

HERCA Multi-Stakeholder Workshop on "Accidental and Unintended Exposures", Paris, 26-27 October 2016

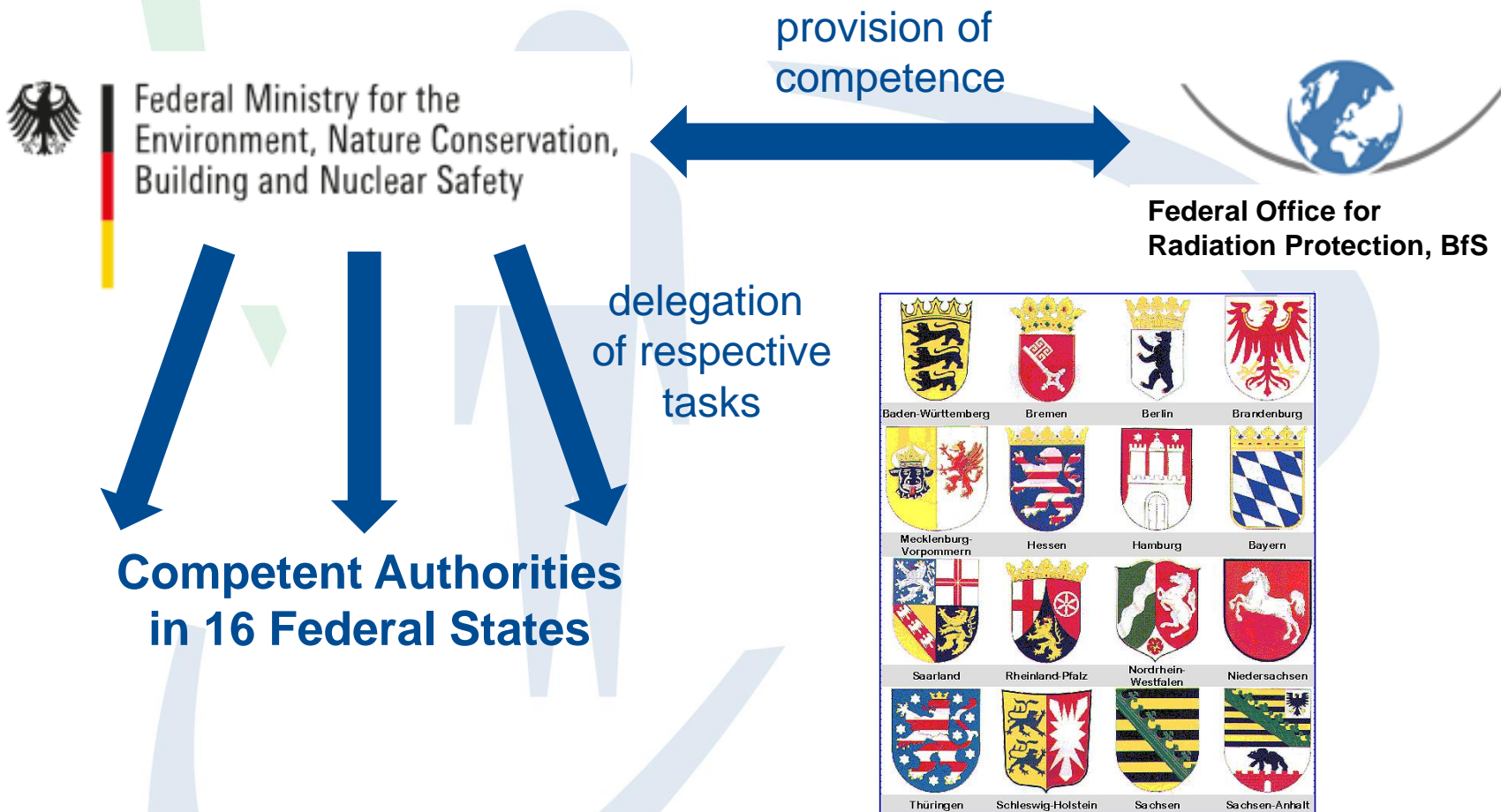
National Approaches Relating to Definition and Notification of Significant Events:

Germany

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System of Radiation Protection in Germany



Transposition Process of Council Directive 2013/59/Euratom in Germany



Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety



responsible for the
transposition of
*Council Directive
2013/59/Euratom*



Federal Office for Radiation Protection, BfS



providing competences
in the fields of
radiation protection



Transposition Process of Council Directive 2013/59/Euratom in Germany: What have we done?

➤ **BfS-Multi-Stakeholder Meeting:**

- 09 July 2014
- conceptual considerations

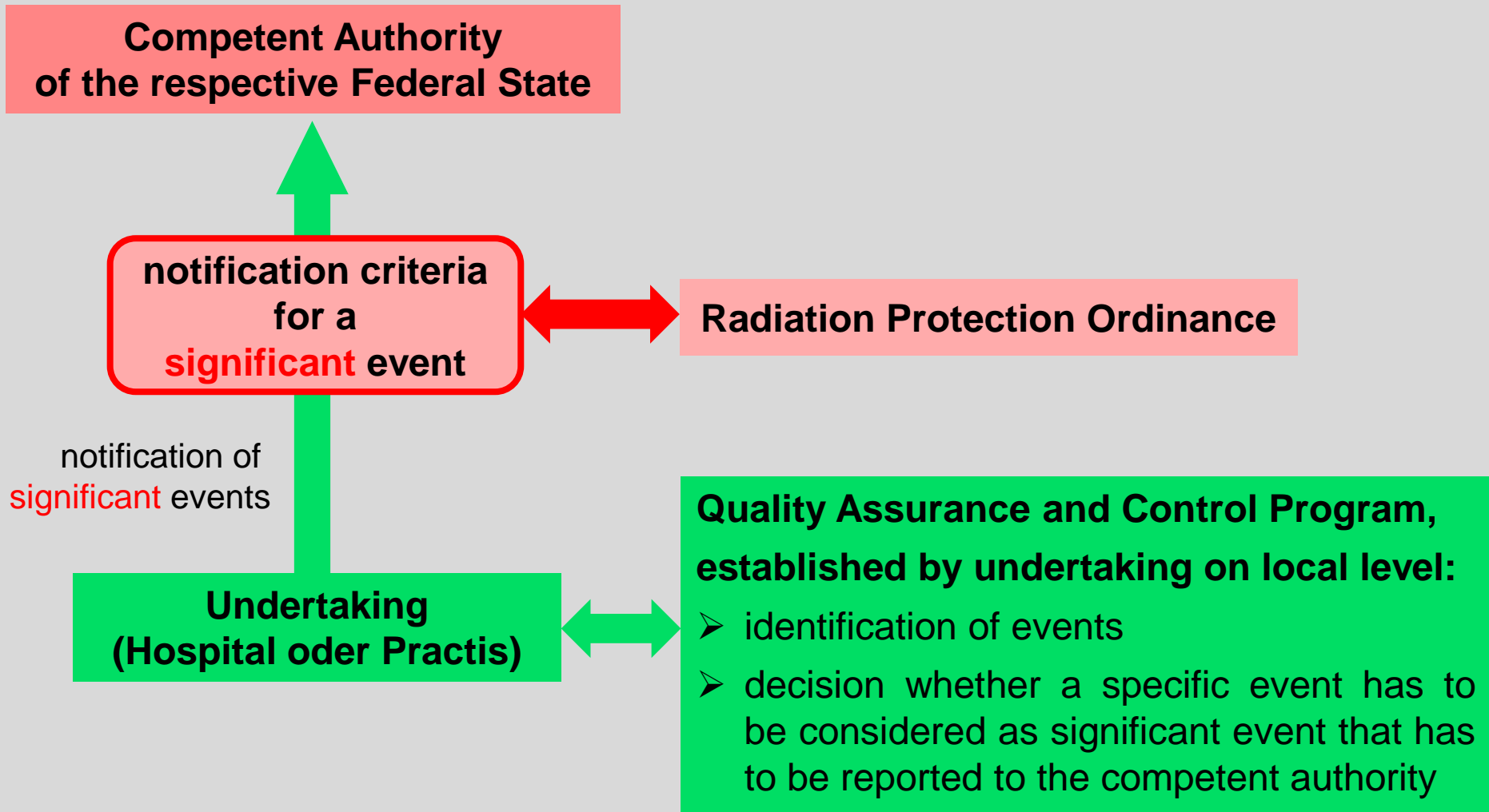
➤ **BfS-Multi-Stakeholder Meeting:**

- 03 June 2015
- notification criteria

- Professional Bodies
- Authorities from Federal States
- Federal Ministry for the Environment (BMUB)



I. Conceptual Considerations



II. Definition of Terms

II.1 Event involving accidental or unintended medical exposures:

An event that due to organisational, technical or other reasons has resulted

- in an **unintended deviation** from the **intended application of ionising radiation** as defined within the **justification process** or
- in an **unexpected radiation health effect**.

II. Definition of Terms

II.2 Event potentially involving accidental or unintended medical exposures (near-miss event):

An event that due to organisational, technical or other reasons could have resulted in

- an **unintended deviation** from the **intended exposure** as defined within the **justification process**

and that was not detected by

- the **quality assurance and control program** established by **undertaking on local level**.

II. Definition of Terms

II.3 Significant event involving accidental or unintended medical exposures:

An event which has a **comparatively high potential** to result in a **radiation health effect**

- either for a **single individual affected**
- or for a **group of individuals affected.**

} → **radiation hygiene
relevance**

The **occurrence of a near-miss event** is to be considered as significant event, when it could have a comparatively high potential to result in a radiation health effect for the individual affected

→ to be evaluated by a radiological practitioner with the **necessary qualification in radiation protection.**

II. Definition of Terms

II.4 Radiation hygiene relevance:

The term radiation hygiene relevance is related to one of the following adverse health effects of ionising radiation:

- **deterministic effects**, such as harmful tissue reactions, or
- **stochastic effects**, such as cancer development in exposed individuals

and refers

- either to a single individual affected (→ **individual approach**)
- or to a group of individuals affected (→ **collective approach**).

III. Application to Types of Medical Exposure

Framework of Significant Events				
	Therapy: Radiation Therapy	Diagnostics: X-Ray Diagnostics Nuclear Medicine		Intervention: X-Rays
	Nuclear Medicine	Collective Approach	Individual Approach	
Adverse Health Effects	deterministic	stochastic	stochastic	deterministic
Relevance for	single individual affected	group of individuals affected	single individual affected	single individual affected

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IV. Notification Criteria: Significant Event

	Diagnostics: X-Ray Diagnostics / Nuclear Medicine	
	Collective Approach	Individual Approach
Criterion:	DRL_{national} or DRL_{local} is exceeded by 100%	intended effective dose is exceeded by 20 mSv and / or intended organ dose is exceeded by 100 mSv for a single exam
Criterion - other:		in defined cases*: repeated exam when above criterion is fulfilled

*: wrong patient, wrong side,
performance error, technical defect

IV. Notification Criteria: Significant Event

	Intervention: X-Rays
Criterion:	<p>dose area product (DAP) exceeds a value of 50.000 cGy cm²</p> <p>⇒ clinical control of the respective skin area is to be performed</p> <p>⇒ significant events is given, when a skin damage grade 2 or higher develops acutely or within 21 days</p>
Criterion - other:	<p>any unexpected deterministic effect, wrong side, wrong patient</p>

IV. Notification Criteria: Significant Event

	Radiation Therapy	Nuclear Medicine Therapy
Criterion:	<p>significant deviation from the prescribed treatment concept:</p> <p>any deviation of</p> <ul style="list-style-type: none"> • total dose in target volume by 10%, but at least by 4 Gy • local dose limit in risk organ by 10% • total treatment time by more than 1 week (if not patient related) 	<p>any deviation of</p> <ul style="list-style-type: none"> • total activity by 10%
Criterion - other:	<p>any unexpected deterministic effect, wrong patient, wrong side, wrong treatment plan</p>	<p>any unexpected deterministic effect, wrong patient, wrong radiopharmakon</p>

Thank You for Your Attention!



**Federal Office for Radiation Protection, BfS:
Location Neuherberg / Munich**