EUROPEAN SOCIETY OF RADIOLOGY

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REPORT

Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology

European Society of Radiology (ESR)

Question to be discussed

Q2.5 Is there any term related to accidental and unintended exposures in BSSD that the stakeholders do not fully understand especially in relation to the terms in other international documents?

Q2.5: It is questionable if a common consensus about the terms "accidental" and "unintended" exposure exists.

2.3 The BSSD includes definitions of both accidental exposures and unintended exposures:

- "Accidental exposures" means an exposure of individuals, other than emergency workers, as a result of an accident. - Clearly this applies to all exposures (occupational, public and medical).

5.1 **Article 63(a)** requires

"Member States shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental and unintended exposures of individuals subject to medical exposure".

Questions to be discussed

Q5.1.1 Do stakeholders believe current regulatory requirements are sufficient to satisfy this requirement?

Q5.1.2 Is sufficient attention given to diagnostic exposures as well as therapeutic exposures?

Q5.1.1: Current regulations work rather good.

Q5.1.2: Sufficient attention for therapeutic procedures, diagnostic exposures can be improved and need some more attention (e.g. by MPEs).

5.3 **Article 63(c)** requires

"Member States shall ensure that for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice"

Questions to be discussed

Q5.3.1 In practice, what systems are already in place for record keeping and analysis of all incidents involving diagnostic and therapeutic radiological services?

Q5.3.2 Where these systems are in place, do they separate out accident and unintended exposures or do they mix them together with other adverse events that can occur in medical care and that aren't related to ionising radiation?

Q5.3.3 Do these systems include events potentially involving accidental or unintended exposures (ie near misses – see below)?

Q5.3.4 While outside the direct requirements of the BSSD, do stakeholders believe reporting of potential accidental or unintended medical exposures is desirable and if so, should this be to the competent authority or to another body (eg professional organisation)?

Q5.3.1: very few, e.g. dose management systems
Q5.3.2: if existing, they collect only radiation events
Q5.3.3: critical incidents - NO
Q5.3.4: potential events should be recorded locally and provided as a summary report for regular clinical inspections. It could be desirable to provide these summary data anonymous to scientific organizations.

5.4 **Article 63(d)**

Questions to be discussed

Q5.7.1 Are the professional bodies best placed to provide guidance on clinically significant events and are they willing to do so?

Q5.7.2 To what degree is such guidance already available – for diagnostic exposures, for interventional procedures, for radiotherapy?

Q5.7.3 Can this be provided at European level or should this be left to be solved out within each Member State (for example by professional bodies themselves or in cooperation with the competent authority)?

Q5.7.1: YES if there is a good cooperation with regulatory bodies
Q5.7.2: diagnostic NO, interventional partly, therapy YES
Q5.7.3: recommended by EU, required by MS

5.8 **Article 63(e)(i)** requires

"Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority"

Q5.8.1 Do stakeholders have experience of criteria which have been developed that have credibility within their communities that could be used as part of requirements for reporting of significant events?
Q5.8.2 What is the purpose of reporting significant events as soon as possible to the competent authority? What should the competent authority do with such immediate reports?
Q5.8.3 Should events, which the competent authority should know about but they don't need any quick intervention of the authority, be reported later? (i.e. they wouldn't be significant events for reporting as soon as possible and the duty to report them later would go beyond the requirements of BSSD)?

Q5.8.1: little to nothing
Q5.8.2: in case of accidents with injuries: set a time frame for corrective measures.
If risk of such an accident exists at other sites: inform others to prevent similar events
Q5.8.3: YES

Question to be discussed
Q5.10 What are stakeholders' views on the value of reporting total numbers of events (with some description graded with the risks) within a specified period, which could later be used as part of inspection processes etc when considering local safety culture?

Q5.10: Periodically reporting a sum of events is a good solution

5.18 **Article 63(e)(ii)** requires

"Member States shall ensure that results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State"

Questions to be discussed

Q5.18.1 Should a maximum time period for investigations of significant events be stipulated within Regulations?

Q5.18.2 Should a specific time period for each investigation be determined and agreed on a case-by-case basis?

Q5.18.3 In competence of which employee of the undertaking should be making of these investigations and summarising of them?

Q5.18.1. National authorities should define the common time period for corrective measures.

Q5.18.2. Shorter or longer time periods should be specified in individual cases, if a general time period is not appropriate.

Q5.18.3. Responsible MPE or equivalent person on highest position in radiation protection

5.19 **Article 63(f)** requires

"Member States shall ensure that mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events"

Questions to be discussed

Q5.19.1 Is dissemination of information a responsibility of the competent authority, the health Ministry (or similar) or individual undertakings that have experienced significant events?

Q5.19.2 What experience do stakeholders have of the value of dissemination of this type of information?

Q5.19.3 How practical is it to produce valuable but anonymised information that meets the needs of the wider radiological community while respecting the wishes of individual patients involved in significant events?

Q15.19.1: YES, by authority

Q15.19.2: Limited experience, but scientific organizations have wide and fast access to practitioners.

Q15.19.3: Practicable and important

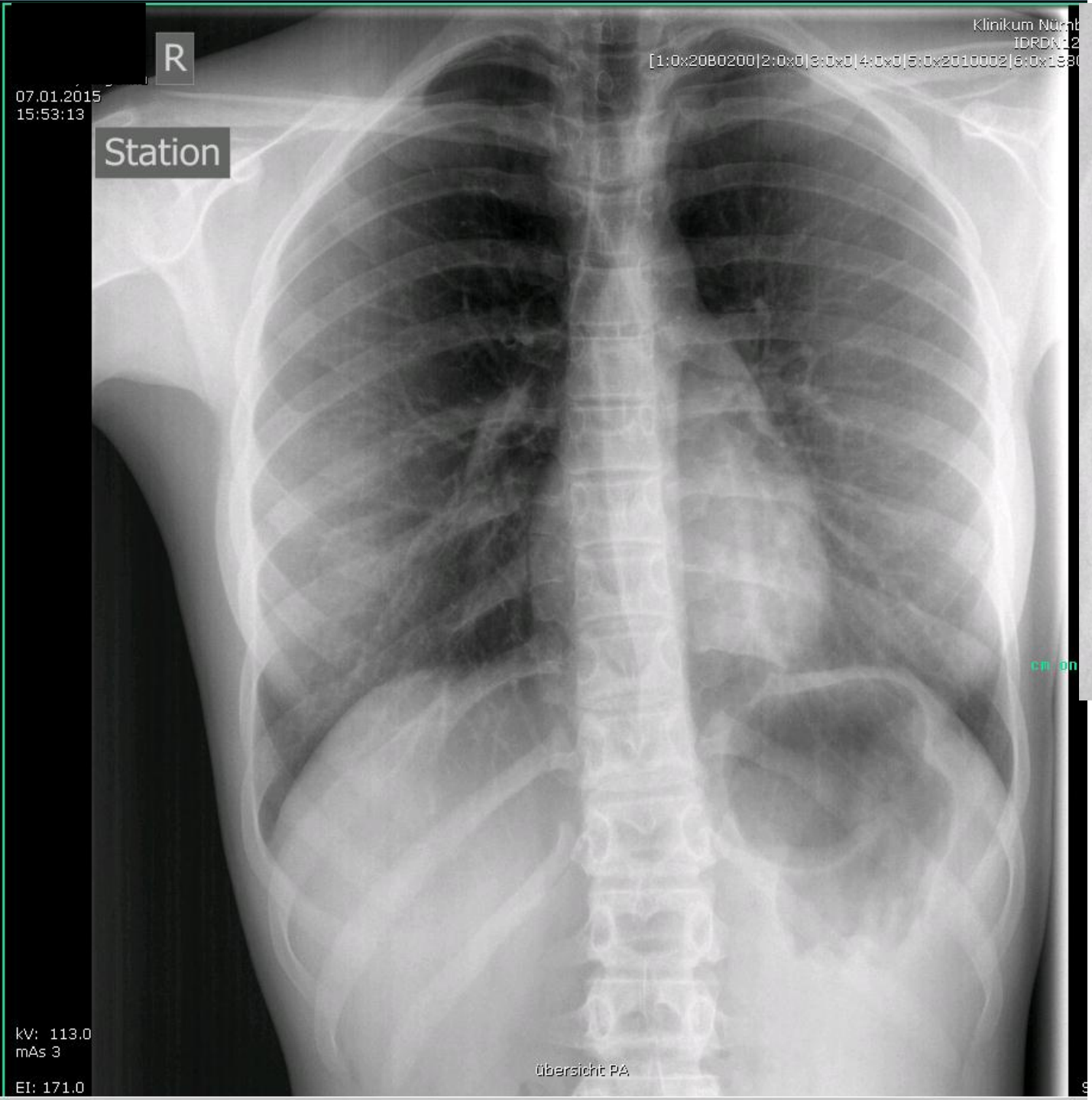
ESR view of important topics

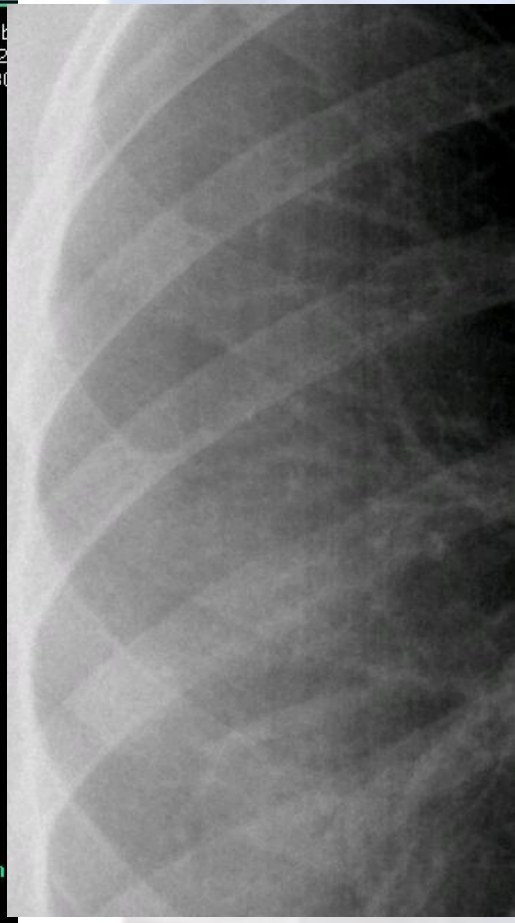
- Priority is patient safety
- Occupational incidents / overexposure should be included
- Reports to authorities should go through an effective filter to avoid a spam situation
- Non-reporting of incidents with “zero dose” should be considered (should be managed in a general local CIRS Critical Incident Reporting System) Finland: wrong patient referral ???
- Definition of significant events France: ASN guide n°11
- Criteria for collective overexposures (DRLs, LDRLs, intended dose)
- Criteria for individual overexposures (absolute dose excess, DRLs)
- Criteria for incidents / accidents to be stored locally e.g. for summary reports
- Non-reporting of medically justified overexposures

ESR view of important topics

EU-BSS will foster dose management systems for all digital modalities for:

- QC
- Detection of technical errors
- Reporting for clinical inspection
- Regulators for national dose survey
- Regulators for setting up DRLs
- Local incident detection





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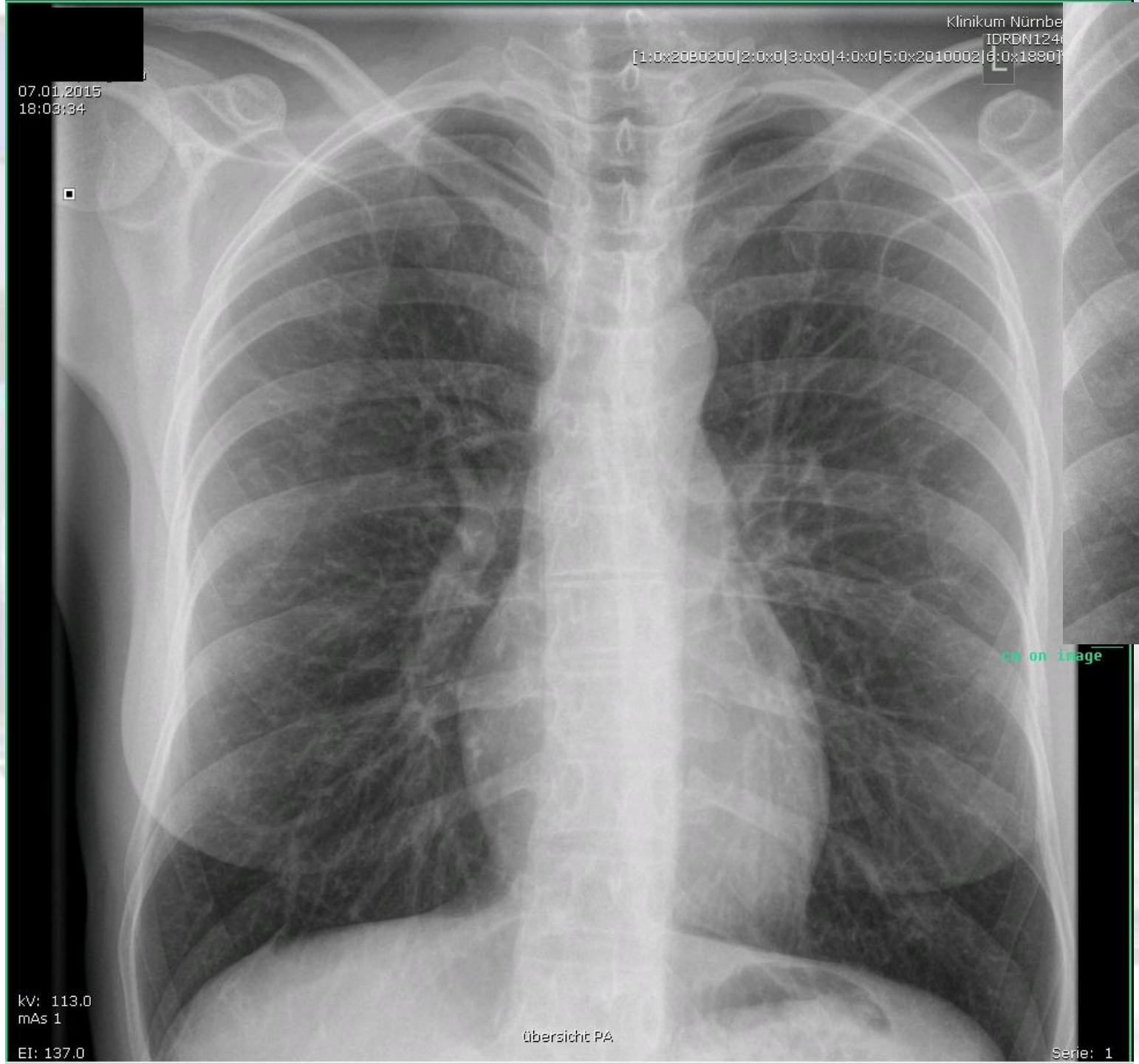
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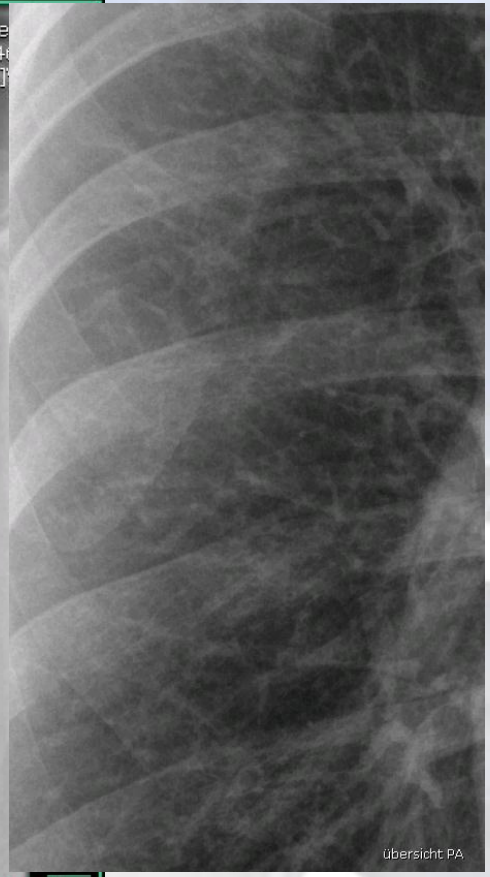
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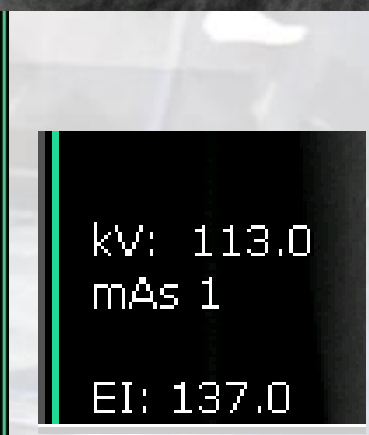
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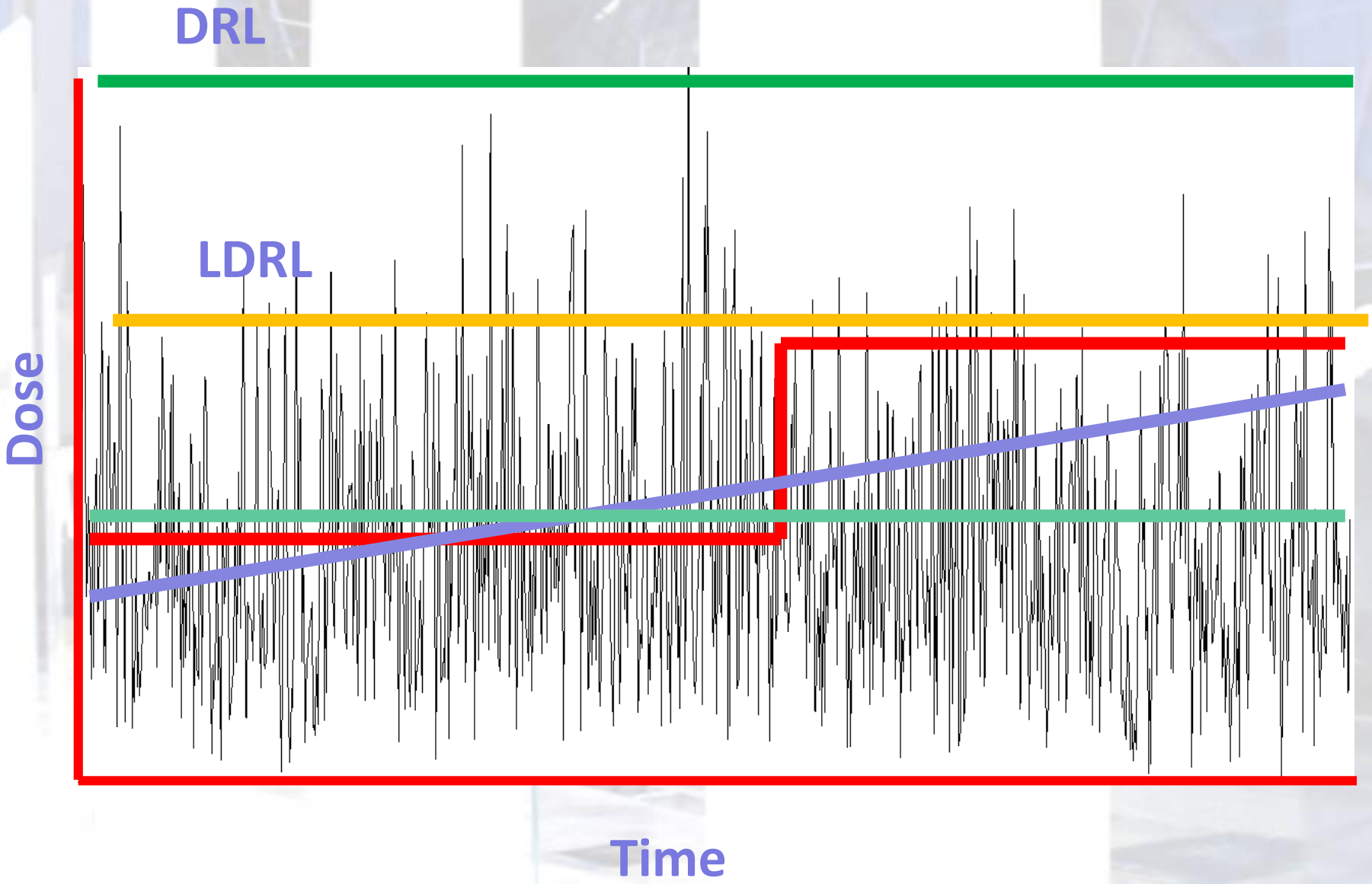
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