



ISO 15189

Preparation for Reassessment

Martin Stearn, Senior Assessment Manager, UKAS

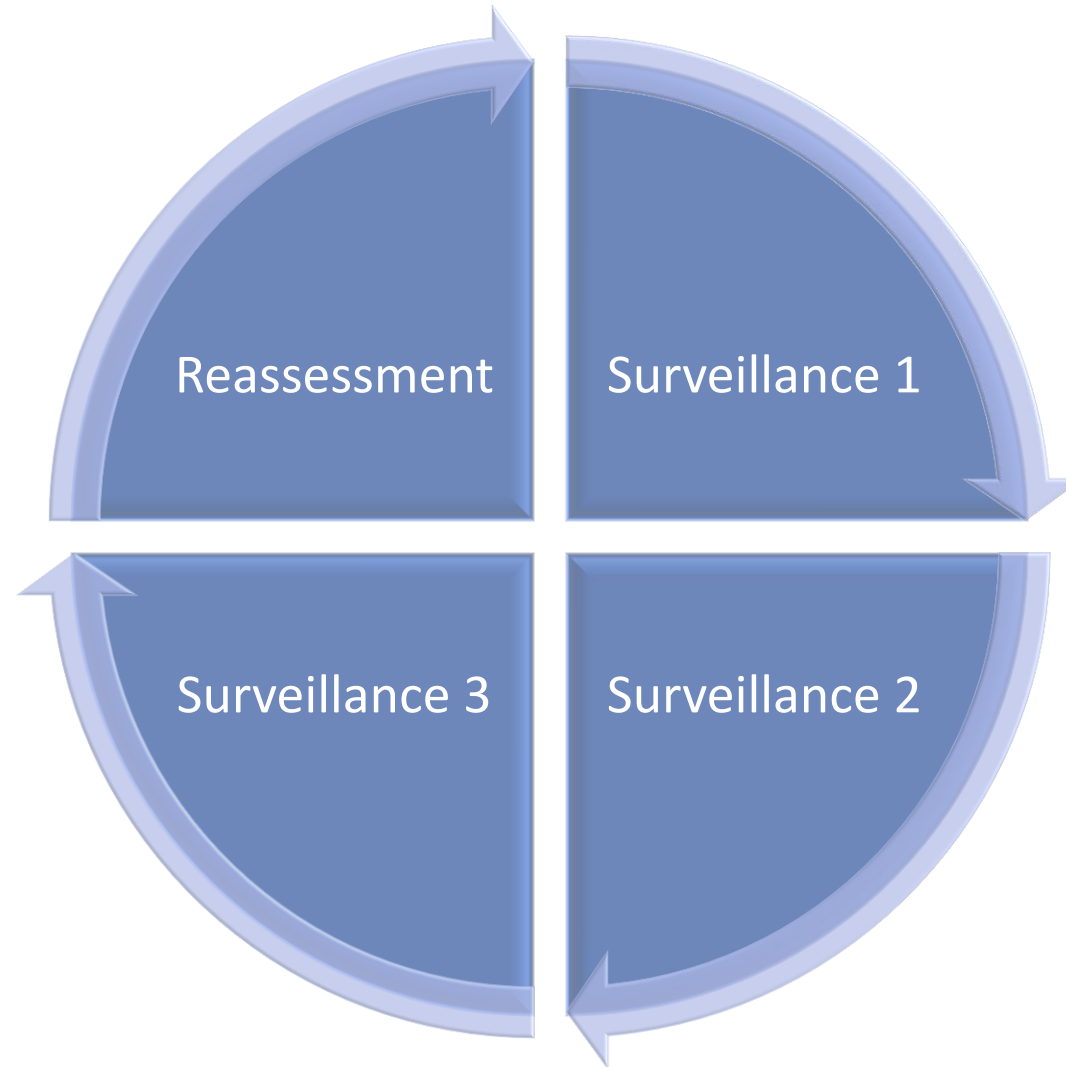
Introduction

- Explain what UKAS four-year cycles of accreditation are
- UKAS process
- Why the need for a Reassessment
- Expectations of laboratories undergoing Reassessment

- ~650 ISO 15189 UKAS accredited laboratories
- First grants were in 2014, first Reassessments in 2018
- ~162(½) Reassessments each year
- ~250 granted in 2018, 2022 will be busy
- 207 ISO 15189 accredited 'Haematology' laboratories

- Pay attention, there is a prize.....

Four-Year Cycle of Accreditation




Surveillance vs Reassessment

	Surveillance	Reassessment
Timing	First surveillance 6 months after initial grant of accreditation	Final assessment in a 4YC (3.5 years after grant)
Frequency	Annually in the same 'profile' month (+/- 1 month)	Every 4 th year (obviously)
Locations	All at least once within the 4YC	Main laboratory plus sample of others
Management system	All 4.x clauses & any other requirements between IA/RA & RA (i.e. SU1-3) Internal audit, management review & complaints	All 4.x clauses Any other requirements
Technical activities	All areas of competence SU1-3 EQA coverage & performance	All key techniques, methods & competencies EQA coverage & performance
Personnel	Sample of staff aligned with technical activities Clinical/advisory at least one SU	Sufficient to provide assurance of competence across all testing fields & clinical/advisory

4YC Forward Plan

UKAS Haematology & Blood Transfusion - Assessment Programme (2018 - 2021)						
1						
2						
4						
5	Customer Name	Haematology & Blood Transfusion				
6	Customer Number	1234				
7	Accreditation Number	1234				
8	Profile Month	October				
9	Project Number	123456				
10						
11						
12	Assessment Team					
13						
14	ID	Role / Area	Employee Reference	Name	From year	Comments (e.g. when to change; history)
15	1	Assessment Manager	E01119	Martin Stearn	2017	
16	2	Haematology/BT BMS	E01234	Carol Moore	2017	Change at RA 2021
17	3	Immunophenotyping	E05678	Flo Rida	2018	Change at RA 2021
18	4	Molecular Haematology	E09123	Gene Etics	2018	Change at RA 2021
19	5	Consultant Haematologist	E04567	Dr Mike Roscope	2020	Change at RA 2021
20						
21						
22						

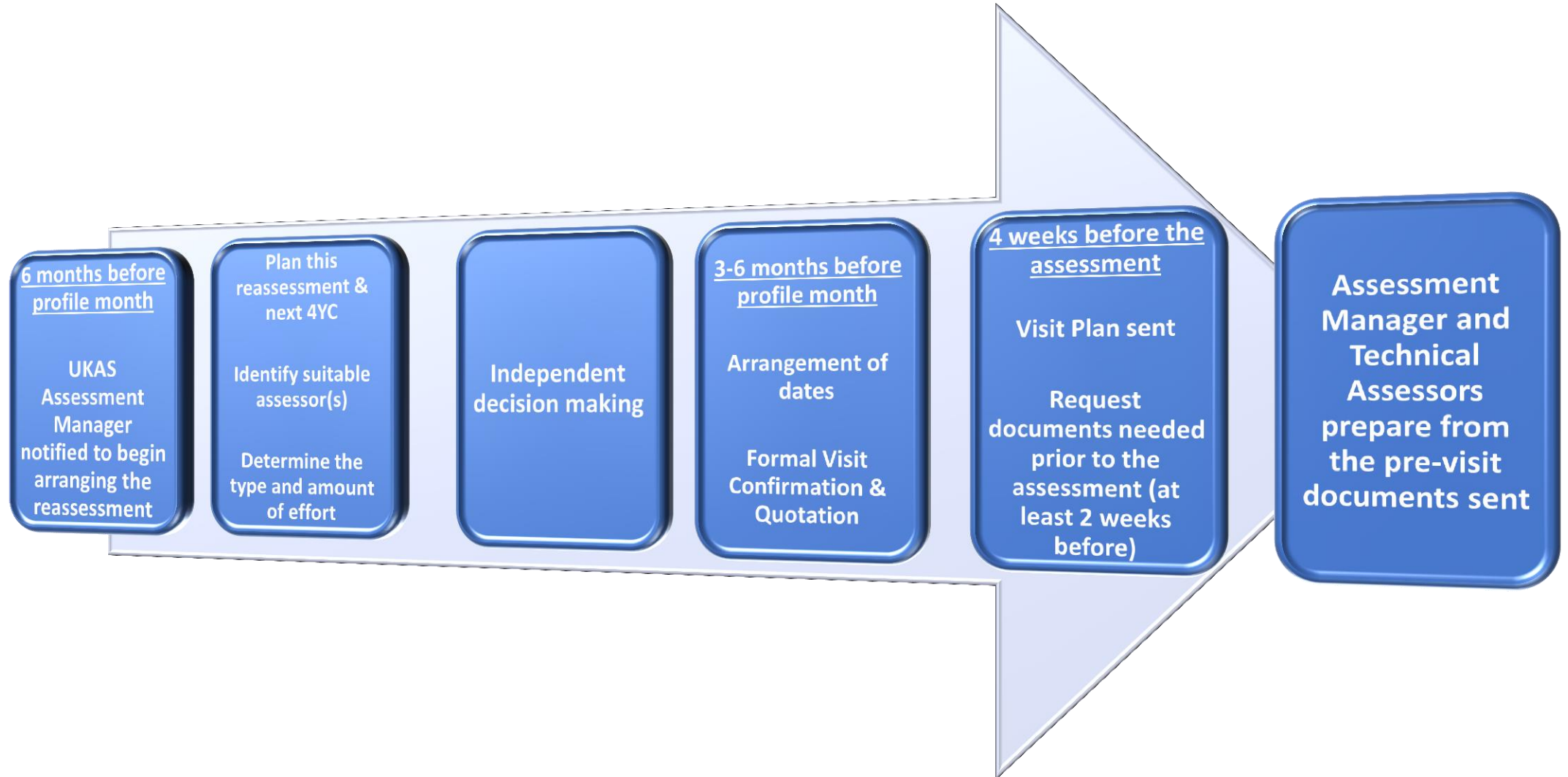
4YC Forward Plan

B		C	D	E	F	G	H	I	J	
 Haematology & Blood Transfusion - Assessment Programme (2018 - 2021)				F438 issue 4 - Forward Plan (Basic)						
				Assessed		Not assessed				
Accreditation Standard	Aspect	SU 1 2018	SU 2 2019	SU 3 2020	RA 2021	Required Skills <i>(Refer to TCC documents)</i>	Notes / Comments <i>(e.g. locations, specific concerns)</i>			
ISO 15189:2012	4 Management requirements									
	4.1 Organisation & management responsibility		See below							
	4.1.1.2 Legal entity	1	1	1	1					
	4.1.1.3 Ethical conduct	1			1					
	4.1.1.4 Laboratory Director		1		5					
	4.1.2.2 Needs of users	1	1	1	1					
	4.1.2.3 Quality Policy		1		1					
	4.1.2.4 Quality objectives and planning	1	1	1	1					
	4.1.2.5 Responsibility, authority and interrelationships			1	1					
	4.1.2.6 Communication	1			1					
	4.1.2.7 Quality Manager		1		1					
	4.2 Quality management system		See below							
	4.2.1 General requirements	1	1	1	1					
	4.2.2.1 Documentation requirements			1	1					
	4.2.2.2 Quality Manual	1	1	1	1					
	4.3 Document control			1	1					
	4.4 Service agreements			1	1					
	4.5 Examination by referral laboratories	1			1					
	4.6 External services and supplies		1		1					
	4.7 Advisory Services			5	5	3015.016				
	4.8 Resolution of complaints	1	1	1	1					
	4.9 Identification and control of nonconformities	1	1	1	1					
	4.10 Corrective action	1	1	1	1					
	4.11 Preventive action	1	1	1	1					
	4.12 Continual improvement			1	1					
	4.13 Control of records	1			1					
	4.14 Evaluation and audits		See below							
	4.14.2 Review of requests, suitability of procedures and sample requirements			5	5					
	4.14.3 Assessment of user feedback	1	1	1	1					
	4.14.4 Staff suggestions		1		1					
	4.14.5 Internal audit	1	1	1	1					
	4.14.6 Risk management			1	1					
	4.14.7 Quality indicators	1	1	5	5					
	4.14.8 Reviews by external organisations	1			1					
	4.15 Management review	1	1	1	1					

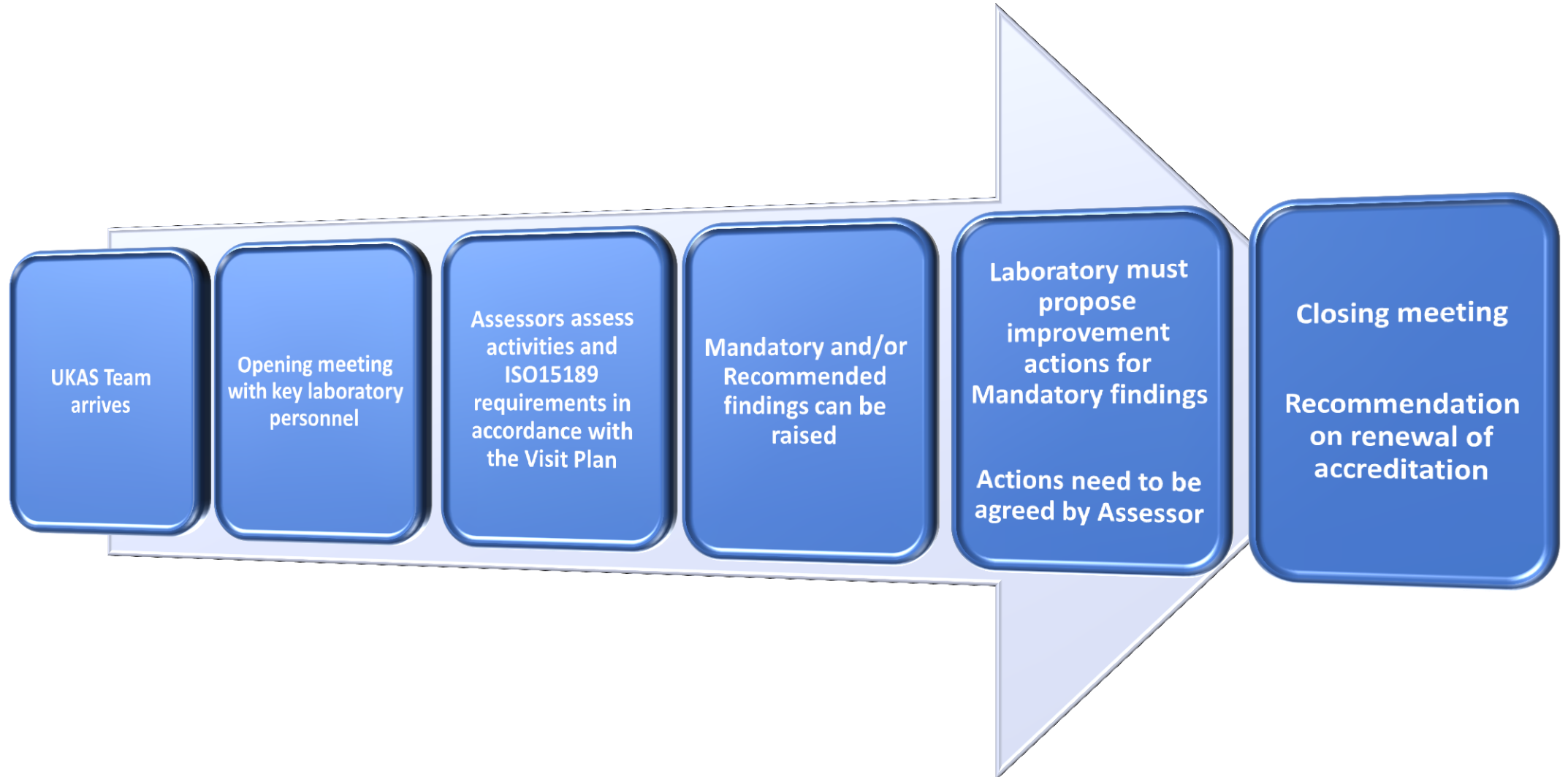
4YC Forward Plan

Haematology & Blood Transfusion - Assessment Programme (2018 - 2021)				F438 issue 4 - Forward Plan (Basic)					
				Assessed		Not assessed			
Test group	Testing Activity	Method / Procedure	SU 1 2018	SU 2 2019	SU 3 2020	RA 2021	Notes / Comments (e.g. additional schemes)	Required skills (Refer to TCC documents)	
Haematology Site 1	Full blood count	Analyser A	2			2		3015.003	
	Malaria microscopy	Giemsa stain & microscopy		5		5		3015.009	
	Malaria antigens	Rapid kit			2			3015.009	
	Infectious mononucleosis screen	Latex agglutination usign kit B			2	2		3015.002	
	Bone marrow morphology	MGG stain* and microscopy		5		5	*staining covered by 2	3015.013	
Haematology Site 2	Full blood count	Analyser A	2			2		3015.003	
	Malaria antigens	Rapid kit			2	2		3015.009	
Blood Transfusion Site 1	ABO & RhD typing	Automated Analyser X	2			2		3015.005	
	ABO & RhD typing	Manual methods		2				3015.005	
	FMH	Manual Kleihauer			2	2		3015.005	
Blood Transfusion Site 2	ABO & RhD typing	Automated Analyser X	2					3015.005	
	ABO & RhD typing	Manual methods		2		2		3015.005	
Blood Fridges	Laboratory		2					3015.005	
	Maternity			2				3015.005	
	ICU				2			3015.005	
	Theatre					2		3015.005	
Immunophenotyping	Leukaemia panel	Flow cytometry using analyser Y	3	3*	3*	3	*remote review of test assurance	3015.011	
	Immunoplatelet count	Flow cytometry using analyser Y	3	3*	3*	3		3015.011	
	CD19 Rituximab	Flow cytometry using analyser Y	3	3*	3*	3		3015.011	
Molecular Haematology	DNA extraction	Manual methods		4		4		3015.008	
	Alpha thalassaemia deletions	PCR using thermal cycler W		4		4		3015.008	
	Factor V Leiden	PCR using thermal cycler W		4		4		3015.008	

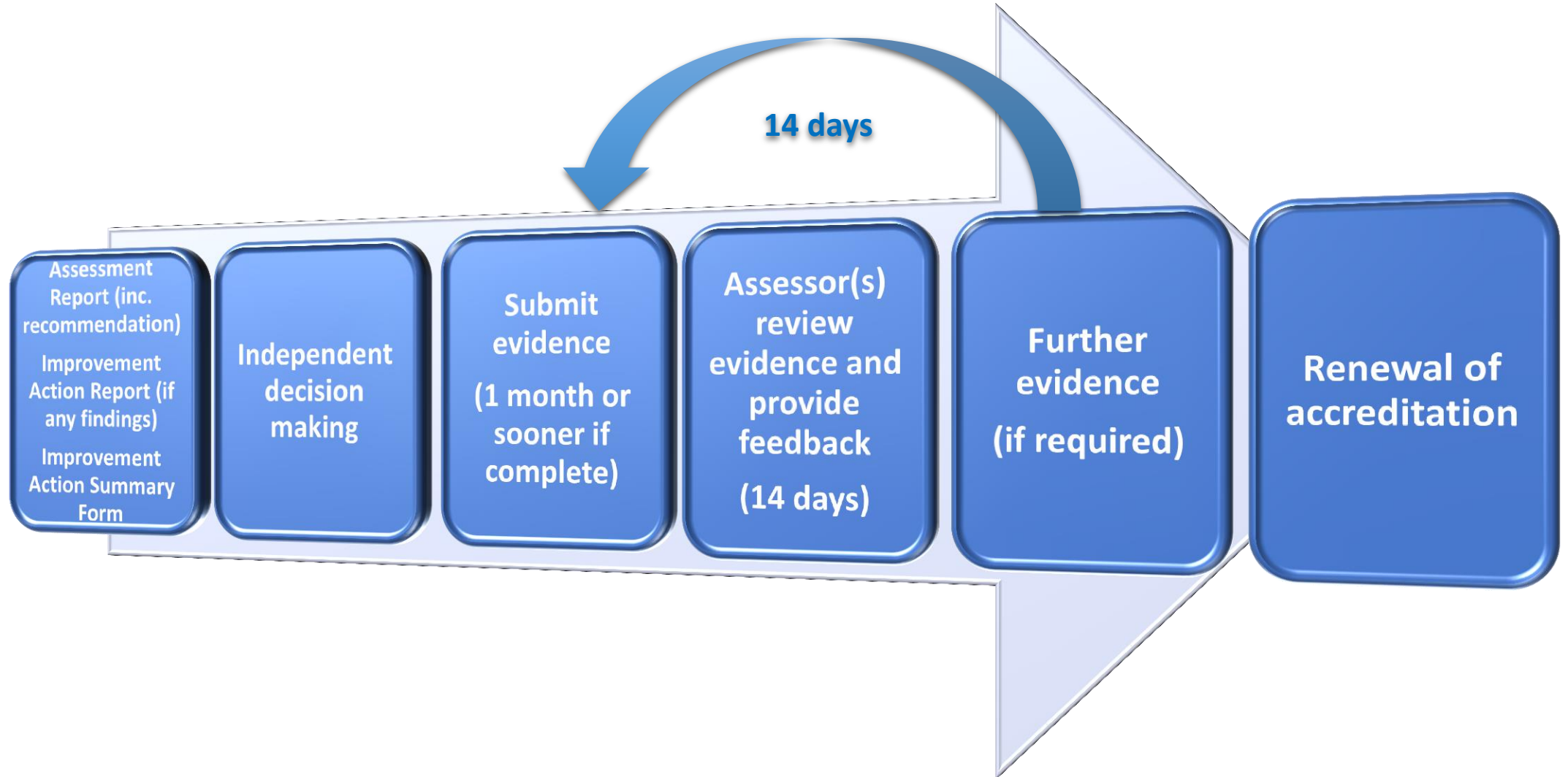
Pre-Reassessment



Reassessment



Post-Reassessment



Reassessment

- Initial accreditation expiry date is 4 years from initial grant of accreditation (sort of)
 - Expiry date stated on the initial grant letter
- Profile month and visits are 6 months after initial grant
 - Reassessment will be 6 months before accreditation due to expire
- Allows 6 months to complete everything before accreditation is due to expire
 - Clearance of all mandatory findings
 - UKAS decision process (no decisions for surveillances, usually)
- Expiry extension process
- New expiry date will be 4 years on from last expiry date (not from any extension)
- Confirmed with formal renewal of accreditation

Preparation for Reassessment

- Begins 4 weeks before when a Reassessment Plan is received

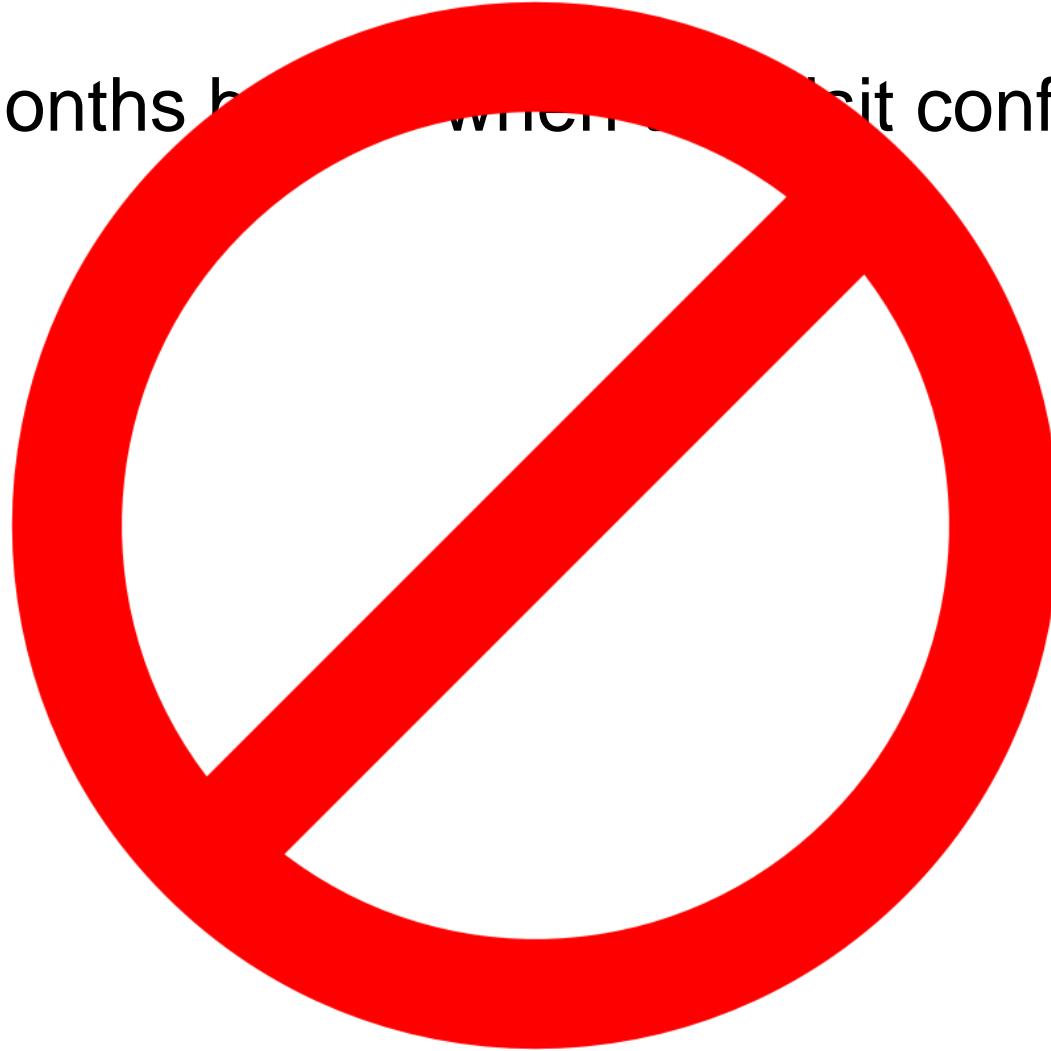


Preparation for Reassessment

- Some preparation of practicalities begins when the Visit Plan is received:
 - Confirms the locations being assessed
 - Confirms when assessors will be at each location
 - Confirms the specific activities being assessed at each location
 - Logistics
- Receipt of the Visit Plan is not the time to tell UKAS you've changed your analysers
- nor is the opening meeting at the Reassessment
-or when the technical assessor gets in the lab

Preparation for Reassessment

- Begins 6 months before when exit confirmation is received



Preparation for Reassessment

- Visit confirmation is just that:
 - Dates
 - Identity of each assessor (plus current employer)
 - Quotation for the cost of the Reassessment
- All of these should have been discussed and communicated prior to receipt of the formal visit confirmation:
 - UKAS office agree dates with the lab
 - Assessors are identified by the Assessment Manager during planning
 - Estimate for the effort (days) sent with initial grant or at renewal, revised if any changes (\times current day rate = cost)

Preparation for Reassessment

- When the \$£%! should we start preparing then?
- I'd rather ask myself:
- Why do we need to prepare for a Reassessment?
 - At least 4 previous assessments
 - Entire management system has been assessed at least twice (at IA and across SU1-3)
 - All areas of competence have been assessed at least twice
 - Maintaining a management system should ensure ongoing conformity to ISO 15189, not just conformity immediately before the Reassessment when preparation begins
 - Unannounced visits!

Reassessment of ongoing conformity



The free finding clearance token goes to.....



I promise to give the bearer on demand one cleared mandatory finding

Signed on behalf of UKAS:



Martin Stearn, Senior Assessment Manager

Assessment Team

ID	Role / Area	Employee Reference	Name	From year	Comments (e.g. when to change; history)
1	Assessment Manager	E01119	Martin Stearn	2017	
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Reassessment of ongoing conformity

- Document control should avoid the need to review/revise SOPs immediately before the Reassessment
 - and avoid revision before & after assessment
- Control of records should ensure everything necessary for assessment is available & complete
- Internal audit should identify non-conformity to ISO 15189 and internal procedures
 - including any missing/incomplete records
- Management of non-conformities, inc. complaints, root cause analysis & implementation of corrective/preventive actions should address gaps on an ongoing basis
- Management reviews should evaluate overall effectiveness and identify improvements
 - please stop calling it the AMR

Reassessment of ongoing conformity

- Internal audit should identify non-conformity to ISO 15189 and internal procedures
- Management of non-conformities, inc. complaints, root cause analysis & implementation of corrective/preventive actions should address gaps on an ongoing basis
- Management reviews should evaluate overall effectiveness and identify improvements



Nothing to prepare

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