



2019 ANNUAL REPORT

NATIONAL HEALTH REGULATORY AUTHORITY

KINGDOM OF BAHRAIN



**His Royal Highness
Prince Khalifa Bin Salman
Al Khalifa**

The Prime Minister
of the Kingdom of Bahrain



**His Majesty
King Hamad Bin Isa Al Khalifa**

The King of the Kingdom of Bahrain



**His Royal Highness
Prince Salman Bin Hamad
Al Khalifa**

The Crown Prince & Deputy
Supreme Commander & First Deputy
Prime Minister of the Kingdom of
Bahrain

nhra
B A H R A I N



الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Contents:

Executive Summary	5
Message From The CEO	9
NHRA Operational Plan 2016 - 2020	11
Regulating Healthcare Facilities	17
Regulating Healthcare Professions	41
Regulating Alternative Medicine Facilities	50
Regulating Pharmaceutical Products	53
Regulating Pharmacy Licensing	58
Regulating Medical Devices	63
Regulating Continuous Professional Development / Continuous Medical Education And Clinical Trials	71
Accrediting Healthcare Facilities	78
Medical Complaints	85
Achievements Of The Legal Affairs Unit	97
Activities Of The Investors Office	99
Human And Financial Resources	104
Customer Engagement Activities	108

THE NATIONAL HEALTH REGULATORY 2019 ANNUAL REPORT

EXECUTIVE SUMMARY

In 2019, the authority introduced many updates to the health sector's regulatory frameworks and continued to review its operations regularly and in particular with regards to regulating health care facilities and professionals, supervising registration and licensing of drugs and medical devices, regulations for conducting clinical trials, and continuing medical education reviews.

Over the past year, the legal affairs unit has been engaged in developing new regulations and updating existing ones. Four important resolutions were published during the course of 2019: Resolution No. 2 of 2019 regarding classification of health facilities, health, technical and safety requirements that must be met in the facilities, Resolution No. 62 of 2019 regarding the licensing requirements for the use of medical technologies to assist in artificial insemination and fertilization, Resolution No. 63 of 2019 regarding regulations for the practice of pharmacy professions and licensing of pharmacy centers, drug factories, pharmaceutical preparations and pharmaceutical facilities and Resolution No.95 of 2019 regarding investigating medical errors and reporting incidents and medical errors. Additionally, the unit has also finalized the following: A draft resolution of the regulations and requirements for health facilities licensed for the treatment and rehabilitation of addiction, a draft resolution regarding the issuance of the regulations for registering medicines and pharmaceutical preparations, pricing medicines and determining the profit margin, a draft resolution to issue a list of requirements and procedures for licensing and monitoring governmental health facilities. These draft resolutions are pending the legislation and legal opinion commission approvals. The unit has also collaborated with the Bahrain Medical Society, the Ministry of Health and the private health sector to work on a draft legislation for The Practice of Medicine and Dentistry.

In relation to regulating healthcare facilities, the total number of registered health care facilities in 2019 reached 746, an increase of 4% from 2018. This increase was largely due to a 10% increase in the number of registered medical centers. Meanwhile, the total number of hospitals decreased to 19 from 21 in 2018 as there was a change in classification of two hospitals into medical centers. The health facilities regulatory department issued 81 new licenses and renewed 657 licenses for existing facilities. The department also carried out 943 inspection visits, an increase of 35% over last year, which resulted in the

identification and correction of 1599 violations, 455 of which were related to the safety of the facility.

In terms of health professions licencing, there was an increase in new licenses for health professionals, mostly in the field of nursing (63%), followed by allied health professions (26%). The department has completed 3,253 new applications for all categories of professionals, that includes 651 medical licenses, 271 dentist licenses, 1,221 nursing licenses, 840 allied health professional licenses and 270 pharmacist licenses. One of the biggest challenges for the health professions regulatory department in 2019 was the development of the electronic system to apply for new licenses and renew existing ones. The Authority has worked closely with the Information and E-Government Authority (IGA) to transfer all its professional licensing operations electronically. By mid-2019, all professionals were able to submit their applications electronically to obtain a license. The Authority looks forward to automating other procedures that are still manually processed, such as submitting requests for visiting consultants and requesting certificates of good conduct. We will continue to improve all services to make it easier for facilities and professionals to complete all their requests without having to submit them manually.

With respect to the regulation of pharmacies, NHRA processed 41 new pharmacies licenses in 2019, 7 of which were operated in health facilities and 34 were private pharmacies, reflecting a 17% increase in the number of licensed pharmacies compared to 2018. The total number of licensed pharmacies in Bahrain reached 307 in 2019 out of which 235 operate as a private pharmacy and 72 operate in health facilities. The department conducted 731 inspection visits, a 22% increase in the number of inspections carried out in 2019 due to the hiring of additional pharmacy inspectors at NHRA. This contributed to the detection and correction of 962 violations, 38% of which were drug violations, followed by 17% violations of temperature and humidity.

The pharmaceutical products regulation department processed 518 pharmaceutical product license renewals and 384 new products registrations. Using the drug utilization review (DUR) system the department processed 9,053 electronic invoices and 1,550 manual invoices. In 2019, there were 3,491 registered medication products, 328 pharmaceutical products were classified, 3,163 temporary importation of non-registered products were processed, and 2,608 medications were priced.

In 2019, the medical complaints unit received 257 cases for investigation, an increase of 13% since 2018. Of the 257 cases received, 167 complaints were reported by individuals, 33 incidents were reported by healthcare facilities, and 57 lawsuits were referred by jurisdiction authorities. Forty two percent of the cases were related to the treating physician, 44% related to the healthcare facility and the rest were related to allied health professionals, nurses, pharmacists or others. The technical investigating

committees were able to complete the investigations of 177 cases in 2019, demonstrating an increase of 53% from the previous year. The disciplinary committee issued 37 disciplinary actions that included 10 suspensions, 18 warning notices, and 1 professional license was cancelled.

In the field of medical device regulation, the Authority registered 2,513 medical devices in 2019. The registration process aims to assess compliance with safety and performance requirements set out in applicable regulations and standards. The total number of new medical device applications evaluated by medical device engineers reached 9,174, of which 8,783 applications were processed through the Electronic System of Customs (OFOQ), while 391 requests were manually processed in relation to the combined medical devices. The total cost of the imported devices was 30,382,973.400 BD. The authority rejected 24% (2,160) of the total applications submitted for import due to either the detection of a false certificate or a counterfeit device.

In keeping with our mission and vision we continue the process of evaluating the performance of healthcare facilities since the implementation of the national accreditation program. At present we have successfully accredited 16 hospitals and 20 medical centers. Analysis of hospital accreditation criteria has revealed several areas of improvement for the authority to assist healthcare facilities in gaining and maintaining accreditation and thus to continuously improve the quality of services provided to the people of Bahrain. The Accreditation department has achieved 60% of its targets set for this endeavour in this past year.

Since the issuance of resolution No. (40) of 2016 regarding the validity of licenses of healthcare providers and conditions of renewal, there has been a major increase in the number of continuous medical education activities attended by all healthcare professionals. In 2019 the Continuous Medical Education (CME) / Continuous Professional Development (CPD) and Clinical Research Unit had received and processed 19,400 CME activities of which 78% were offered in the government sector. Most of these activities were in the form of lectures followed by workshops and conferences. The highest CME activities were conducted for the nursing sector.

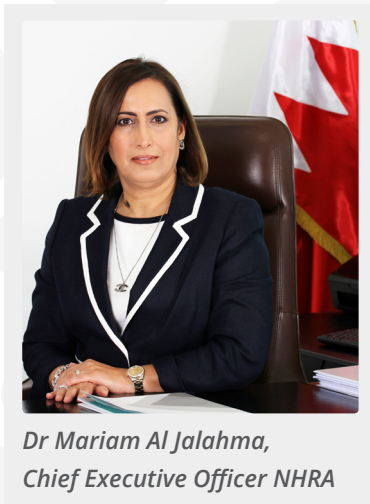
NHRA has well established guidelines for conducting clinical trials in Bahrain, and in 2019 the Stem Cells Clinical Trials Guidelines were established and approved by the Supreme Council of Health. The clinical trials unit received 4 applications for clinical trials of which half were from the government sector. The trials submitted were in the field of diabetology, haematology, respiratory disease and obstetrics and gynaecology.

On the customer service front, we had implemented two new initiatives in 2019 that have so far improved our customer satisfaction scores. The first initiative was the commissioning of an investors office with one full time employee to answer all queries

and assist in new investors entering the emerging healthcare market in the Kingdom. This is a full-service initiative provided to investors from conceptualizing their ideas to the final licenses and procedures needed to start healthcare businesses here. The second initiative that was launched was the query/information communication line to NHRA. In the past we have had a lot of feedback from clients regarding our communication response time as a result we launched an open communication line by way of a monitored email with an organizational wide policy on response time. This initiative has significantly reduced the response time to queries to NHRA and subsequently improved many of our customer satisfaction scores.

The achievements of the authority culminated in the awarding of the 2019 Best Government Practices Award for Public Administration Research (MENAPAR) in the MENA region, which was presented to the authority for the successful implementation of accreditation of health facilities in the Kingdom.

Finally, as a future step, the authority seeks to automate all its procedures, including renewing the health facilities licenses, adding or changing services, medicine and medical device registrations.



Dr Mariam Al Jahama,
Chief Executive Officer NHRA

MESSAGE FROM THE CEO

It is an honor for me to present the Annual Report of the National Health Regulatory Authority (NHRA) for 2019. NHRA introduced updates to the regulatory framework and continued to review the services provided in relation to the regulation of healthcare facilities and professionals, overseeing registration and licensing of medication and medical devices, clinical trials regulations, and continuing medical education reviews.

In 2019, we observed an increase in all process activities and applications in relation to facilities and professional licenses, pharmaceuticals and medical devices registrations.

We increased our inspection activities in facilities and pharmacies and identified numerous violations that were rectified in 2019.

The national accreditation program revealed many areas of focus for NHRA to assist facilities in attaining accreditation and therefore improving the quality of services facilities provided.

The launching of the investors' office in 2019 had a very positive impact, on the new investments in healthcare coming into the Kingdom, by providing support and guidance to new investors. Additionally in 2019, processes were put in place to improve NHRA communication with its clients and stakeholders. This initiative has significantly reduced the response time to queries to NHRA and subsequently improved many of our customer satisfaction scores.

The year 2019 also witnessed the enormous task of relocating the NHRA office buildings from the Seef area to our new premises in Sanabis. It was quite impressive to see how seamless this move took place over a period of less than a month and with minimal interruption to the services we provide. We welcome all our clients to our newly improved way of serving our clients.

Unfortunately, early in 2020 we lost a valuable and hardworking member of the NHRA Medical Device team – Miss Mona Alnajeeli. Mona was extremely dedicated to our core values and worked passionately in the Medical Device team. She is sorely missed by everyone at NHRA and her demise has reaffirmed to me the importance of the service we provide at NHRA which is to ensure safe and trusted healthcare for all.

We continue to achieve our vision and suffice it to say that patient safety and the provision of high-quality healthcare remains the highest priority for the authority to achieve its goal of protecting the health and safety of the people of Bahrain.

This annual report demonstrates the Authority's commitment to transparency, accountability and public reporting of performance. I hope that this report provides a useful overview of the Authority's work as it carries out its functions to fulfil its objective of protecting the health and safety of the people of Bahrain.

The progress achieved in 2019 is entirely due to the dedication and commitment of all the NHRA staff and our many partners, including our stakeholders and the patients and families we serve to further our ambition to provide the safest care to the people of Bahrain.

Sincerely,

Mariam Al Jalahma

Chief Executive Officer NHRA

NHRA OPERATIONAL PLAN 2016 - 2020

In August 2016, the Supreme Council of Health endorsed the 5 year strategic plan for the National Health Regulatory Authority (NHRA). This plan was a joint collaboration between NHRA middle management, administrative staff and senior management.

The strategic plan focuses on the most important objectives to be achieved in the next five years. The strategy identifies the vision, mission and specifies the strategic directions and initiatives to achieve our goals, as well as developing key performance indicators to measure both the goals and initiatives.

All departments at NHRA are responsible to implement the initiatives/procedures in the plan in relation to its responsibilities and function, specifying the person in charge of implementation, time frame and the resources required.

The following pages summarize the operational plan for our strategy for each department. The Human and Financial resources department will implement infra-structure initiatives in order to support NHRA functions and enable it to achieve its goals.

PROFESSIONALS REGULATION SECTION

Strategy	Strategy KPI	Initiative	Initiative KPIs	Status	Comments
Ensure the competence of health service providers	Existence of unified criteria for professional categorization	1. Establishing unified criteria of professional licensing categorization	Produce the final document by June 2017	Completed	100%
		2. Regulate Cupping practice	Develop regulations for traditional cupping practice	Completed	100%
	Existence of professional code of ethics	3. Developing professional code of ethics	Produce the final document of Code of Ethics by end of Sept. 2017	Completed	100%
	Percentage of renewed licenses linked to CPD hours of total licenses	4. Developing regulations to link renewal of licensing with CPD	Issue a resolution for professional licensing conditions by end of 2016	Completed	100%
Develop CPD regulations by March 2017			Completed	100%	
Implement a malpractice insurance system	Percentage of health care workers who are covered with malpractice insurance	Setting conditions and regulations for malpractice insurance	Categories of hospitals and professionals to have mandatory malpractice insurance by mid 2018	Pending	2020

HEALTHCARE FACILITY SECTION

Strategy	KPI	Initiative	Initiative KPIs	Status	Comments	
Ensure efficient health care facilities	Existence of regulations for the technical requirements for health facilities	Develop regulations for licensing of health care facilities	Issue a resolution for regulations for licensing of health care facilities by mid of 2017	Completed	Second version published 100%	
	Existence of regulations for the establishment of pharmaceutical facilities, drug warehouses and the establishment of pharmaceutical factories	<ol style="list-style-type: none"> 1. Establish regulations for licensing pharmaceutical facilities 2. Develop regulations for the licensing of drug warehouses 3. Develop regulations for licensing pharmaceutical factories 	Issue a resolution for the following regulations: pharmaceutical facilities, factories and warehouses by the end of 2017	Completed	100%	
	Establishment of regulations for the licensing of specialized health facilities		Develop regulations for specialized health facilities	Develop CAM regulations by the end of 2016	Completed	100%
				Develop Addiction management regulations by end of 2017	Completed	100%
				Develop IVF regulations by mid of 2018	Completed	100%
	Ensure the quality of health services	<ol style="list-style-type: none"> 1. Implement the national accreditation program 2. Developing facility classification 	<ol style="list-style-type: none"> 1. Implementation of the national accreditation program 2. Develop facility classification 	<ul style="list-style-type: none"> • Issue resolution regulating accreditation by end of 2016 	Completed	100%
<ul style="list-style-type: none"> • Issue accreditation policy by January 2017 				Completed	100%	
<ul style="list-style-type: none"> • Implement accreditation by May 2017 				Completed	100%	

PHARMACEUTICAL PRODUCT REGULATION

Strategy	KPI	Procedures	Initiative KPIs	Status	Comments
Ensure the quality of medicines	1. Existence of regulatory standards for registration of medicines and pharmaceutical products	1. Develop regulatory standards for registration of medicines and pharmaceutical products.	Issue regulations by January 2017	Completed	100%
	2. Percentage of categorized pharmaceuticals and health products	2. Develop categorization standards for pharmaceuticals and health products	Update the old version by June 2017	Completed	100%
Ensure the quality of health services	1. Presence of pharmacovigilance system	1. Develop pharmacovigilance system	<ul style="list-style-type: none"> Develop a proposal for initiating a pharmacovigilance system by mid-2019 Implement the system by end of 2019 	Pending	2021-2022
	2. Percentage of destroyed drugs annually from total registered	2. Establish rules for the destruction or re-export of medicines not complying with the specifications and standards	Publish rules for the destruction or re-export of medicines not complying with the specifications and standards	Completed	100%
	3. Percentage of drugs tested annually from registered	3. Subject all drugs for laboratory testing to ensure its compliance with the technical standards	All new drugs are subjected to lab testing	Completed	100%

COMPLAINTS SECTION

Strategy	KPI	Initiative	Initiative KPIs	Status	Comments
1. Professional accountability	1. Percentage of health facilities who received a disciplinary action	1. Initiate a Committee for Medical accountability for health care facilities	Committee established and functioning	Completed	100%
	2. Percentage of professionals who received a disciplinary action	2. Develop Disciplinary committees for different professions	Disciplinary committees established and functioning	Completed	100%
2. Surveillance of medical errors	3. Presence of an effective Surveillance system for medical error reporting	Develop a Surveillance system for reporting medical errors	Medical errors surveillance system under development	Pending	2020

CLINICAL TRIALS & CPD SECTION

Strategy	KPI	Initiative	Initiative KPIs	Status	Comments
1. Safe clinical trials	Presence of guidelines regulating clinical trials	1. Establish clinical trials regulations	CT Guidelines published	Completed	100%
		2. Establish ethical research committee guidelines	Committee guidelines published	Completed	100%
2. Ensure the competence of health service providers	Existence of regulation for accrediting continuous professional educational programs	Develop a national guideline for CPD program approval process	CPD guidelines published	Completed	100%

MEDICAL DEVICE LICENSING

Strategy	KPI	Initiative	Initiative KPIs	Status	Comments
Ensure the quality of medical supplies and devices	1. Existence of regulatory standards for registration of medical supplies and devices	1. Develop regulatory standards for registration of medical supplies and devices by 2017	Standard published	Completed	100%
	2. Percentage of registered medical devices	2. Establish a comprehensive medical device national data base by end of 2018	Database established	In progress	25%
Ensure the safety of medical supplies and devices	1. Percentage of medical devices recall or adverse event	Develop a Surveillance system for reporting medical devices recall, alert and adverse events by end of 2019	Surveillance system for reporting medical devices under development	Pending	2020

HUMAN RESOURCES & FINANCE SECTION

Strategy	KPI	Procedures	Status	Comments
Develop human resources of NHRA	1. Internal policies developed & published.	1. Develop internal NHRA policies & procedures	Completed	100%
	2. The new organizational structure finalized and approved by CSB.	2. Update NHRA organization structure	In process	Proposal under CSB review
	3. Risk assessment plan is in place.	3. Develop a risk assessment plan	Completed	100%
	4. NHRA IT system is developed and functional.	4. Update the IT system of NHRA	In process	25%
	5. All NHRA jobs are occupied.	5. Complete the employment procedures according to budget availability	Completed	90%
	6. All NHRA staff are evaluated annually.	6. Complete performance assessment procedures.	Completed	100%
	7. Existence of an annual training plan for all NHRA staff	7. Develop training plan for all NHRA staff based on performance evaluation.	In process	50%
Develop Financial resources of NHRA	1. The financial plan is adopted and published.	1. Develop the financial policy for NHRA	Completed	100%
	2. Adopted regulations for committees' payment are published.	2. Develop regulations for committees' financial payment.	Completed	100%
	3. Visiting consultants' payment scheme is adopted.	3. Develop Regulations for consultant's payment	Completed	100%

REGULATING HEALTHCARE FACILITIES



HEALTHCARE FACILITIES



In 2019, there were 746 healthcare facilities licensed in the Kingdom of Bahrain. The Health Facilities Department (HCF) issued 81 licenses to new healthcare facilities, and 211 new applications for opening new healthcare facilities that varied from hospitals and various health centers in different specialities. License renewals were given to 657 healthcare facilities.

NHRA is cooperating with the Ministry of Health (MoH) regarding the pre-marital service in the private healthcare facilities. In 2019, the number of private health facilities who offer pre-marital service is 47. Additionally, the total number of private healthcare facilities that added pre-employment services for Expatriates (Standard + Premium) in 2019 was 39.

By the end of 2019, the total inspection visits carried out by the inspection team was 943 of which 179 private healthcare facilities recorded no violations during the inspection visits. Facility Safety violations (455) accounted for the largest segment of the violations in facilities.

The new category in HCF regulations was medical laundry. One facility got the HCF department's clearance to practice the laundry process for medical linen. The department is seeking more laundries that follow NHRA's national standards and the applicable international practices. In this regard, NHRA added an annex for the medical laundries' requirements to the healthcare facilities standards (version 2/2019) to help the facilities to ensure the highest quality of service provided.

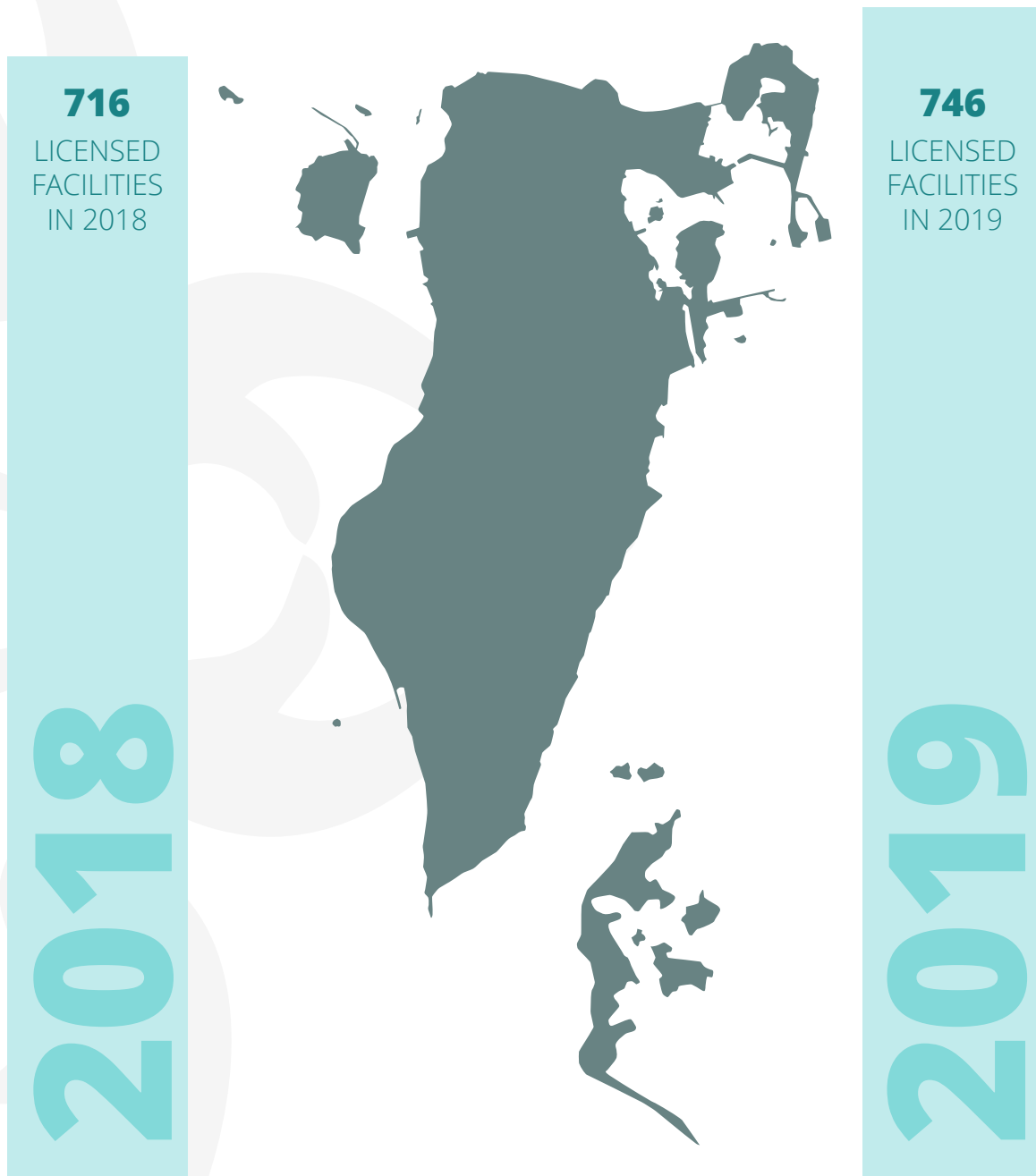
The Quality Control Assessment (QC), which is an internal program, designed by NHRA with cooperation from the Public Health Laboratory to measure the quality and efficiency of private health laboratories, the accuracy of their results, and the quality of equipment and technicians working with infectious diseases. This QC assessment was conducted in 41 private medical laboratories in the Kingdom of Bahrain.

The HCF is working on two additional appendices on food, water and drug labs which will be established in 2020. Updates to the existing resolution no.15 for the year 2017 to formulate the Resolution No.2 for year 2019 will ensue with the addition of the following new appendices for new standards: High dependency unit, telemedicine, endoscopy unit, dialysis unit, medical incubators, chemical waste room, sleep lab, counselling center, orthosis and prosthesis, import and sale of contact lenses, CPR trolley (crash cart), mobile center, laser hair removal services, speech and audio center, laundry services, drug delivery service, teleradiology, generator room, Personal Protective Equipment (PPE), mobile medical clinics and cardiac catheterization suite.

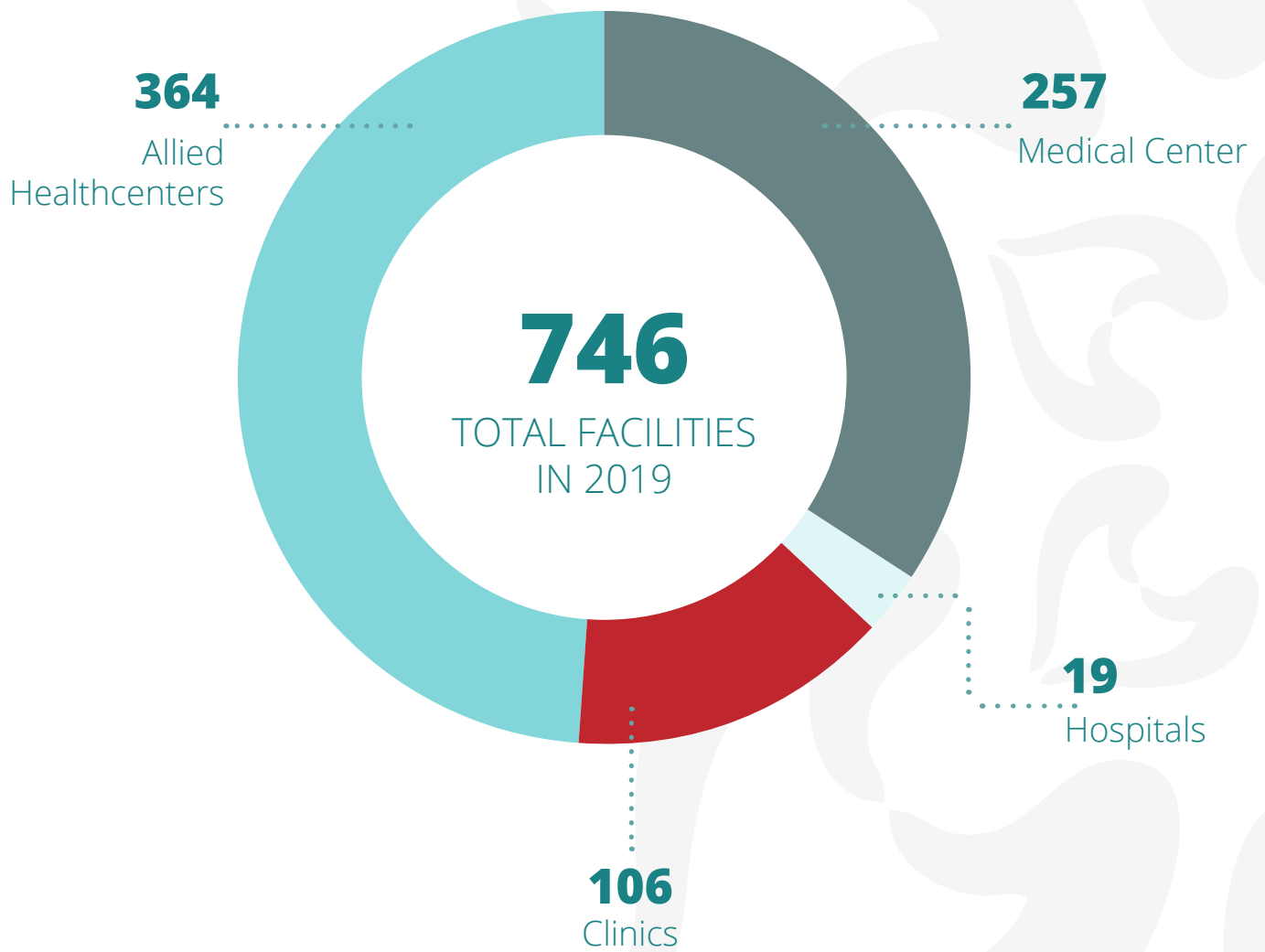
The initial steps have begun for the database for ambulance registration in the Kingdom through cooperation with the Ministry of Interior (MoI). In 2019, 7 ambulance visits were done to evaluate and classify the ambulances according to the common criteria between MoI and NHRA.

Four employees from the department successfully completed the ISO 2016: 13485 course.

TOTAL NUMBER OF LICENSED FACILITIES IN THE KINGDOM OF BAHRAIN



TOTAL NUMBER OF LICENSED FACILITIES BY CATEGORY



TOTAL PRIVATE HEALTH CARE FACILITIES BY GOVERNORATE - 2019



101
Northern
Governorate



108
Muharraq
Governorate



396
Capital
Governorate



141
Southern
Governorate

108 HEALTH CARE FACILITIES IN MUHARRAQ GOVERNORATE



7
Specialized
Centers

3
Residential
Nursing

1
Rehabilitation
Center

1
Tele-Medicine

1
Psychology

2
24hrs Medical
Centers

6
Physiotherapy

31
Optics

1
Nutrition

2
Labs

1
Hospital

10
Health
units

15
Multi-medical
Centers

2
Dental Labs

1
Full Time
Dental Clinic

13
Dental
Centers

4
Company

6
Full Time
Medical Clinics

1
Alternative

8

Facilities Provide
Pre-marital Test

7

Facilities Provide
Pre Employment Test

12

Facilities Provide
Vaccination Services

396 HEALTH CARE FACILITIES IN CAPITAL GOVERNORATE

26
Specialized
Centers

4
Residential
Nursing

8
Rehabilitation
Center

2
Tele-Medicine

2
Radiology

3
Psychology

3
24hrs Medical
Centers

17
Physiotherapy

65
Optics

6
Nutrition

10
Labs

14
Hospital

33
Health
units

61
Multi-medical
Centers

9
Dental Labs

11
Full Time
Dental Clinic

42
Dental
Centers

2
Company

48
Full Time
Medical Clinics

15
Alternative

3
General
Centers

7
Part Time
Medical Clinics

1
24 hrs Clinics

4
Audiology

23
Facilities Provide
Pre-marital Test

18
Facilities Provide
Pre Employment Test

39
Facilities Provide
Vaccination Services

141 HEALTH CARE FACILITIES IN SOUTHERN GOVERNORATE



101 HEALTH CARE FACILITIES IN NORTHERN GOVERNORATE



LICENSING ACTIVITIES IN THE KINGDOM OF BAHRAIN



New licenses
issued

81



Change in
Classification
Of an existing
Facility

22



License
Renewals

657



ENGINEERING ACTIVITIES IN THE KINGDOM OF BAHRAIN

104

NUMBER OF PRELIMINARY APPROVALS ISSUED

211

NUMBER OF NEW APPLICATIONS SUBMITTED

LICENSED FACILITIES IN THE KINGDOM OF BAHRAIN

19

**TOTAL NUMBER OF LICENSED
PRIVATE HOSPITALS**

GEOGRAPHIC DISTRIBUTION OF PRIVATE HOSPITALS IN THE KINGDOM OF BAHRAIN

14
Capital

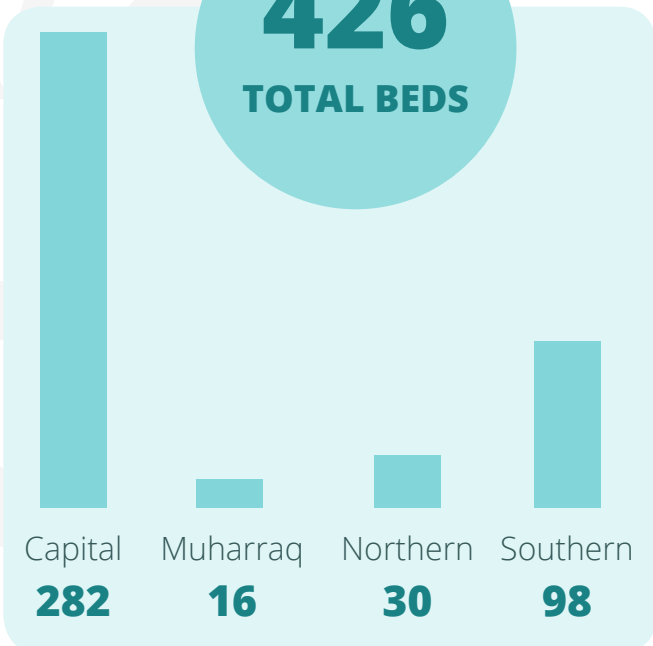
1
Muharraq

1
Northern

3
Southern

NUMBER OF BEDS IN THE IN THE PRIVATE SECTOR

426
TOTAL BEDS





MULTI-SPECIALITY CENTERS



DENTAL CENTERS

257
TOTAL NUMBER
OF REGISTERED CENTERS



SPECIALIZED CENTERS

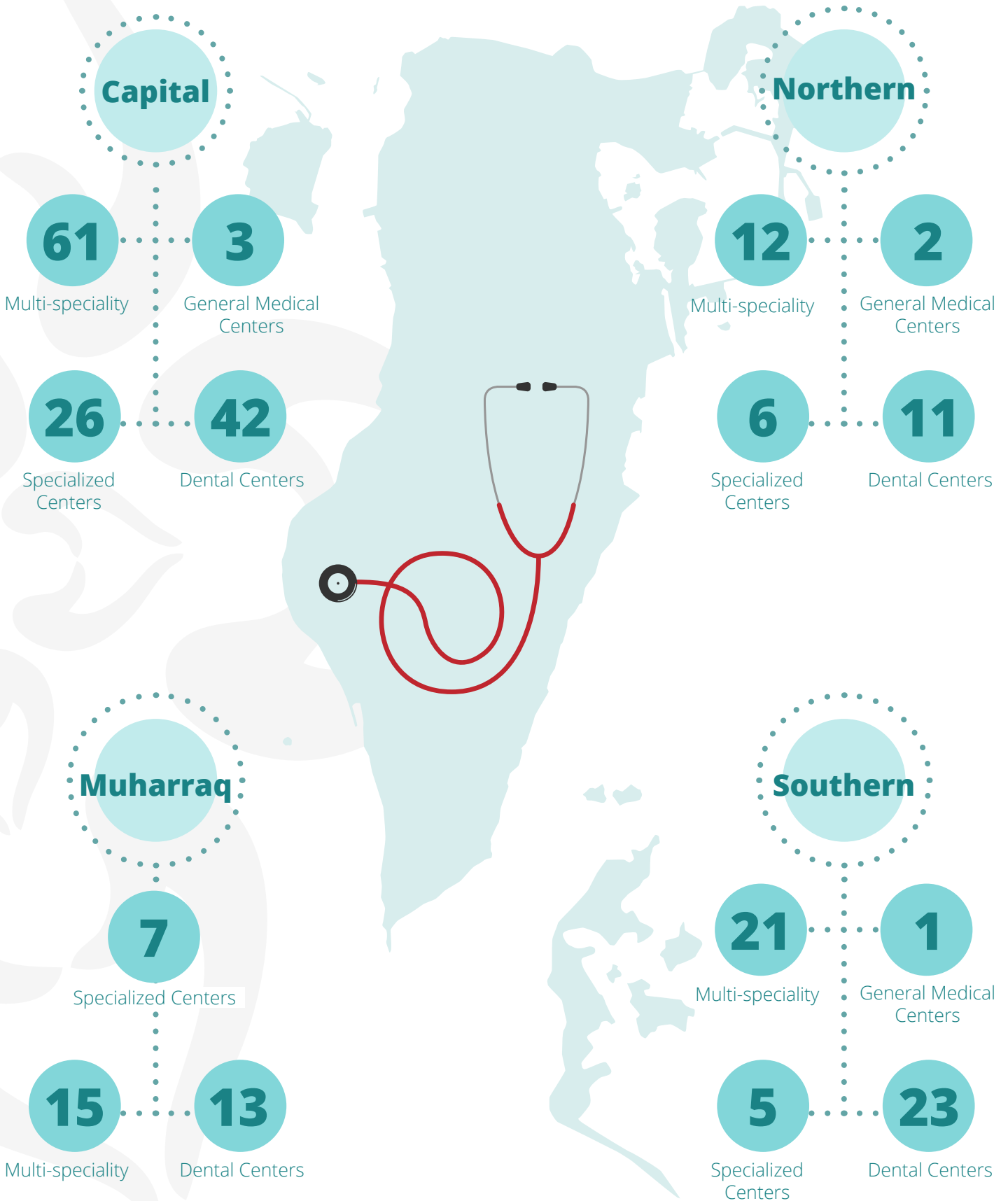


24 HOUR MEDICAL CENTERS

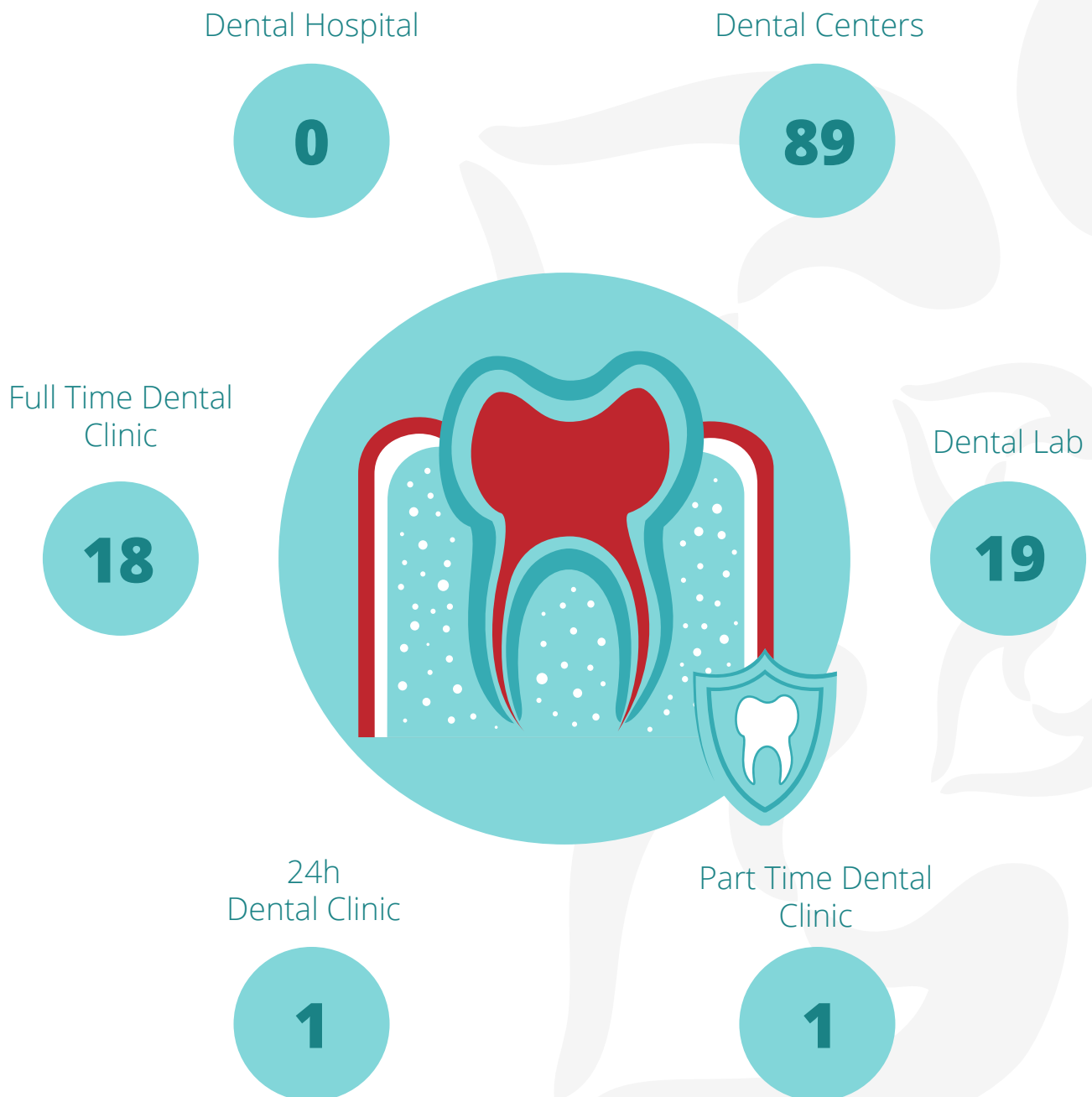


GENERAL MEDICAL CENTERS

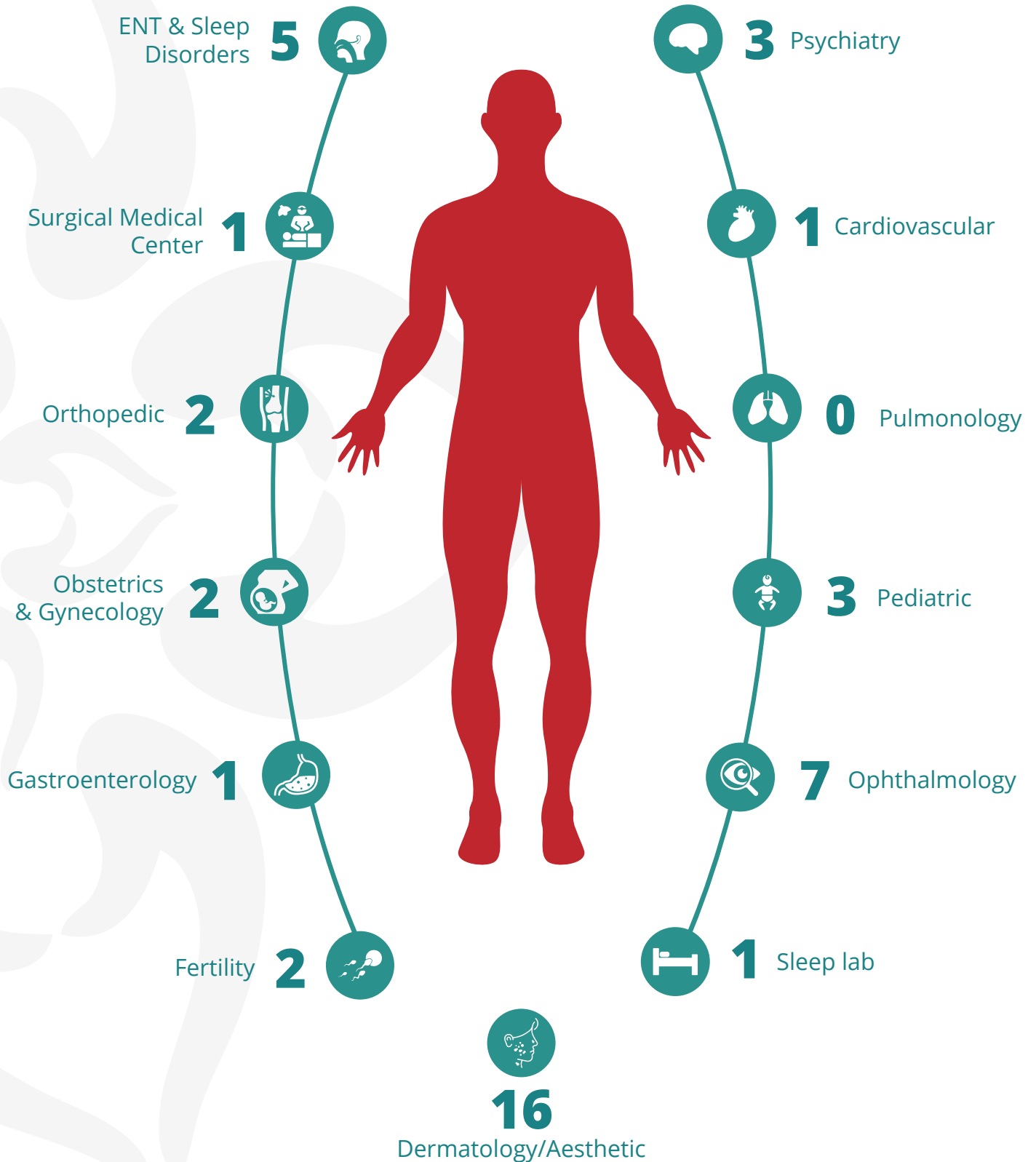
GEOGRAPHIC DISTRIBUTION OF REGISTERED CENTERS



DENTAL FACILITIES BREAKDOWN IN THE KINGDOM OF BAHRAIN



DISTRIBUTION OF SPECIALIZED MEDICAL CENTERS



REGISTERED PRIVATE CLINICS

**Medical Clinics
(Full time)**

74

**Part Time Clinics
(Medical)**

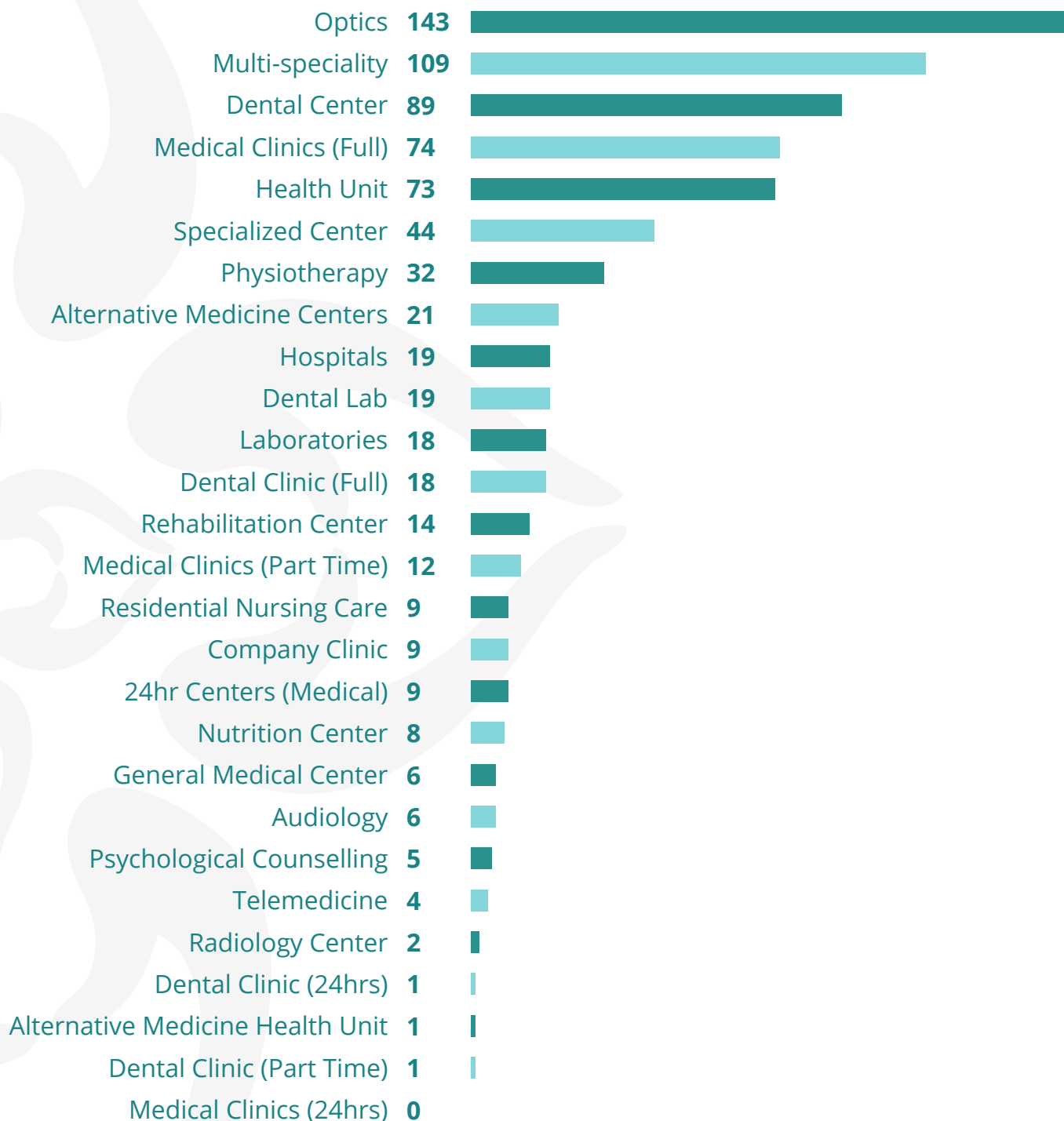
12

**24hrs Medical
Clinic**

0



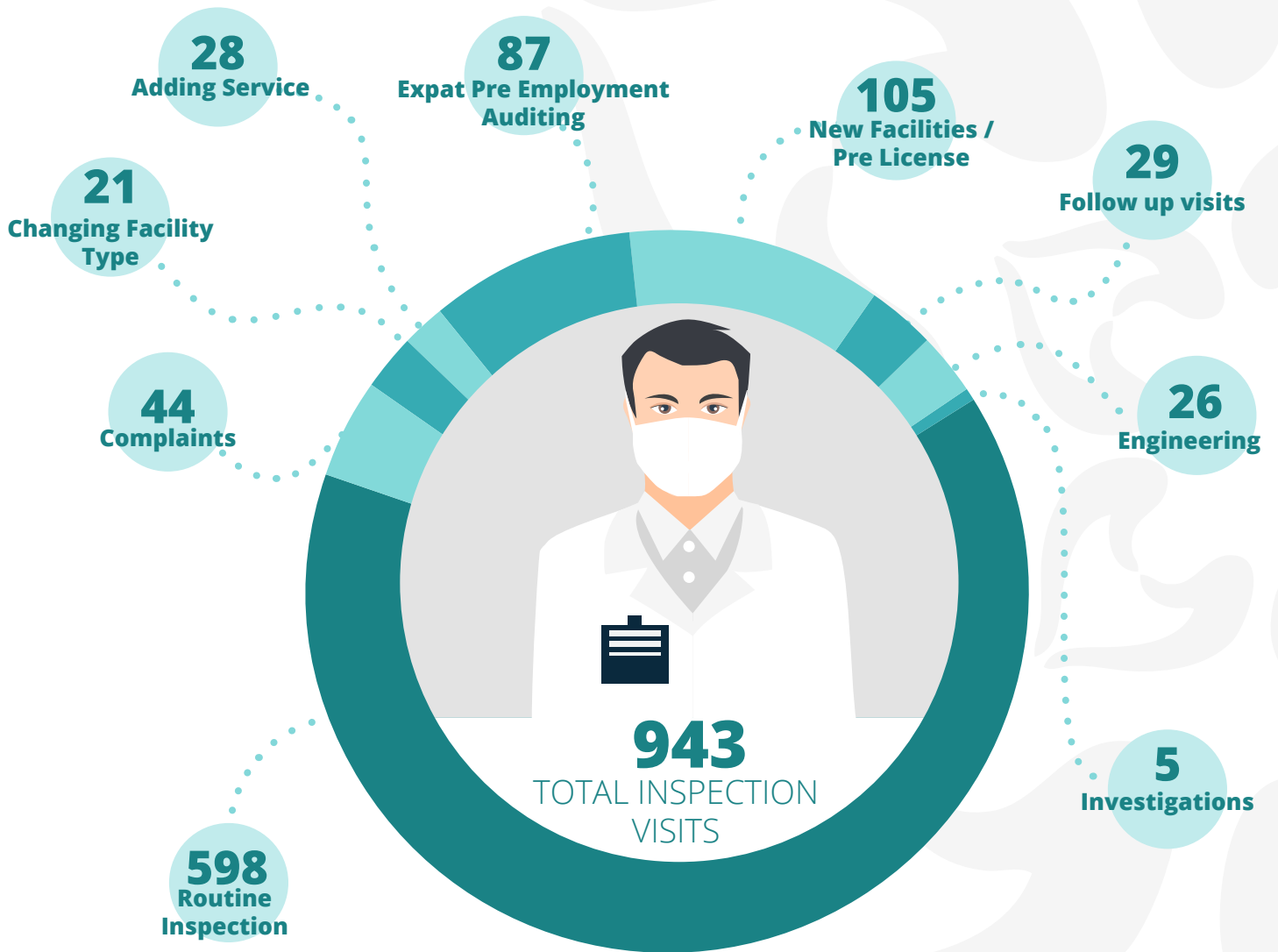
CLASSIFICATION OF FACILITIES



INSPECTION **ACTIVITIES**

943

TOTAL INSPECTION VISITS



TYPES OF VIOLATIONS IDENTIFIED

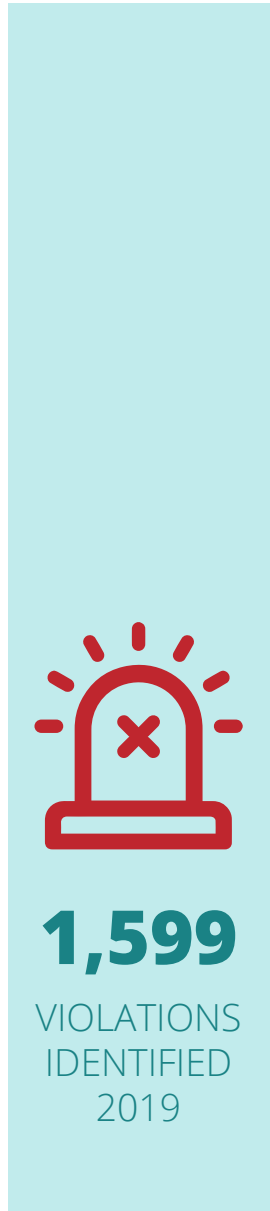


2018



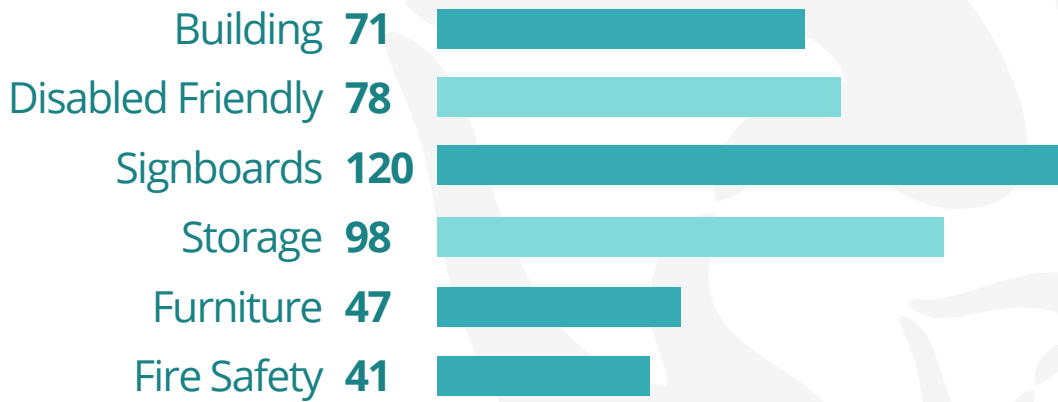
149	Sterilization	228
.....		
229	Medical Waste	266
.....		
12	Laundry	4
.....		
117	Medication	218
.....		
23	Stamp Safety	22
.....		
119	Patient Privacy	49
.....		
12	External Contracts	42
.....		
231	Devices Safety	220
.....		
16	Advertisements	25
.....		
311	Facility Safety	455
.....		
25	Licensing (Facility, professionals, allied)	70

2019



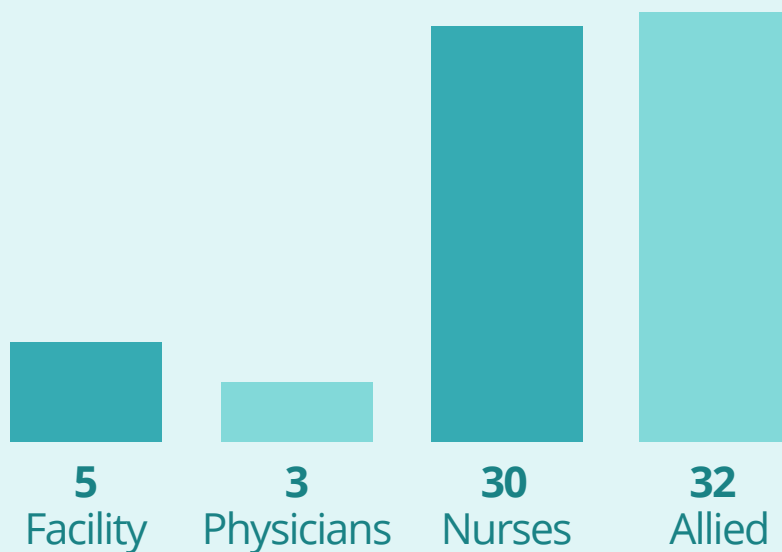
455

FACILITY SAFETY SUB VIOLATIONS



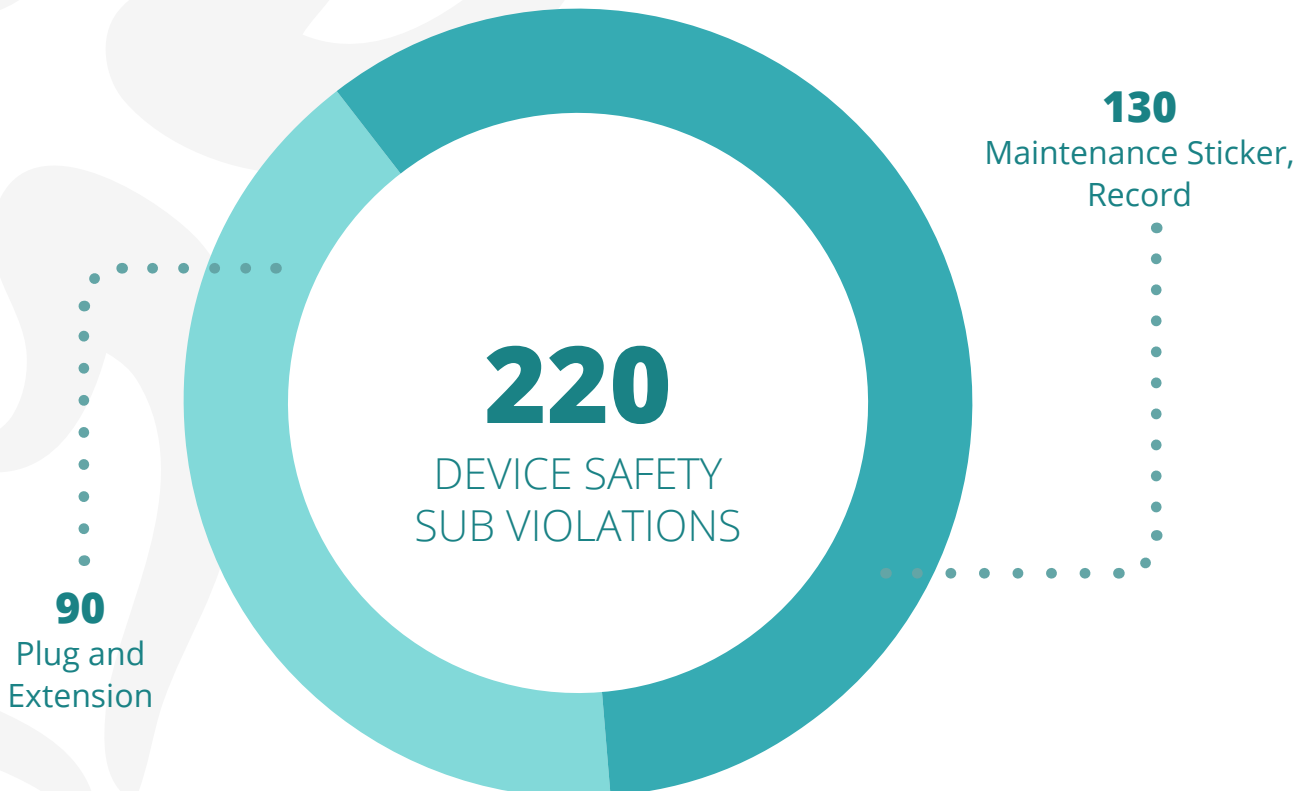
70

LICENSING SUB VIOLATIONS



MEDICAL WASTE MANAGEMENT SUB VIOLATION

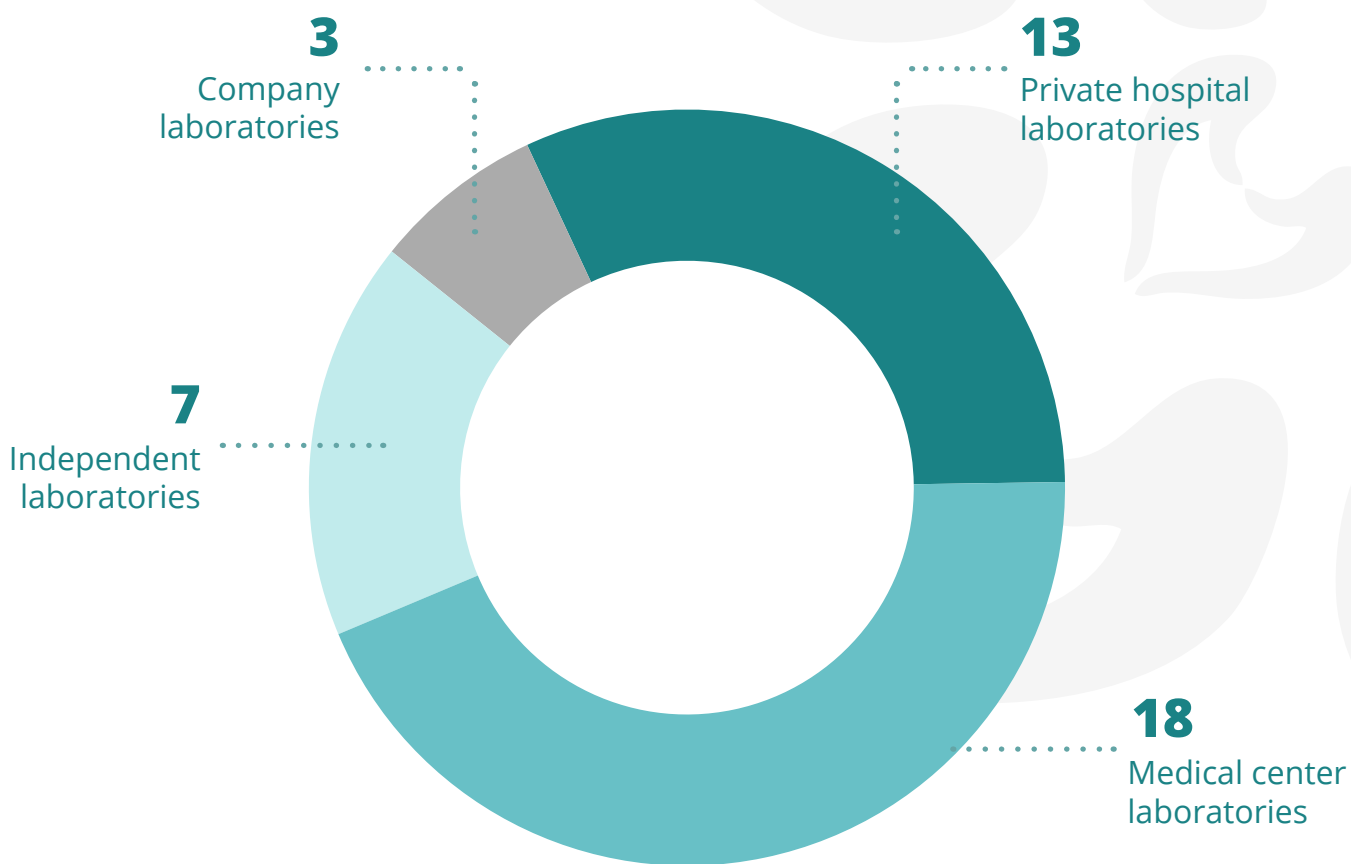
266



ACTIONS TAKEN AGAINST MAJOR VIOLATIONS

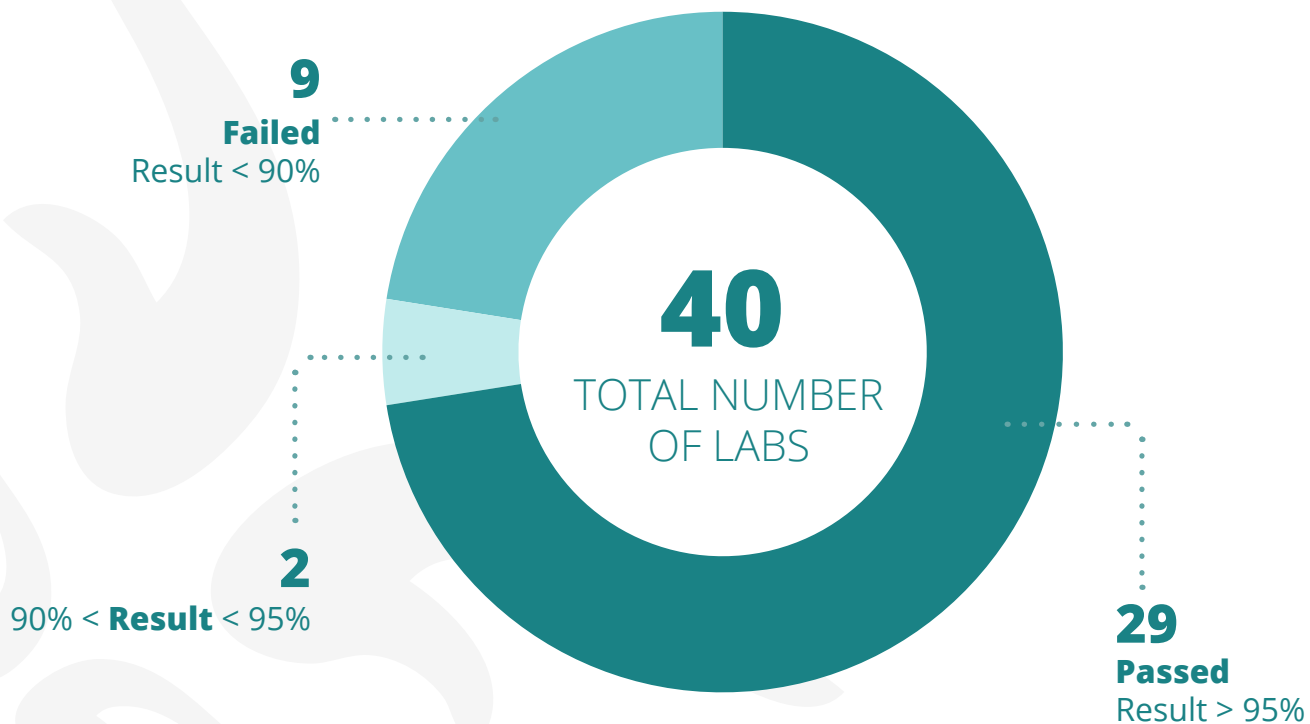


QUALITY CONTROL ASSESSMENTS IN PRIVATE LABORATORIES



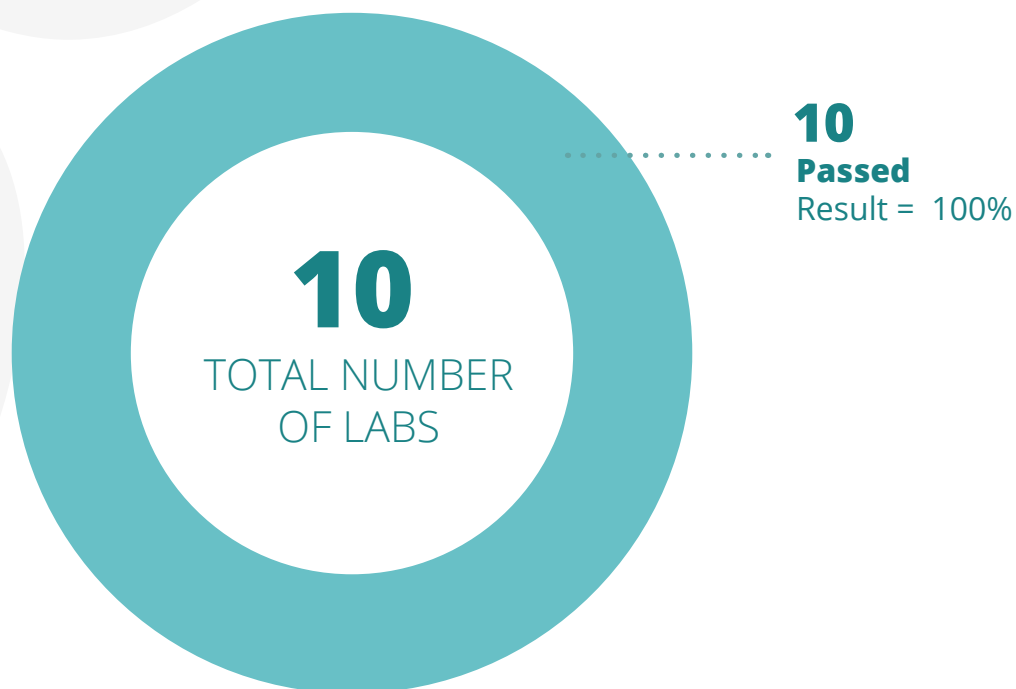
QUALITY CONTROL LAB ANALYSIS

PHASE 1



QUALITY CONTROL LAB ANALYSIS

PHASE 2



HEALTHCARE FACILITIES ACHIEVEMENTS

**1**

3 new categories have been added to healthcare facilities: Sleep labs, Multi-specialty medical centers and mobile facility.

**2**

3 new types of inspections visits were developed: Investigation visits, Engineering visits and combined visits.

**3**

An annex has been issued regarding the medical laundry requirements (version 2/2019). Approval was given to the first laundry to start operations.

**4**

HCF staff in collaboration with the Public Health Directorate visited a multi-speciality medical laboratory in India for expert exchange of best practices.

**5**

A database has been built for ambulance registration in the Kingdom through cooperation with the Ministry of Interior (MoI).

**6**

Four HCF staff have been certified as lead auditors for ISO13485:2016 (Quality Management System for Medical Devices).

**7**

The HCF department has created a systemic online database for all healthcare facilities.

**8**

Update of resolution no.15 for the year 2017 to formulate Resolution No.2 for year 2019. New appendices and standards have been added.

REGULATING HEALTHCARE PROFESSIONS



HEALTH PROFESSIONS LICENSING



One of NHRA's strategic goals has been achieved in 2019 with the establishment of an electronic system for professional licensing processes. One of the biggest challenges for the health professions regulatory department was the manual license application process. It was time consuming not only for the applicants but for NHRA staff as well. The Authority has worked closely with the Information and E-Government Authority (IGA) to transfer all its operations electronically. Now all professionals can process most of their licensing requirements electronically.

There is a total of 31,994 registered professionals out of whom 14,100 hold a valid license in the Kingdom of Bahrain. The health professions licensing department saw a significant increase in new license applications for health professionals, mostly in the field of nursing (63%), followed by allied health professions (26%).

The department has completed 3,253 new applications for all categories of professionals, that includes 651 medical licenses, 271 dentist licenses, 1,221 nursing licenses, 840 allied health professional licenses and 270 pharmacist licenses. In addition, the department issued 860 Prometric examination eligibility codes for the different professional categories.

Furthermore, the department continues to work with IGA to enhance the electronic system. It is also in the process of revising the licensing standard for healthcare professionals.

TOTAL NUMBER OF HEALTHCARE PROFESSIONALS REGISTERED IN THE KINGDOM OF BAHRAIN



BREAKDOWN OF REGISTERED PROFESSIONALS IN THE KINGDOM OF BAHRAIN



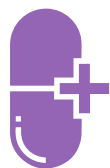
7,487
MEDICAL



15,245
NURSING



5,493
ALLIED



2,280
PHARMACY



1,489
DENTAL

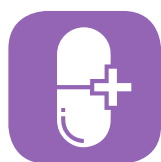
DISTRIBUTION OF ACTIVE PROFESSIONALS LICENCED IN THE KINGDOM OF BAHRAIN



NEW LICENSE APPLICATIONS PROCESSED IN THE KINGDOM OF BAHRAIN



651
Medical



270
Pharmacy



1,221
Nursing



271
Dental



840
Allied

LICENSED MEDICAL /DENTAL PROFESSIONALS BY CATEGORY

MEDICAL
3,183

DENTAL
838

Consultant



975

88

Specialist



633

181

General



1,569

569

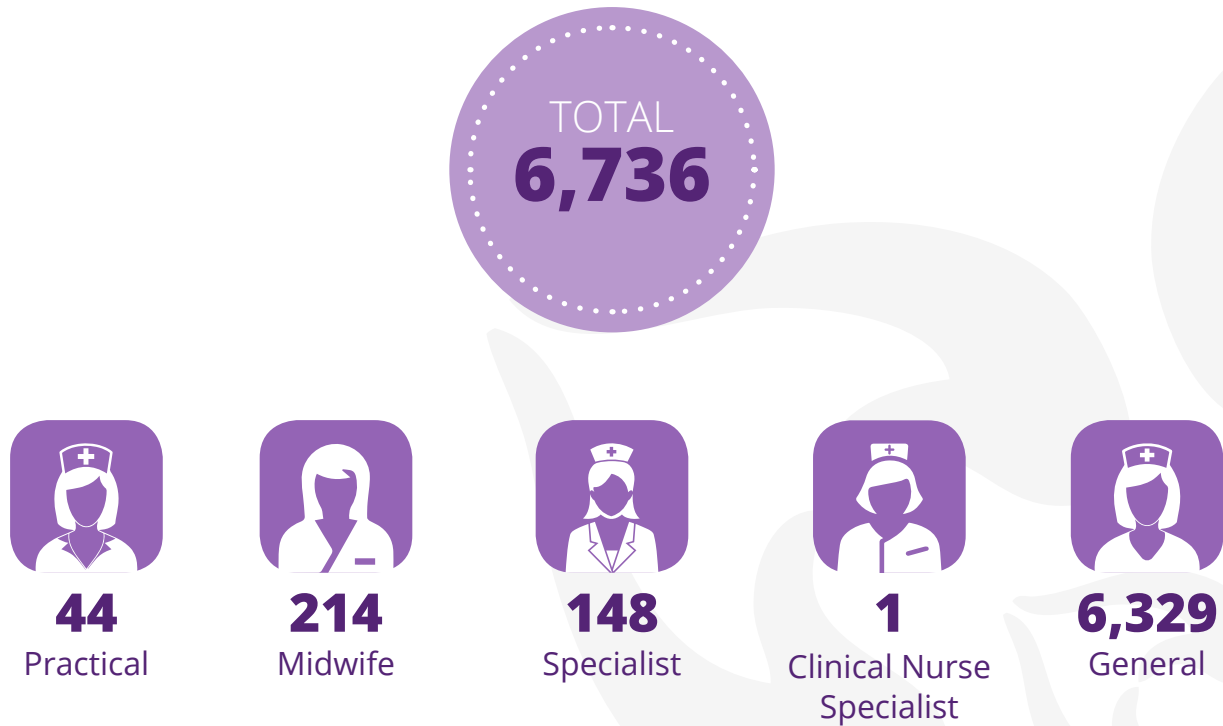
Visiting



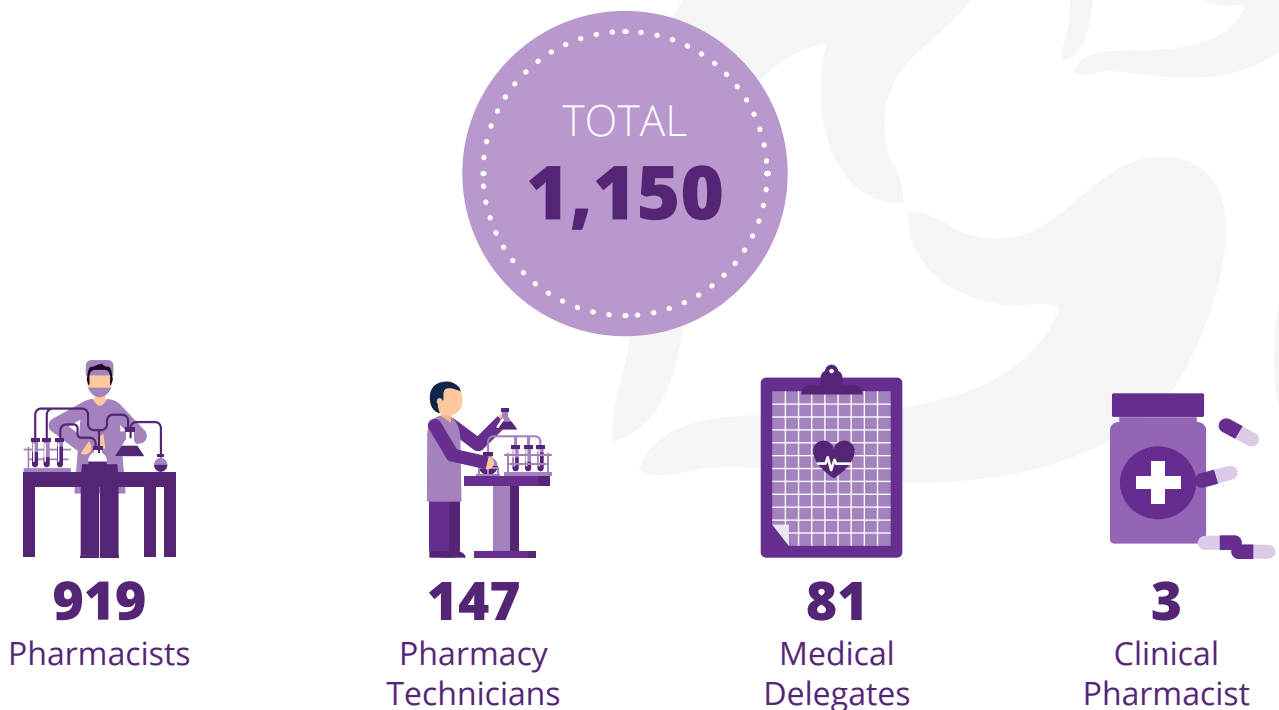
6

0

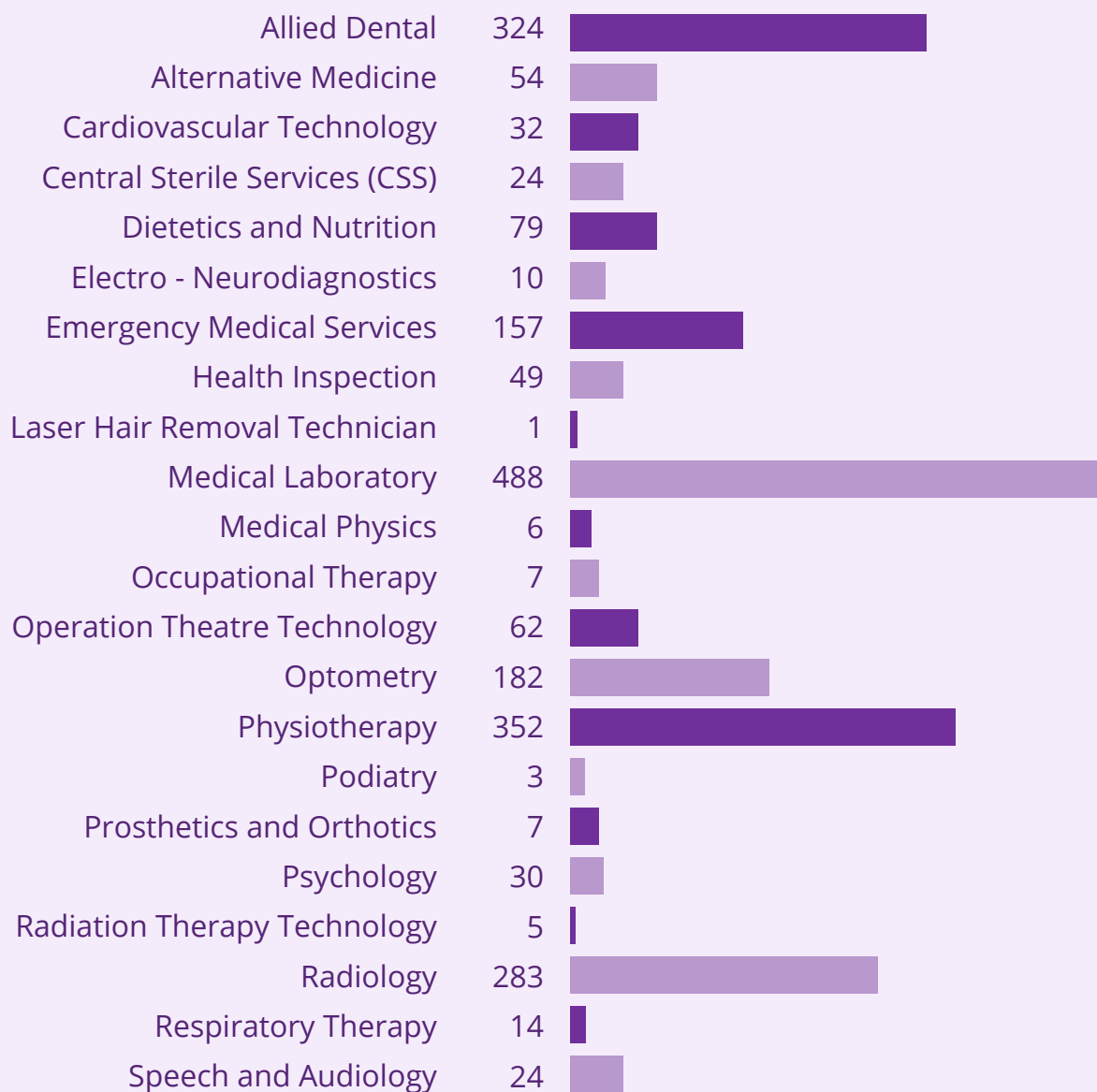
NHRA LICENSED NURSES BY CATEGORY



LICENSED PHARMACY PROFESSIONALS BY CATEGORY



LICENSED ALLIED HEALTH PROFESSIONALS BY CATEGORY



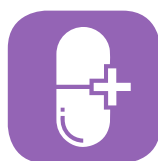
CATEGORIES OF LICENSE RENEWALS



2,041
Medical



1,906
Allied



406
Pharmacy



4,722
Nursing



565
Dental

LICENSURE EXAMINATION RESULTS

	Pass	Fail	Pass %
Medical Licensure Examinations	102	53	66%
Dental Licensure Examinations	45	41	52%
Nursing Licensure Examinations	409	127	76%
Pharmacy Licensure Examinations	35	33	51%
Optometry Licensure Examination	10	5	50%

HEALTHCARE PROFESSIONS REGULATION DEPARTMENT

ACHIEVEMENTS



Launching the online Health Professionals Registration System



Publishing regulations for Aesthetic Medicine Practice



Participation in Consultation and Disciplinary Committees



Licensing Standards Revisions



REGULATING **ALTERNATIVE MEDICINE FACILITIES**



ALTERNATIVE MEDICINE FACILITIES IN THE KINGDOM OF BAHRAIN

54

TOTAL NUMBER OF LICENSED
ALTERNATIVE MEDICINE PROFESSIONALS

22

Total Number of Licensed
Alternative Medicine Facilities
(Center + Health Unit)

15

Total Number of Facilities providing
Alternative Medicine Services

12

New Applications for
Alternative Medicine
Facilities

**ALTERNATIVE MEDICINE
FACILITIES**



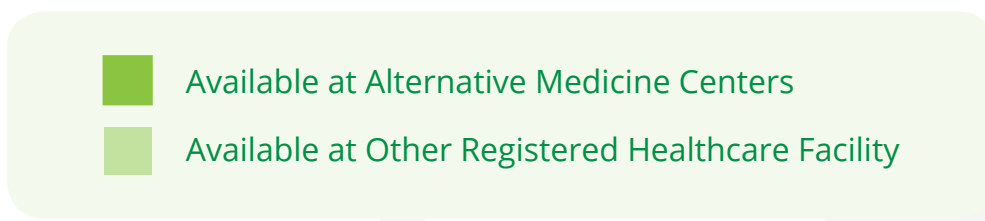
99

Total Number of Licensed
Alternative Medicine Products
Approved

46

New Alternative Medicine
Products Processed

TYPES OF ALTERNATIVE MEDICINE SERVICES AVAILABLE IN THE KINGDOM OF BAHRAIN



REGULATING PHARMACEUTICAL PRODUCTS



PHARMACEUTICAL PRODUCTS REGULATIONS



In 2019 the pharmaceutical products regulation department processed 518 pharmaceutical product license renewals and 384 new medicines registration. Using the Drug Utilization Review (DUR) system the department processed 9,053 electronic invoices and 1,550 manual invoices

In 2019, there were 3491 registered medication products, 328 pharmaceutical products were classified, 3,163 temporary importation of non-registered products were processed, and 2608 medications were priced.

TOTAL NUMBER OF REGISTERED MEDICATIONS

3491



Medicine Variations Assessed



Medicines National Pricing Assessed



Non-Registered Medicines Pricing



New Registration



Hospital Pack Registration



License Renewal



Pre-Approval Applications Processed



Electronic DUR Invoices



Manual Invoices Processed



Temporary Importation of Non-Registered Products



Pharmaceutical Products Classification



International Manufacturing Sites Registration

ALTERNATIVE / COMPLEMENTARY MEDICINES

99

Alternative Medicines
Registered

46

New Alternative Medicines
Applications Processed

**TOTAL NUMBER OF
HEALTH PRODUCTS REGISTERED**

681

**ELECTRONIC COMMON
TECHNICAL DOCUMENT (ECTD)**

2,621



61

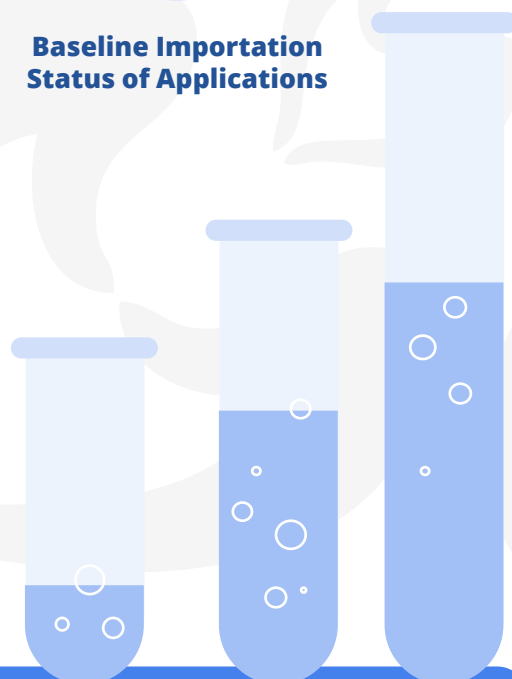
New Registrations



54

License Renewal

Baseline Importation
Status of Applications



PHARMACEUTICAL PRODUCTS REGULATION **ACHIEVEMENTS**



Attendance at the Bioequivalence Workshop.



PPR team collaborative meeting with company representatives in the Kingdom of Bahrain.



PPR and Bahrain Customs Collaboration Meeting.



PPR staff training with the Supreme Council of Health on the Drug Utilization System (DUR)



The PPR department has developed and published the following guidelines:

- Complementary and Alternative Medicines Guideline V. 1.0
- International Manufacturing Site Registration Procedure V. 1.0
- Pharmaceutical Product Destruction Procedure V. 1.0
- Medicines Barcoding and Serialization Guideline V. 1.2
- Medicines Renewals Guideline V. 1.3
- Procedure for Pharmaceutical Preparation at Healthcare Facilities V. 1.1
- Procedure for Pharmaceutical Facilities V. 1.1

REGULATING PHARMACY LICENSING



PHARMACY REGULATIONS



A total of 41 new pharmacies were licensed in 2019, of which 7 were opened in a healthcare facility and 34 were private pharmacies, reflecting a 17% increase in the number of licensed pharmacies compared to 2018.

The total number of pharmacies licensed in the Kingdom of Bahrain are 307 of which 235 are operating as private pharmacies and 72 are operating in a healthcare facility.

The department conducted 731 inspection visits, a 22% increase in the number of inspections carried out in 2019 due to the hiring of additional pharmacy inspectors at NHRA.

There were 962 violations were identified and corrected out of which 38% were related to medicine violations followed by 16% related to temperature and humidity violations.

TOTAL NUMBER OF LICENSED PHARMACIES IN THE KINGDOM OF BAHRAIN

72
FACILITY
PHARMACIES

235
PRIVATE
PHARMACIES



15 SOUTHERN **50**

10 MUHARRAQ **47**

5 NORTHERN **43**

42 CAPITAL **95**

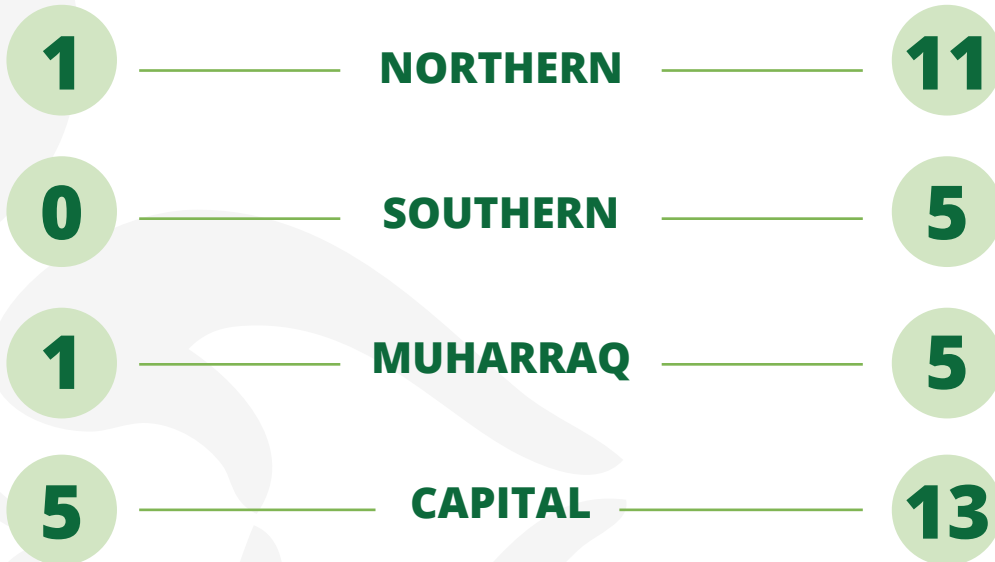
NEW LICENSES ISSUED

41

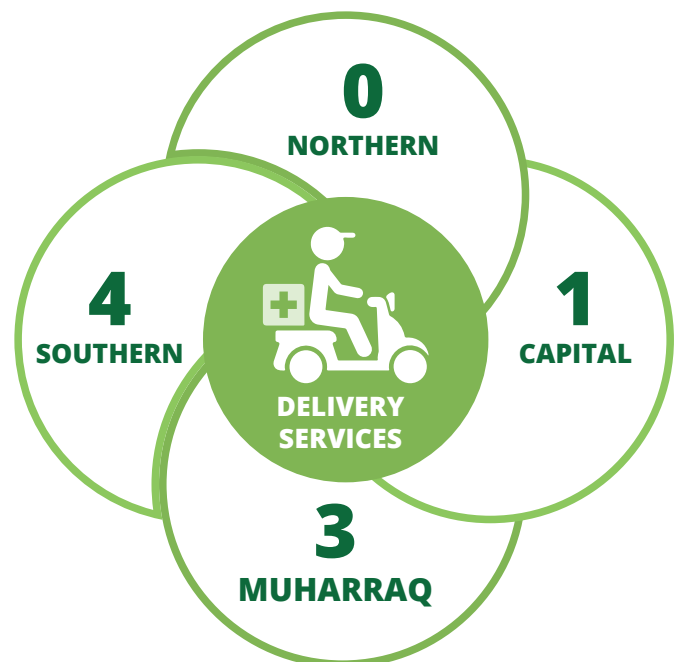
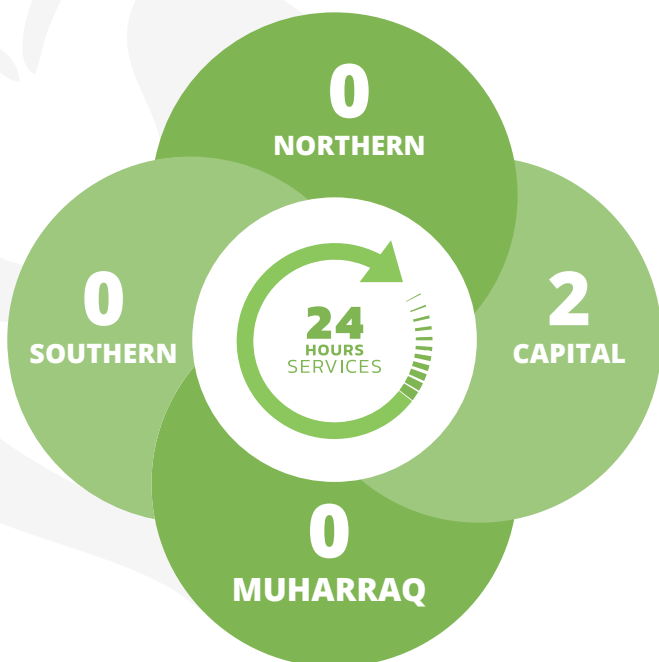
TOTAL LICENSES ISSUED

FACILITY PHARMACIES

PRIVATE PHARMACIES



GEOGRAPHIC DISTRIBUTION OF PRIVATE PHARMACIES WITH SPECIAL SERVICES



598

2018

TOTAL NUMBER OF INSPECTION VISITS

731

2019

40

2018

TOTAL NUMBER OF VIOLATIONS IDENTIFIED

962

2019

5

Pharmacy set-up Violation

6

Temperature / Humidity / Fridge violation

8

Price violation

6

Licensing violation

15

Medicine violation

38

VIOLATIONS WERE REFERRED TO THE JUDICIAL COURT

239

Pharmacy set-up Violation

160

Temperature / Humidity / Fridge violation

50

Price violation

369

Medicine violation

144

Licensing violation



TYPES OF VIOLATIONS IDENTIFIED

REGULATING MEDICAL DEVICES



MEDICAL DEVICE REGULATION

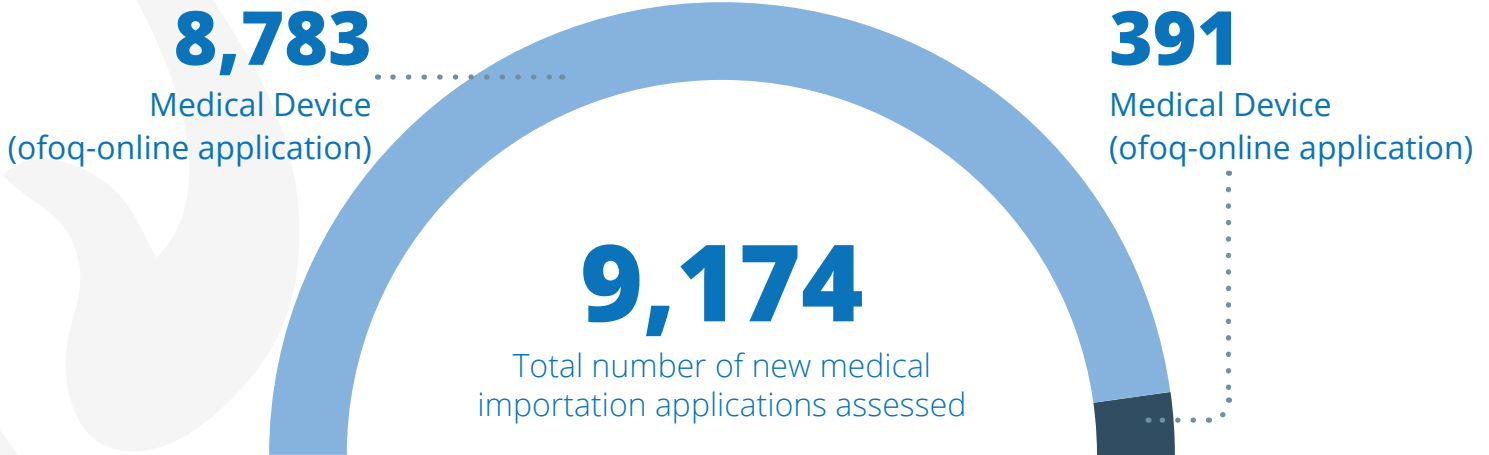
The medical regulation department registered 2,513 medical devices in 2019. The registration process aims to assess compliance with safety and performance requirements set out in applicable regulations and standards.

The total number of new medical device applications evaluated by medical device engineers reached 9,174, of which 8,783 applications were processed through the Electronic System of Customs (OFOQ), while 391 requests were manually processed in relation to the combined medical devices.

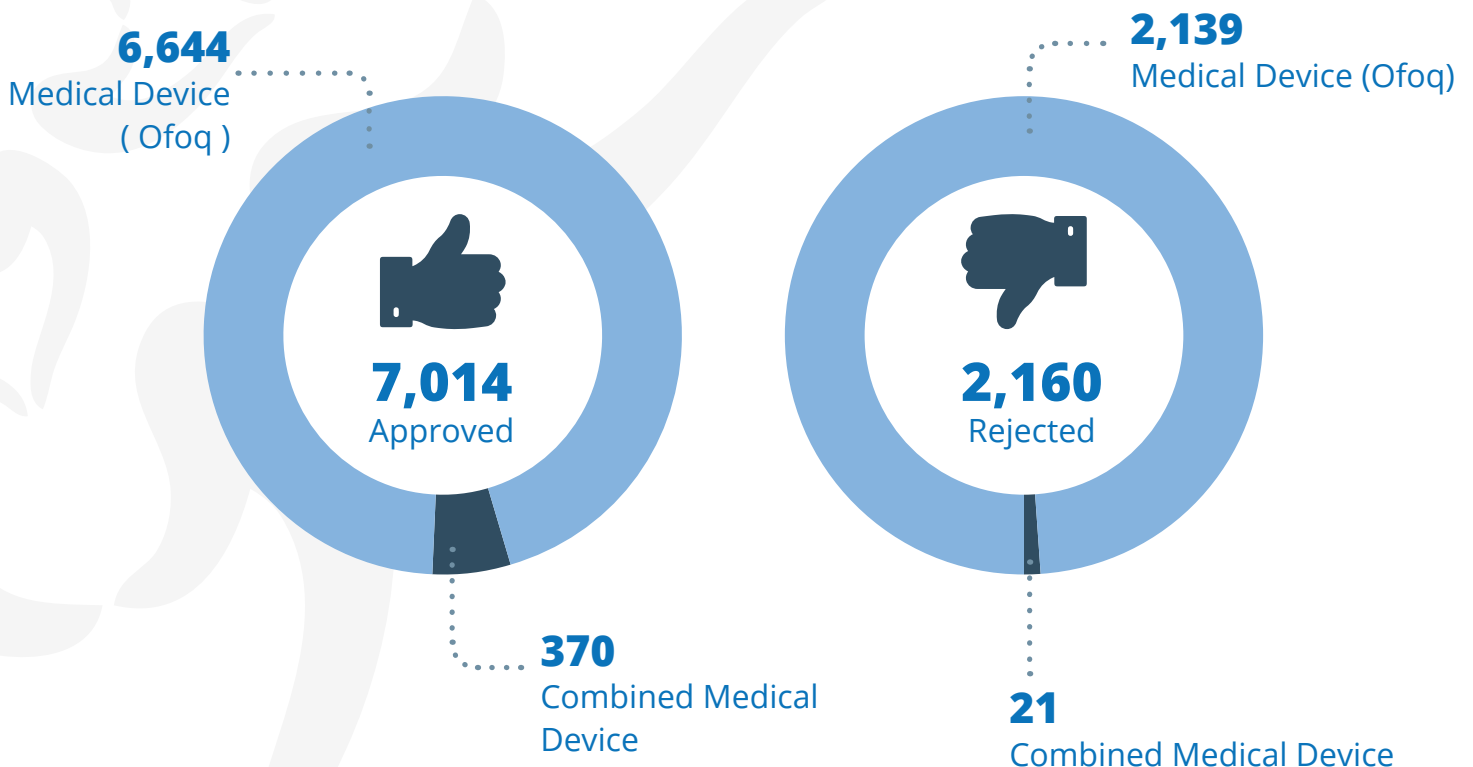
The total cost of the imported devices was 30,382,973.400 BD. The authority rejected 24% (2,160) of the total applications submitted for import due to either the detection of a false certificate or a counterfeit device.



MEDICAL DEVICE IMPORTATION REGULATION

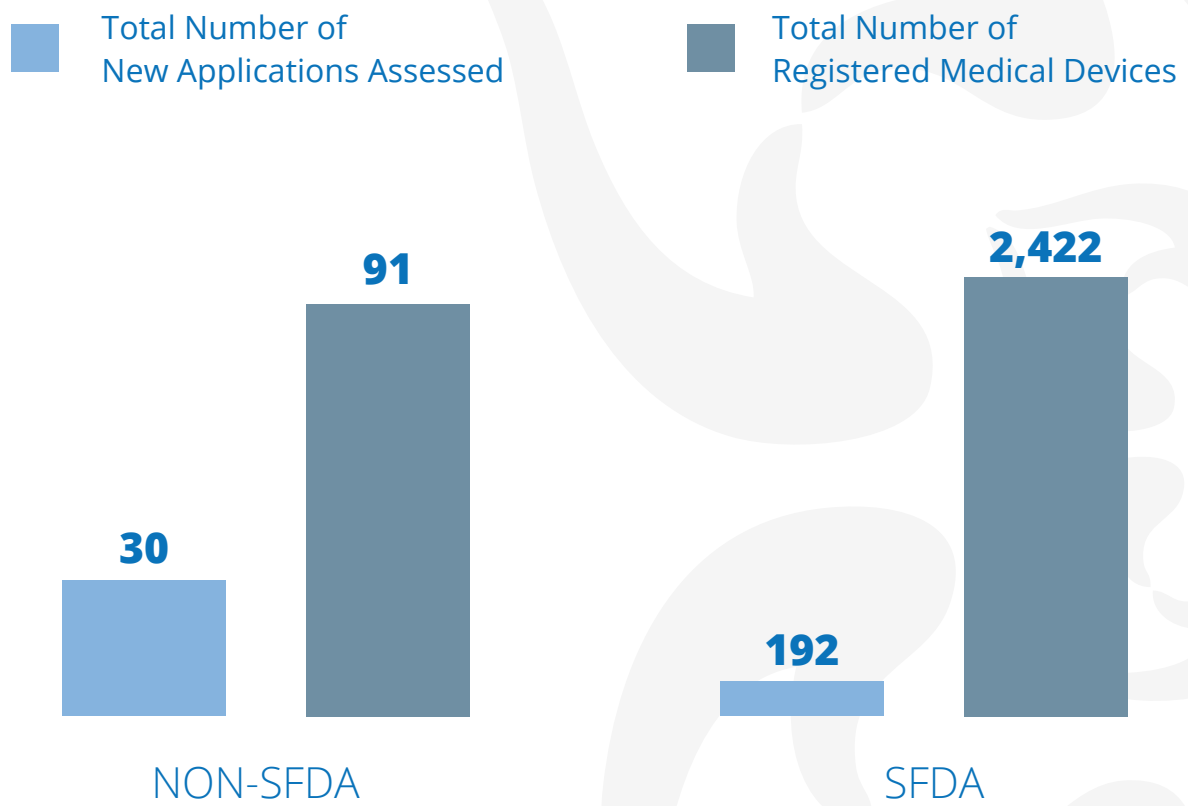


OUTCOMES OF IMPORTATION APPLICATIONS ASSESSED

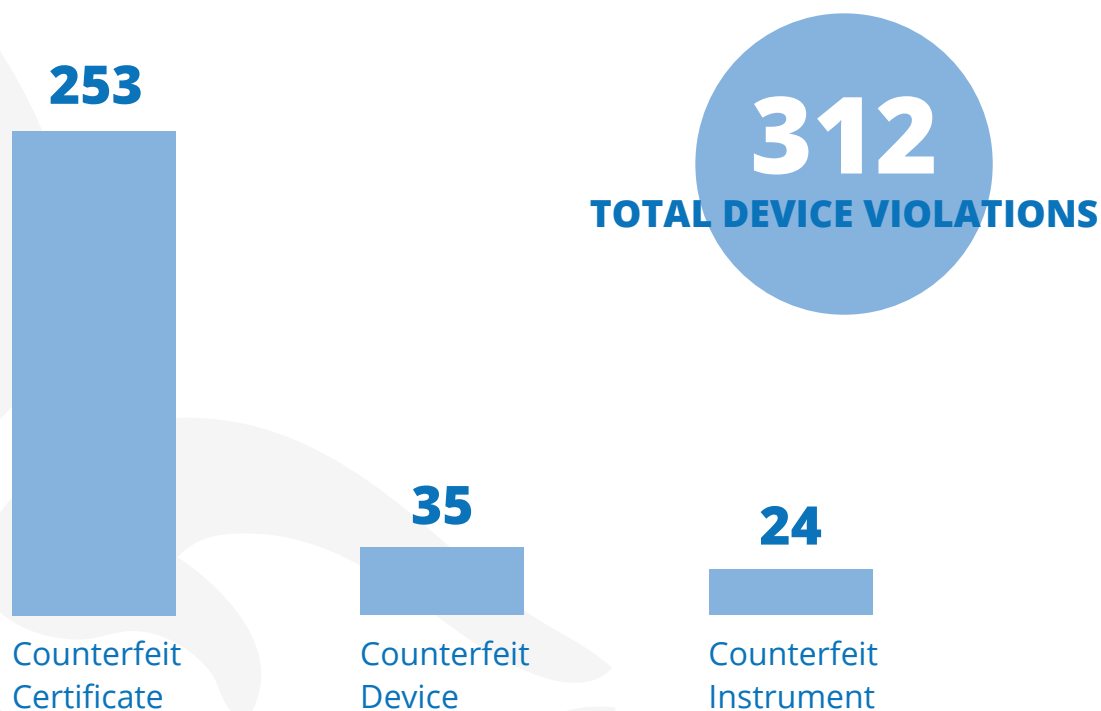


TOTAL VALUE OF MEDICAL DEVICES IMPORTED: **30,382,973.400**
Bahraini Dinar

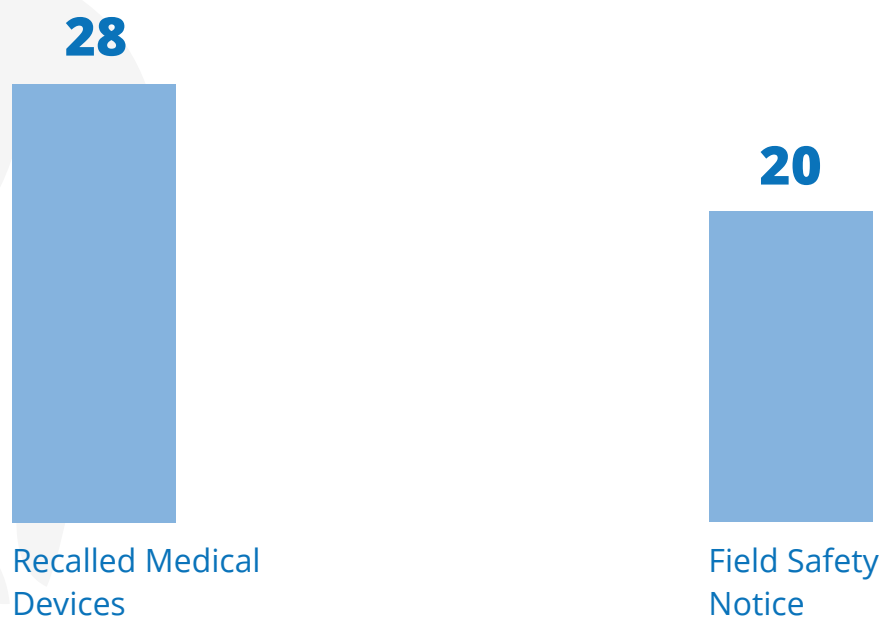
REGISTERED MEDICAL DEVICES



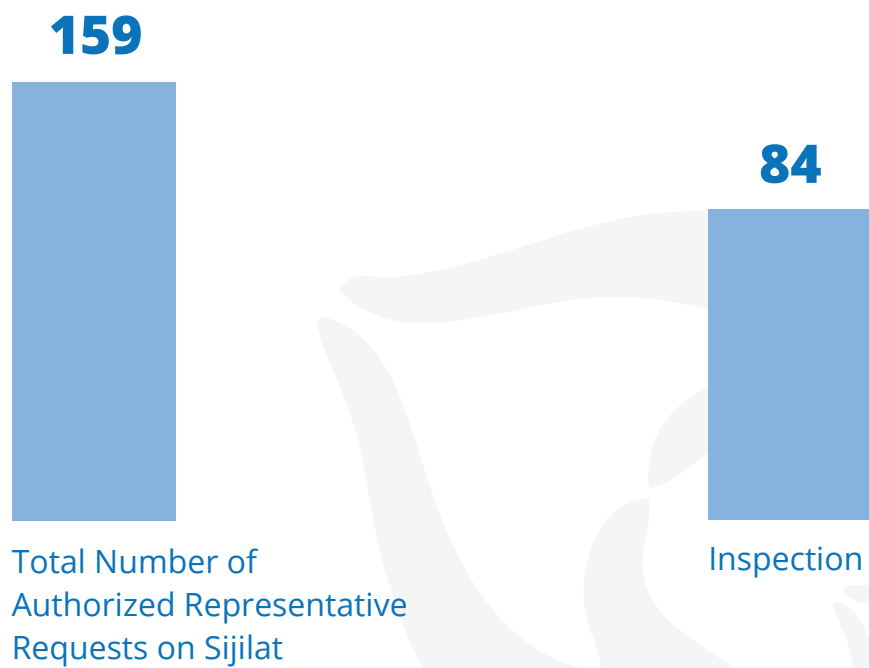
TYPES OF MEDICAL DEVICE VIOLATIONS IDENTIFIED



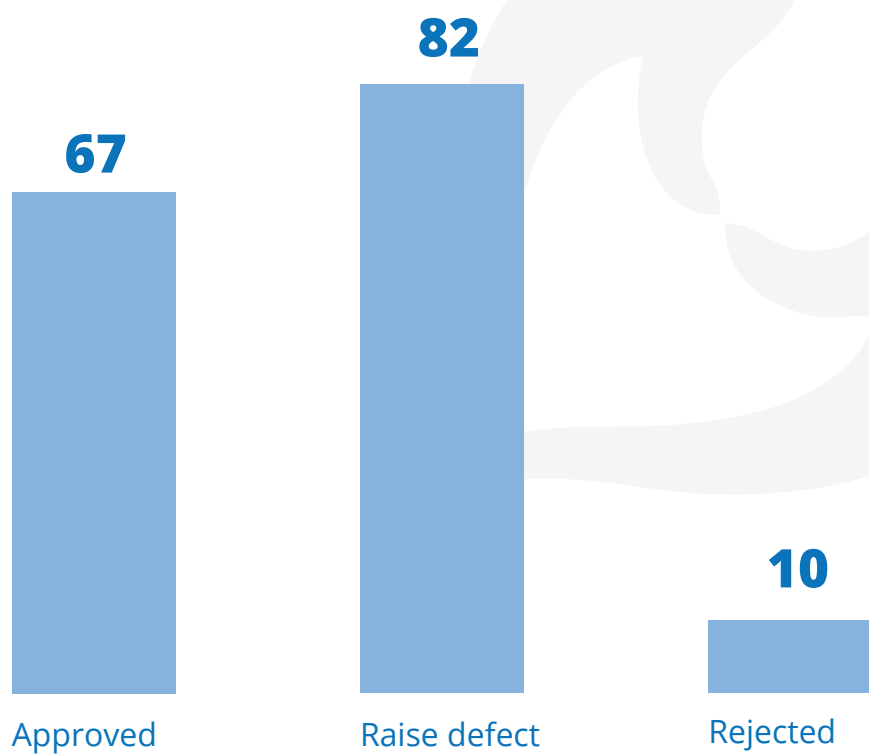
TYPES OF MEDICAL DEVICE RECALLS



MEDICAL DEVICE AUTHORIZED REPRESENTATIVE REGISTRATION



MEDICAL DEVICES AUTHORIZED REPRESENTATIVE ASSESSMENTS



MEDICAL DEVICE APPROVALS FOR USE

48

Total Number of New
Healthcare Facility Applications
Assessed

15

Total Number of New
Applications Assessed

2,962

Total Number of Medical
Devices in Healthcare Facility

40,091

Total Number of
Authorised Representative
Listed Medical Devices

MEDICAL DEVICE ACHIEVEMENTS

-  10 NHRA staff have been certified as a lead auditors for ISO13485:2016 (Quality Management System for Medical Devices).
-  Started controlling medical devices importation prices through the Ofoq system.
-  Implementation of processes to efficiently review applications of Ofoq within 24 hours.
-  Implemented a 5-year plan to be the first national initiative on a permit to use medical devices in healthcare facilities.
-  An online appointment system was established.
-  Translated 9 international ISO standards to Arabic in order to be recognized by GSO.
-  Signed an MOU with Saudi Food and Drug Authority.
-  14 new guidelines were issued.
-  Created sub codes for HS on a national level to facilitate the importation of spare parts and accessories.
-  Decision issued to create the first National Committee for Medical Device Standards to review GSO draft standards before being recognized on a GCC level.

REGULATING CONTINUOUS PROFESSIONAL DEVELOPMENT / CONTINUOUS MEDICAL EDUCATION (CPD/CME) AND CLINICAL TRIALS



CONTINUOUS PROFESSIONAL DEVELOPMENT AND CONTINUOUS MEDICAL EDUCATION (CPD/CME)



Since the issuance of resolution No. (40) of 2016 regarding the validity of licenses of healthcare providers and conditions of renewal, there has been a major increase in the number of CME activities attended by all healthcare professionals.

In 2019 the CME and Clinical Research Unit had received and processed 19,400 CME activities of which 78% were offered in the government sector. The majority of these activities were in the form of lectures followed by workshops and conferences. The highest CME activities were conducted for the nursing sector.

CLINICAL TRIALS

NHRA has well established guidelines for conducting clinical trials in Bahrain, and in 2019 the Stem Cells Clinical Trials Guidelines were established and approved by the Supreme Council of Health.

The clinical trial unit received 4 applications for clinical trials of which half were from the government sector. The trails submitted were in the field of diabetology, haematology, respiratory disease and obstetrics and gynaecology.

DISTRIBUTION OF CPD/CME APPLICATIONS RECEIVED BY SECTOR

4,289
Private



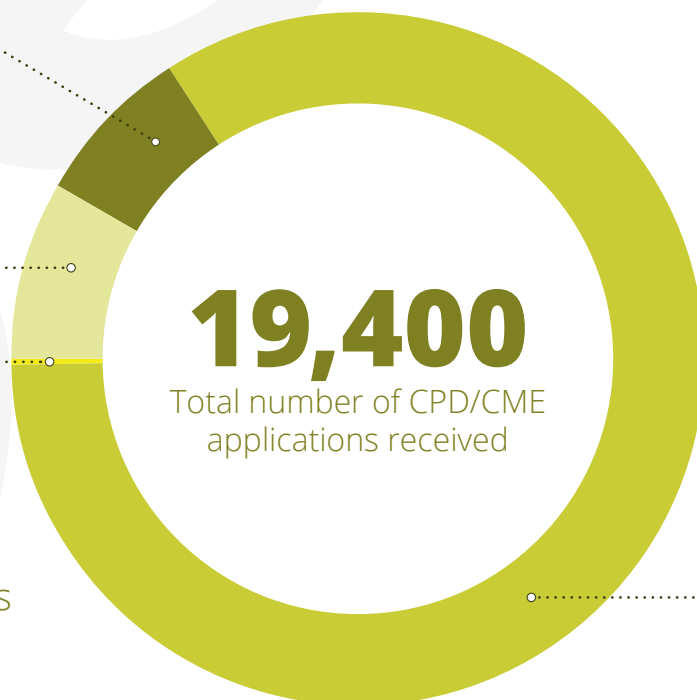
15,111
Government

TYPES OF APPROVED CPD/CME ACTIVITIES

1,472
General
Workshop

1,633
Specialized
Workshop

33
Conferences



16,262
Lectures

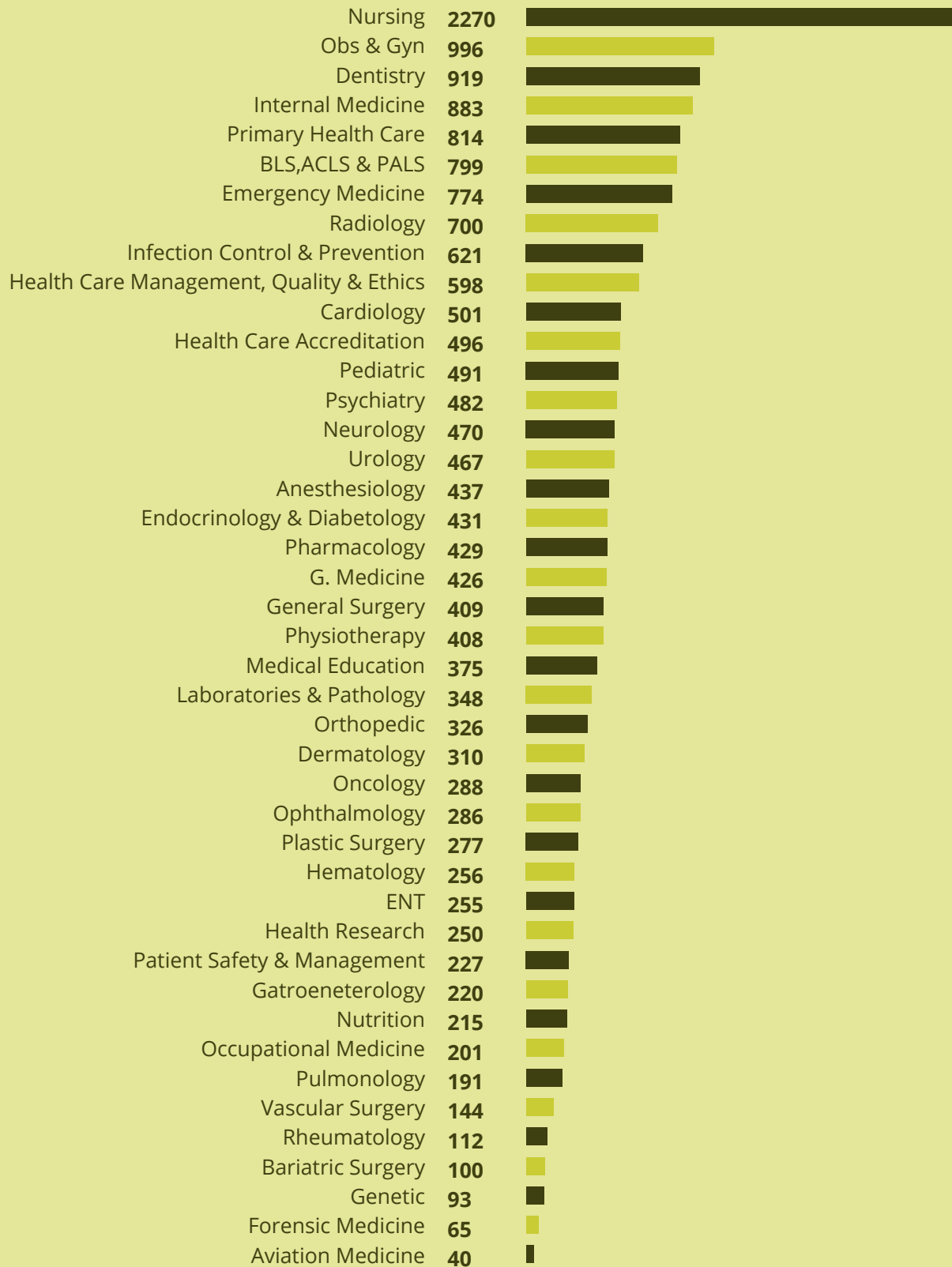
General Workshop

Specialized Workshop

Lectures

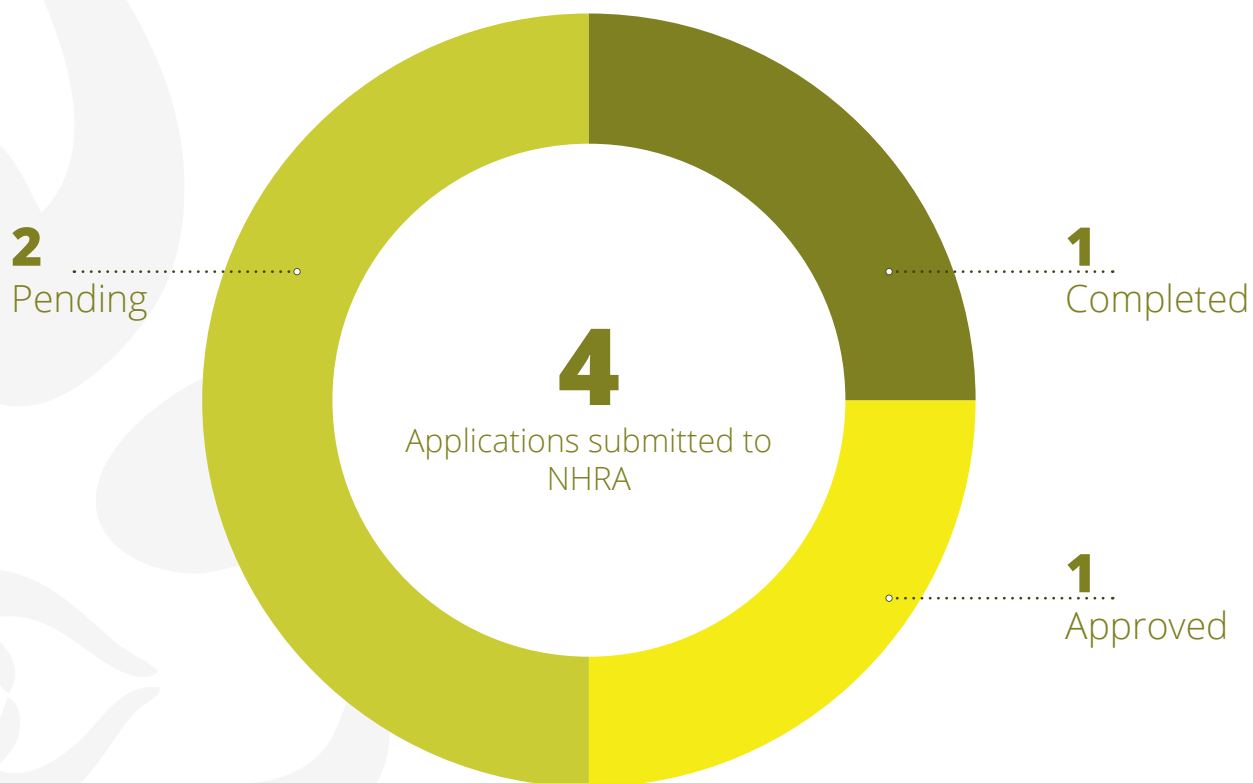
Conferences

DISTRIBUTION OF APPROVED CPD/CME ACTIVITIES BY SPECIALITY



CLINICAL TRIALS REGULATION

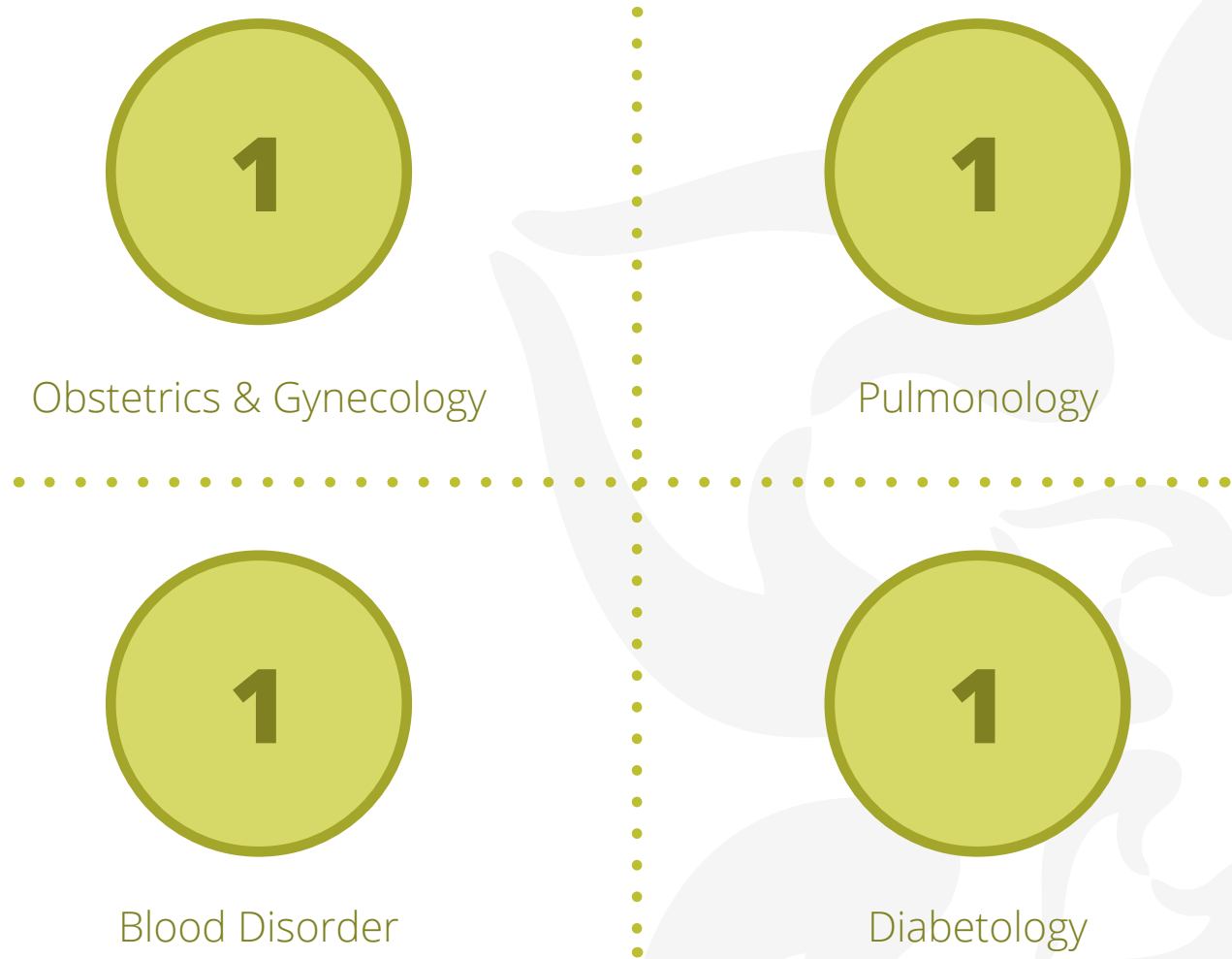
OUTCOMES OF CLINICAL TRIAL APPLICATIONS SUBMITTED TO NHRA



CLINICAL TRIALS SUBMISSIONS BY SECTOR



DISTRIBUTION OF CLINICAL TRIALS APPLICATIONS BY SPECIALITY



CONTINUOUS PROFESSIONAL DEVELOPMENT / CONTINUOUS MEDICAL EDUCATION (CPD/CME) AND CLINICAL TRIALS

ACHIEVEMENTS

- 1 November 2019 - Organized and executed the 1st NHRA Regulatory Conference
- 2 Formulation of the NHRA Bioethics Committee for all Healthcare facilities and universities
- 3 Re-Review & Update of the Clinical Trials Regulations in Kingdom of Bahrain
- 4 Formulation of the NHRA Clinical Trial Committee for all members from Academia & NHRA
- 5 Re-Review & Update of the Standards & Requirements for Independent Research Ethics Committee (IREC) involved in clinical trials in the Kingdom of Bahrain
- 6 Activation of the online CPD Committee Application Reviews
- 7 Re-Review & Update The Clinical Trails by Using Stem Cells Regulations & Standards in Kingdom of Bahrain
- 8 Joint Committee the NHRA – MoL & SD for Health Care Professional Training Program Application. Conducted several meetings for reviews and approval of health training programs and health training centres
- 9 2nd Edition CPD Regulations Charter sent to Supreme Council of Health for approval
- 10 Study to unify Clinical Trials Regulations in both NHRA & Saudi Food & Drug Authority (SFDA)
- 11 CPD Code for Internal Activities has been granted to 30 Health Care facilities

ACCREDITING HEALTHCARE FACILITIES



ACCREDITING HEALTHCARE FACILITIES



In keeping with our mission and vision we continue the process of evaluating the performance of healthcare facilities since the implementation of the national accreditation program in 2016. At present we have successfully accredited 16 hospitals and 20 medical centers.

Analysis of hospital accreditation criteria had revealed several areas of improvement for the authority to assist healthcare facilities in gaining and maintaining accreditation and thus to continuously improve the quality of services provided to the people of Bahrain. The Accreditation department successfully achieved 60% of its targets set for this endeavour in the past year. An analysis of the Quality Improvement Project Plans submitted by hospitals for their recommendations showed that more than 50% of the recommendations in the Core elements have been resolved before their accreditation renewal date.

The department organized 4 patient safety specific workshops through the year and trained over 400 participants from various medical facilities in the Kingdom on high risk areas in the accreditation standards.

This past year also saw the implementation of the first Surveyor Development Program. Existing and new surveyors were trained and assessed on the art of surveying. The accreditation department now has 30 NHRA surveyors an increase of 50%.

We are continuing our initiatives to implement the accreditation of private labs and in 2019 held 2 surveyor training sessions with mock surveys of 50% of the labs.

The department has held many activities in collaboration with the Ministry of Health to ensure they have the support in their preparations for the national accreditation in the coming year. Activities such as Risk Assessment Training workshops were a huge success and we look forward to the primary healthcare facilities surveys.

The department issued numerous publications in 2019 most notably the NHRA Accreditation Guide and the Surveyor Handbook.

The achievements of the authority in the successful implementation of accreditation of health facilities in the Kingdom culminated in NHRA being awarded the 2019 Best Government Practices Award for Public Administration Research (MENAPAR) in the MENA region.

We look forward to another fulfilling year.

ACCREDITATION ACTIVITIES



Healthcare
Facilities Surveyed



Accreditation Committee
Meetings Convened



Accreditation Workshops
Conducted by NHRA



Consultation
Visits



Annual
Follow Up Visits



6 Months
Follow Up Visits



QI Plan
Submission

DISTRIBUTION OF HOSPITAL AWARDS



Diamond



Platinum



Gold



Silver

DISTRIBUTION OF MEDICAL CENTER AWARDS



Diamond



Platinum

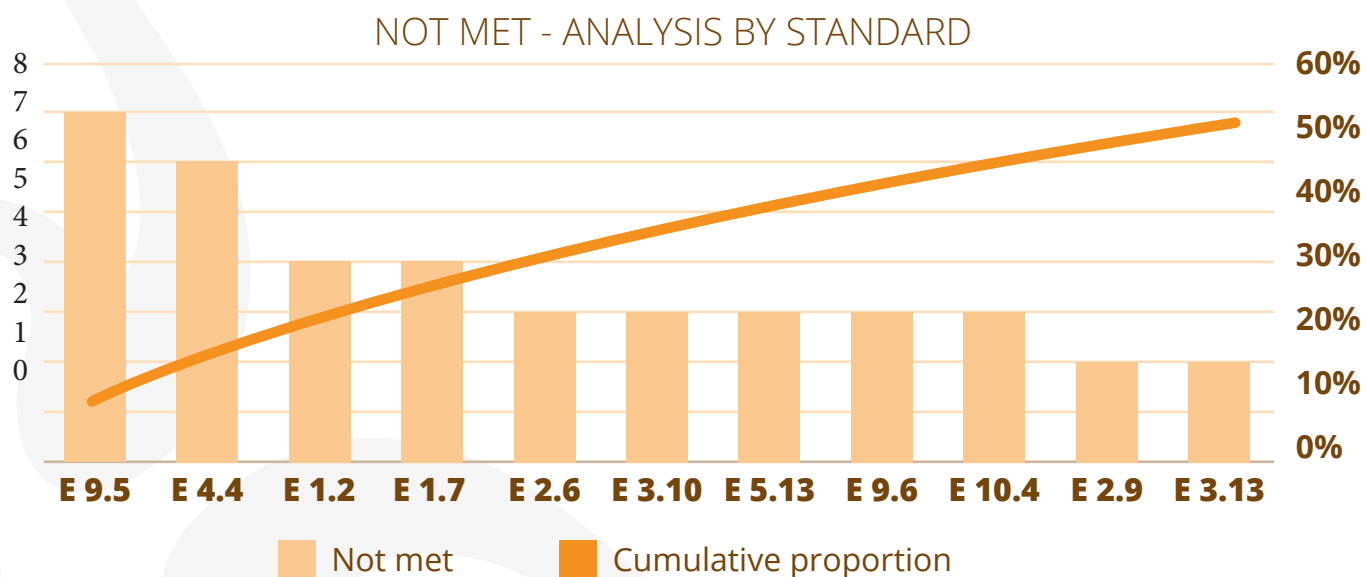


Gold



Silver

MEDICAL CENTER CORE ELEMENTS ANALYSIS - NOT MET



Element	Standard	Description
E 9.5	9. Provision of Care	Clinical practice guidelines
E 4.4	4. Quality Management and Patient Safety	The Medical Center develops a risk management plan
E 1.2	1. Governance, Management and Leadership	Periodic evaluation of governing body
E 1.7	1. Governance, Management and Leadership	The facility should have a 3 to 5-year strategy
E 2.6	2. Human Resources	Management recommends educational needs of staff
E 3.10	3. Patient and Family Rights	All patient complaints are analyzed
E 5.13	5. Management of Information and Medical Records	All laboratory/radiology results reviewed
E 9.6	9. Provision of Care	The Medical Center identifies the healthcare needs through an appropriate assessment process
E 10.4	10. Medical Staff	Medical Staff organization
E 2.9	2. Human Resources	The facility has a clearly defined and documented process for staff privileges
E 3.13	3. Patient and Family Rights	The facility has a defined process for informing patients of adverse events

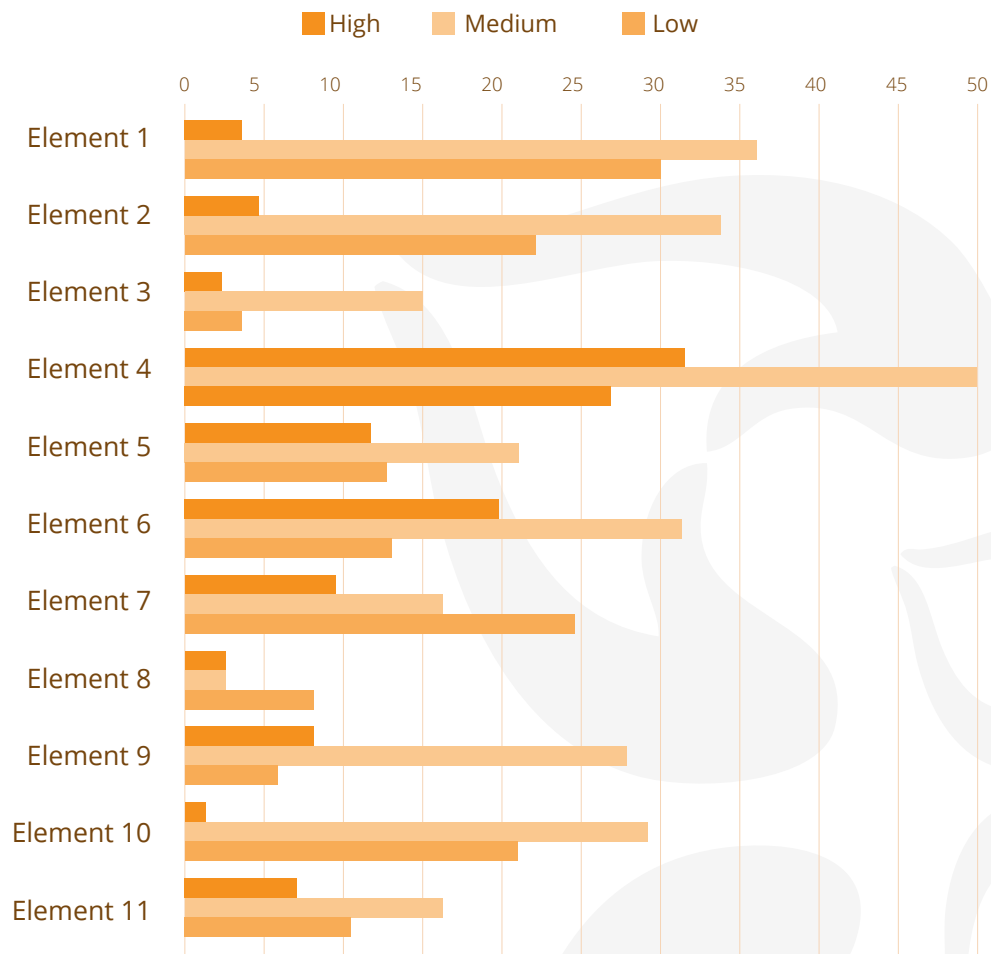
50th Percentile of standards that are not met by the medical centers.

Of the 125 elements considered in evaluating the standards of the medical centers, 50% of the NOT met criteria could be resolved by regulating the standards of the 11 elements shown above.

First 5 standards comprise 30% of the elements

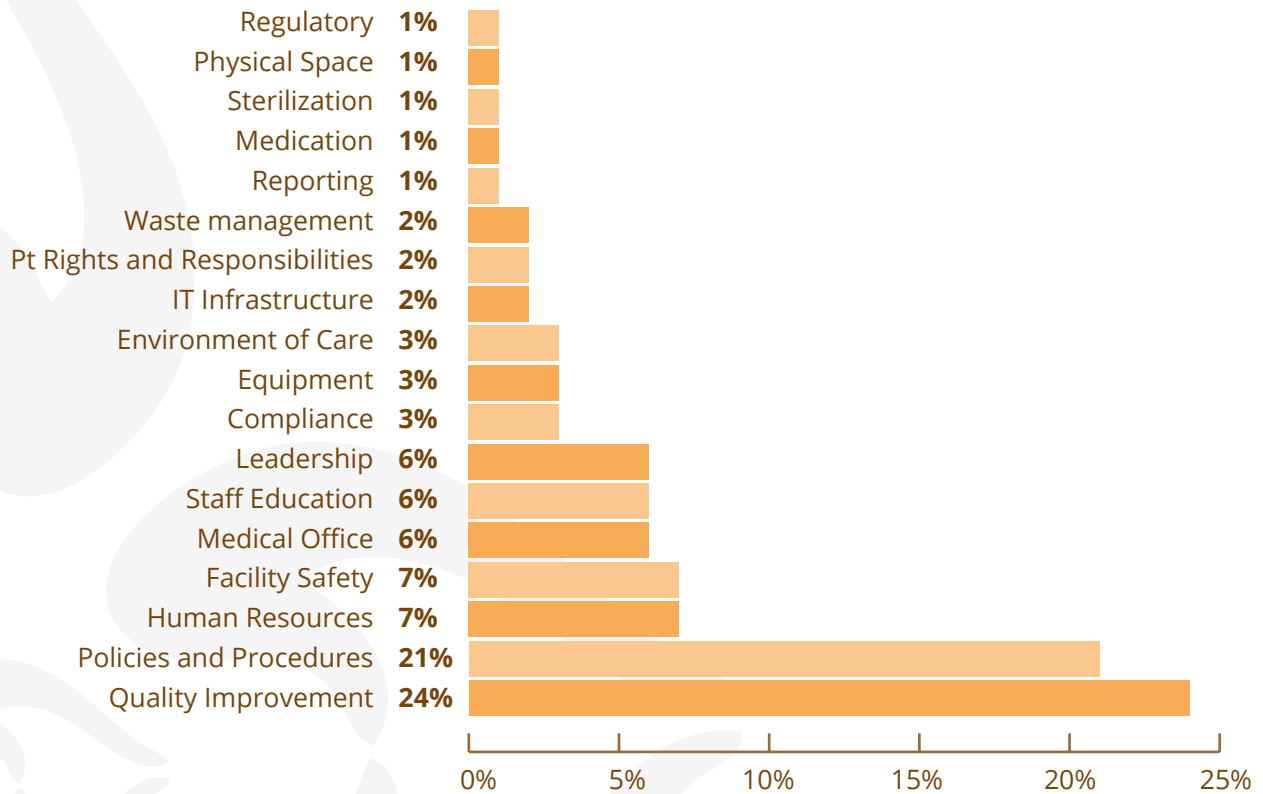
MEDICAL CENTER CORE ELEMENTS ANALYSIS

DISTRIBUTION OF RECOMMENDATIONS BY PRIORITY
(HIGH, MEDIUM, AND LOW)

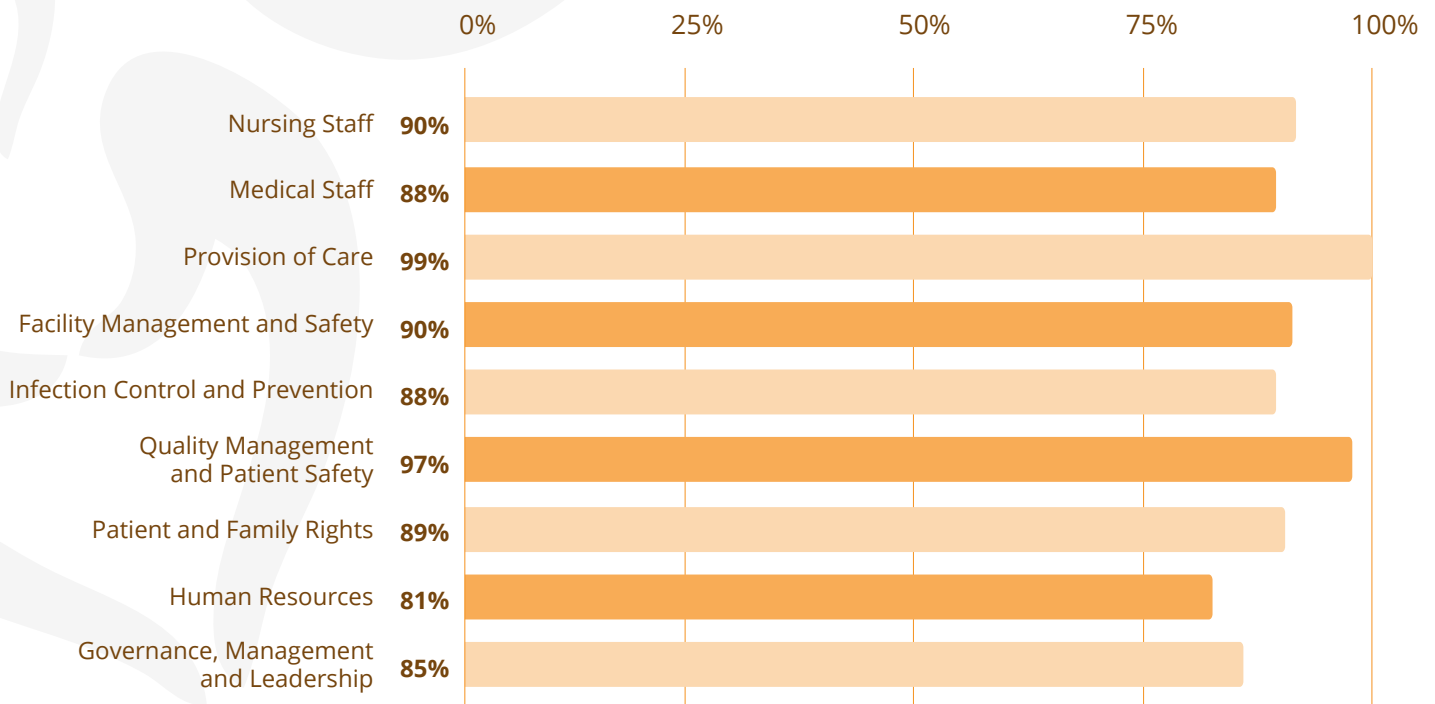


Element	Description
1	Governance, Management and Leadership
2	Human Resources
3	Patient and Family Rights
4	Quality Management and Patient Safety
5	Management of Information and Medical Records
6	Infection Prevention and Control
7	Facility Management and Safety
8	Patient & Family Education
9	Provision of Care
10	Medical Staff
11	Nursing Staff

AGGREGATE DISTRIBUTION OF CATEGORIES OF RECOMMENDATIONS IN THE CORE REQUIREMENTS FOR MEDICAL CENTERS



POST ACCREDITATION HOSPITAL QUALITY IMPROVEMENT ANALYSIS PERCENTAGE COMPLETION OF RECOMMENDATIONS GIVEN TO HOSPITALS



ACCREDITATION ACHIEVEMENTS

1

The MENA Public Administration Research Best Government Practice Award was presented to NHRA for the successful implementation of health facility accreditation in the Kingdom.

2

Workshops

4 Accreditation Workshops conducted
Accreditation Results Analysis Session
Lab Accreditation Training

3

ISQua (International Society for Quality in Healthcare) Activities.
Staff of Accreditation Department attain the ISQua Fellowship.

4

Publications

- Accreditation Results Analysis Book
- National Accreditation Handbook
- Accreditation Surveyor Handbook

5

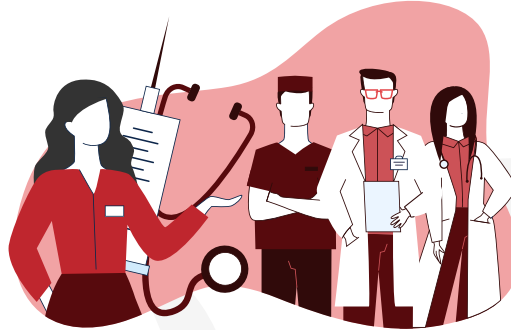
Surveyors

July 2019 – Health Facility Surveyor Development Training. 10 new surveyors were inducted
November 2019 – Lab Accreditation Training

MEDICAL COMPLAINTS



MEDICAL COMPLAINTS



In 2019, the medical complaints unit received 257 cases for investigation, an increase of 13% since 2018. Of the 257 cases received, the number of complaints reported by individuals was 167, 33 incidents were reported by healthcare facilities, and 57 lawsuits were referred by jurisdiction authorities.

Forty two percent of the cases were related to the treating physician, 44% related to the healthcare facility and the rest were related to allied health professionals, nurses, pharmacists or others.

The technical investigating committees were able to complete the investigations of 177 cases in 2019, demonstrating an increase of 53% from the previous year. Of the closed cases, no medical error /violation of the principles, duties, requirements and of ethics was determined in 39% meanwhile medical error/violation of the principles, duties, requirements and of ethics was identified in 20%.

The disciplinary committee issued 37 disciplinary actions that included 10 suspensions, 18 warning notices, and 1 professional license was cancelled.

TOTAL NUMBER OF CASES RECEIVED BY NHRA

57

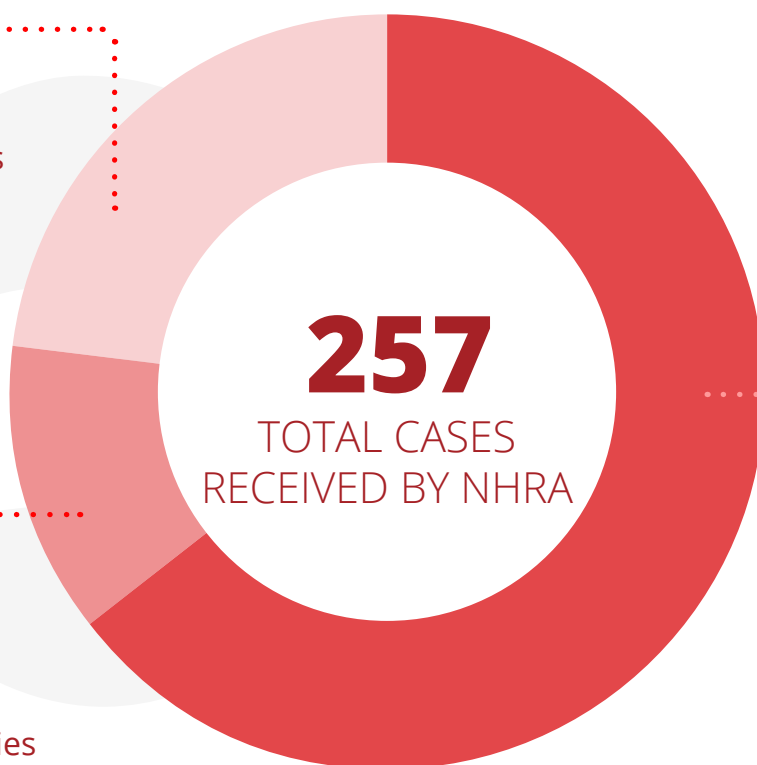
Lawsuits

Referred by
Judicial Authorities

33

Incidents

Reported by
Health Care Facilities



257

TOTAL CASES
RECEIVED BY NHRA

167

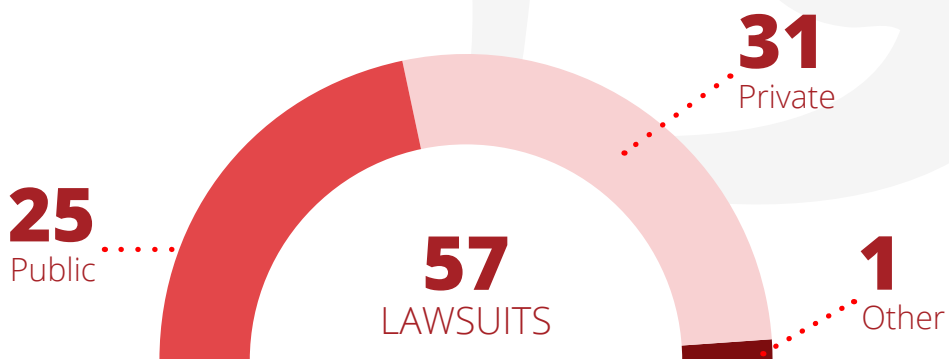
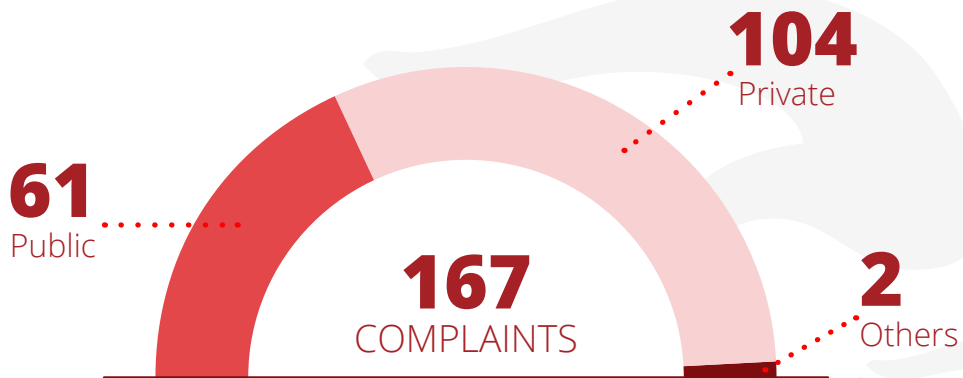
Complaints

Reported from the
Public

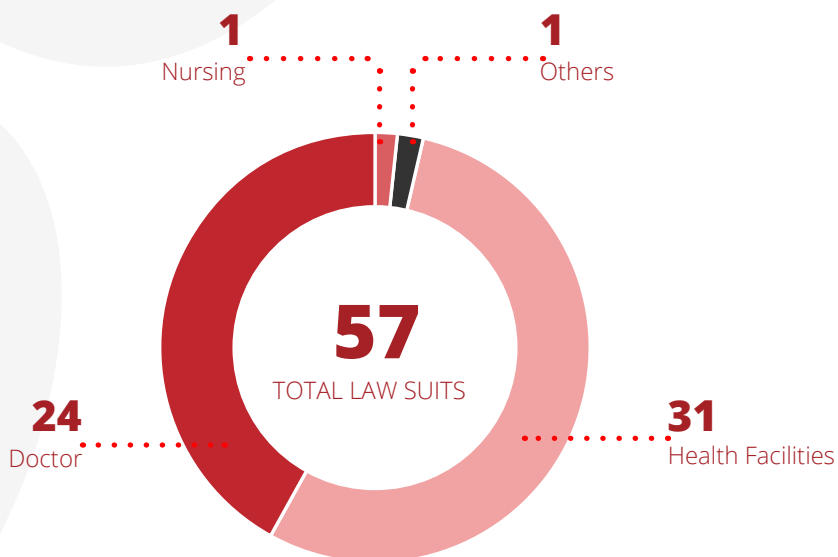
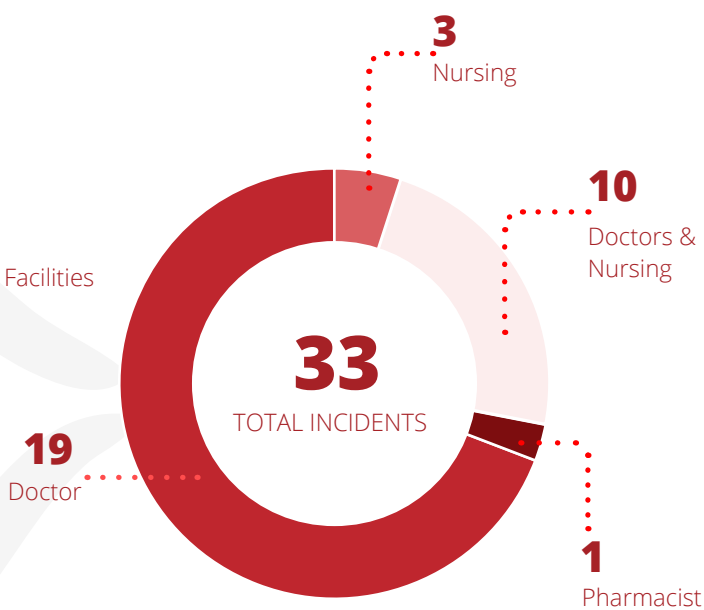
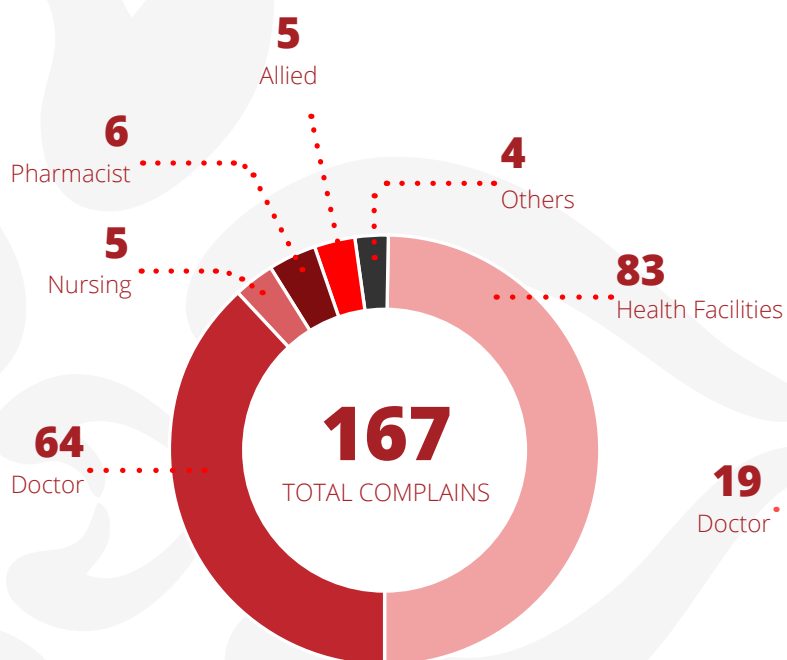
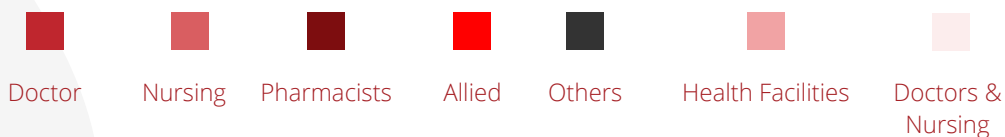
DISTRIBUTION OF COMPLAINTS, INCIDENTS & LAWSUITS

BY HEALTH SECTOR

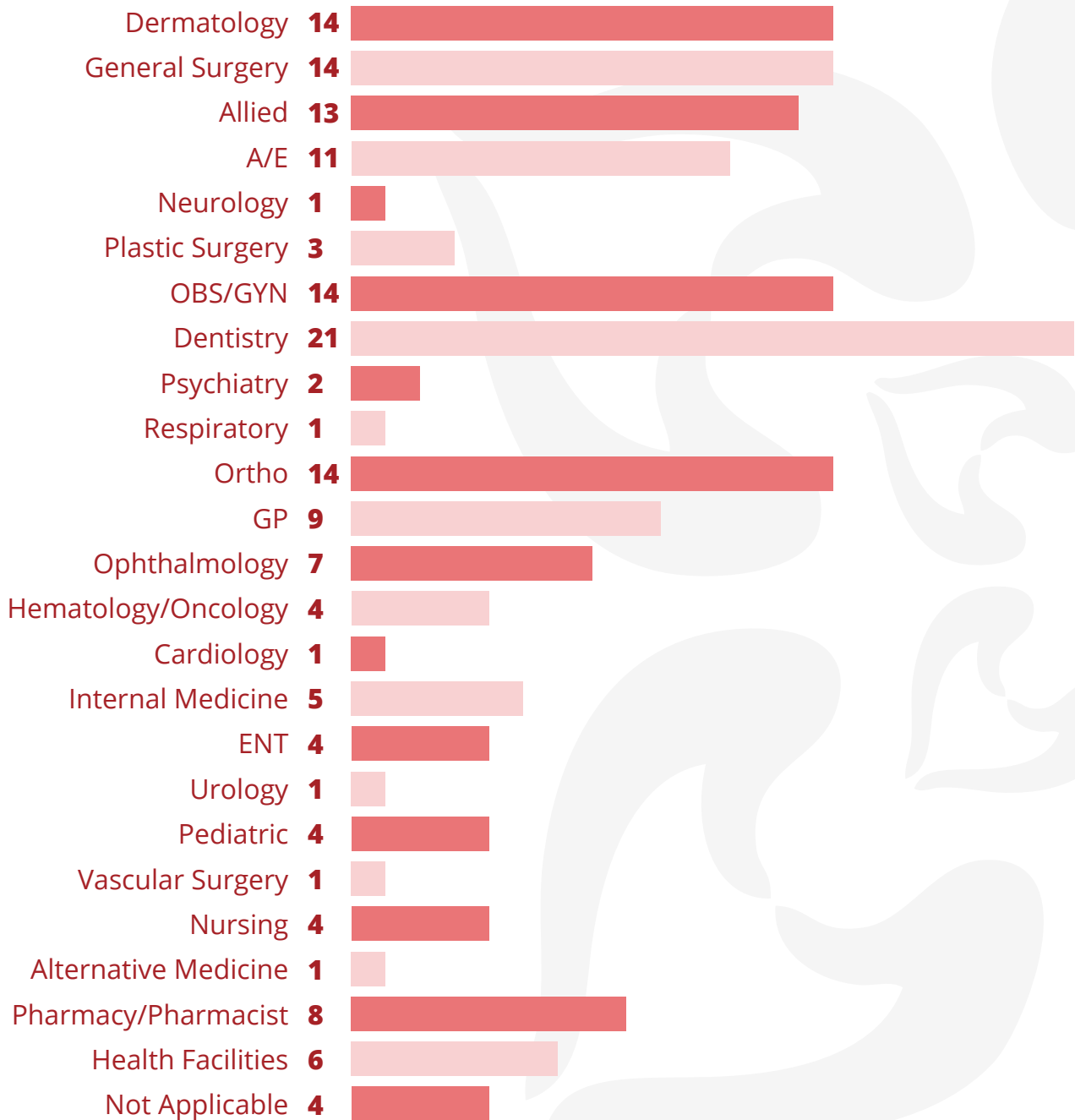
Public Private Both Other



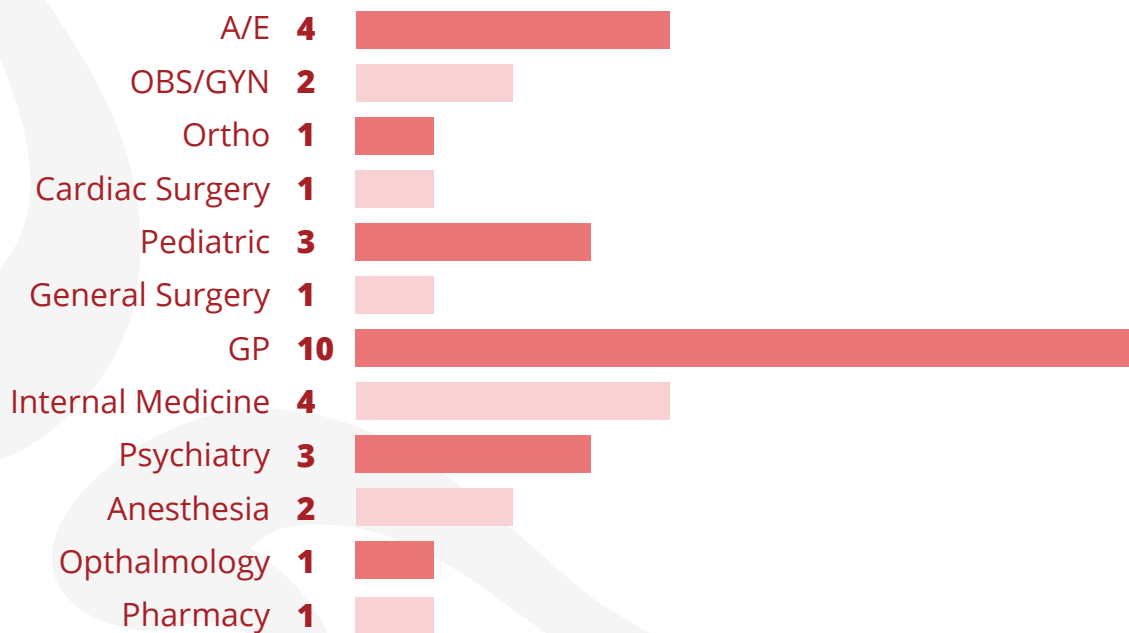
DISTRIBUTION OF COMPLAINTS, INCIDENTS & LAWSUITS BY HEALTH PROFESSION



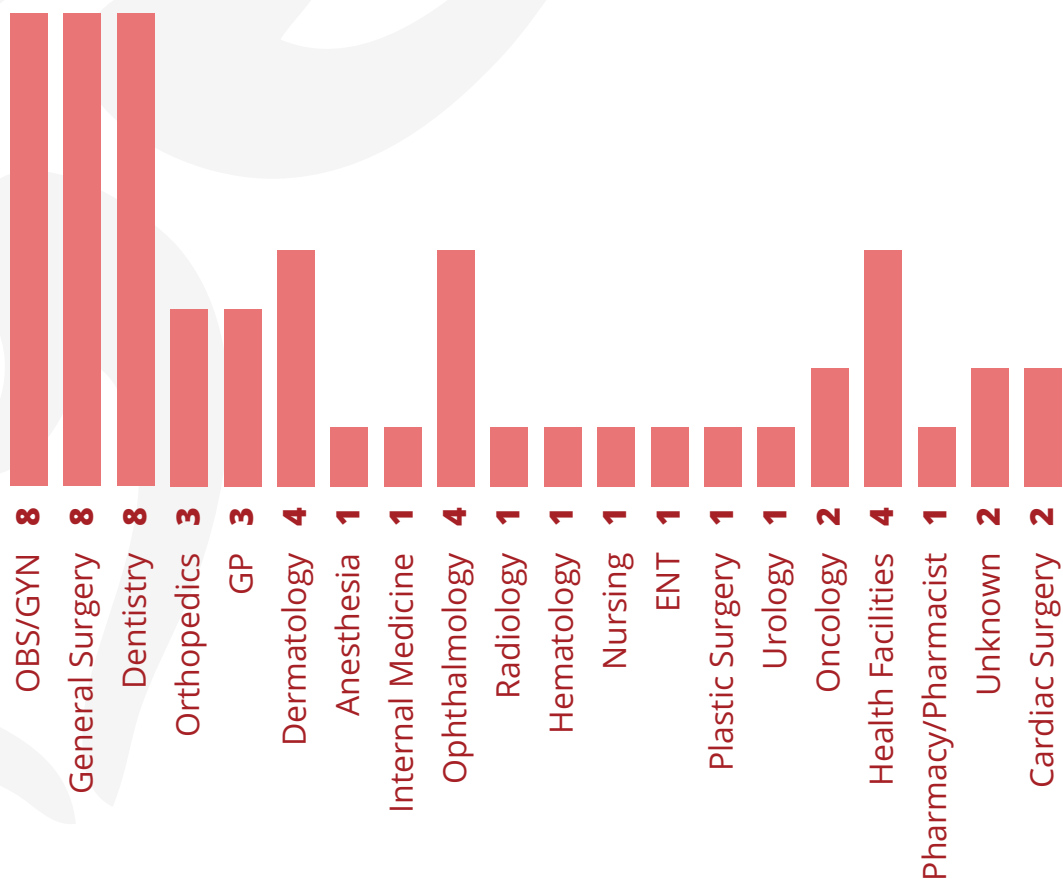
DISTRIBUTION OF COMPLAINTS BY THE MOST FREQUENT SPECIALITY



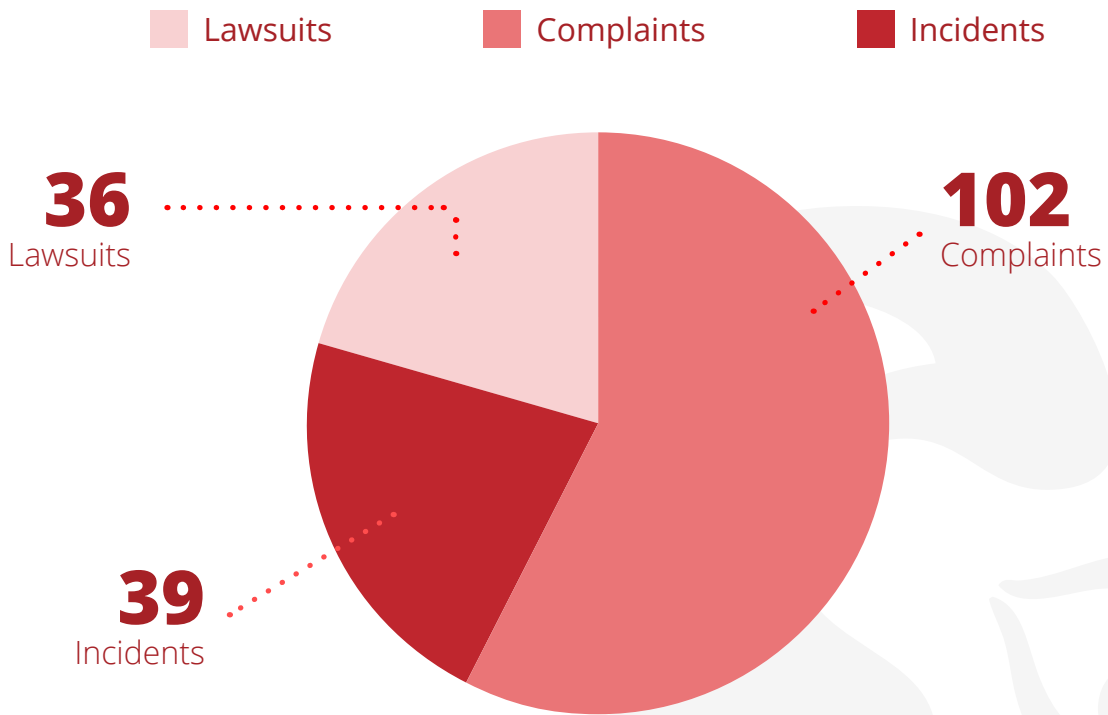
DISTRIBUTION OF INCIDENTS BY THE MOST FREQUENT SPECIALITY



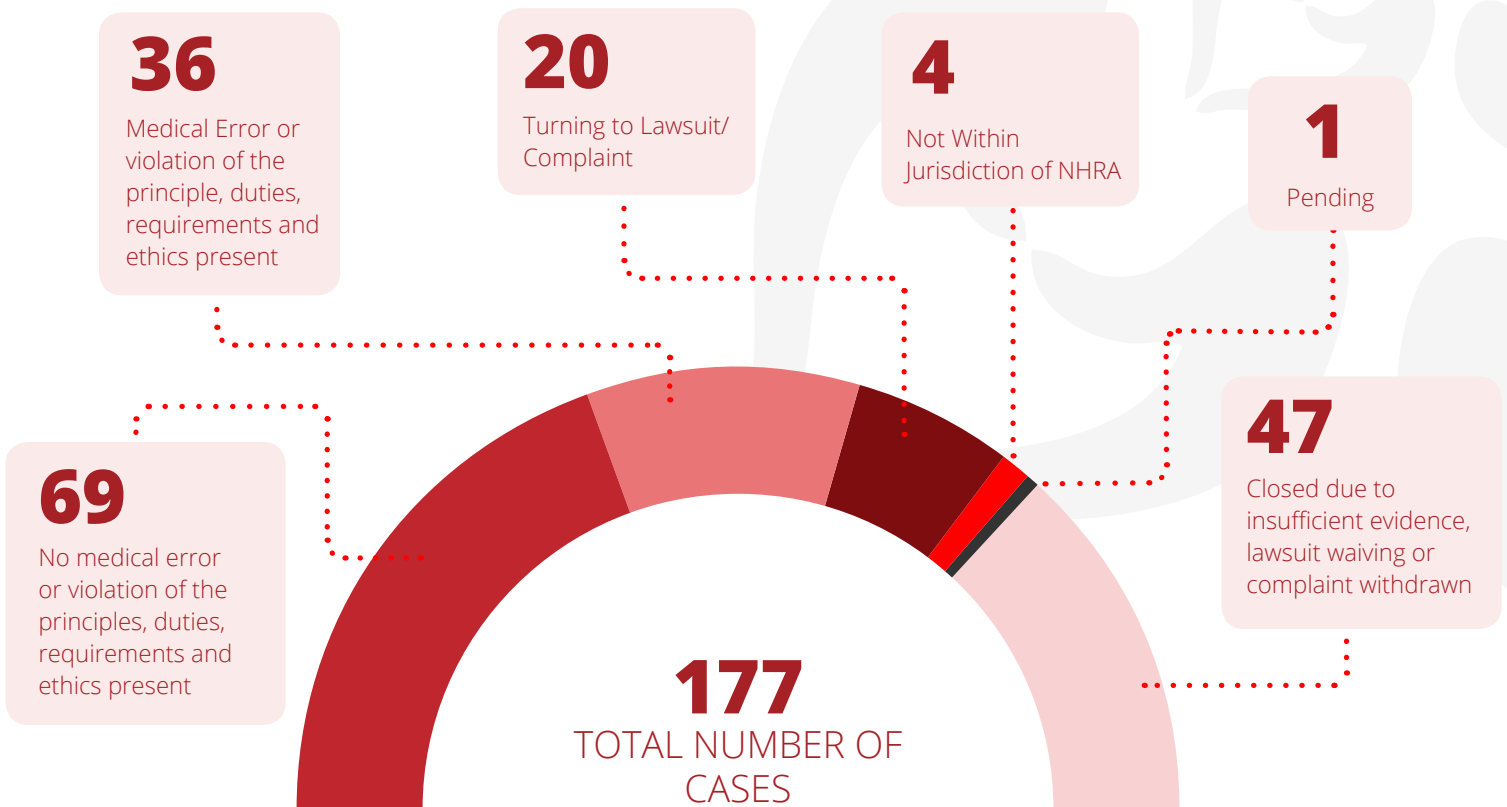
DISTRIBUTION OF LAWSUITS BY THE MOST FREQUENT SPECIALITY



TYPES OF CASES INVESTIGATED / CLOSED



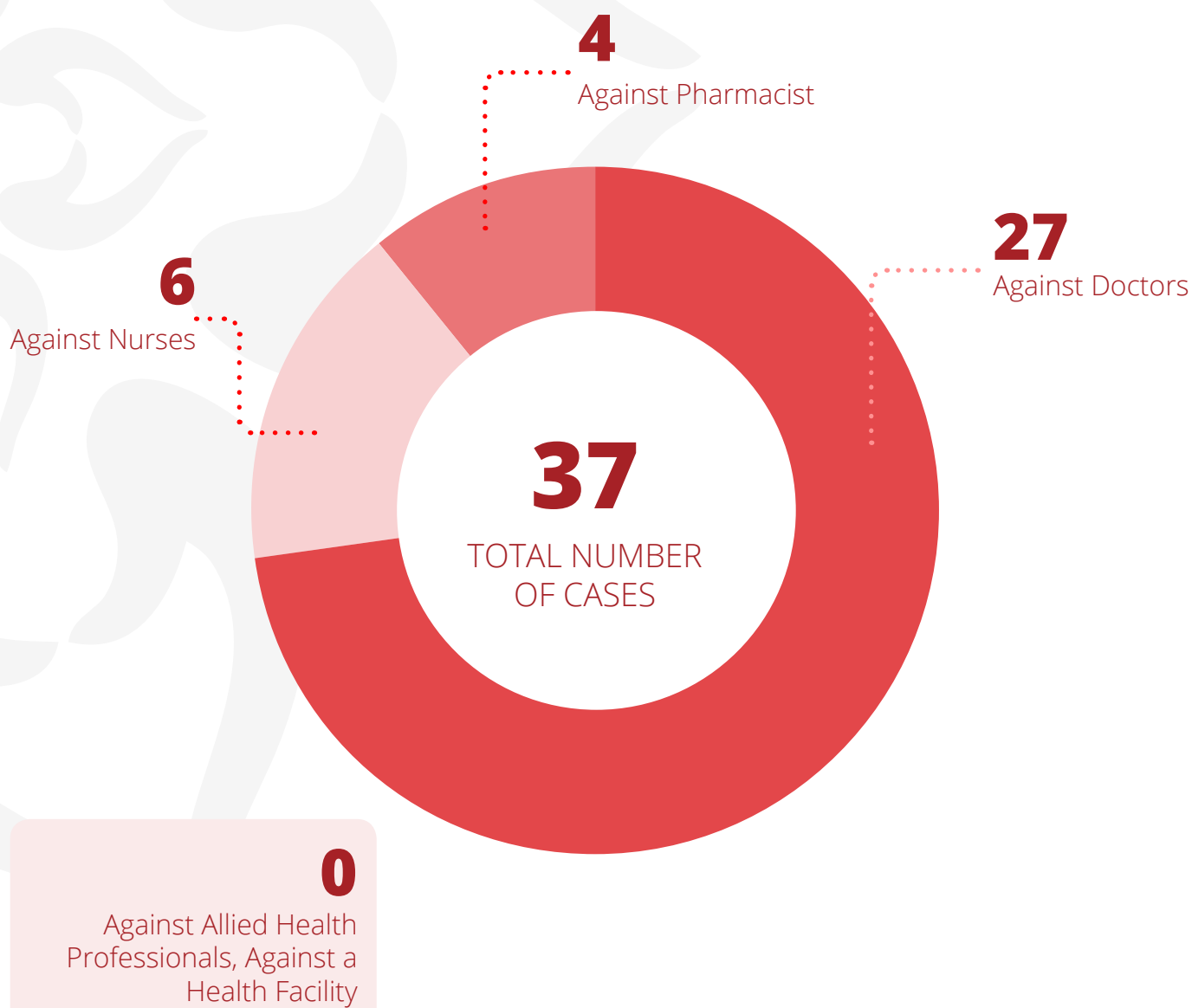
RESULTS OF INVESTIGATION



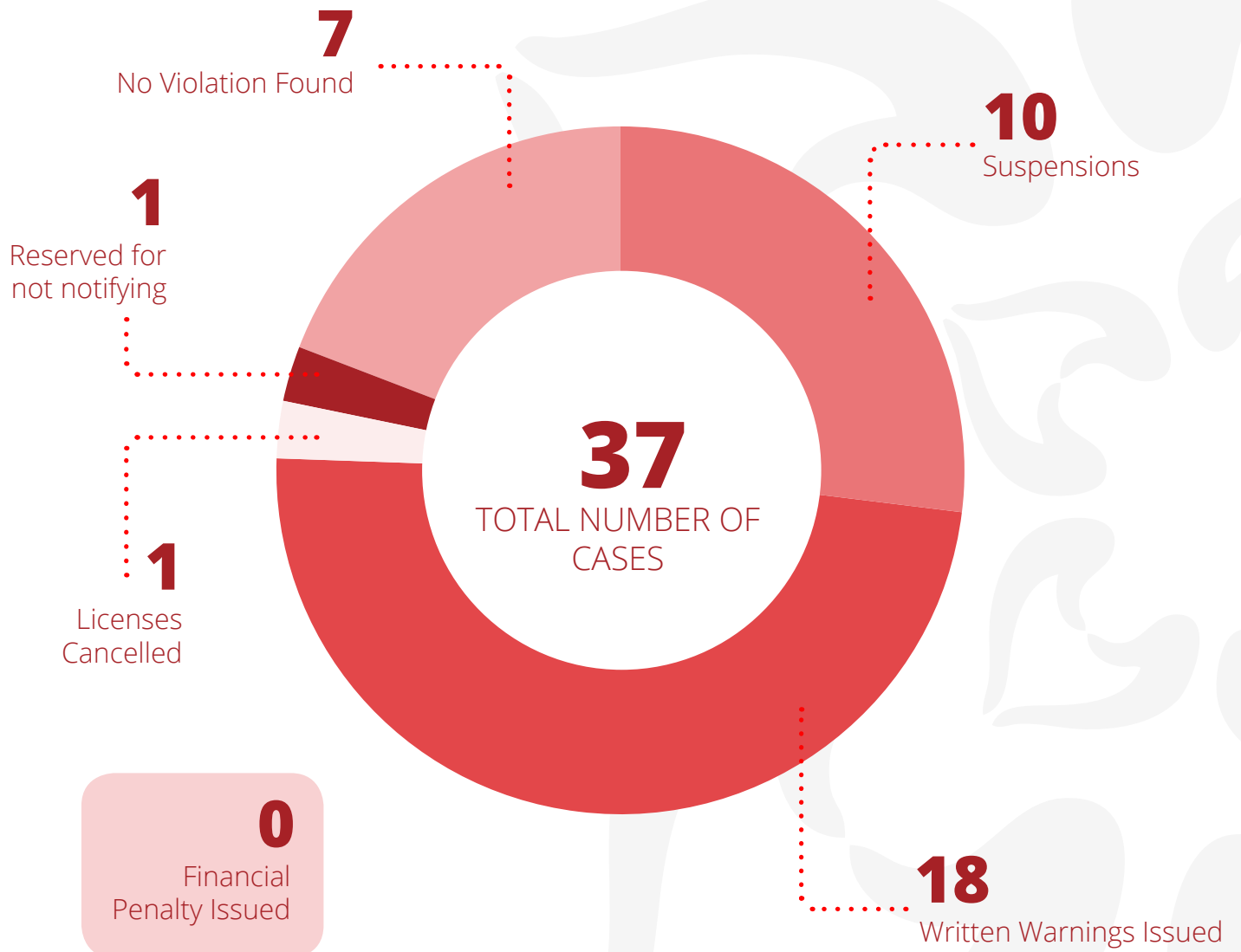
TOTAL NUMBER OF DISCIPLINARY DECISIONS ISSUED BY DISCIPLINARY COMMITTEES AT NHRA

37

DISTRIBUTION OF DISCIPLINARY ACTIONS BY PROFESSIONAL CATEGORY



DISTRIBUTION OF DISCIPLINARY ACTIONS ISSUED



DISTRIBUTION OF DISCIPLINARY ACTIONS ISSUED

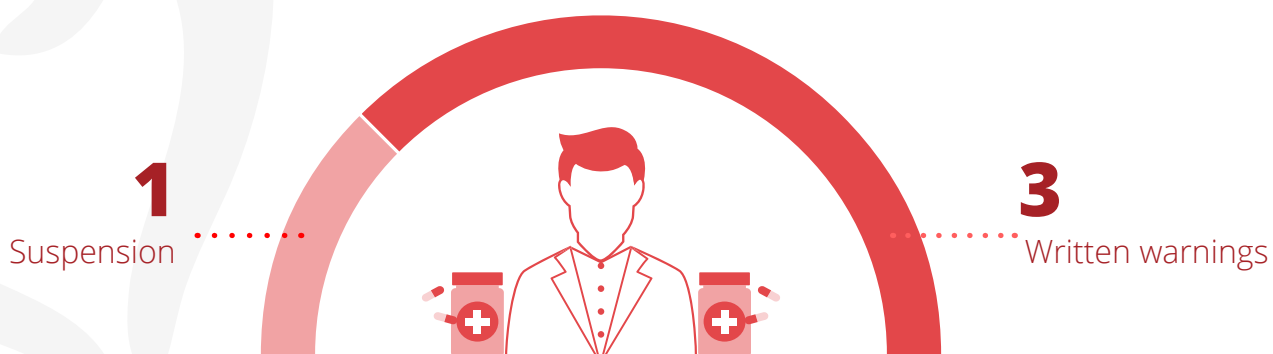
AGAINST DOCTORS



AGAINST NURSES



AGAINST PHARMACISTS



MEDICAL COMPLAINTS

ACHIEVEMENTS



An Appeal Committee has been formulated to look into the appeal requests submitted by medical doctors/dentists regarding disciplinary decisions issued against them.



Review of department's workflow and methods of efficiency.



The committees have conducted a total of 122 meetings as follows:

- The Technical Committee for investigating professional and ethical errors for the practitioners of the medical profession (42)
- The Technical Committee for investigating professional and ethical errors for the practitioners of dentistry (31)
- The Disciplinary Committee for licenses to practice the profession of medicine and dentistry (21)
- The Disciplinary Committee for licenses to practice pharmacy profession (8)
- The Disciplinary Committee for licenses to practice the professions of nursing, midwifery and obstetrics (7)
- The disciplinary committee for licenses to practice one of the allied professions (3)
- Appeal committee to look into the requests submitted by medical doctors and dentists against disciplinary decisions issued against them (9)
- Accountability committee (1)



Issuing of Decision No. 95 of 2019 by the Supreme Council of Health regarding the investigation of medical professional errors and reporting of accidental and serious incidents in health institutions.

ACHIEVEMENTS OF THE **LEGAL AFFAIRS UNIT**



LAWS AND DECISIONS ISSUED IN 2019

In 2019, the legal affairs unit has been engaged in developing new regulations and updating existing ones. Four important resolutions were published during the course of 2019:

- Resolution No. 2 of 2019 regarding classification of health facilities, health and technical requirements and safety requirements that must be met in their facilities and equipment.
- Resolution No. 62 of 2019 regarding the licensing requirements for the use of medical technologies to assist in artificial insemination and fertilization.
- Decision No. 63 of 2019 regarding regulations for the practice of pharmacy professions and licensing of pharmacy centers, drug factories, pharmaceutical preparations and pharmaceutical facilities.
- Resolution No.95 of 2019 regarding investigating medical errors and reporting incidents and medical errors.

DRAFT LAWS AND DECISIONS (UNDER STUDY)

Additionally, the unit has also finalized the following:

- A draft resolution of the regulations and requirements for health facilities licensing for the treatment and rehabilitation of addiction,
- A draft resolution regarding the issuance of the regulations for registering medicines and pharmaceutical preparations, pricing medicines and determining the profit margin.
- A draft resolution to issue a list of requirements and procedures for licensing and monitoring governmental health facilities.

These draft resolutions are pending the legislation and legal opinion commission approvals. The unit has also collaborated with the Bahrain Medical Society, the Ministry of Health and other related health institutions to work on a draft legislation for The Practice of Medicine and Dentistry.

ACTIVITIES OF **THE INVESTORS OFFICE**



INVESTORS SUPPORT SERVICES

The Economic Vision 2030, launched in October 2008 by His Majesty King Hamad bin Isa Al Khalifa, is a comprehensive economic vision for Bahrain, providing a clear direction for the continued development of the Kingdom's economy and, at its heart, is a shared goal of building a better life for every Bahraini.

There are many reasons to do business in the Kingdom of Bahrain including its central Gulf location, low cost of operations, talented workforce and stable economy.

In response to the increased interest in investing in the emerging healthcare market in the Kingdom of Bahrain, NHRA has launched the investors office to provide support and guidance to investors planning to operate a healthcare business in the Kingdom. The investors office serves as a liaison between NHRA departments and other important business support authorities such as the Economic Development Board (EDB), Supreme Council of Health (SCH), Tamkeen, and other government entities as needed.

Since its inception the office has received 26 inquiry requests for varied healthcare investments from the markets of the GCC, Europe and Asia. Out of the total inquiries, 23% were inquiries on establishing hospitals, 50% on establishing medical centers and 15% were inquiries on pharmaceutical and medical devices sectors.

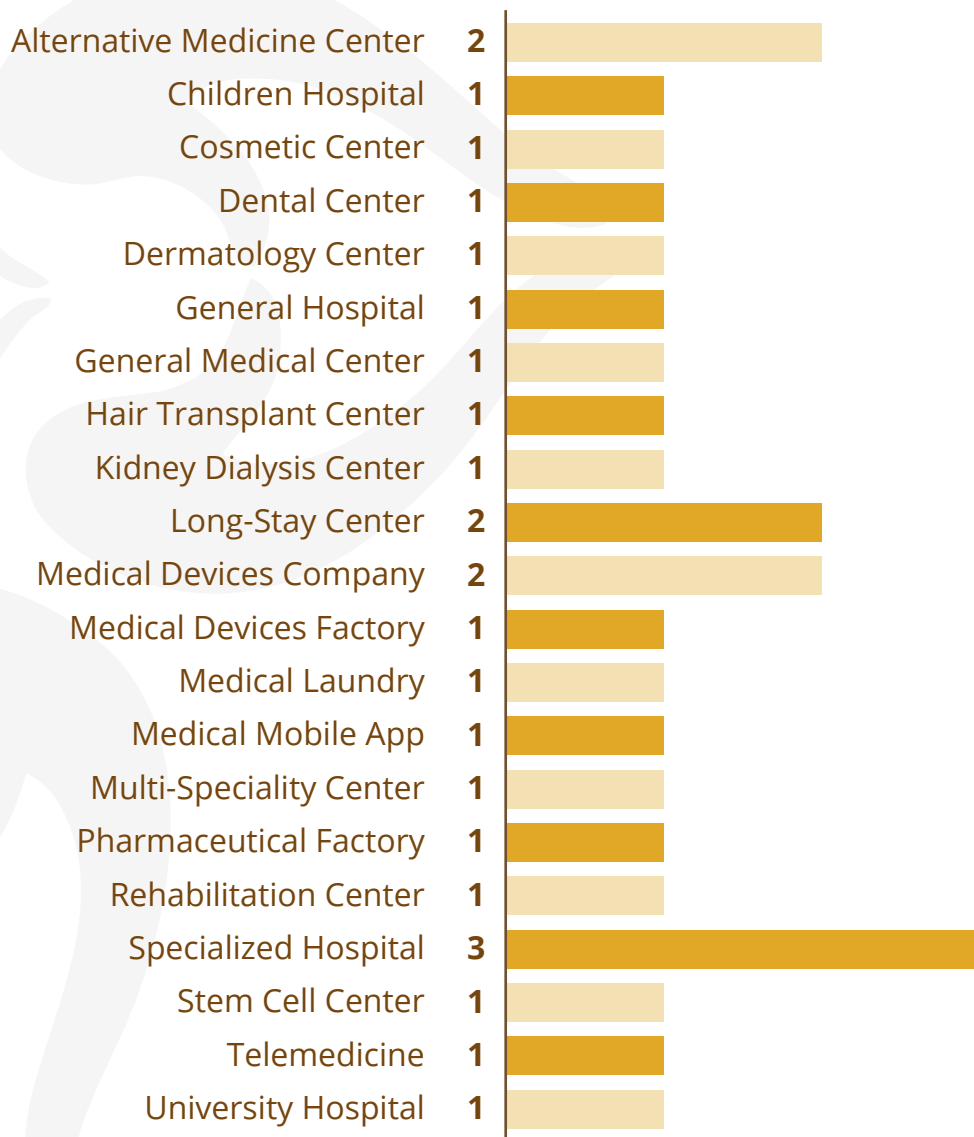
The investors office is a full-service initiative provided to investors from conceptualizing their ideas to the final licenses and procedures needed to start healthcare businesses here.



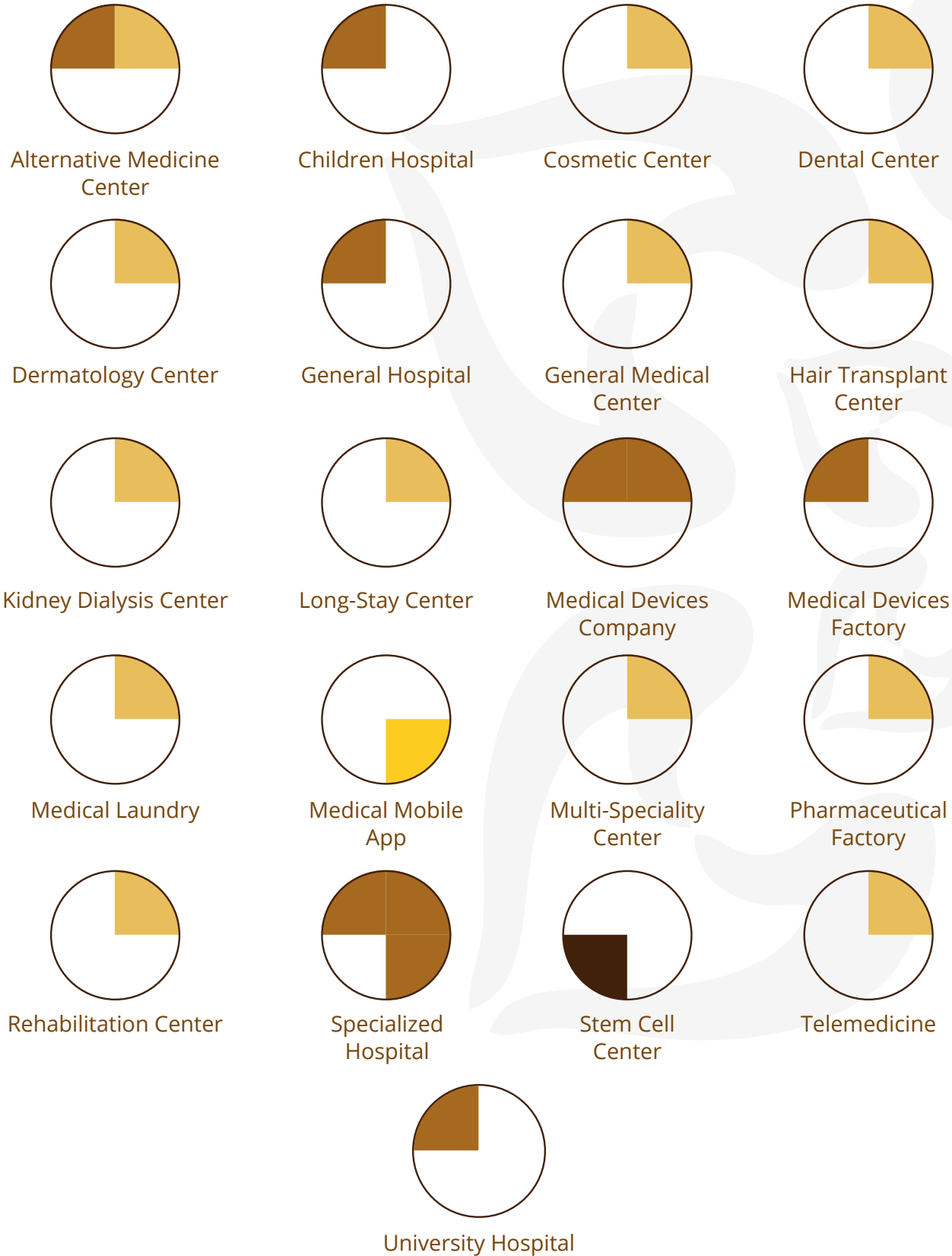
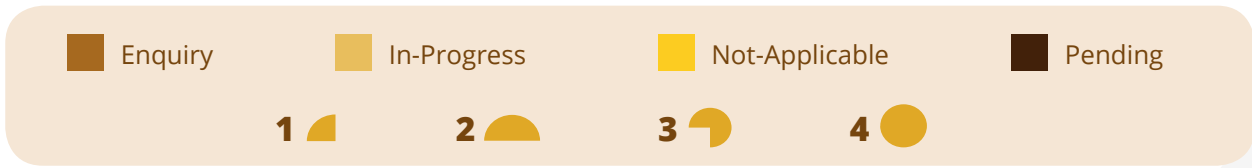
DISTRIBUTION OF REQUESTS RECEIVED

26

TOTAL NUMBER OF REQUESTS RECEIVED



OUTCOMES OF REQUESTS



COUNTRY OF ORIGIN AND INVESTMENT TYPE



TOTAL 26

HUMAN AND FINANCIAL RESOURCES



HUMAN AND FINANCIAL RESOURCES



The Human and Financial Resources Section is concerned with managing and organizing the affairs of the Authority related to the job conditions of its employees by providing the necessary professional cadres and creating an ideal and stimulating production work environment.

The finance section is responsible for preparing and implementing the budget and supervising it according to the laws and regulations of the Kingdom and achieving a financial balanced budget by using the optimal available resources so as not to negatively affect the progress and quality of work.

The section also specializes in information technology management by providing a secure, integrated and fast electronic environment for completing transactions and facilitating procedures.

In addition to other administrative services provided the Human and Financial Resources Section organize all the necessary requirements for employees and other related parties to complete their tasks easily and conveniently.

FINANCE

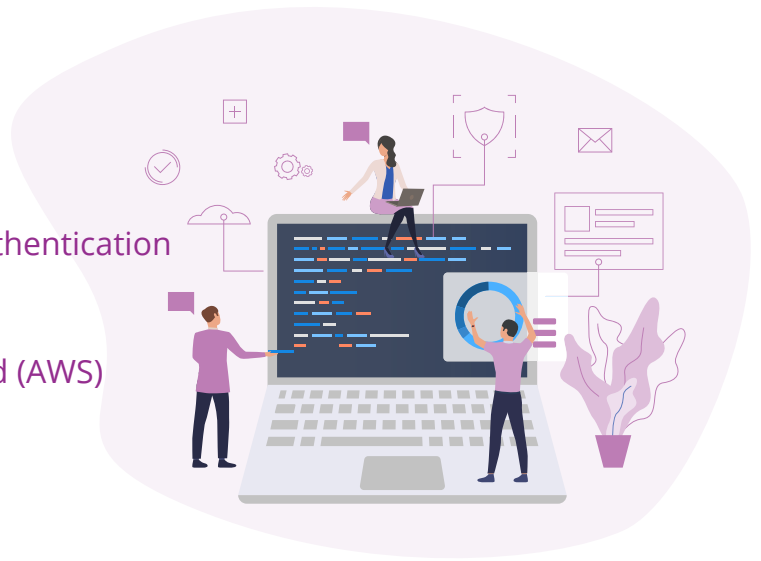
- NHRA moved to a new office in December 2019. This move was budget neutral with no additional expenditure.
- The offices were furnished & equipped from the current budget.
- The online payment system was developed for professional healthcare services and the volume of transactions in the first year exceeded 11,000 transactions with a total value of more than BD 665,000.00

REVENUES & EXPENDITURES STATEMENT FOR YEAR END DEC 2019

Revenues	Actual		Budget 2019
	2018	2019	
Taxation & Fees	2,045,621	1,803,923	2,400,000
Government Goods & Services	250	640	-
Fine, Penalties & Misc	191,802	151,864	100,000
Total Revenues	2,237,673	1,956,427	2,500,000
Recurrent Expenditures			
Manpower	1,700,400	1,764,785	1,764,786
Services	563,586	693,148	665,041
Consumables	45,008	61,017	62,831
Assets	30,346	85,782	87,087
Maintenance	11,680	5,714	5,996
Total Recurrent Expenditures	2,351,020	2,610,446	2,585,741
Project Expenditures	-	-	-
Total Expenditures	2,351,020	2,610,446	2,585,741
Surplus (Deficit)	(113,347)	(654,019)	(85,741)

INFORMATION TECHNOLOGY

- Migrating all devices to Windows 10
- Migration to Office 365
- Deploying and activating Multi-Factor Authentication on email exchange
- Starting the process of migration to cloud (AWS)
- Launching the new NHRA website



HUMAN RESOURCES

18%
PROMOTION

20%
AWARD

7.6%
RECRUITMENT
(Were recruited out of the total approved structure)

90%
TRAINING

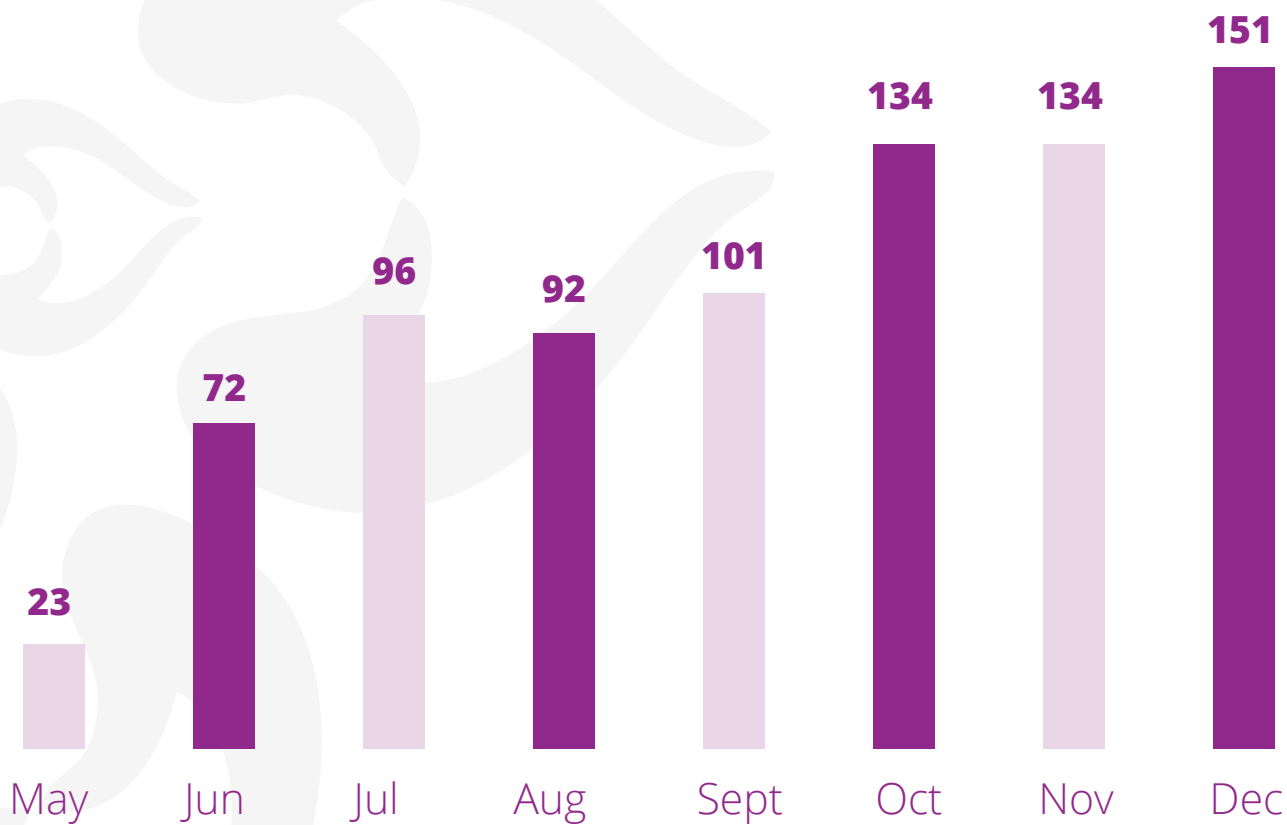


CUSTOMER ENGAGEMENT ACTIVITIES

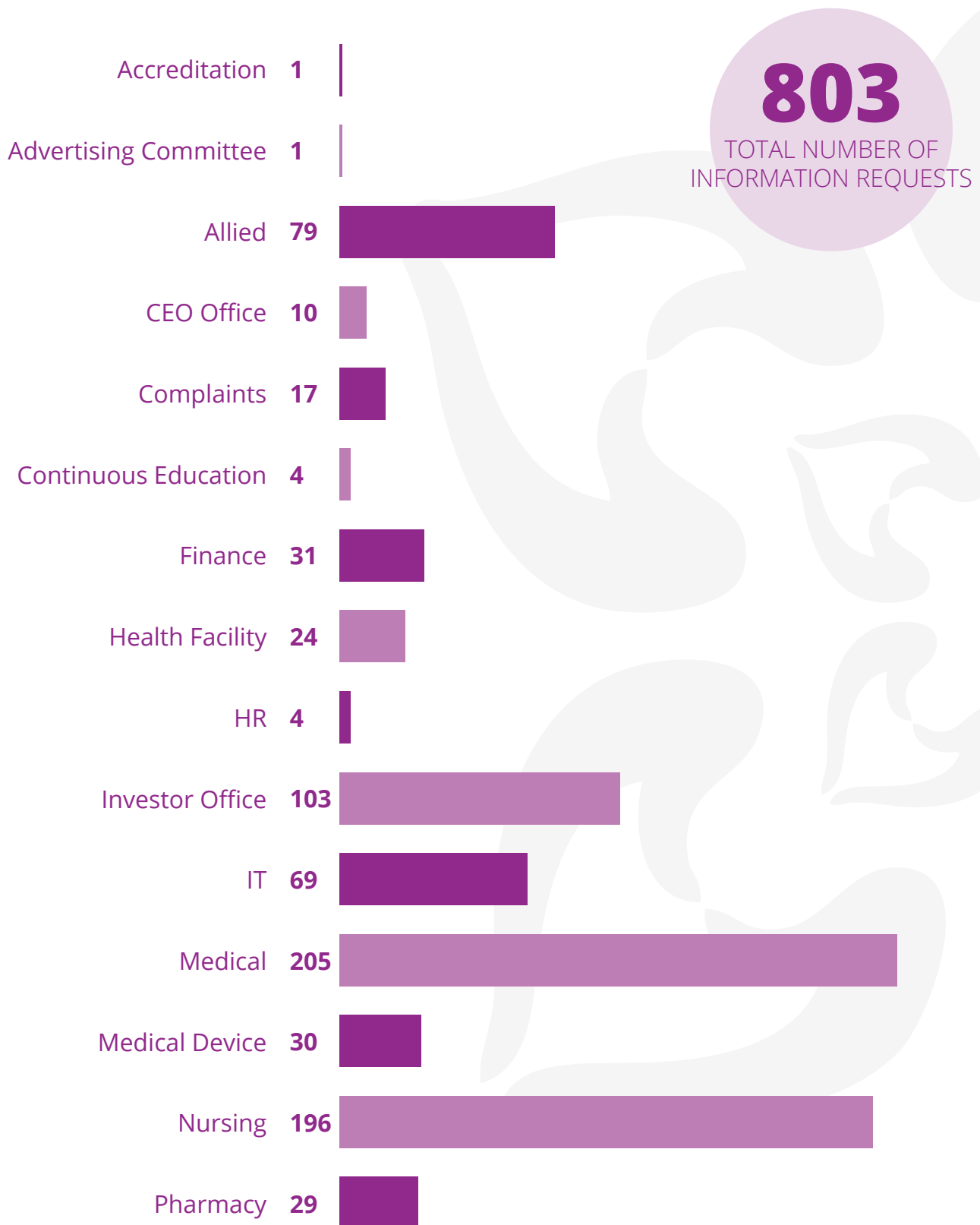


803

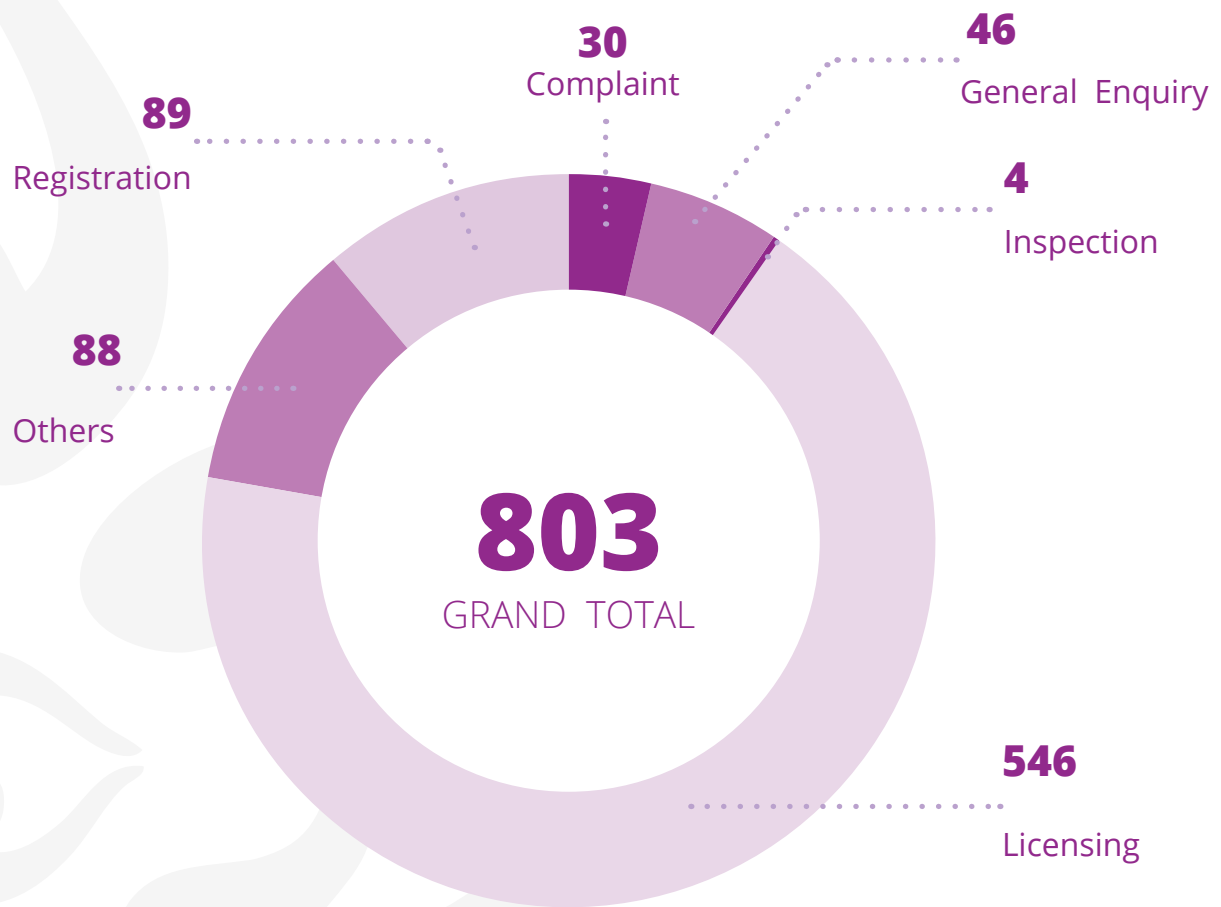
TOTAL NUMBER OF INFORMATION REQUESTS
BY MONTH



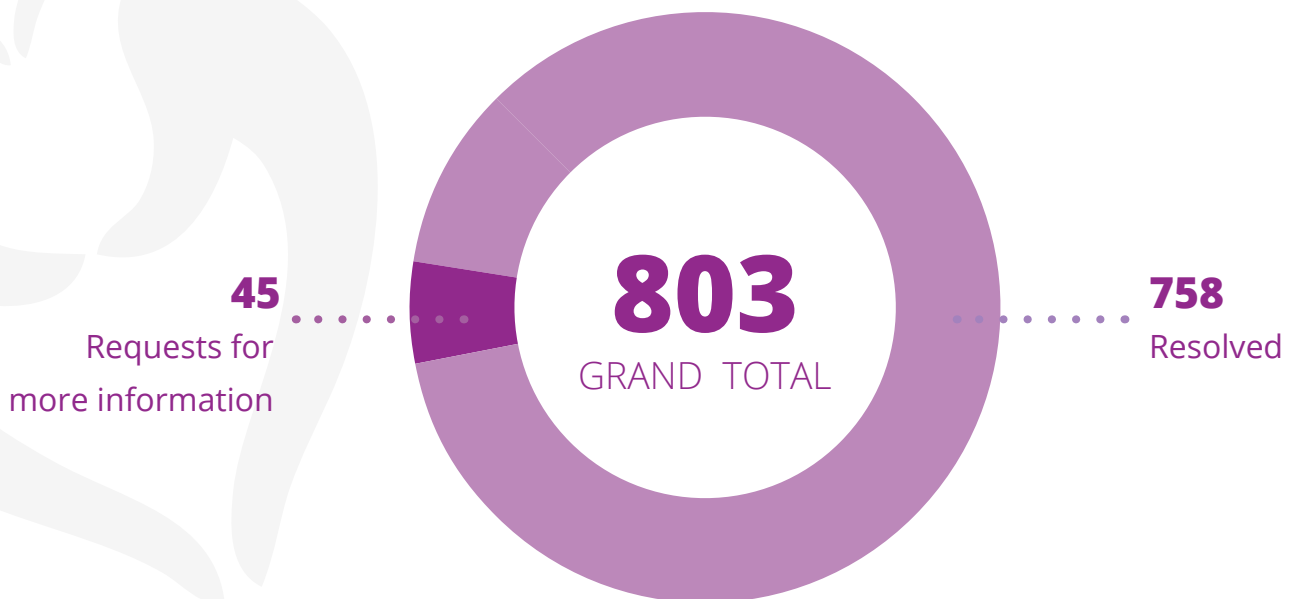
DISTRIBUTION OF INQUIRIES BY SECTION



TYPES OF INQUIRIES RECEIVED



OUTCOME OF INQUIRIES





2019 ANNUAL REPORT

Copyright © National Health Regulatory Authority