



Public Health  
England

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# BSS Directive 2013/59/Euratom Article 56 – background, intentions and implications for UK transposition and implementation

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# BSS Directive 2013/59/Euratom - background

- 2013/59/Euratom is a revision of previous Basic Safety Standards and associated Directives including Medical Exposure Directive 97/43/Euratom
- the Directive originally started as a “recast” rather than a “revision” ie the intention was for small changes and little national negotiation

# BSS Directive 2013/59/Euratom - background

- based on Article 4.1(b) of 97/43/Euratom, Article 56.1 paragraph 2 addresses aspects of optimisation for radiotherapeutic purposes and states

“For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned **and their delivery appropriately verified** taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable *and consistent with the intended radiotherapeutic purpose of the exposure*”

# BSS Directive 2013/59/Euratom - intentions

- Article 4.1(b) of 97/43/Euratom was originally drafted to address external beam radiotherapy
- during mid 1990s, some external beam radiotherapy for palliative purposes was not planned taking into account patient parameters
- during the drafting process, radiotherapy with sealed and unsealed sources was considered, but no text changes were deemed necessary

# BSS Directive 2013/59/Euratom - intentions

- Article 56.1 para 2 of 2013/59/Euratom was similarly originally drafted to address external beam radiotherapy
- additional text “**and their delivery appropriately verified**” was added but still with external beam radiotherapy in mind – consistent with Article 60.3(c) on equipment
- during the drafting process, radiotherapy with sealed and unsealed sources was considered, but again no text changes were deemed necessary

# BSS Directive 2013/59/Euratom - intentions

- there are no additional requirements regarding planning of exposures ie prior to the exposure taking place
- planning of the exposure needs to be undertaken on an individual basis
- regarding “**delivery appropriately verified**” - this implies retrospective action
- the Directive is goal setting and does not include detail

# BSS Directive 2013/59/Euratom – implications for UK transposition and implementation

- consultation on optimisation is expected to begin late 2015/early 2016
- consultation will address therapeutic nuclear medicine and will consider clinical and radiation protection aspects
- for transposition – changes will reflect the Directive's text
- implementation and regulatory guidance is more likely to be influenced by consultation process