



Office for Product  
Safety & Standards

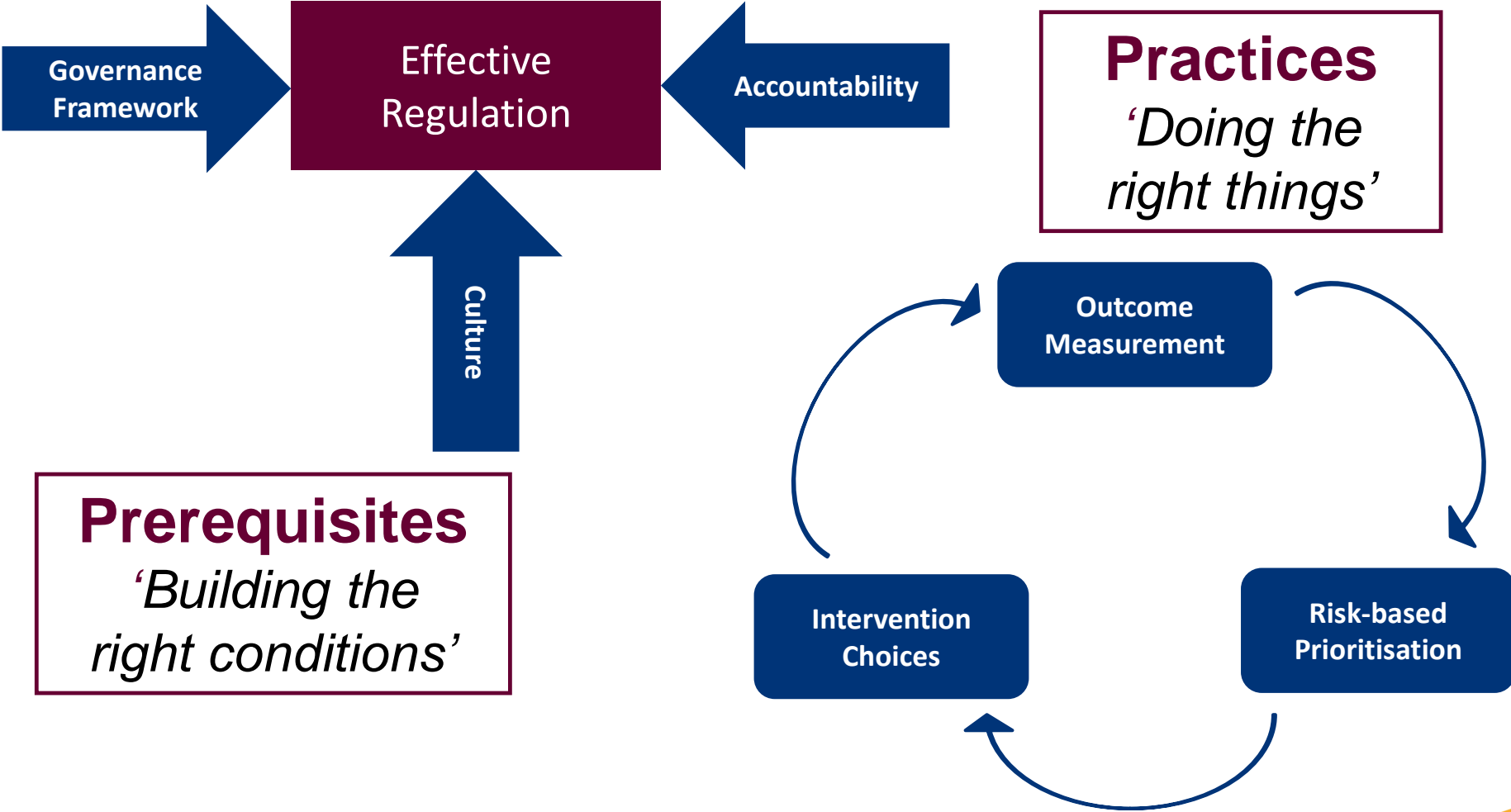
# UK Regulatory Easements on PPE: Supporting businesses while ensuring public protection during COVID-19

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August 2020

# The Regulatory Delivery Model



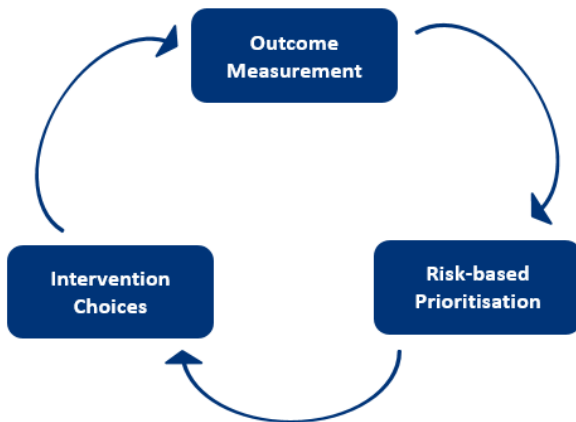
# Personal Protective Equipment: the regime

## Applicable Legislation and Assessment Requirements

Non protective Lower risk (e.g. facemasks) ←	Cat I PPE	Cat II PPE	Cat III PPE	Higher risk →
<b>General Product Safety Regulations 2005</b> <u>No</u> third party assessment required, but product <b>must be safe</b>	<b>Regulation EU 2016/425; Personal Protective Equipment (Enforcement) Regulations 2018</b>			
	Self Assessment. Must meet Essential Safety Requirements (ESR)	Third Party Conformity Assessment required Must meet ESR		
<b>Enforcement Authorities</b>	Cat I PPE	Cat II PPE	Cat III PPE	
Non workplace Inc passengers, shoppers ( <i>most will be Cat I</i> )	Trading Standards			
Workplace – any PPE designed for use in the workplace	<div style="border: 2px solid blue; border-radius: 50%; padding: 10px; display: inline-block;"> <p><i>BEIS SoS (OPSS) has powers to enforce for GPSR and for all PPE (except medical devices)</i></p> </div>			
Nuclear sites ( <i>most will be Cat III</i> )	Health & Safety Executive/ HSENI  Office for Nuclear Regulation			
Medical use ( <i>most will be Cat III</i> )	HSE/ HSENI if the purpose is to protect the wearer (PPE) MHRA if purpose is patient protection (medical device rather than PPE)			

Agencies shown are the Market Surveillance Authorities for each area.

# PPE: Adapting an existing regulatory regime



## Regulatory Outcomes

1. PPE is available – to the NHS, care homes and other businesses that need it
2. PPE is safe – it protects the user

## Regulatory Delivery Changes

- Changes to conformity assessment requirements, to maintain a **risk-based** approach but speed up supply.
- Guidance and tailored support for businesses making or importing PPE.
- A regulatory coordination cell with the Health and Safety Executive and Medicines and Healthcare products Regulatory Agency.
- A team deployed to the NHS supply hub to assess the safety of shipments of PPE.

## Enforcement

- Intelligence feeds into risk model to identify suspect PPE entering the UK.
- Enforcement deployment to intercept unsafe PPE and deter businesses from taking a careless, or criminal approach to compliance.
- Enhanced market surveillance, particularly online and direct imports