# HERCA MSW
# Accidental and unintended exposures
# *Manufacturer feedback*

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# 2013/59/EURATOM

- Manufacturers clearly in scope of 2013/59/EURATOM
  - *Establishes uniform basic safety standards for the protection of health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation.*

# Article 63

- Chapter VII, which includes article 63, relates specifically to Medical Exposures of patients as part of medical diagnosis/treatment
  - (a) all reasonable measures to be taken to minimise probability and magnitude of accidental/unintended exposures
  - (b) study of the risk of such exposures for radiotherapeutic practice
  - (c) appropriate system for record keeping and analysis by *undertaking*
  - (d) inform referrer, etc
  - (e) reporting to CA of significant events ASAP by *undertaking*
- Only (a) and (b) could apply to *manufacturers*.

# Article 96

- Chapter IX, which includes Article 96, provides general responsibilities of member states and CAs
- The requirement in Article 96 for notification and reporting of significant events is directed towards the *undertaking*, and not the *manufacturer*.

# Medical Device Directive 93/42/EEC (1)

- Essential Requirements (Annex I)
  - Design and manufacture to not compromise clinical condition/safety of patients.
  - Article 63 (a) and (b), from the manufacturer's responsibility, already addressed in MDD.

# Medical Device Directive 93/42/EEC (2)

- Information on *incidents* occurring following placing of devices on the market (Article 10)
  - Manufacturer has responsibilities for reporting any *incident*
    - MEDDEV reporting criteria
      - malfunction may lead to/might have led to death or to a serious deterioration in state of health
      - trending
  - BSSD *significant event* ≠ MEDDEV *incident*
    - Does *clinically significant event* more closely match MEDDEV *incident*?

# Medical Device Directive 93/42/EEC (3)

- Information on *incidents* occurring following placing of devices on the market (Article 10)
  - Timescale
    - Serious public health threat: immediately
    - Death/unanticipated serious deterioration in health: immediately link established between device and event - no later than 10 days
    - Others: immediately link is established between device and event - no later than 30 days.

# Summary

- The issues addressed in Articles 63 and 96, are already covered by the MDD in terms of the manufacturer's role
- The difference between "significant event" and the MEDDEV "incident" will likely result in clinics reporting more events relating to device malfunction to the CA, than will the manufacturer.
- The failure to define "significant event" will lead to inconsistency between different member states and lack of harmonisation.