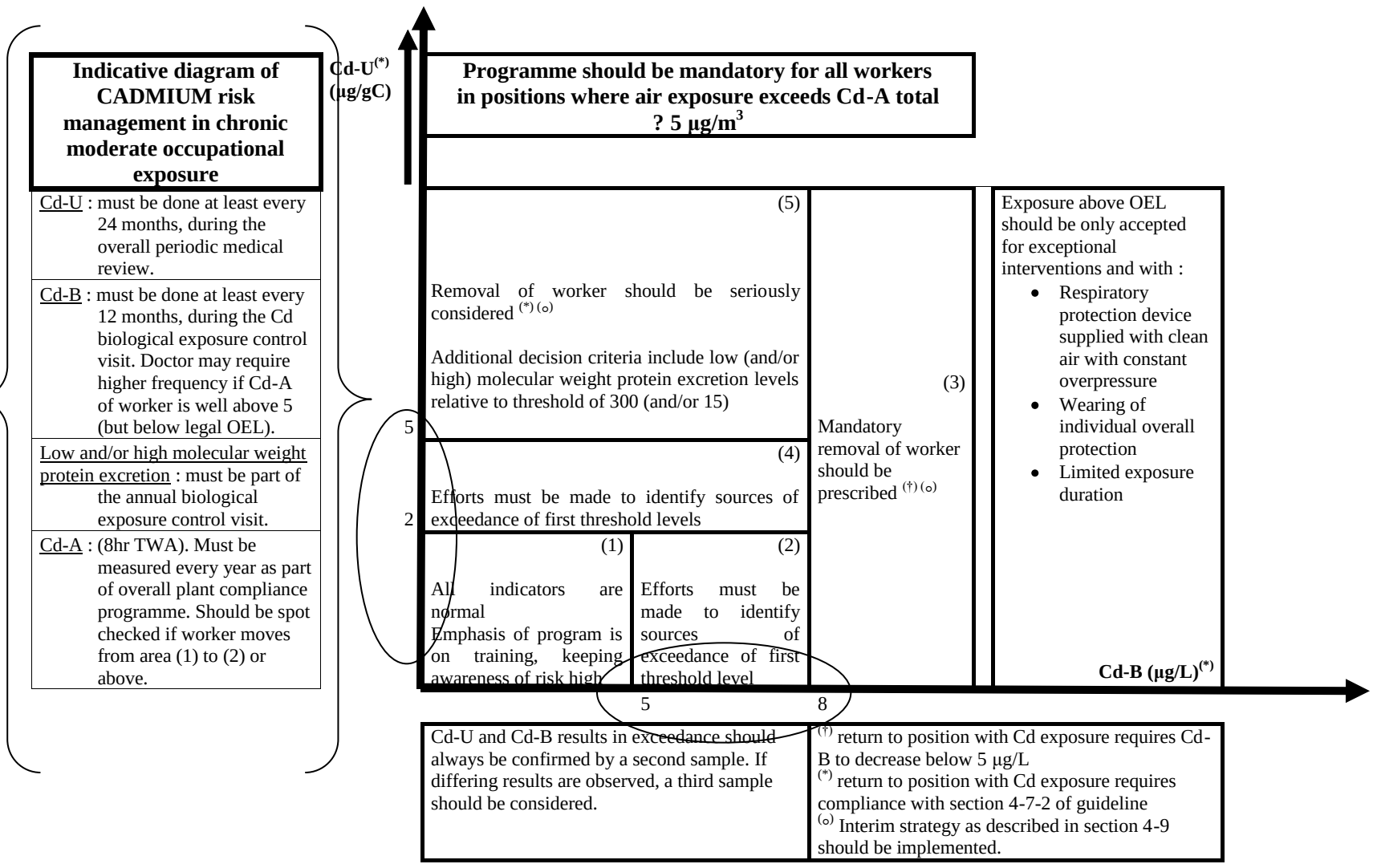
15 companies follow the ICdA Guidance

3 companies do not have it available or are just member

1 company not filled in

1 knows it but doesn't follow it.

3 of the 15 have not a good understanding of the guidance
(French version, rest ?)


Indicative diagram of CADMIUM risk management in chronic moderate occupational exposure
Cd-U : must be done at least every 24 months, during the overall periodic medical review.
Cd-B : must be done at least every 12 months, during the Cd biological exposure control visit. Doctor may require higher frequency if Cd-A of worker is well above 5 (but below legal OEL).
Low and/or high molecular weight protein excretion : must be part of the annual biological exposure control visit.
Cd-A : (8hr TWA). Must be measured every year as part of overall plant compliance programme. Should be spot checked if worker moves from area (1) to (2) or above.
Cd-U(*) (µg/gC)
Programme should be mandatory for all workers in positions where air exposure exceeds Cd-A total ? 5 µg/m3
(5)
Removal of worker should be seriously considered (*)(o)
Additional decision criteria include low (and/or high) molecular weight protein excretion levels relative to threshold of 300 (and/or 15)
5
(4)
Efforts must be made to identify sources of exceedance of first threshold levels
2
(1)
All indicators are normal
Emphasis of program is on training, keeping awareness of risk high
(2)
Efforts must be made to identify sources of exceedance of first threshold level
(3)
Mandatory removal of worker should be prescribed (†)(o)
Exposure above OEL should be only accepted for exceptional interventions and with :
Respiratory protection device supplied with clean air with constant overpressure
Wearing of individual overall protection
Limited exposure duration
Cd-B (µg/L)(*)
5
8
Cd-U and Cd-B results in exceedance should always be confirmed by a second sample. If differing results are observed, a third sample should be considered.
(†) return to position with Cd exposure requires Cd-B to decrease below 5 µg/L
(*) return to position with Cd exposure requires compliance with section 4-7-2 of guideline
(o) Interim strategy as described in section 4-9 should be implemented.

HOW TO MOVE

from:
the present state

to:
the ICdA Guidance document recommendations?

Patrick de Metz

Plan of Presentation

- Where are we?
  - Where we are going?
  - How shall we get there?
- What needs to be implemented?
  - Decision table
  - Several procedural details
- Programme must be holistic and balanced
  - With cleanliness policies
  - With individual and collective hygiene policies
  - Introduction must be progressive
- Conditions for success
  - Joint effort between Occ Dr and plant departments
  - Good coordination between Occ Dr and nurse/med secretary
  - We control what we measure
- Conclusion: Occ Dr holds key role

Where are we? Where are we going?

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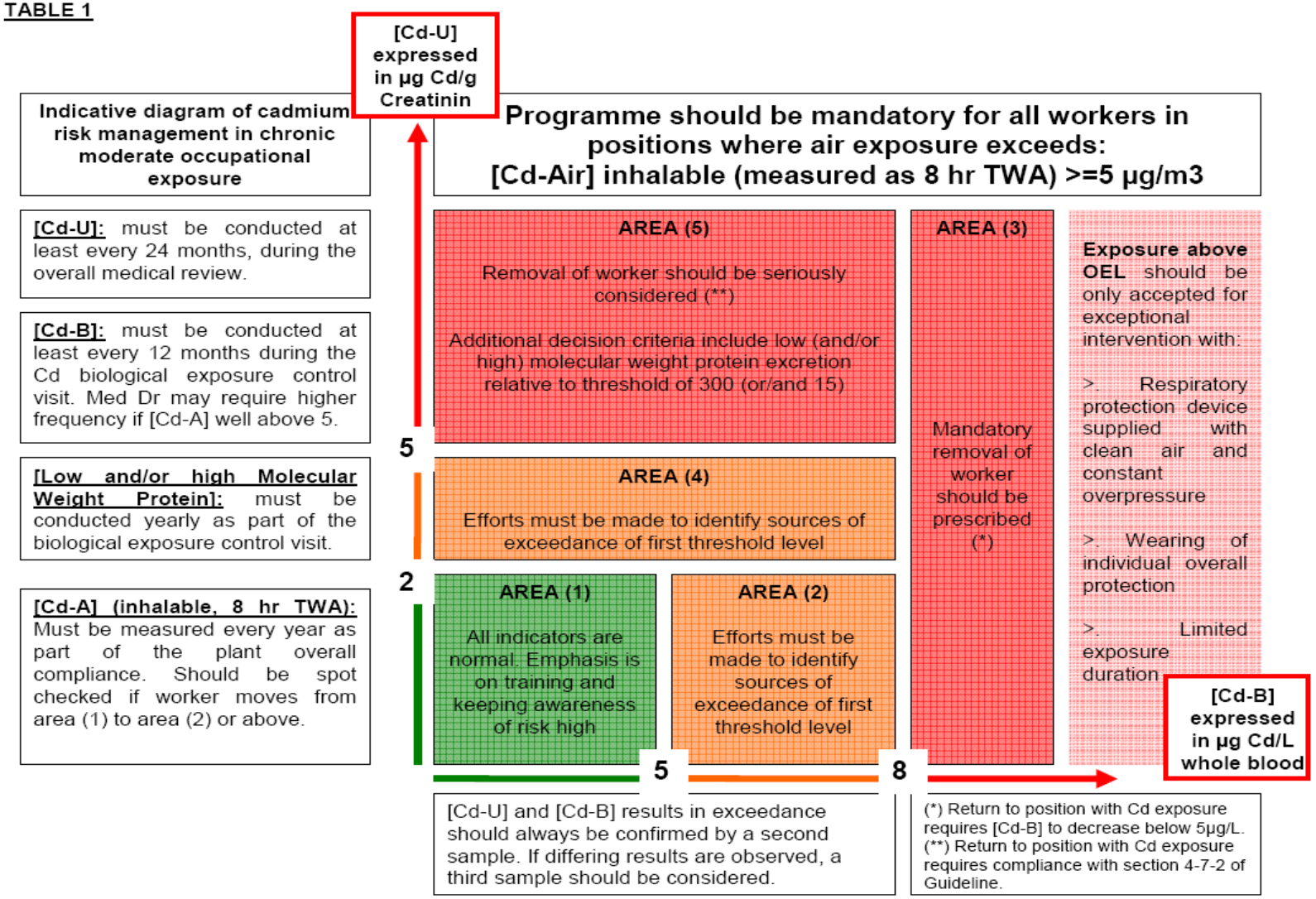
- Different plants have different systems in place:
  - Different biomarkers are used to track body load and effect
  - Different frequencies of measurement are used
  - Different action levels are set and different actions are taken
  - Concept of Green-Orange-Red zones are not always used (Green/Red model is in place in several plants)
- Regulatory changes are on-going
  - OEL: respirable: 4, inhalable: 10-20
  - BLV: [Cd-U] = 2 µg Cd/g Creatinine
  - Employer responsibility:
    - ✓ From an obligation to provide means to
    - ✓ Obligation to ensure result
  - Extension of list of official occupational illnesses

Where we are? How shall we get there?

- A ONE step move to the ICdA system is not possible:
  - ICdA medical surveillance programme not in balance with other elements of risk management system:
    - ✓ Workplace cleanliness
    - ✓ Personal and collective hygiene
- Everything needs to be coherent or else:
  - It may prove impossible to keep workers below [Cd-U] and [Cd-B] thresholds
  - A significant portion of workers may end up being categorized as UNFIT
  - You go out of business!

What to implement: The decision table

TABLE 1



What to implement: many procedural details!

- Inclusion criteria?
- Criteria to set frequency of [Cd-B] analysis?
- Information content and communication process in case of move from GREEN to ORANGE risk zone?
- Information content and communication process in case of move from ORANGE to RED risk zone?
- UNFIT recommended if [Cd-U]>5; detailed criteria?
- Which proteine excretion bio-marker? Which creatinine limit?
- Which frequency of [Cd-B] measurement one worker is in ORANGE zone, in RED zone?
- How shall we manage « historical » workers, same programme, separate programme?
- How shall we manage temporary workers?
- Which pre-employement medical screening? Discrimination?

System must be balanced (1)!

- Or you may have difficulties in controlling your course

Balance: need for a comprehensive, coordinated, holistic approach (2)

- Need good balance with Plant Cleanliness (partially covered in H&S Ctee meeting #2):
  - Set a plant target for [Cd-Air] + cleanliness
  - Refer to inhalable and respirable OEL foreseen by SCOEL
  - Identify areas of non conformance
  - Develop compliance plan with timeline
  - Track progress over time and report to general management
- Plant manag't responsibility
- Your ideas:

Balance: need for a comprehensive, coordinated, holistic approach (3)

- Need good balance with Individual and Collective hygiene procedures (not yet covered in ICdA H&S Ctee)
- Develop inventory of policies and evaluate them against best in class (to be covered in upcoming H&S Ctee)
  - Smoking habits
  - Eating/drinking policies
  - Work clothes change policies and frequencies and
  - Change rooms structure
  - Shower policies
  - …
- Plant manag't responsibility + Occ. Dr involvement
- Your ideas:

Need for a comprehensive, coordinated, holistic approach (4)

- Need to introduce new biomarkers progressively (example of plant with [Cd-U] only):
  - Year ONE: introduce yearly [Cd-B] for all exposed
  - Year TWO: for selected workers, introduce classes of [Cd-B] frequencies based on assessment of risk
    - ✓ One a year
    - ✓ Twice a year
    - ✓ Four times a year
  - Year THREE: introduce action levels/thresholds on [Cd-B]
  - Over time: progressively bring these levels down to Swedish regulation
- Shared responsibility of plant manag't and Occ. Dr.
- Your ideas:

How to ensure a system works? (1)

- Corporate and Plant management must support goal
- Execution needs to be coherent between the three pillars:
  - Plant cleanliness
  - Individual and collective hygiene procedures
  - Medical surveillance programme
- Communication needs to exist between all actors:
  - EHS managers (training, identification of problem areas)
  - Engineering dept (plant layout and equipment improvements)
  - Plant area managers (team training and sending workers to merdical tests)
  - Medical team (training, testing and feed-back)
  - Plant H&S Ctee (must be an ally)
  - Employees (nothing can work if they do not buy into the system)

How to ensure a system works? (2)

- Strong coordination needed:
  - WITHIN the medical team
  - With medical team AND rest of plant
- Strong coordination between Occ. Dr. and nurse/med secretary:
  - Planning of bio-marker visits
  - Logging results in data base
  - Generating statistical analyses
- Strong coordination needed between medical team and rest of plant:
  - Providing employee feed-back (on his data) and training (on personnal and collective hygiene rules)
  - Inform plant of risk zone change (Green to Orange, Orange to Red) With EHS manager
  - With employees
  - With plant engineering
  - With plant area managers
  - With H&S Ctee

How to ensure a system works? (3)

- We control what we measure:
- Individual bio-monitoring data with visible employee name usually may NOT be shared with plant Environment, Health and Safety (EHS) manager or/and General Management
- Group data can (and must) be shared with management since management has respopnsibility:
  - To verify systems in place do ensure that risk is properly controlled
  - Identify weaknesses and re-evaluate system
- Anonymous time series of plant bio-marker distribution need to be developped and shared at a regular frequency (yearly at minimum) with EHS manager

Conclusion

- Occupational team:
  - Doctor,
  - Nurse,
  - Medical secretary
- hold THE key role in the process!

Occupational Cadmium Bio-Indicators Observatory

- OCdBIO -

Patrick de Metz

Main conclusions of last meeting

- OCdBIO only deals with distributions of bio-markers within brackets, no individual data
- OCdBIO does not track plant activity (metals, chemicals, batteries, recycling, pigments)
- OCdBIO plant data is retained and consolidated at ICdA level
- Two sets of aggregated data ([Cd-U] & [Cd-B] distributions) are communicated to an external expert (expected to be Pr Bernard)
- Misc:
  - no sex differentiation,
  - inclusion criteria is: « under Cd medical surveillance »

Next steps

- First run for 2008 (to test and firm-up)
- Individual plants need to sign-up:
  - Must declare participation:
    - ✓ Give an estimate of size of monitored workforce
    - ✓ Give name of person in charge in each plant and contact details
  - Deadline to declare is:
    - ✓ Friday June 26th
- Distribution tranfer:
  - Simple questionnaire to be sent by ICdA on Mo June 29th
  - Two distributions should be returned by Fri July 17th to ICdA
  - Consolidation done and forwarded to Pr Bernard
- Data return with comments from Pr Bernard:
  - First week of september
  - Communication during 4th H&S Ctee

Two Distributions

4.5. [Cd-U] classes:

Cd-U (µg Cd/g creatinine)	Number of workers
0.00 – 1.00	
1.01 – 2.00	
2.01 – 3.00	
3.01 – 5.00	
5.01 – 7.00	
7.01 – 10.00	
>10.00	

4.6. Cd-B classes:

Cd-B (µg Cd /L whole blood)	Number of workers
0.00 – 2.00	
2.01 – 3.00	
3.01 – 5.00	
5.01 – 7.00	
7.01 – 10.00	
>10.00	

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The organisation of the ICdA Occupational Cadmium Bio-Indicators Observatory (OCdBIO)

After the 2nd H&S committee decisions on the organisation of an Observatory (cf. minutes), the purpose of this paper is to clarify the details of the organisation required to implement this decision as soon as possible.

1. The objectives of such an observatory:

1.1. It is a requirement of the EU (Cd) risk assessment process that where risks are identified, a risk management programme must be developed by the EU
1.2. Industry (through ICdA) has voluntarily proposed to the Commission a Guidance document as part of a strategy to mitigate the risk to workers. This proposal has been integrated in the final Commission Risk Reduction Strategy
1.3. The best way to convince ourselves and authorities that our efforts bring results is to monitor workers exposure (as it is done, for example, in the competing Pb industry) by means of the OCBIO
1.4. The gathered data may be communicated to EU or national authorities
1.5. It is interesting for members to compare their own data with aggregated data from the whole Cd using industry
1.6. A follow-up is interesting only if there is a long-term involvement of the companies (at least 3 years).

2. ICdA trustee:

2.1. The data collection will be done by one person of ICdA.
2.2. This person will be responsible for establishing and sending the questionnaire, collecting the answers, aggregating the data and then transmitting them to the external trustee, and if necessary presenting aggregated results to the H&S committee.
2.3. Statistics confidentiality
- The communication made by ICdA on the statistics received will be:
  - To the outside trustee as aggregated data for the purpose of analysis
  - To the members as aggregated data for the purpose of communication
- The statistics of the different ICdA sites will not be aggregated by company or by industrial sector by ICdA
- Formal assurances need to be given by ICdA to its members on these points.

2.4. In order to expand members' participation to the Observatory, only those members that share their statistics with ICdA will receive OCBIO information back.

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3. External trustee for data analysis:

3.1. An external expert, the professor Pr Alfred Bernard, will periodically write a data analysis report, on the basis of anonymous data prepared by the ICdA trustee.
3.2. The external trustee should generate mainly analysis of trends.
3.3. Presentation of analysis report: ICdA has to decide if the external trustee will make a presentation of his analysis to the board and/or to the H&S committee.

4. The bio-indicators data:

4.1. Two bio-indicators will be collected: Cd-U (Cd in urine) and Cd-B (Cd in blood)
4.2. the respective units will be:

- [Cd-U]: µg Cd/g creatinine
- [Cd-B]: µg Cd/L whole blood

4.3. The data of males and females will **not** be communicated separately
4.4. For each class of each bio-indicator, the company will give only the number of workers falling within this class (one value/person).

4.5. [Cd-U] classes:

Cd-U (µg Cd/g creatinine)	Number of workers
0.00 – 1.00	
1.01 – 2.00	
2.01 – 3.00	
3.01 – 5.00	
5.01 – 7.00	
7.01 – 10.00	
>10.00	

4.6. Cd-B classes:

Cd-B (µg Cd /L whole blood)	Number of workers
0.00 – 2.00	
2.01 – 3.00	
3.01 – 5.00	
5.01 – 7.00	
7.01 – 10.00	
>10.00	

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5. Periodicity and inclusion criteria:

5.1. The observatory period is one year. A questionnaire will be sent to the companies in January of each year regarding the previous year, the goal is to get the whole process finalized by June.

5.2. Age of the data:

As the sampling periods differ between countries, companies or sites, the data to be included in the annual report are the most recent data which are available at the end of the year. It means that some data could be as old as 2 or 3 year and some only 1 or 2 month old.

5.3. Workers included:

All workers present in the workforce on Dec 31st and undergoing Cd specific medical surveillance (currently exposed or previously exposed) are integrated in the annual reports sent by individual sites to the ICdA trustee.

TO BE DECIDED:

Workers no longer present in the workforce on Dec 31st and workers not subject to Cd specific medical surveillance are not to be reported.

6. The first run : data of 2008:

6.1. With only one report per year, it is interesting to get the first report as soon as possible also for the purpose of testing whole process. For this reason the ICdA trustee will soon send a questionnaire for the purpose of receiving the bio-indicator values available on 31st December 2008 (cf. above definitions).

6.2. Provisional agenda for the first run:

6.2.1. Identification of the sites concerned by the questionnaire and of the name of the OCdBIO responsible person on each site. This will be checked using the latest ICdA Ctee member's list.

6.2.2. Questionnaire sent by ICdA before the 1st of July 2009

6.2.3. Data collected for the 15th of July

6.2.4. Data sent to Pr Bernard by the end of July

6.2.5. Report from Pr. Bernard first week of September for communication during the 4th H&S committee (15th September 2009).

***