



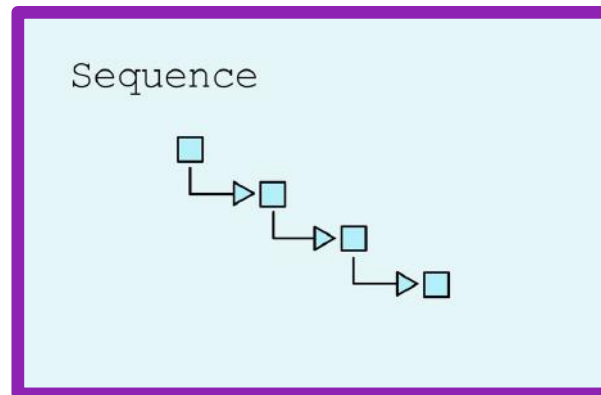
ASRU Change Programme Stakeholder meeting

Welcome to this important meeting

- Second in a sequence of **three critical communications**
- Previous meeting on May 27th
- Next meeting on June 29th
- Each meeting will cover **different aspects** and will build on previous material

Sequence of communication

1. **On May 27th** we covered the direction of the Change Programme and our External Engagement framework
2. **Today** we will cover changes to our **operating model** which we will start to transition to in July
3. **On June 29th** we will answer questions raised on material presented



Questions and feedback

- Please raise comments on the chat function but we may not be able to answer these all in the session
- After this session the slides and an updated Question and Answer document will be circulated
- If you have comments or feedback please send them by email to the Change Programme inbox (ASRUChangeProgramme@homeoffice.gov.uk)

Purpose of today

1. To recap briefly the **ASRU Change Programme**
2. To recap briefly the **ASRU External Engagement Framework**
3. To outline our **new operating model**(bridging ways of working)



1 ASRU Change Programme



Drivers for Change

1. Concerns raised by ASC about lack of assurance
2. **Benchmarking against leading practice regulation**
3. Home Office Transformation (One Home Office)
4. Opportunities highlighted by Brexit and COVID19



Two key benchmarking inputs

1. Review of risks of regulatory failure:

- Review of key cases and causes of regulatory failure
- Assessing the degree to which ASRU is at risk

2. Critical to Quality Assessment:

- Semi structured interviews with ASRU staff, ASC members and some selected members of the regulated community to determine what features of quality were important for ASRU
- Review of public opinion in Ipsos-Mori poll
- Review of leading regulatory practice literature

Summary of Risks of Regulatory Failure

Risk	ASRU Rating	Key Issue(s)
Regulatory Capture	Very High	Operational model with high reliance on relationship between inspectors and establishments Strategic engagement with special interest groups direct and unbalanced
Closed Systems	High	Less than optimal transparency Inadequate oversight or input by those with regulatory expertise
Too Big to Fail	High	Confusion between regulatory decision making and customer service
Regulatory Drift	High	Lack of clear regulatory identity Lack of horizon scanning strategy
Regulatory Layering	Moderate	Lack of clarity of policy ownership Lack of clarity about accountability for compliance
Unintended Consequences	Moderate	Less than optimal focused input at strategic level by both regulatory experts and the regulated community

Summary of Critical to Quality report

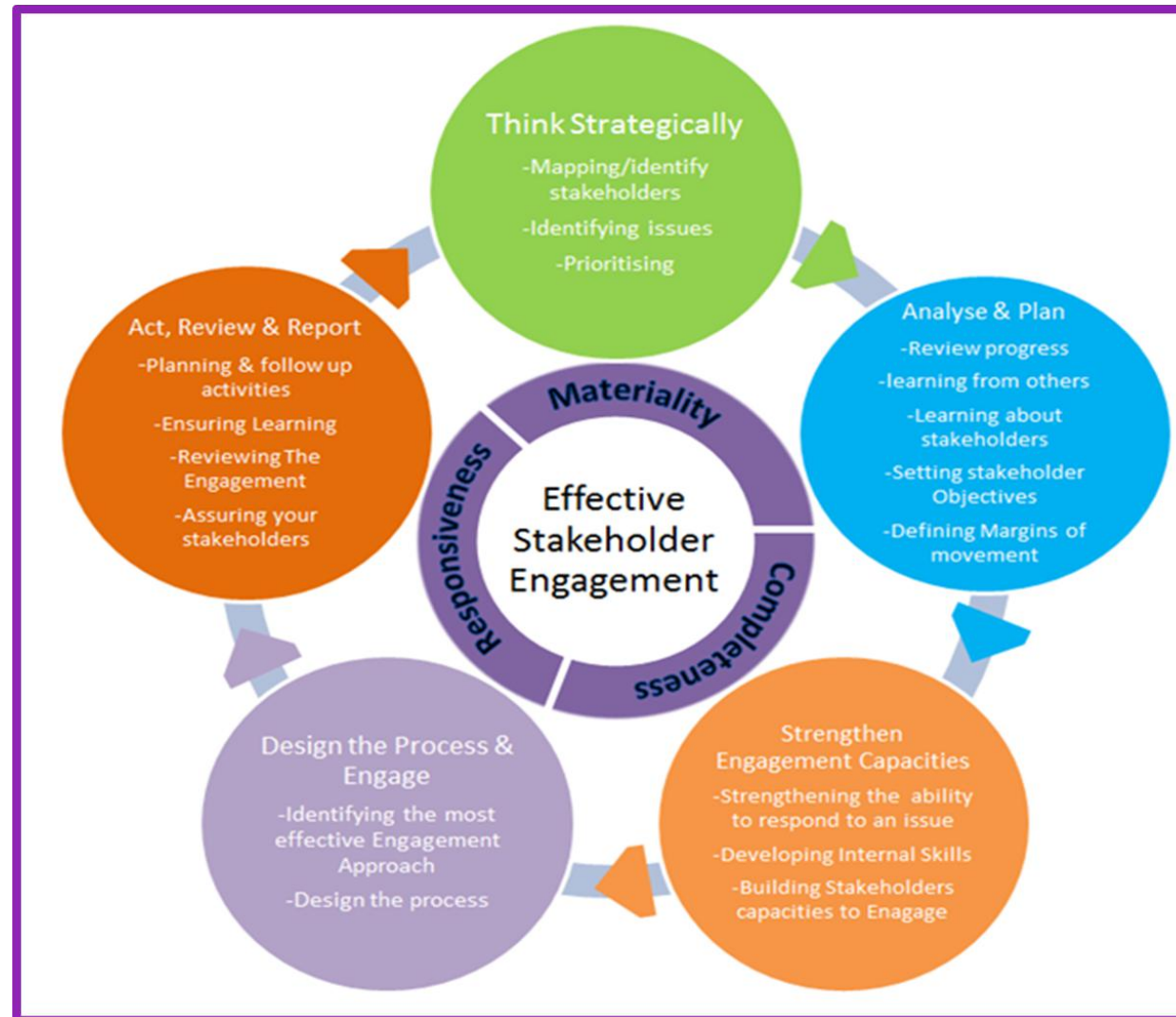
Theme	Key issue
Don't be a black box	Less than optimal transparency
How can I comply when I don't know what you want?	Less than optimal decision making, guidance and consistency
Take your place in the network	Lack of focus on core role
Lead the way	Lack of proactivity and horizon scanning
Ensure a level playing field	Inconsistency
Put the pieces together to add value	Less than optimal use of data and trends
Hold others to account	Lack of clarity of role as regulator
Find the right distance	Operating and engagement models risk lack of balance and consistency



Opportunities straight ahead

1. Clearly defining our role and scope as a **regulator**
2. Providing **clear guidance** to enable the regulated community to comply
3. Increasing **transparency and proactivity**
4. Being **consistent** and creating a **level regulatory playing field**

2 External Engagement Framework



Why change our engagement model?

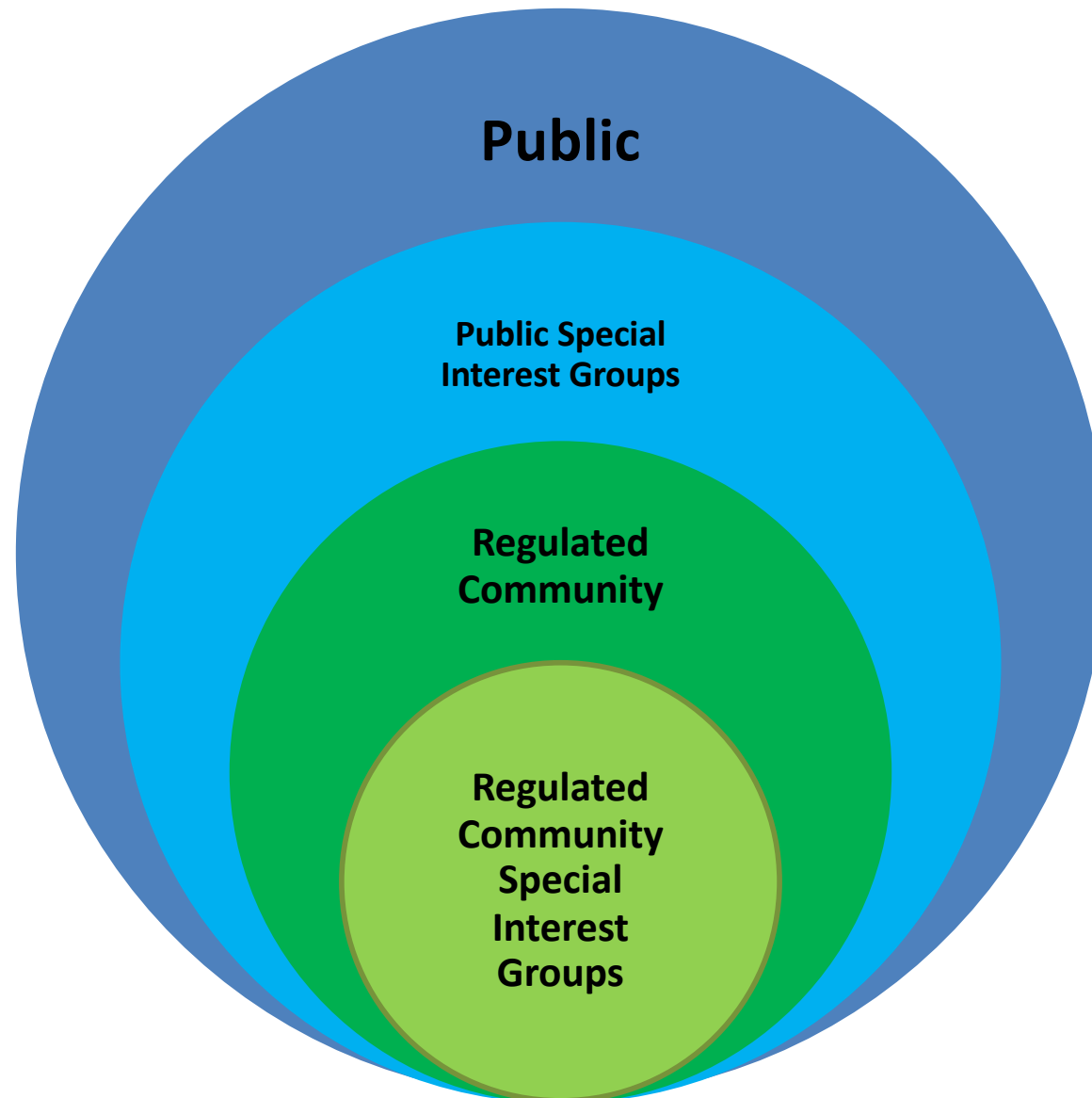
- Ensure that engagement is **focused** and clear about outcomes required and value for both ASRU and those we engage with
- Ensure that engagement is **differentiated** for each stakeholder sector
- Ensure that strategic input is achieved in a balanced way which **prevents direct lobbying** of the regulator
- Ensure operational relationship management is **separate** from the delivery of regulatory decisions



Segmentation of external parties

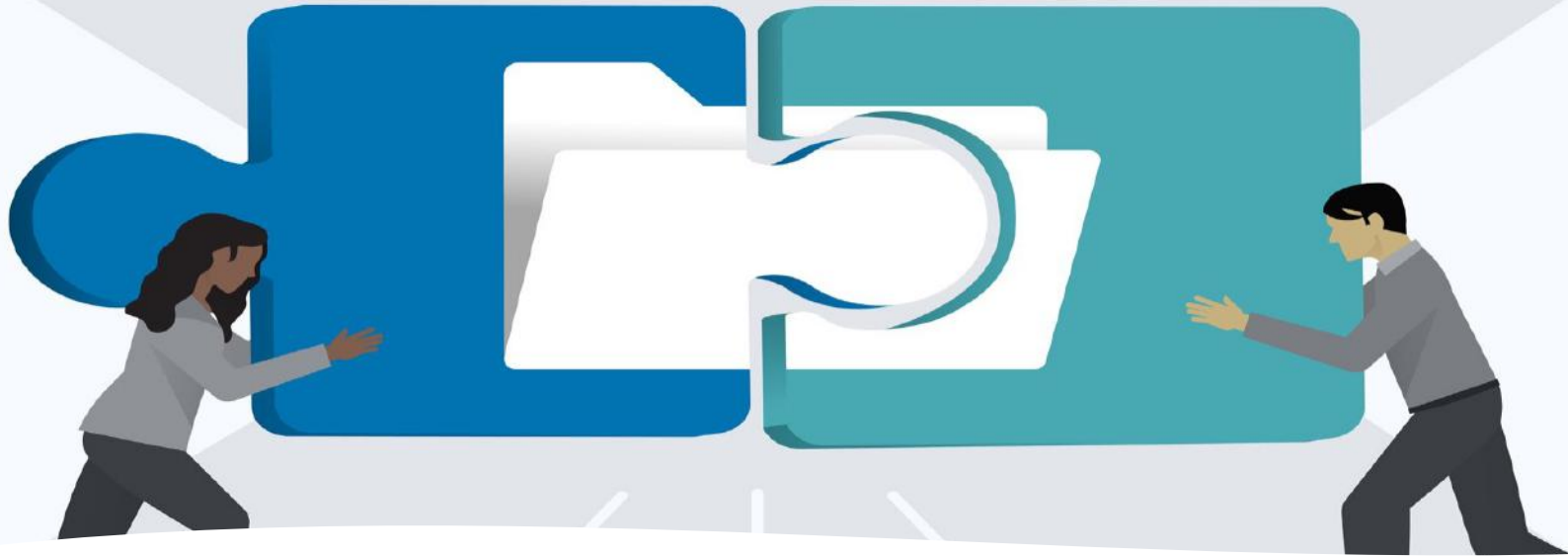
	Interdepartmental	Specialist Research Bodies	Public
Scope	BEIS, DEFRA	Funders, NC3Rs, Accreditation Boards	Advisory Bodies, Special Interest Groups, Regulated Community
Focus for engagement	Defining policy ownership	Using as specialist assessors of and setting standards for regulated community	Transparency of regulatory policy and practice Providing information and advice to enable regulated community to comply
	Collaborating for horizon scanning	Collaborating for horizon scanning	Collaborating for horizon scanning

The `public` is not a single entity



Public Engagement Framework

	Advisory Groups	Special Interest Groups (SIGs)	Regulated Community
Scope	Animals in Science committee (ASC)	Excludes SIGs from within the regulated community	Includes SIGs from within the regulated community and the Regulated Community Change Team
Role	Formal role to provide advice and guidance	Represent a particular interest	Are the subject of the regulation
Aim(s) of engagement	Provide input and challenge to policy, strategy and regulatory delivery	Provide information in a transparent manner	Provide clarity needed to comply Assess level of customer service provided
Key risks of engagement	Failure to be evidence based Failure to offer an integrated balanced view	Undue influence upon regulator and lobbying	Regulatory capture



Summary of regulated community engagement

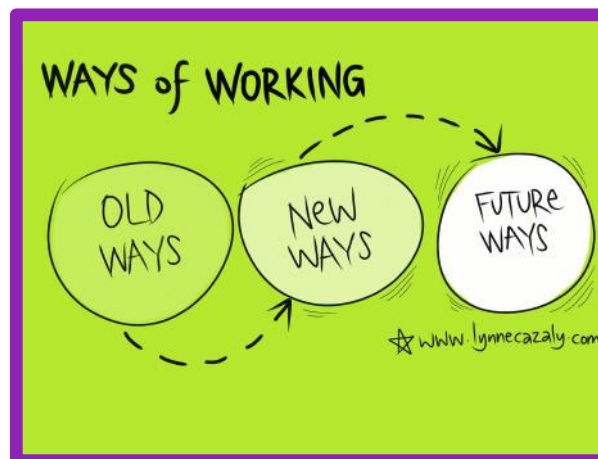
- **Strategic** – via ASC and Regulated Community Change Team
- **Communication**- via newsletters, HOLTIF forum and stakeholder meetings
- **Relationship management and customer service**
 - Dedicated inbox and lead
 - Service levels
 - Complaints process
 - Quarterly reviews
 - Annual survey
- **Operational**

3 Bridging Ways of Working

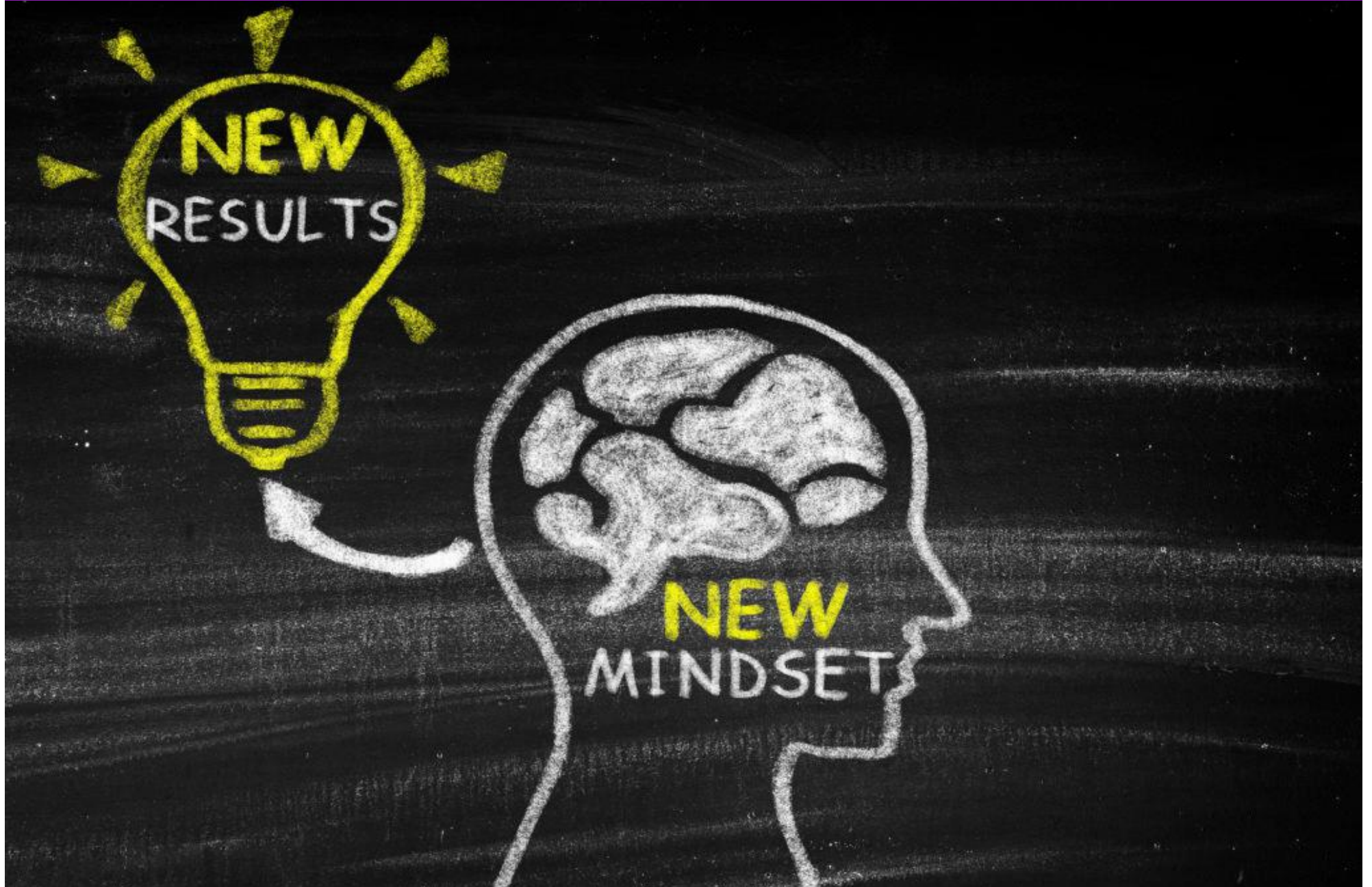


Bridging ways of working

- We are going to transition to a new operating model starting in July 2021
- These changes are in line with our strategic direction
- These ways of working will not necessarily be permanent but are part of our transition process
- We will use information and feedback from these ways of working to further and develop the operationalisation of our strategy



Change to current model of allocating individual inspectors and SPOCs to establishments





Key components of bridging ways of working

1. **Regulatory Advice** provided through a dedicated team
2. **Compliance Assurance** delivered by a dedicated team with a range of risk based activities
3. **Licensing assessments** shared across the inspectorate with associated QC plan
4. Dedicated expanded **relationship/customer service management model**



1 Dedicated team for Regulatory Advice

- All requests for regulatory advice come through **dedicated mailbox**
 - Is this a regulated procedure
 - Does my licence authorise this?
 - How do I best structure this licence?
- **Dedicated phone number** for urgent queries if needed
- Executive Officer and `On call inspector` provide **triage**
- Establishments receive **centralised advice** from the team
- Clear **timelines** given for responses
- **Review of trends** from this team will be used to prioritise policy development and issue of regulatory advice/guidance



Advantages of this approach

- All queries will be answered **consistently**
- All queries will be answered in writing thus **less ambiguity**
- Records will be kept of questions and answers provided-this will enable **prioritisation** of regulatory guidance being issued across the regulated community
- Dedicated resources will enable these tasks to be progressed more **efficiently**
- **Timeliness** of answers will be tracked

2 Dedicated team for Compliance Assurance

1. Compliance assurance team will **deliver** the compliance assurance activities
2. Main activities of this team will be:
 - Conduct facility, systems and thematic **audits**(inspections)
 - Investigate potential cases of **non-compliance**
 - **Review reports** related to compliance assurance(retrospective reviews, SC18)
 - **Manage action plans** for establishments at high risk of non-compliance
3. All compliance assurance information will be **integrated** to prioritise establishments and areas of risk
4. All inputs related to compliance assurance (SC 18, self reported non compliance, retrospective assessment, required reports) come through **dedicated mailbox**
5. **Dedicated phone number** for urgent queries if needed



Compliance Assurance Audits

An audit is a process which verifies **conformance to standards** through review of **objective evidence**

Our compliance assurance programme will have three types of audit:

- **Facility audits-** focusing on ensuring facilities meet code of practice and required standards
- **Systems audit** – focusing on particular governance systems
- **Thematic audit-** focusing on areas of high risk across the regulated community , primarily by remote methodologies



Management of establishments at high risk

- Small group of establishment at **highest risk of non compliance** designated as being in **`special measures`** commencing in approximately October 2021
- This is a standard regulatory term which indicates an establishment needs **more assistance and oversight** to maintain compliance
- Initially based on **non-compliance history and a detailed focused audit**(occurring between July –September 2021)
- Will be **adjusted quarterly** based on new compliance assurance information



Approach for establishments in special measures

- Each establishment will have a **documented transparent plan** with specific compliance assurance activities linked to areas of concern
- **Plan and progress reassessed** quarterly or as needed based on new evidence
- **Inspector** allocated to each establishment in special measures who oversees all activities for that establishment to ensure all aspects of work align to overall improvement plan
- Establishments move into and out of special measures so no long term allocation of inspector to an establishment



Advantages of this approach

- More **integrated approach** to assessment of compliance
- Greater **clarity** of standards
- Greater **transparency** of assessments
- Greater focus on **governance systems and risk prevention**
- Greater focus on **areas of risk and outcomes** not on process or numbers of inspections
- Increased **consistency of approach but more nuanced joint problem solving**



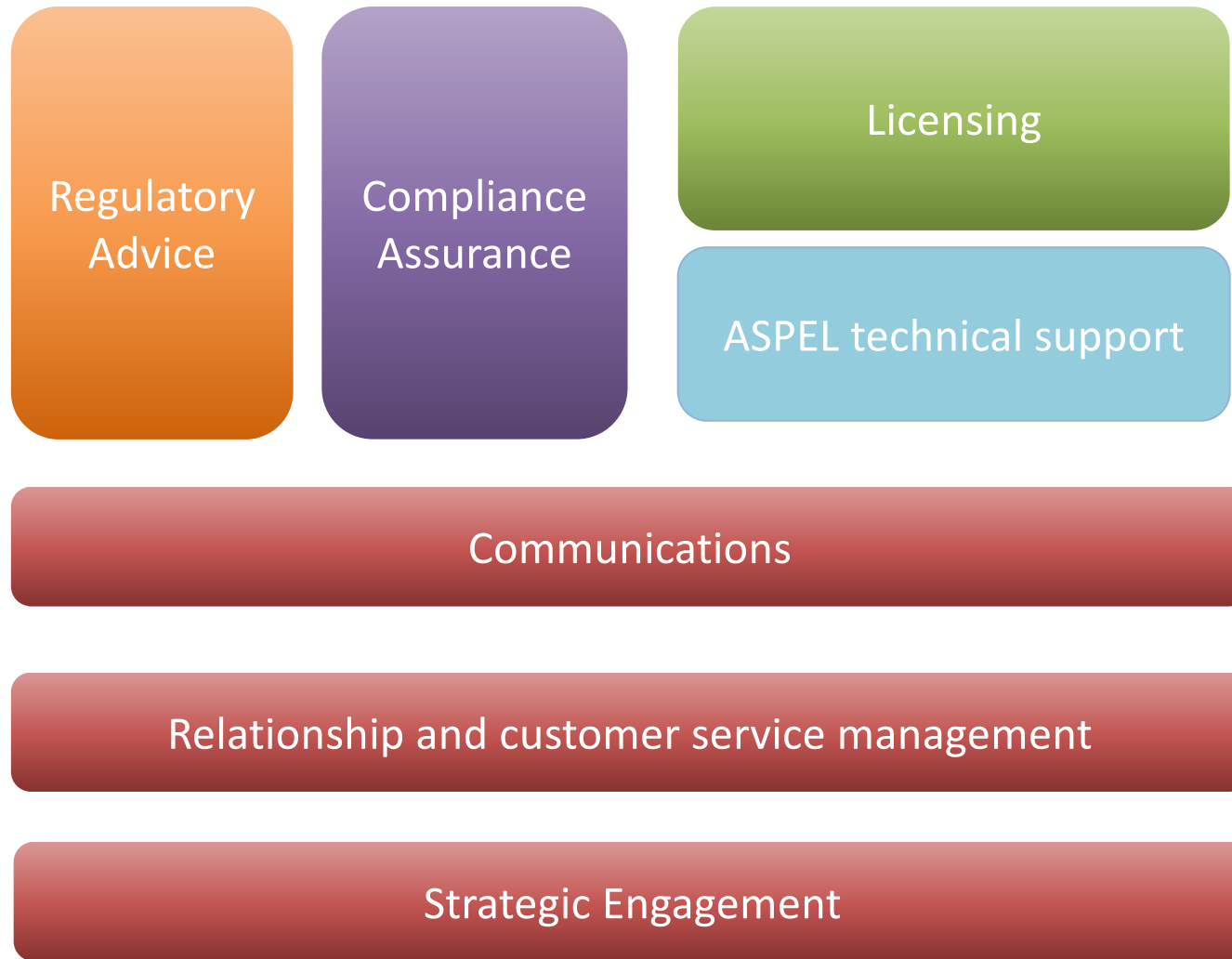
3 Licensing

- Prioritising issuing of **regulatory guidance**
- ASPeL focus on **optimising PPL application process**
- PPL assessments picked up on **`taxi rank` basis**
- **Assessment of particular types of PPL allocated to leads** e.g. work in the wild, regulatory toxicology, neuroscience severe primate work
- Introduction of a **PPL Quality Control process** to improve consistency and drive improvements to licensing process and requirements

Advantages of this approach

- More **timely processing** of licences
- **Avoidance of backlogs** with one inspector due to workload fluctuations
- Increasing focus on **refining ASPeL process** to simplify and clarify licences and processes
- Data from Quality Control process will drive further **consistency** and refinement of processes and standards

4 Supporting regulatory delivery



Mechanism for relationship and customer service engagement

- One Licensing Officer to be allocated as lead for regulated community relationship management
- Support to be provided from other staff on flexible basis as needed
- Pillars of engagement:
 - Regular newsletters and communications to members of the regulated community
 - Regular attendance at HOLTIF
 - Quarterly scheduled 1:1 meetings with each HOLC
 - Conduct and interpretation of annual regulated community survey
 - Managing a formal complaints process
 - Measuring, communicating and taking action on service level metrics



Advantages of this approach

- More robust holistic dedicated approach to service components separated from regulatory decision making
- Introduction of Service Levels to set and maintain clear expectations



Key components of bridging ways of working

1. **Regulatory Advice** provided through a dedicated team
2. **Compliance Assurance** delivered by a dedicated team with a range of risk based activities
3. **Licensing assessments** shared across the inspectorate with associated QC plan
4. Dedicated expanded **relationship/customer service management model**



How do I ask questions?

- You will receive these slides and an updated question and answer document
- Please direct questions to our dedicated inbox

ASRUChangeProgramme@homeoffice.gov.uk

- We will answer questions directly by email, update the Q and A document and answer the common themes at the meeting on June 29th

