

FFM / GHTF - Training Seminar on Risk – Management, Luebeck, 24th June 2005

# Risk Management in the Context of the Medical Devices Vigilance System



## BfArM's Perspective

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## Topics to be addressed

- General characteristics, purpose, objectives and main elements of the medical devices vigilance system
- PMS by manufacturers
- Incident reporting (criteria, exemptions)
- Risk assessment
- Corrective action (CAPA / risk control)
- Risk communication and transparency
- Review of vigilance cases – examples / possible options



## General characteristics

- Legal requirement
- Involving manufacturers as well as competent authorities (+ others)
- Related to serious safety concerns
- Important mechanism to ensure and maintain product safety
- Linked to the postmarketing part of the life cycle risk management concept
- Reflecting the limitations of premarketing planning, verification and validation

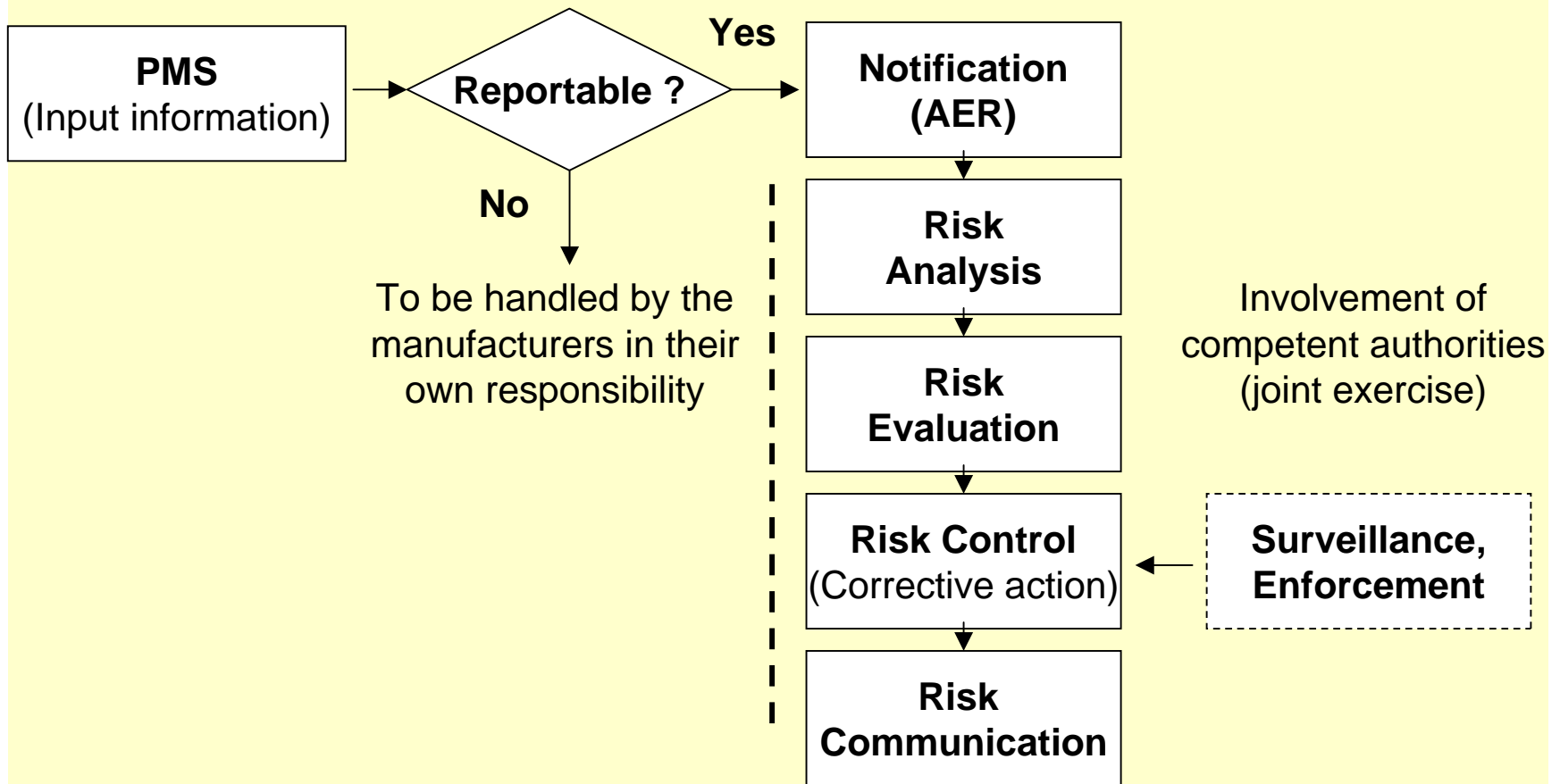
## Purpose and objectives

- Improving the safety of medical devices (not: prosecution, sanctions and fines)
- Effective risk management in any individual vigilance case
- Providing appropriate information to prevent recurrence of similar problems

# Medical Devices Vigilance System



## Main elements (overview)



# Postmarket Surveillance by Manufacturers



## Input information to be considered („minimum programme“ – if applicable)

- Customer / user / patient complaints (submitted directly or indirectly)
- Notifications of sales representatives
- Information provided by service and maintenance staff
- Internal test reports / quality system data
- Information provided by competent authorities
- Scientific (standard-) literature / media reports
- Product modifications implemented by competitors .....

## Examples of additional strategies to gather data (depending on product nature and risks)

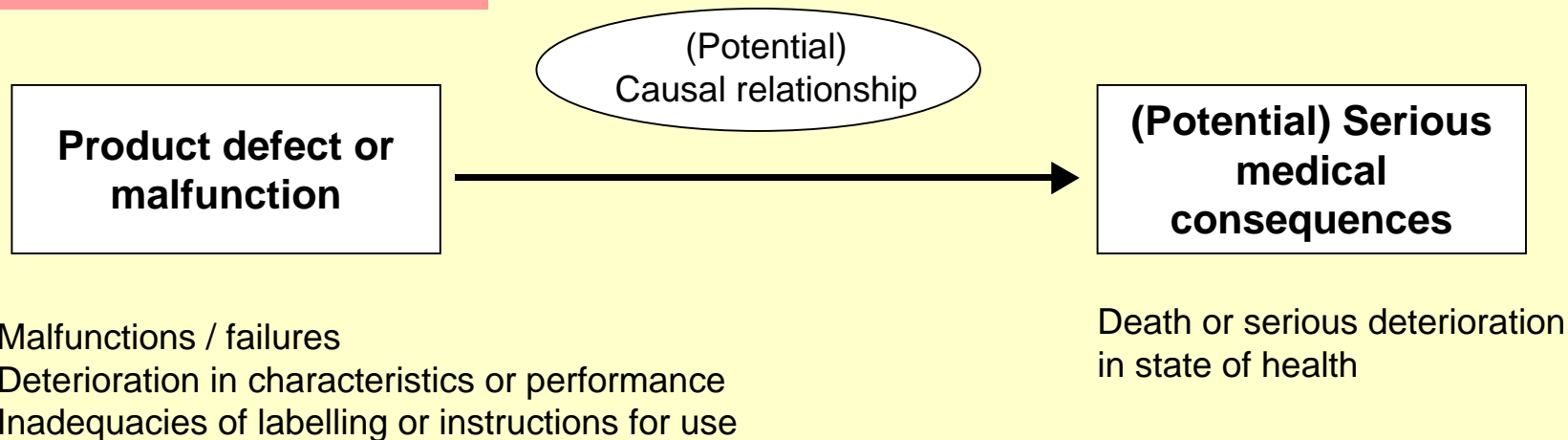
- Comprehensive and systematic literature reviews
- Systematic surveys to review user experience
- Additional product testing / technical studies
- Additional clinical investigations of products already on the market / PMCF
- Implant registries .....

# Reporting Requirements



## Reporting criteria

Incidents / near incidents



Recalls (if risk related)



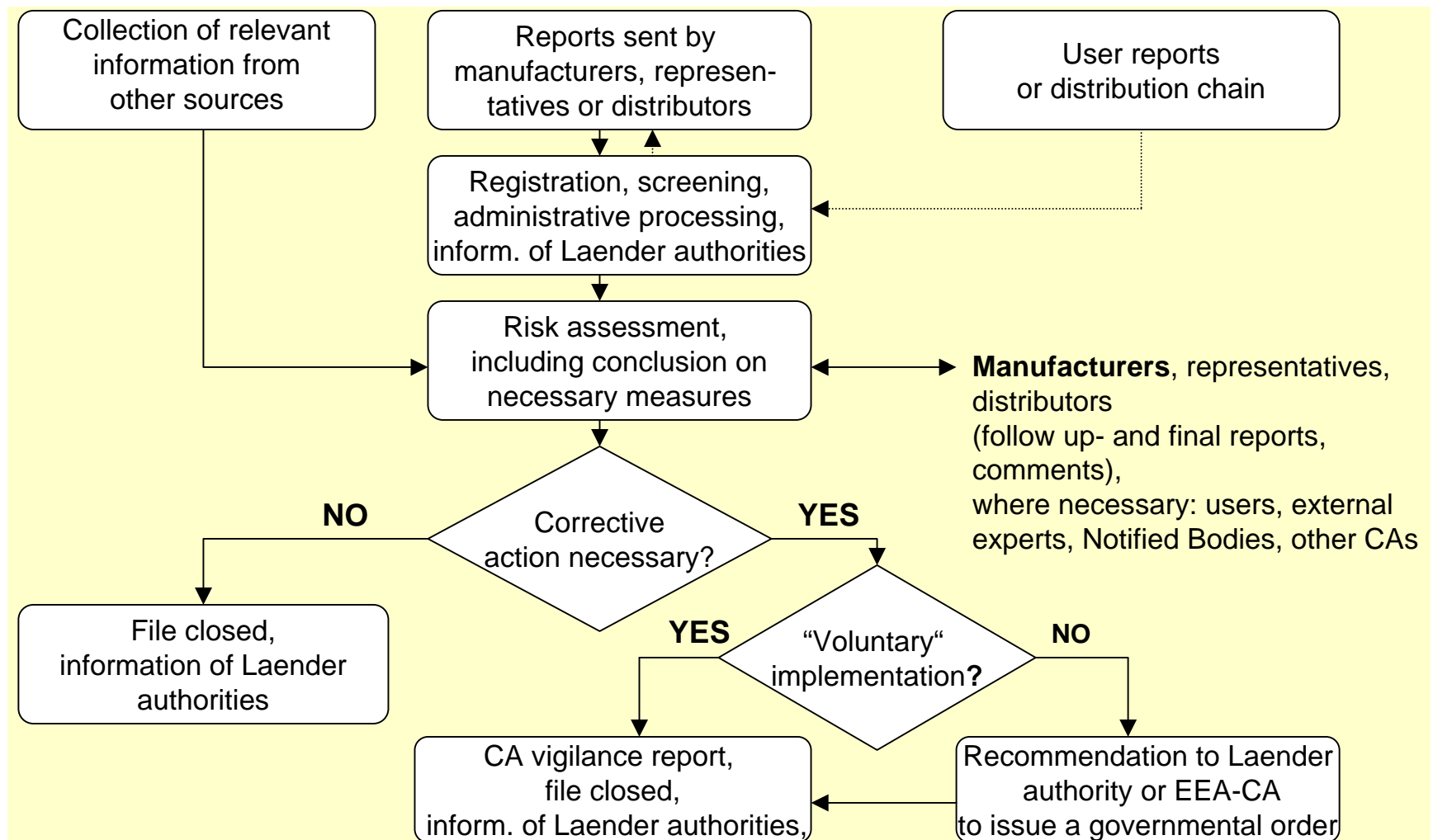
## Definition of „incident“ not met

- User errors
- Problem clearly visible prior to use of the device
- Event caused by patient conditions
- Off label use (unless problem may also occur with regular use)
- Use of a device although its expiry date has elapsed (if problem is stability related)
- End of specified service life
- Expected and foreseeable side effects / complications  
(if correctly described in the product information)
- Correct functioning of protection means against a single fault condition
- Remote likelihood of occurrence of death or serious injury

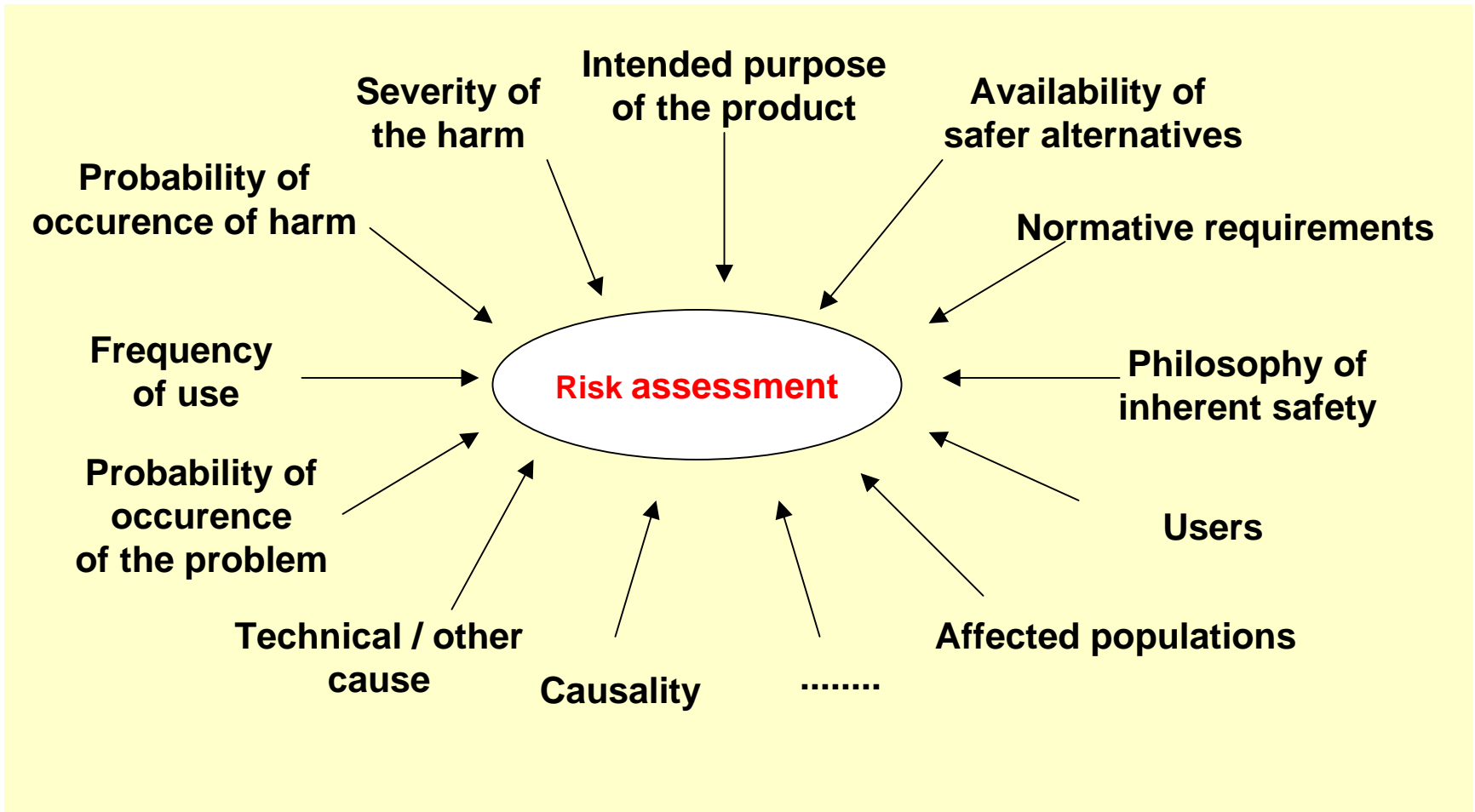
+

**Reporting exemptions granted by legislation or the competent authority**

# Risk Assessment Procedure (BfArM)



# Risk Assessment Criteria



# Risk Estimation Scheme



## Probability of occurrence of harm

frequent



11	16	20	23	25
7	12	17	21	24
4	8	13	18	22
2	5	9	14	19
1	3	6	10	15

unlikely

negligible

death

Severity of the harm

# Risk Control - Corrective Action



## **Measures aiming at limitation of harm**

= mainly related to products currently marketed

- Recall
- Stop of distribution / production
- Stop of usage
- User information .....

## **Measures aiming at elimination of the root cause**

= mainly related to future production

- Change of design / construction
- Change of product information (labelling, IFU)
- Optimization of production process
- Improvement of user training .....

# Risk Communication - Advisory Notices



## Information to be provided by the manufacturer

- Contact person / point
- Clear identification of the affected product(s) / batch(es)
- Description of the product failure or malfunction
- Root cause of the problem, if known
- Risk associated with the defective product (including underlying facts and deliberations)
- Unambiguous specification of the necessary corrective action
- Other useful information (e.g. re-testing of specimens)

## To be avoided

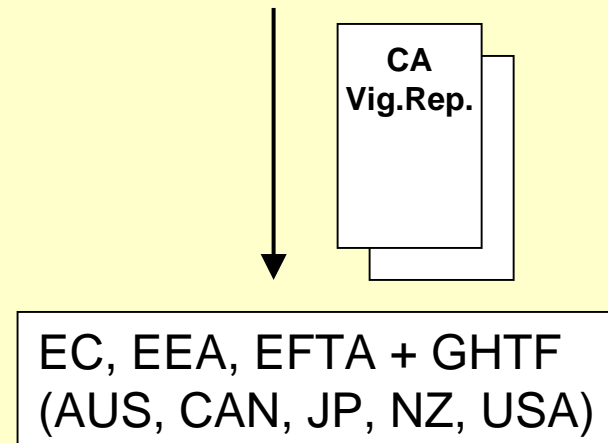
- Playing down the risk
- Advertising

# Risk Communication – CA Vigilance Reports



## Main purposes

- Official and neutral information
- Enabling other competent authorities to supervise the corrective actions in their area of responsibility
- Creating awareness of problems that might be relevant also for similar products of other manufacturers
- Contribution to harmonising competent authorities' approaches and practice
- Vehicle to communicate additional and confidential information



**Different policies** ⇒ **Unbalanced situation (number of BfArM-reports > all others)**  
⇒ **New information tools implemented by BfArM (e. g. information via internet)**



## BfArM's new strategy

### Information about specific vigilance cases

- To be provided on request to everybody, if there is a legitimate interest
- Information about field corrective actions to be published via the internet
- As a consequence, number of BfArM- vigilance reports to be reduced

### Statements / recommendations about generic problems

- To be published via the internet

### Review of the risk assessments performed

- Systematic statistical analysis of vigilance cases to be made available to the parties concerned
- Detailed reviews of specific product groups or categories to be progressively performed and published in scientific or regulatory journals or via the internet

**www.bfarm.de**  
**Medizinprodukte**  
Medical Devices  
**Informationen über Risiken**  
Information on Risks



## Statistical analysis of vigilance cases

- I. Number of vigilance cases, sources of reports, products concerned, regulatory classification, Notified Bodies**
    - Number of recorded reports (vigilance cases), trends
    - Sources of reports
    - Differentiation by product groups
    - Regulatory classification
    - Notified Body involved (*non-public part*)
  - II. Analysis of the problem: kind of failure, root cause of failure, outcome**
    - Incident description: Kind of failure (if not known, alternatively: clinical manifestation)
    - Root cause of failure
    - Actual clinical outcome
    - Possible clinical outcome (in case of recurrence)
  - III. Corrective measures and vigilance reports**
    - Corrective measures aiming at the limitation of harm
    - Corrective measures aiming at the elimination of the root cause
    - Vigilance reports
- + Detailed review of specific product groups or categories**

# Risk Communication – Analysis of Vigilance Cases



## BfArM product catalogue (product groups)

AI = AIMD

EF = Electro-magnetic-fields

ER = Control of conception

IT = Injection, infusion, dialysis

MD = Medical software

NI = Non-active implants

OP = Surgery equipment and anaesthesia

OT = Ophthalmic products

TH = Radiation

VM = Dressings and suture materials

DT = Dental products

EM = Electromedical devices

HU = Medical instruments

IV = IVDs

ME = General treatment equipment

OF = Optics and precision mechanics

OR = Orthopedic / rehabilitation devices

PT = Physical therapy

US = Ultrasonic equipment

XN = Radiology

## Example: Analysis by product category

Product group: Electromedical devices (EM)

Subgroup: Electrodiagnostic devices (EM – 01)

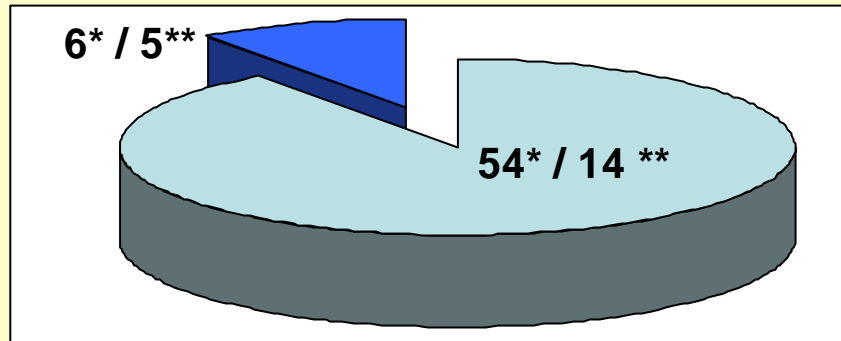
Product category: Patient monitoring equipment (EM – 01 – 13)



# Analysis of BfArM Vigilance Cases (Jan. - May 2005)

Product category: EM-01-13 „Monitors“ (total number of cases: n = 60 )

## Incident description (What was observed?)



Functional defects

Others

\* = number of vigilance cases

\*\* = number of products affected

### Functional defects

- total loss of function (43 / 6)
- partial loss of function (1 / 1)
- no alarm (7 / 6)
- measurement or data transfer problem (3 / 3)

### Other problems

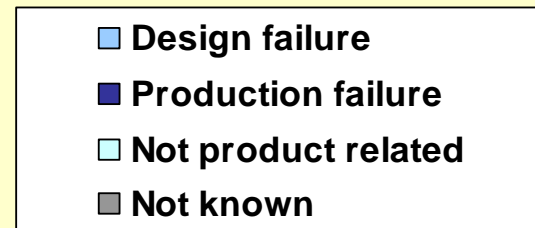
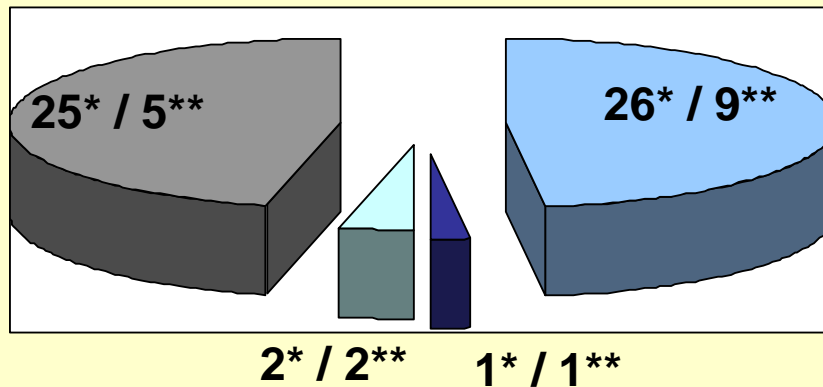
- electrical failure (1 / 1)
- overheating (1 / 1)
- software issue (1 / 1)
- mechanical problem (1 / 1)
- burns (2 / 1)



# Analysis of BfArM Vigilance Cases (Jan. - May 2005)

Product category: EM-01-13 „Monitors“/ Incident description= functional defect  
(total number of cases: n = 54)

## Root cause



\* = number of vigilance cases  
\*\* = number of products affected

### Design failures

- usability issue (3 / 3)
- material or component (19 / 2)
- electrical wire issue (2 / 2)
- software problem (2 / 2)

### Production failure

- .....

### Not product related

- .....

### Root cause not known

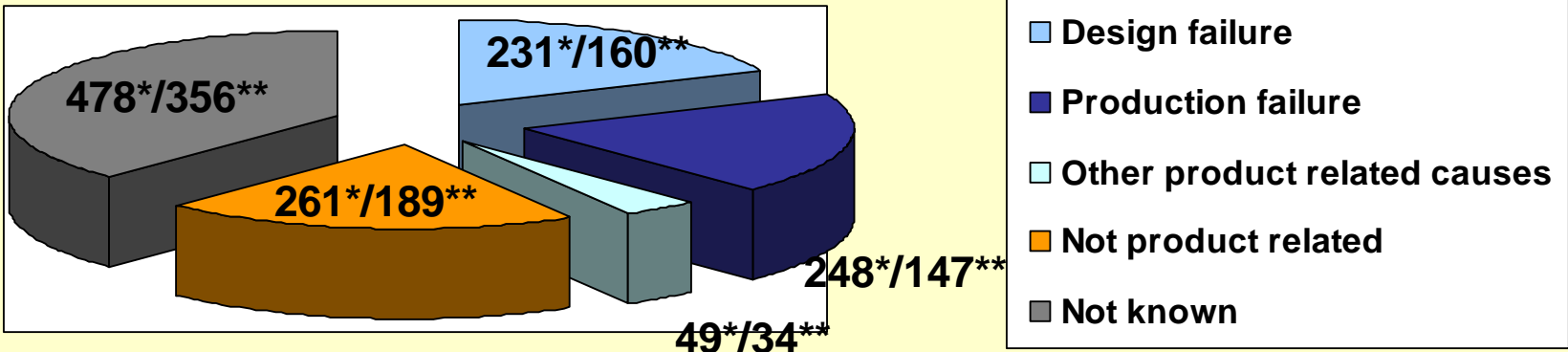
- .....



# Analysis of BfArM Vigilance Cases (Jan. - May 2005)

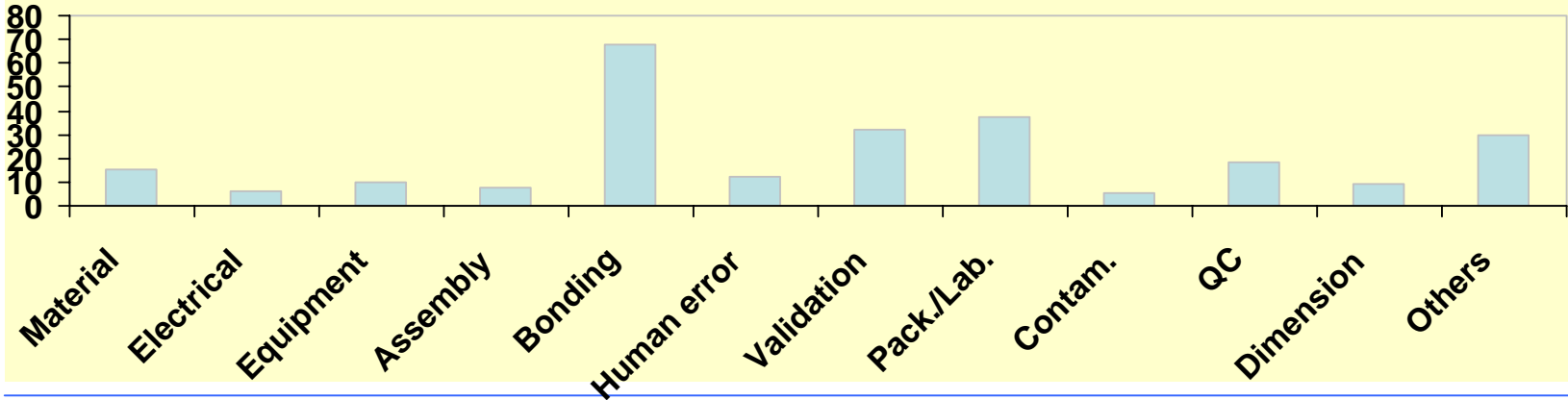
## Example: Analysis by root cause

(all reported incidents, total number of cases: n = 1360)



\* = number of vigilance cases  
 \*\* = number of products affected

## Production failures (n = 248 cases)

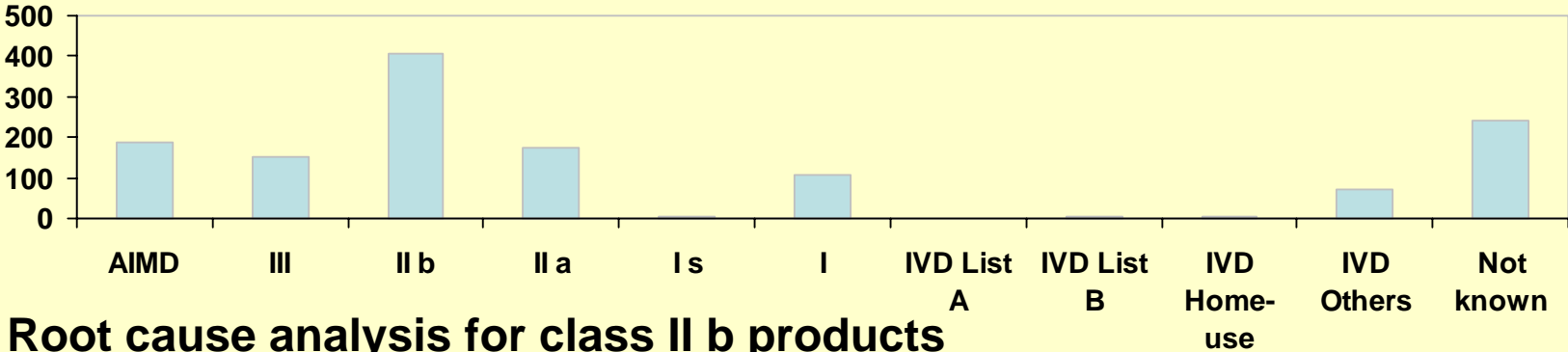




# Analysis of BfArM Vigilance Cases (Jan. - May 2005)

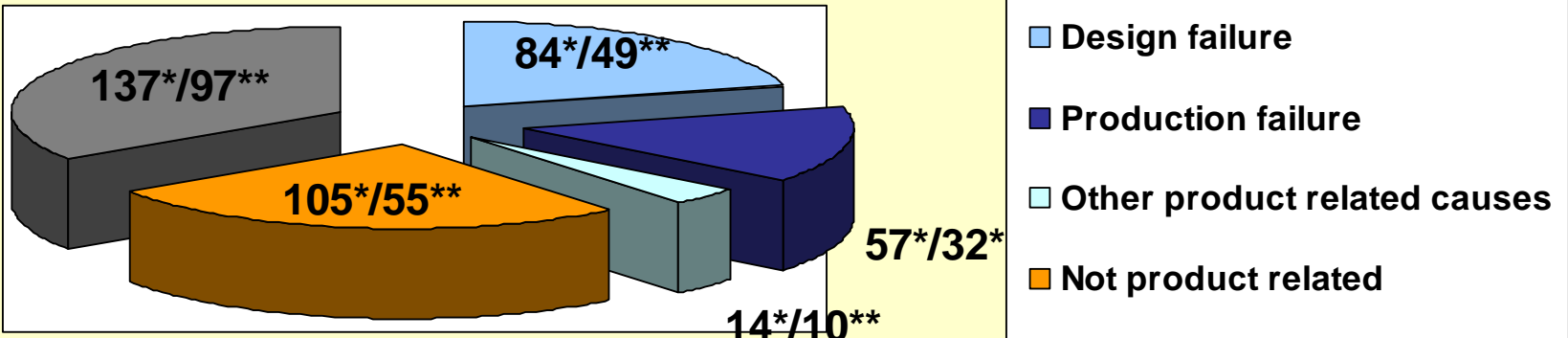
## Example: Analysis by product classes

(all reported incidents, total number of cases: n = 1360)



## Root cause analysis for class II b products

(n = 408 cases / 235 products)



\* = number of vigilance cases  
 \*\* = number of products affected

- Design failure
- Production failure
- Other product related causes
- Not product related
- Not known