

Drafting guidance for accidental and unintended exposure



Pravna podrška pregovorima - Policy & Legal Advice Centre

Realization period: 13 – 28 July 2020

TASK

Assistance in drafting a **Guidance on accidental and unintended exposures** as required by Articles 63 and 96 of the Council Directive 2013/59/Euratom.



HIGA'S 2019 OVERVIEW REPORT ON ACCIDENTAL OR UNINTENDED MEDICAL EXPOSURES TO IONISING RADIATION

In 2019, we received 68 notifications

But some notifications from some relatively high-dose services from 3-dimensional Radiotherapy and Cyberknife.

Patient safety culture

To prevent errors, you need to implement robust and efficient measures. These include, at least, resilient systems and processes as a whole, human error being only one part of a system.

Why should I report near-misses locally?

- To be compliant
- To improve patient safety
- To minimise the probability of preventable events

Diagnostic Imaging

In 2019, the majority of the notifications came from CT scan related to the incorrect service user being imaged.

The key findings were to have strong central identification systems in place to correctly establish the right patient at all stages of the patient journey for X-ray.

Radiotherapy

HIGA received 15 notifications from radiotherapy services in 2019.

Overall, there was a positive culture of reporting across radiation oncology services.

READ OUR FULL REPORT AT WWW.HIGA.EU

RESULT

Regulatory requirements for accidental and unintended exposures in the form of a **Rulebook** was produced.

Guidance on accidental and unintended exposures and safety culture was provided.

The above deliverables align the Serbian legislation with articles 63 and 96 of **Council Directive 2013/59/Euratom**.

CONCLUSIONS & RECOMMENDATIONS

The new regulatory requirements for authorised persons to report incidents to SRBATOM and formally investigate and record significant events involving accidental and unintended exposure will improve the safety culture in radiological healthcare environments.

It is recommended that the Rulebooks and Guidance documents are implemented when the new bylaws are produced.