Blood Consultative Committee Meeting

03 March 2020

Medicines & Healthcare products Regulatory Agency

Department of Health & Social Care

Blood EU and Trade Update

Last updated 09/03/2020

EU and Trade Update

The Transition Period and the UK's Negotiating Approach

- Following the UK's departure from the EU on 31 January 2020, the UK entered a time-limited Transition Period (TP). During this time, the UK remains in the Single Market and Customs Union, retains access to critical databases, and freedom of movement continues. During the TP, EU law will continue to apply in the UK and the UK will need to pass the necessary legislation to implement updates to EU law.

- Government policy is that the TP will not be extended beyond 31 December 2020 and that economic and political independence will be fully recovered from 1 January 2021. During the TP, the Government's focus is to negotiate a future relationship with the EU, deliver the Withdrawal Agreement, and prepare for the end of the TP. We are committed to ensuring uninterrupted care at the end of the TP, helping to maintain the quality and safety of health services in the UK.

- Since the start of the year, significant progress has been made in setting the Department's priorities for the negotiating approach with the EU. The EU negotiating mandate was published on 25 February; the UK Approach was published on 27 February. It is based on precedent created by other EU-third country Free Trade Agreements; the UK's government position is clear there will be no alignment and the UK will be out of CJEU jurisdiction. Formal negotiations are due to commence in March.

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2019 SABRE Data

BCC update March 2020

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National SAE Data

- No change in overall numbers of SAEs received
- Increase in Storage errors
- Decrease in “Other” category errors
- Decrease in reports attributed to slips and lapses
- Increase in reports showing improvements to QMSs

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Storage errors

- Storage errors occur in lab and clinical areas
- Incorrect storage of components most likely to occur in clinical areas
- Increases to component expiry and return to stock errors

Storage sub-classification	2019 (+/- 2018)	2018 position
Incorrect storage of component	102 (+4)	1
Component expiry	71 (+14)	2
Sample expiry	39 (-2)	3
Return to stock error	22 (+14)	6
Storage temperature deviation	15 (-3)	4
Failure to action alarm	12 (+1)	5
Miscellaneous	8 (+2)	8
Security	5 (NC)	9
30minute rule	3 (-5)	6
Total	277 (+25)	x

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Storage

- Components stored in unmonitored drug fridges
- Components stored in decommissioned blood fridges
- Components stored at the incorrect temperature
- Errors often involve untrained staff including bank and locum staff

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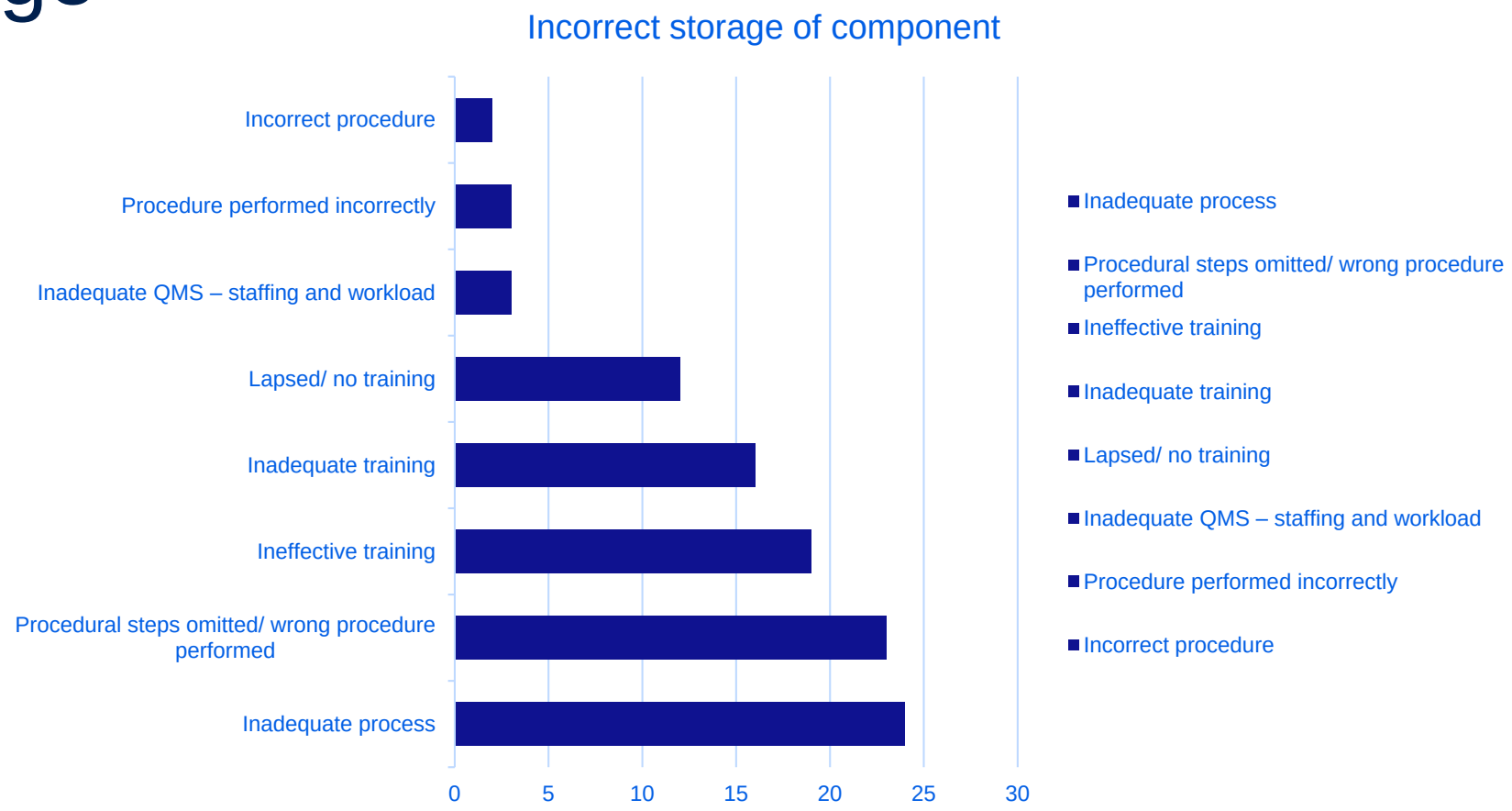
Storage



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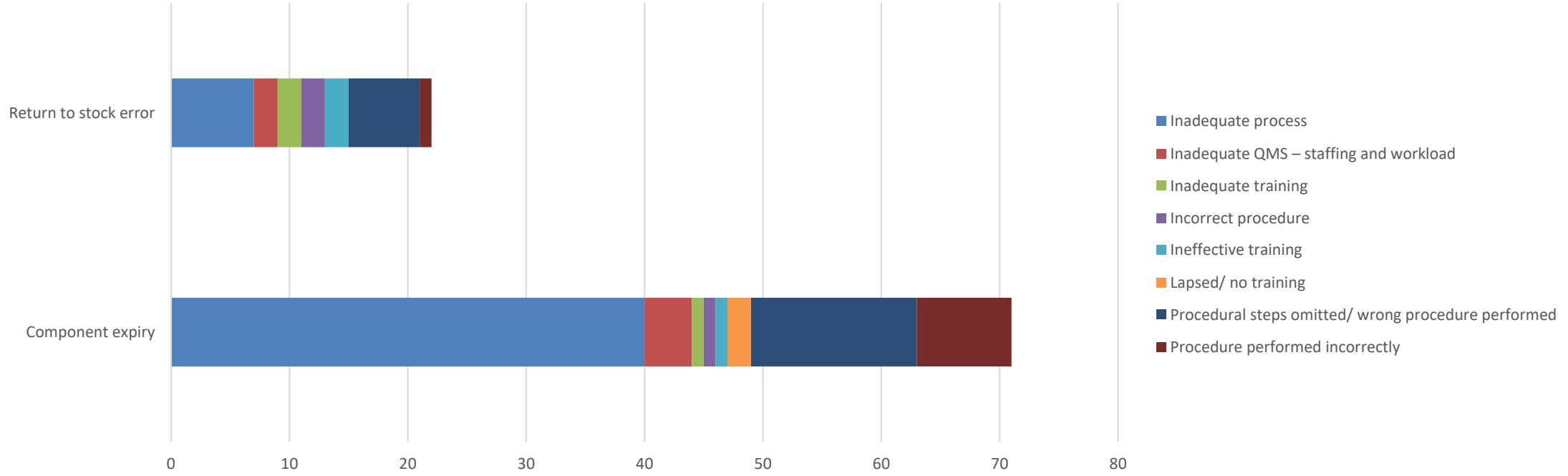
Storage – human error sub-categories



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Storage

- Improve the design of processes involved in storage and quarantine of components.
- All staff involved in handling and storage of components must be appropriately trained to do so.
- Ensure staff are identified for training, that training material is thorough and that staff competencies are assessed.
- Ensure new, locum and bank staff are informed of storage arrangements before they can handle blood

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Other

Other sub-category	2019 (+/- 2018)	2018 position
Incorrect blood component issued (IBCI)	190 (-22)	1
Sample processing error (SPE)	142 (-43)	2
Pre-transfusion testing error (PTTE)	119 (+26)	5
Component collection error (CCE)	117 (+3)	4
Component labelling error (CLE)	114 (-17)	3
Data entry error (DEE)	56 (-17)	6
Component available for transfusion past de- reservation (CATPD)	10 (+4)	7
Expired component available for transfusion (ECAT)	9 (+4)	10
Unspecified (UNSPEC)	9 (+4)	9
Failed recall (FR)	6 (NC)	7
Incorrect blood component ordered (IBCO)	5 (+1)	11
Handling damage (HD)	1 (-1)	12
Incorrect blood component accepted (IBCA)	1 (NC)	13
Total	779 (-58)	x

- Other category mostly relate to lab activities
- Increase in testing errors
- Decreases in
  - IBCI
  - SPE
  - CLE
  - DEE

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Human error sub-categories

- 101 fewer reports attributed to slips and lapses
- Improvements to QMS
  - Process design
  - SOP content
  - Training

Human error sub-category	Total 2019 (+/- 2018)	2018 position
Procedure performed incorrectly	310 (-50)	1
Inadequate process	282 (+69)	3
Procedural steps omitted/wrong procedure performed	199 (-51)	2
Ineffective training	140 (+14)	4
Inadequate QMS – staffing and workload	90 (-8)	5
Inadequate training	58 (+1)	6
Incorrect procedure	36 (+16)	7
Lapsed/no training	27 (+5)	8
Inadequate supervision	15 (+1)	9
Total	1173 (-3)	

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Conclusions

- Fewer lab errors
- Why?
  - Fewer units transfused, but that does not neatly account for all the steps in a process that can go wrong
    - Better use of blood/ re-stocking of units
    - More patients? More samples? More Testing? More labelling?
  - Improvements to QMS
- Does this mean that lab quality systems are improving and improving component and patient safety?

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Haemovigilance Team Managers Report

BCC update March 2020

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2019-2020 Activity up to March 2020

HBB, BE, RTC/Lab Managers/ TP meetings and Visits =	21
Manufacturers =	6
Education Days =	12
Total =	39

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Common issues

- Lack of available capacity and knowledge to balance operational need with MHRA compliance.
- Manufacturers not meeting a site's needs.
- Delays to SABRE investigations

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Lack of available capacity and knowledge to balance operational need with MHRA compliance.

A capacity plan should be in place to demonstrate that the staffing level is sufficient to cover:

- Workload – Routine and Out of Hours
- Effective implementation, development and management of an appropriate QMS

Where a shortfall is identified, senior management should take action to ensure sufficient resource is made available.

To help sites with lack of experience/knowledge of Good Practice principles the Haemovigilance team now offers education days either on site or at MHRA HQ at Canary Wharf.

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Manufacturers not meeting a site's needs.

- LIMS systems upgrades and patches being installed without an appropriate explanation and assessment of their impact

- Analysers not meeting the users expectations and as a result secondary processes and systems being introduced within the operation process flow

If an error/deviation is the fault of the analyser/LIMS then the laboratory will be expected to show a detailed examination, RCA, Risk assessment and CAPA has been made and implemented.

LIMS/Software manufacturers should provide clear and unambiguous release notes for every version of any upgrade so the site can assess its impact in line with good practice principles

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Delays to SABRE investigations

- SABRE confirmation reports have been delayed because of the Trust's risk management departments taking over the investigation process leading to delays of up to and over six months.

- Good practice for investigations is to include people with the knowledge of the processes, procedures and systems and those with knowledge of the event.

Investigations performed remotely are at a higher risk of drawing inappropriate conclusions, not identifying correct root cause and therefore not implementing effective CAPA.

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Blood forum http://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

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Blood Compliance Report (BCR) Process Update

Shirley Stagg

03 March 2020

Topics for discussion

BCR 2019

BCR Assessment Outcome

Inspection Outcome

BCR 2020

Further changes and Improvement

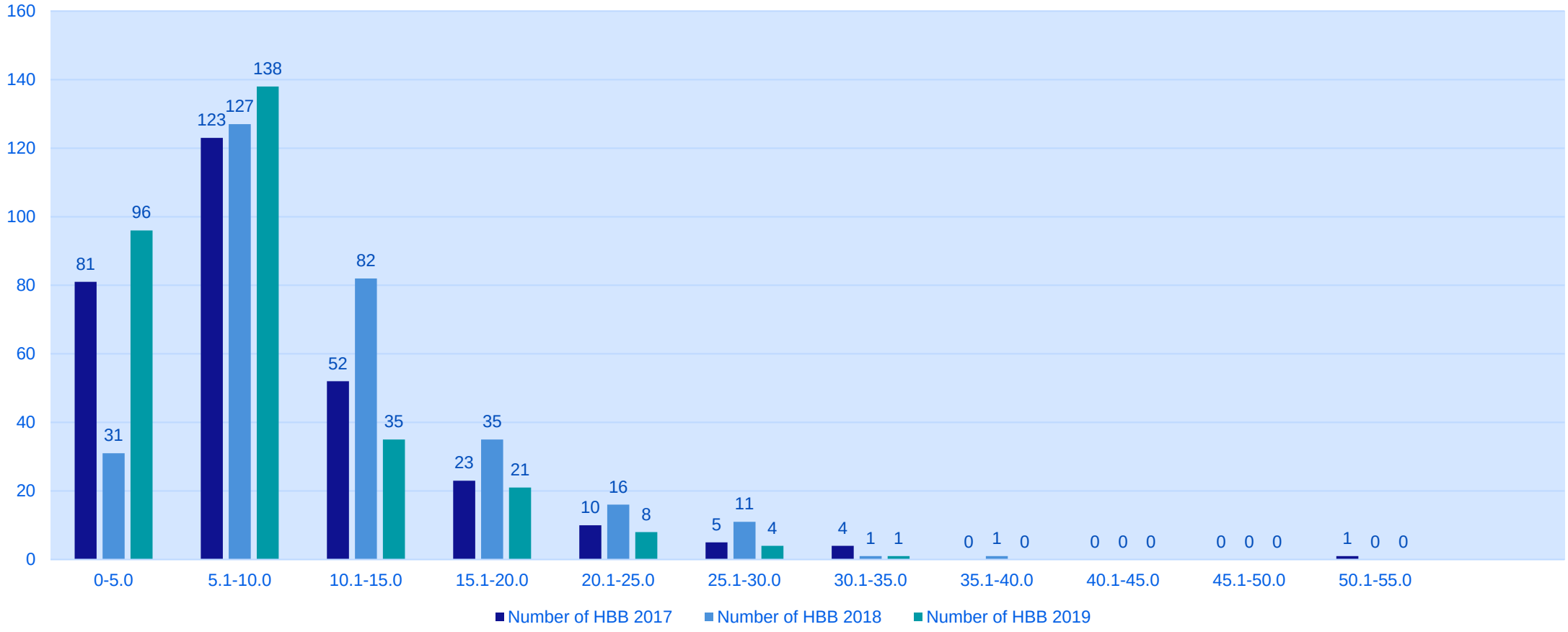
Facilities

2018/19 BCR Assessment - Outcome

BCR Assessment Outcome

HBB BCR received	303
Late submission (after 30 April 2019)	9
Range of risk score	0.5 – 31.5
Inspections	25 (2 control)

Range of risk score 2017, 2018, 2019



BCR Assessment Team (BAT)

- Includes blood inspectors, Inspection action group (IAG) / Compliance management team (CMT) Representative, SABRE team
- Review BCR submissions each year
  - For 2019/20 inspections discussed 26 sites in detail
  - Consideration given to BCR scores, BCR responses, SABRE history, CMT/IAG history, inspection history, related sites e.g. within same Trust / pathology partnership, significant changes
- Decide on inspection list

2019/20 Inspection Outcome

Good Practice Guidelines

The Good Practice Guidelines (GPGs) jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe are contained in the 18th Edition of the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components. In addition they can be found through the following link https://www.edqm.eu/sites/default/files/goodpracticeguidelines-19th_edition_guide_preparation_use_qa_blood_compon ents-december2016.pdf on the webpage for the Blood Transfusion Guide https://www.edqm.eu/en/blood-transfusion-guides-1608.html .

2019/20 Inspection Outcome

Number of inspections	19
Critical Deficiency	0
Major Deficiency	28
Other Deficiency	70
IAG referral	2 (+1 in IAG follow-up)
CMT referral	2 (+2 in CMT follow-up)
Type 2 letter	3

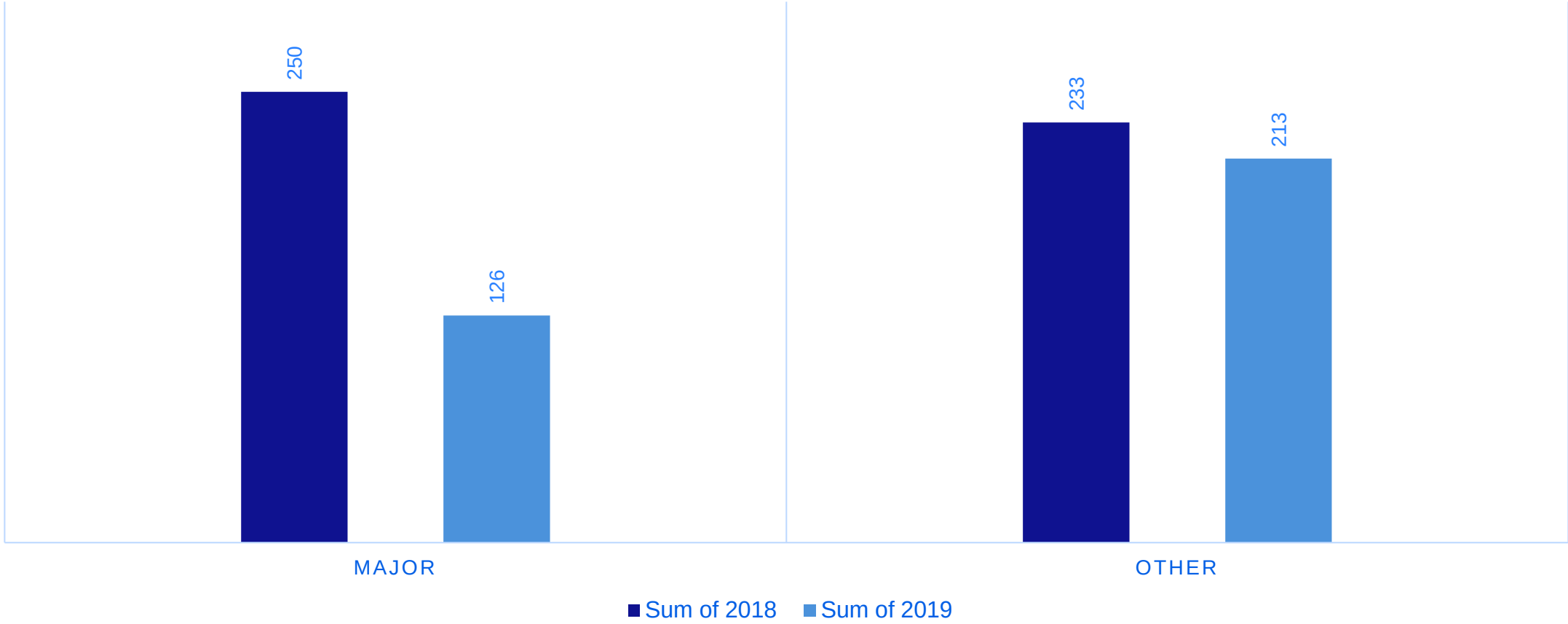
Example of a deficiency

Other

The control of equipment and reagents for making tea were deficient in that:

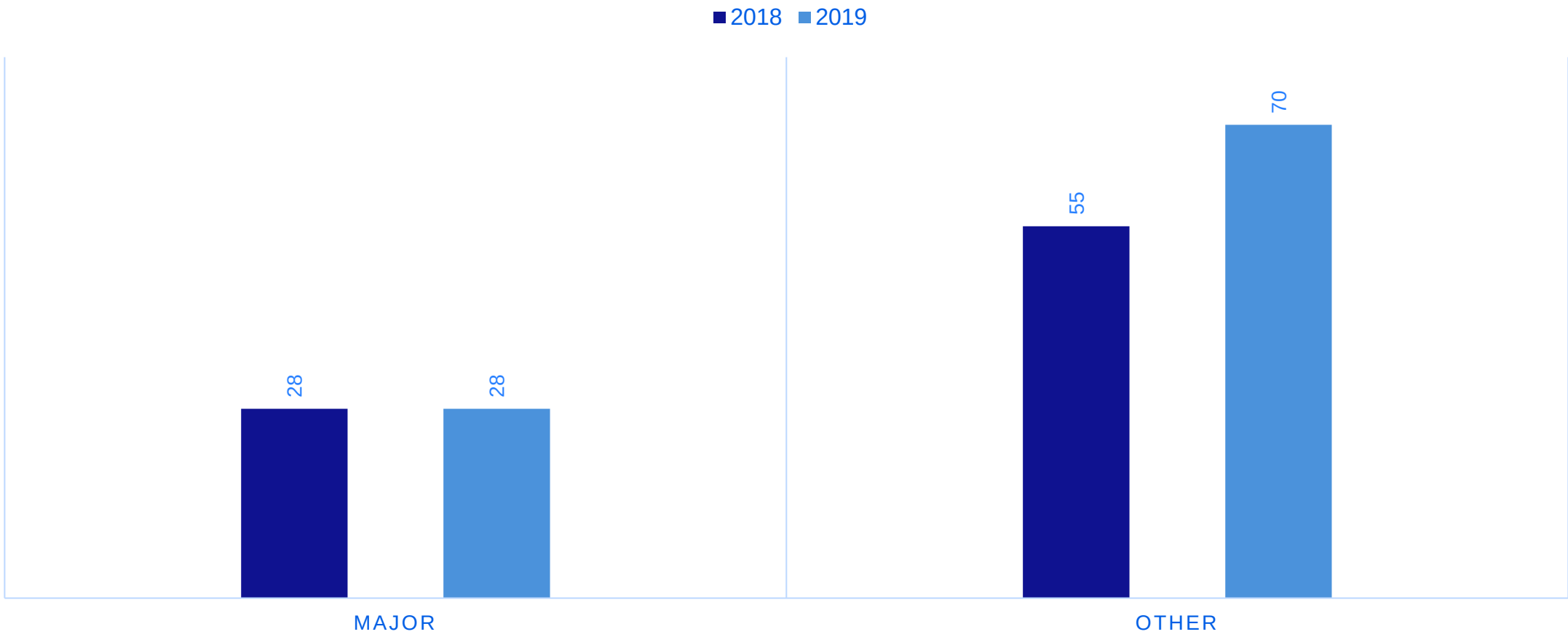
- The kettle did not have maintenance carried out in December 2018 as required in SOP – TEA.
- The kettle was not assessed by personnel after repairs carried out in July 2019.
- There was a build up of rust and dirt underneath the spout due to the design of the kettle.
- The use of the kettle was not described in a procedure.
- An unapproved supplier had been used for the purchase of tea.
- GPG 4.1.1, 4.1.12, 4.1.17, 4.7.1.3.2, 5.2.2.3

Number of GPG references cited in 2018 inspection cycle versus 2019



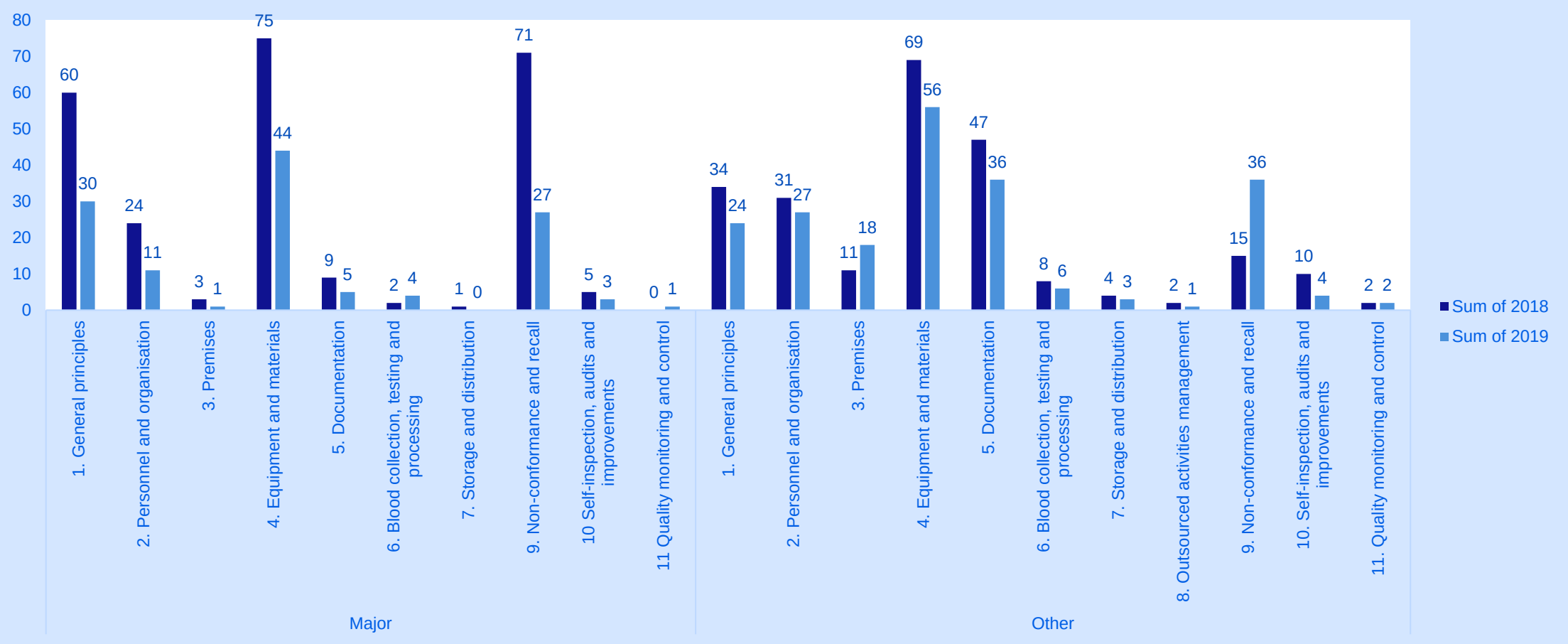
Based on 26 inspections in 2018 cycle and 19 so far in 2019 cycle

Number of deficiencies raised in 2018 inspection cycle versus 2019

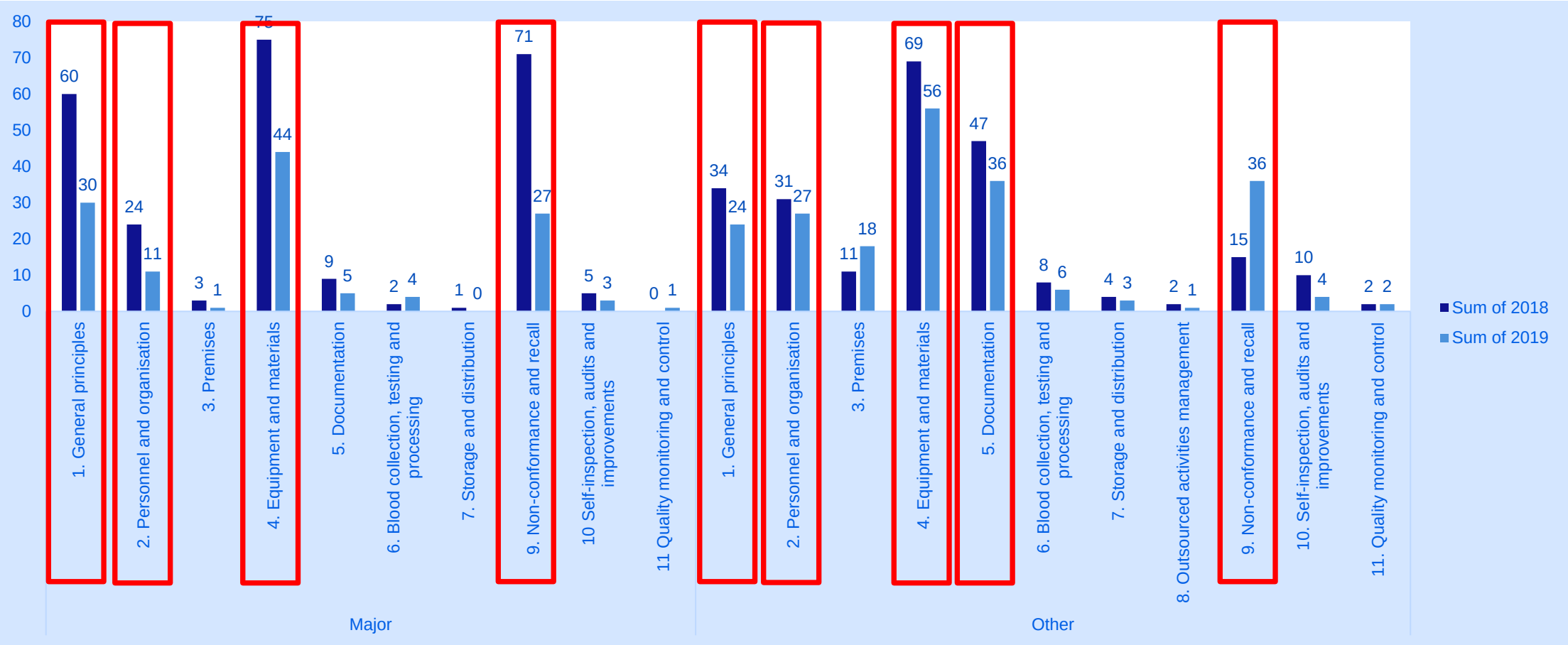


Findings are consistent between 2018 and 2019 (based on first 19 inspections in each cycle)

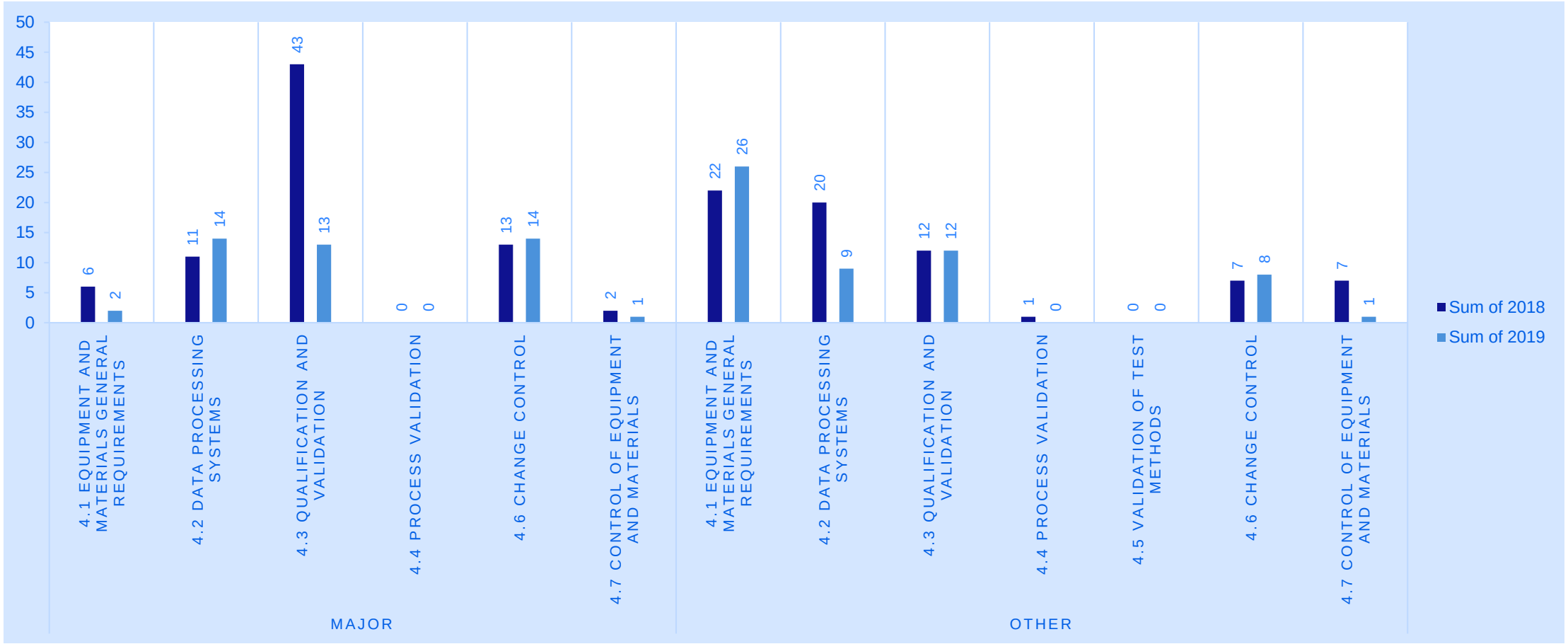
Citing of GPG reference by chapter



Most cited deficiencies by GPG Chapter



GPG Chapter 4 - Equipment and materials



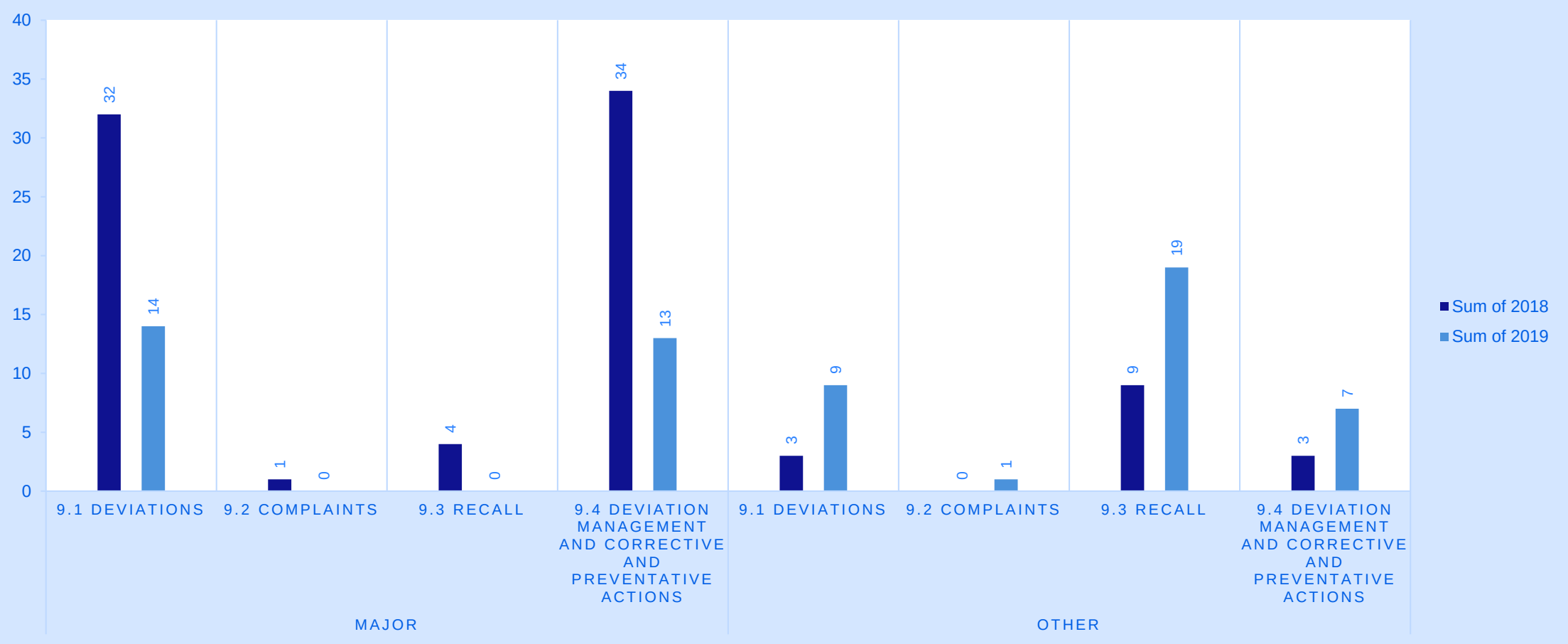
GPG Chapter 4 - Equipment and materials

- Data integrity
  - Lack of audit trails
  - Lack of control of user access to computerised systems
  - Insufficient control of duplicate patients
- Change control
  - Not raised for all relevant changes
  - Not raised in timely manner
  - Insufficiently detailed
  - No post-implementation review

GPG Chapter 4 - Equipment and materials

- Validation
  - Insufficient scope
  - Lack of formal release between stages
  - Results which fail to meet pre-defined acceptance criteria not raised as deviations
  - Insufficient control of temperature mapping exercises

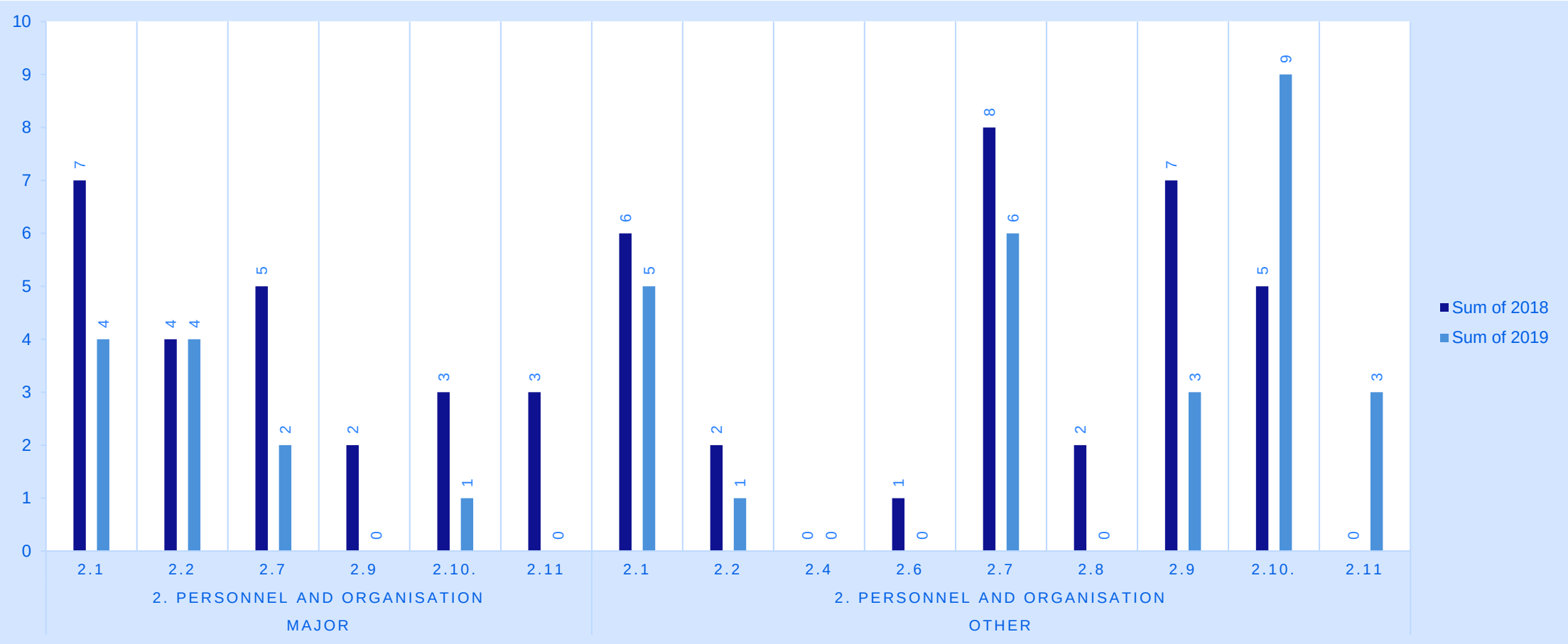
GPG Chapter 9 – Non-conformance and recall



GPG Chapter 9 – Non-conformance and recall

- Non-conformances
  - Lack of detail in event description and investigation
  - Lack of effective root cause analysis
  - No care taken to ensure that process, procedural or system-based errors were not overlooked
  - Use of hospital risk management systems which focus on actual harm alone and do not include potential harm
  - Overdue investigations and CAPA without justification
  - Lack of effective trend review

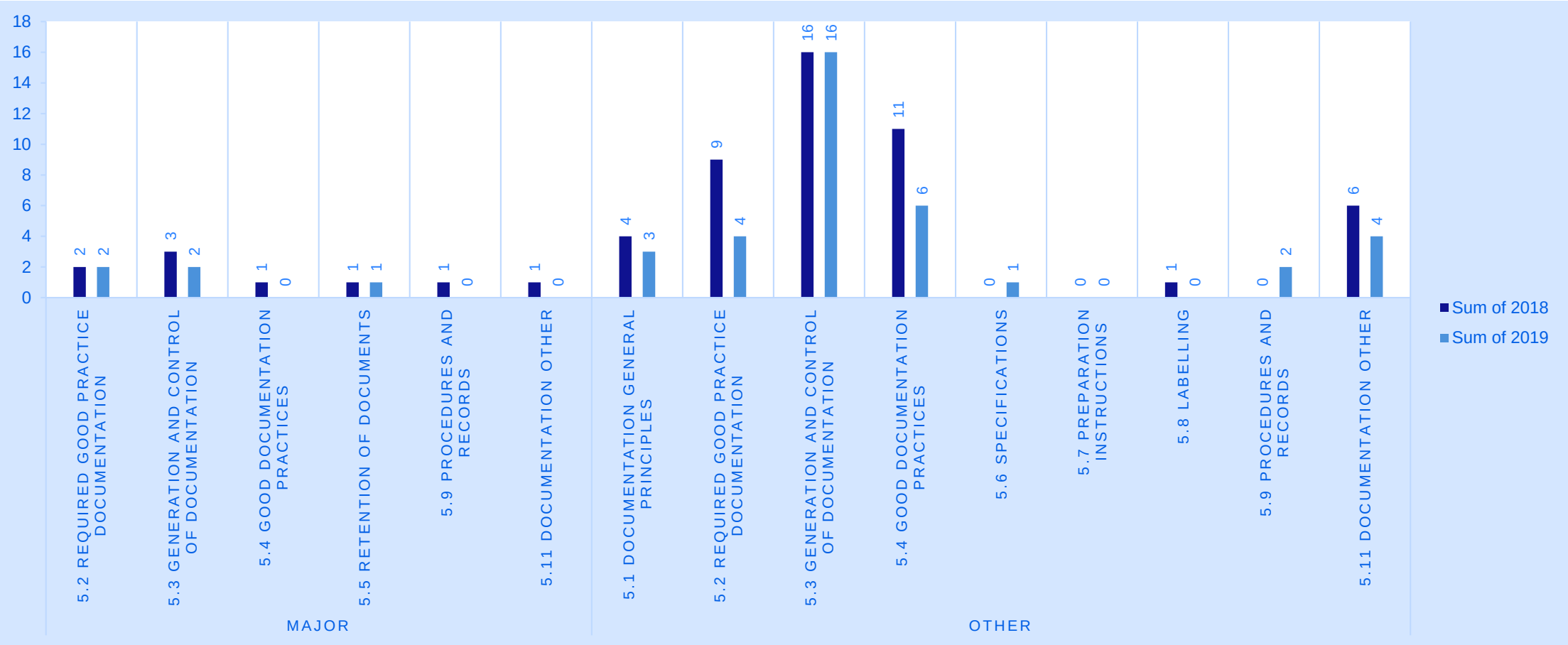
GPG Chapter 2 –Personnel and organisation



GPG Chapter 2 –Personnel and organisation

- Insufficient numbers of personnel to carry out laboratory activities and maintain the QMS
  - Evidence in quality of investigations etc
  - RCA ‘busy’
- Incomplete training records
- Lack of demonstration of competence in key aspects of the QMS such as recall and deviations (esp lone worker)
- Overdue competency assessments

GPG Chapter 5 - Documentation



GPG Chapter 5 - Documentation

- SOPs contain insufficient detail
- Document review overdue
- Insufficient control of ‘change requests’ for documents
- Insufficient control of document acknowledgment
- Overwriting

Most referenced GPG paragraphs 2019

Major

- 1.2.13
- 1.2.5
- 4.6.4
- 9.1.5

Other

- 2.10
- 4.1.21
- 2.7
- 9.3.8

General finding

Incomplete or overdue actions in relation to a previous inspection.

Any changes to commitments including agreed target dates must be communicated to the inspector.

2020/21
Changes and improvement

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Changes and Improvement

- Complete revision of the BCR Guidance Notes document
- Please read this
- Update to the BCR Declaration
- Separate Blood Facility Declaration Guidance Notes
- Also useful for HBB to read
- Update to the Facility Declaration Form

Revised questions in BCR

Section A				General Information	
1				Hospital name (Full name)	
2				Trust / Private Healthcare Organisation Name (where the hospital blood bank is located)	
3				Address line 1:	
4				Town/city:	
5				Post Code	
6				Contact name	
7				Telephone	
8				Email	
9				If transfusion services at the above site are provided by an external contractor or another hospital site please provide the name of the entity or hospital	
10				Please indicate the address that the invoice should be sent for the assessment of your BCR submission	
11				Please provide a Purchase Order Number to be included on the invoice for assessment of your BCR submission if required The fee for 2020 is £683	

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Revised questions in BCR

Section E				Key personnel	
1				Name of Transfusion Laboratory Manager	
2				Full address	
3				Post Code	
4				Telephone	
5				Email	
6				Is there an authorised document (e.g. a capacity plan) that considers demand on the laboratory and is used to plan the number of personnel required including those responsible for laboratory and quality management?	
7				How many staff do you have within the transfusion laboratory during core working hours (Please give full time equivalents and indicate 0 [zero] where applicable)?	
	7.1			Senior BMS	
	7.2			BMS	
	7.3			MLA / Other	
	7.4			Does the site have on-going staffing issues that are impacting on the laboratory workload, training, or QMS tasks? If so, please indicate the level of understaffing as a decimal fraction (i.e. if 20% understaffing, enter 0.20). If not please enter "0" (zero)	

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Revised questions in BCR

Question F5

Have all staff who may work unsupervised in the transfusion laboratory (including out of hours cover) been trained and assessed in the tasks that they are performing according to the systems mentioned above in questions 1 to 4?

Question G1.2

Email address for person accountable for quality.

Question G1.7

Are effective senior and executive level oversight mechanisms in place to assure compliance of the Quality Management System (e.g. Are there documented actions from senior management meetings addressing overdue deviations, CAPA, change controls, documentation, etc)

Question H4

Are incidents graded on the potential to cause harm rather than just actual harm?

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Revised questions in BCR

Section I				Procedures in place for quality assurance within the transfusion laboratory – Component recall	
1				Is there a system to recall / retrieve blood components after release from the transfusion laboratory?	
	If response to question I1 was 'Yes'				
	1.1			Does the system consider recall / retrieval following information obtained from external sources (e.g. the UK Blood Services)	
	1.2			Does the system consider recall / retrieval following information involving multiple units (e.g. recall of reagents from the suppliers).	
	1.3			Does the system consider internal sources (e.g. laboratory errors or incidents)?	
	1.4			Has the effectiveness of the recall system been verified for all potential sources (e.g. by performing 'mock' recalls as a paper exercise and incorporating examples from I1.1, I1.2 and I1.3)?	

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Revised questions in BCR

8				Is there a documented system in place which is compliant with 1.2.12 and 4.6 of the Good Practice Guide, that describes the system for change control? (*This should demonstrate assessment and management of the impact of any procedural or equipment changes on the validation status of existing processes, and to ensure that training and documentation is available prior to the implementation of a change).*	
	If response to N8 was 'Yes':				
	8.1			Does this system control changes to:	
		8.1.1		Documentation (SOPs and records)?	
		8.1.2		Equipment and facilities?	
		8.1.3		Laboratory staffing structure?	
		8.1.4		Reagents and testing processes?	
	8.2			Are changes implemented prior to the completion and approval of documents, training and validation?	
	8.3			How many change control reports / requests were raised during the reporting year 1st April 2019 to 31st March 2020?	

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Revised questions in BCR

Question P3.4.3

Are patient samples permitted to be run concurrent with the QC test?

In the event of an IQC failure do you consider the impact of all results since the last successful run - including any run concurrently with the failing test?

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Facilities

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Blood Facilities

A hospital ward, hospice or care home etc which receives blood from a hospital blood bank for transfusion purposes (but does not perform compatibility tests on site) is defined as a ‘Facility’.

Facilities may perform three key tasks which are covered by the scope of a blood compliance report (BCR). These are:

- The control of monitoring, maintenance and calibration of any controlled temperature storage equipment on site
- Reporting of serious adverse events and reactions to SABRE
- Maintenance of traceability records

A ‘Facility’ should have a Service Level Agreement (or similar document) in place if the supplying Hospital Blood Bank is responsible for these functions.

Blood Facilities are required to complete the Blood Facility Declaration Form.

Blood Facilities

2018

- Only 111 out of an expected 808 declaration forms received.

2019

- Letter was sent to blood facilities that did not submit the declaration form:
  - Request for 2019 declaration form / clarification of requirement
- 514 out of an expected 797 declaration forms received
  - Issues with many forms

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Blood Facilities

Reason for non-return

- Contacts for facilities pulled from BCR – accurate? Up to date?

Reason for issues

- Not actually wet signed (Typed or cut and paste)
- Not signed by correct person

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Changes to Blood Facility Declaration 2020

- Addition to section R 1.15 of BCR
  - If this site meets the definition of a facility please confirm that you have forwarded a notice of the Blood Facility Declaration Form to the facility
- Notice for Blood Facility Declaration to be sent to HBB with BCR email – HBB just need to cut and paste and forward to facilities
- Clarification of requirement for signatures within the Declaration

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Blood Facility Declaration Form

I am the “person responsible for the management of a facility”*

Signature	*Ensure wet signature not typed or cut and paste*
Name	BLOCK CAPITALS
Position	*Note **must** be Chief Executive in the case of a Health service Body or Registered Person in the case of an independent hospital**
Employer	

*Signatories should include the person completing the form and the "person responsible for management of a facility", as defined by Regulation 1 of the Blood Safety and Quality Regulations, SI 2005 No. 50 (as amended), which in the case of a hospital, facility or service which is owned or managed by an NHS body is the chief executive of that body; or in the case of an independent hospital, an independent clinic or a care home, the registered person; or in the case of a manufacturer or a biomedical research institution, the manufacturer or bio-medical research institution.

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Thank you

Any questions?