

# Improving performance of a pharmacy in a Romanian hospital through implementation of an internal management control system

Lucia Georgeta Daina, Monica Sabău, Cristian Marius Daina, Corina Neamțu, Delia Mirela Tit, Camelia Liana Buhaș, Constantin Bungau, Lotfi Aleya, Simona Bungau

#### ▶ To cite this version:

Lucia Georgeta Daina, Monica Sabău, Cristian Marius Daina, Corina Neamțu, Delia Mirela Tit, et al.. Improving performance of a pharmacy in a Romanian hospital through implementation of an internal management control system. Science of the Total Environment, 2019, 675, pp.51-61. 10.1016/j.scitotenv.2019.04.231. hal-02111006

HAL Id: hal-02111006

https://hal.science/hal-02111006

Submitted on 22 Oct 2021

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers. L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



- 1 Improving Performance of a Pharmacy in a Romanian Hospital through
- 2 Implementation of an Internal Management Control System
- 5 Lucia Georgeta Daina<sup>1</sup>, Monica Sabău<sup>1</sup>, Cristian Marius Daina<sup>1</sup>, Neamţu Corina<sup>2</sup>, Delia
- 6 Mirela Tit<sup>3</sup>, Camelia Liana Buhaș<sup>4</sup>, Constantin Bungau<sup>5</sup>, Lotfi Aleya<sup>6\*</sup>, Simona Bungau<sup>3</sup>
- <sup>1</sup>Department of Psycho-Neuroscience and Rehabilitation, University of Oradea, 410073
- 10 Oradea, Romania;

3

4

7

8

- <sup>2</sup>Clinical County Emergency Hospital of Oradea, 410167 Oradea, Romania;
- <sup>3</sup>Department of Pharmacy, University of Oradea, 410028 Oradea, Romania;
- <sup>4</sup>Department of Morphological Disciplines, University of Oradea, 410073 Oradea, Romania;
- <sup>5</sup>Department of Engineering and Management, University of Oradea, 410087 Oradea,
- 15 Romania;

17

21

22

23

24

- <sup>6</sup>Laboratoire Chrono-environnement, Université de Franche-Comté, Besançon, France
- \*Corresponding author: lotfi.aleya@univ-fcomte.fr
- 19 Phone: + 33 (0) 3 81 66 66 66
- 20 Fax: + 33 (0) 3 81 66 57 97

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

**Abstract** 

According to general principles of good practice, adopted at the international level, quality control is a key function in management and not just a simple means of verification. In a clinic or hospital pharmacy, the chief pharmacist has the training and authority to take the control measures necessary to develop and implement an Internal Managerial Control System (IMCS). The present article analyzes and describes the case of the County Hospital of Oradea, Romania, and presents how the IMCS was adopted and integrated. Quality assessment in the health services takes place via an accreditation process and quality certification, as well as through an internal audit of the hospital pharmacy. The authors report a retrospective and descriptive study carried out from 2012 to 2017, analyzing how current legislative standards are applied. The IMCS in the hospital pharmacy is a dynamic process of continuous transformation, permanently adapted to hospital requirements, achieved under the direction of the chief pharmacist and involving all pharmacy employees, as well as through good coordination practices applied by hospital management. In this specific case, the IMCS features 11 annually updated compliance standards, classed under the headings of work procedures, risk register, job descriptions and staff training. The pharmacy's good practice model for IMCS development, was adopted by all of the hospital's sectors, services and departments.

44

45

46

**Keywords**: Internal Management Control System (IMCS); hospital pharmacy; quality; quality

management

47

48

49

50

51

52

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

#### 1. Introduction

A hospital management system consists of all the elements (principles, rules, methods and decision-making procedures) that ensure the exercise of management functions (Donabedian, 2003; Furtunescu and Mincă, 2010). By means of this system, hospital performance and the degree of achievement of objectives in terms of financing, out-turn and efficiency (economy of resources) (Mossialos et al., 2002) are defined. An important part of the hospital management system is the quality management system used for guidance and quality control. In accordance with the general principles of international good practices, control is not simply an action aimed at verification, but rather a key management function that ensures quality (Badulescu et al., 2015). The exercise of the control function is carried out by persons/structures specialized in control, persons in managerial positions at different levels of management (manager, directors, heads of department, head assistant), ending with the last employee who has the responsibility to fulfil a certain type of control. Management control issues in public hospitals are important, risky and therefore require adequate managerial support (Vera et al., 2014). Considering the particularities of the legal framework for organization and functioning, as well as for internal managerial control standards (Ciuhureanu, 2016; Daina et al., 2018; Flostoiu, 2012; Order of the Minister of Public Finance no. 946/2005; no. 400/2015; Order no. 200/2016), the chief pharmacist is authorized to take the control measures necessary to develop and implement the internal managerial control system (IMCS) in the hospital pharmacy. In a hospital pharmacy, the quality management system consists of two components: a) how well the requirements of both external (patients, suppliers) and internal (employees) clients are fulfilled, and b) how well the quality of the services provided is ensured (Tăerel et al.,

2014). Internal managerial control (IMC) is essential for attaining and maintaining the major goal of the pharmacy – that of conducting day-to-day activities quickly and well, under the specific conditions of the activity of an emergency hospital. Additionally, from an ecological perspective purchases and resources at the pharmacy level should always be managed towards a reduction in waste residues from hospital activity.

Based on the IMCS, the present study examines how a hospital pharmacy has implemented a quality management system. To evaluate the quality of health services the authors examined the process of hospital pharmacy accreditation and quality certification, and also undertook an internal audit. The audit indicators presented here verify that the standards required by law are met, show how to correctly apply certain improvement proposals that lead to efficient management. For instance, no other studies have been conducted in Romania examining the close interdependence between waste management and pharmacies management services. Obviously, implementation practices are country-specific, and we believe that comparing different quality management types among hospitals in different countries can introduce optimization strategies for sanitary, pharmaceutical, etc. units.

#### 2. Materials and methods

Between 2012 and 2017, a retrospective, descriptive study was carried out in the Pharmacy Service of the County Clinical Emergency Hospital (885 beds) of Oradea, Romania. The study is based on the Ordinance of the Ministry of Public Finance no. 946/2005, updated and republished in the Official Gazette of Romania, Part I, no. 469/5 July 2011, with the subsequent amendments and additions, and Order no. 400/2015 for the approval of the Code of Internal Managerial Control of Public Entities, Appendices 3 and 4.1 (Order of the Ministry of Public Finances nos. 946/2005, 400/2015, and 200/2016).

A standardized evaluation questionnaire, used nationally and provided by the Ministry of Finance, was used to verify the stage of implementation for the IMC standards. Comprised of 25 standards in the 2012-2014 period, and of 16 standards in 2015-2017, the questions were grouped under the five following headings: environmental control, performance and risk management, control activities, information and communication, and evaluation and audit. Each standard was built around three components: description of the standard, general requirements and main references. During the studied period, the hospital underwent important stages influencing IMCS: accreditation (Decision no. 68, 2012; no. 1.148, 2008) and quality certification (ISO certification, 2015) as well as internal audit of the hospital pharmacy (Order of the Minister of Public Finance no. 252 of 2004; no. 423, 2004; no. 1702, 2005; Law no. 672, 2002); therefore, these processes were also analyzed.

The analysis dynamically followed the internal control as well as the way the hospital pharmacy has permanently adapted to legislative changes.

#### 3. Results

#### 3.1. The control environment

Thus, the control environment included six standards in 2012-2014 and four standards in 2015-2017 (the two omitted standards were the sensitive functions and delegation) (**Figure 1**). In 2017, the Contractual Staff's Code of Ethics and Deontology (Crişan and Iacob, 2016) was revised. Since then, all pharmacy staff have been hired through competitive admission exams, and the number of personnel has grown steadily. Professional as well as personal skills led to their nomination as certifiably qualified in the aforementioned activity sectors. Each activity is conducted under the coordination of the chief pharmacist and other pharmacists. In addition, each employee takes training courses annually, and their professional performances are evaluated by their hierarchies.

The pharmacy's internal organization plan was implemented due to the exponential growth in collective work. Areas of managerial activity included: tablets, phials, infusion solutions + reagents + consumables, sanitary materials, Emergency Reception Unit and Mobile Emergency, Reanimation and Download Service, sanitary supplies, computers, formulation, goods reception and ambulatory program (from 2017). Activities included reception, storage, release, document/sector archiving and Entrance Reception Notes (computer sector). Each sector was managed by a team of two persons, except for sanitary supplies, supervised by a team of three in 2017. This organization also involved collaboration between sectors. The pharmacy's entire activity is known to the whole staff, but achieving maximum efficiency is the responsibility of each sector team. The specific activities corresponding to each of the control environment's standards are presented in **Figure 2**.

# 3.2. Risk Performance and Management

Risk Performance and Management was comprised of six standards in the 2012-2014 period and four standards from 2015 to 2017, as the "Coordination" "Hypotheses" and "Revaluation" standards were discontinued (**Figure 3**).

In accordance with the hospital's objectives, since 2016 the chief pharmacist been under a management contract, which allowed setting of SMART (Lombardi et al., 2018) individual objectives for each employee. The chief pharmacist is actively involved in the planning of human, material and financial resources in the hospital, and draws up activity plans (for purchase of medicines, sanitary materials and reagents) which are sent for approval to the unit management (**Figure 4**).

# 3.3. Information and Communication

The third criterion analyzed refers to Information and Communication, comprised of four 148 standards in 2012-2014, and three standards in 2015-2017 (Figure 5). 149 Communication of information is also ensured through an integrated information system. The 150 departments have access to a restricted computer module: Pharmacy, Information is available 151 regarding the pharmacy's existing stocks or the shelf life of products; consumption associated 152 with each doctor/section can also be monitored. The hospital's Intranet provides a fast and 153 efficient means of transmitting information throughout the hospital: decisions and 154 155 communiqués (situations related to needs for medicines, sanitary materials and low-flow or soon-to-expire pharmaceuticals (Bungau et al., 2015a,b; Bungau et al., 2018; Tit et al., 2016), 156 drug nomenclatures, updated sanitary materials, Drug Commission decisions, reports of 157 adverse reactions, measures to reduce incidence of infections associated with hospitalized 158 patients, traceability of the medicinal product/sanitary material in the hospital after leaving the 159 160 pharmacy, pharmaceutical waste management (Bungau et al., 2015b), return, and working procedures. Communication from the pharmacy towards the departments is subject to prior 161 162 agreement with the medical director. Printed or hand-written communication contents (written 163 messages from the pharmacy, for example, counselling on adverse drug reactions or drug interactions) (Iancu et al., 2015; Koczorowska-Cerbin et al., 2017), as well as hospital 164 management decisions (materials received by the pharmacy) are archived once the staff has 165 166 read the contents. The pharmacy has its own specific procedures for organizing, storing, using, identifying and 167 168 archiving internal documents (type forms, registers), as well as procedures from outside the institution. Documents are retrieved and sorted by type, according to the hospital/pharmacy 169 nomenclature, being arranged by document type and storage term. All documents are recorded 170 171 in the Entry-Exit Register (**Figure 6**).

#### 3.4. Control activities

173

174 The quality control activities included seven standards in 2012-2014 and three standards in 2015-2017 (**Figure 7**). 175 176 The pharmacy management developed new written procedures for the activities to be carried out (thus increasing the number of procedures over the analyzed period) and the staff was duly 177 informed. The pharmacy's already existing procedures determine the specific ways in which 178 activities or processes were carried out (European Medicines Agency, 2015 a, b, 2017; Order 179 180 no. 75/2010; Tăerel et al., 2014). The manner in which a procedure should be written is presented in a specific set of instructions. Each procedure is individually identified by its own 181 code and edition. Any revised procedure re-edited and the old instructions are archived. 182 With a view to effective implementation, appropriate hierarchical controls are implemented to 183 monitor the activities and operations. The Medicines Committee, the Pharmacovigilance 184 185 Commission, the Sanitary Materials Monitoring Commission, are the levers with which the pharmacy involves itself in the life of the hospital. The Committee for Medicines uses 186 187 documents received from the pharmacy to analyze opportunities to modify specific 188 therapeutic protocols (i.e. rethinking the segment used in analgesia by diminishing metamizole and supplementing the need for nefopam, dexketoprophen and paracetamol for 189 infusions), analyzing drug consumption dynamics and correlating the antibiotic nomenclature 190 191 of the hospital with the acquisition of antibiogram disks. Periodically, the Medicines Committee reviews antibiotic consumption levels, as well as how application dossiers for 192 193 selected antibiotics should be filled in (Daina et al., 2015). The Nomenclature of Medicines reflects an optimal relationship between the different groups 194 of drugs (those defining emergency intervention, new drugs on the Romanian pharmaceutical 195 196 market and those contributing to high-level patient diagnoses). The medical director of the hospital actively collaborates with other hospital personnel for the constant improvement of 197

all activities (modification of existing procedures and implementation of new ones, avoidance 198 of synapses in medicine supplies and sanitary materials, application of work instructions, 199 monitoring of the nomenclatures of medicines and sanitary materials). 200 Decisions delivered in good time by the medical director help to facilitate activities in 201 numerous directions (pharmacy/sectors, pharmacy/purchasing, pharmacy/supply service, 202 pharmacy level, pharmacy/financial accounting service). At the 203 the hospital's pharmacovigilance data sheets are centralized. At the end of each year, the person in charge of 204 205 centralizing data indicates the list of drugs that generate side effects. The information circulates in two directions, not only from the pharmacy sectors towards pharmacy 206 management, but also from management towards the sectors (releases on this topic are 207 downloaded from the National Medicines Agency's website and regularly brought to the 208 attention of the medical staff). 209 210 The hospital work teams, which play an active role in the pharmacy, are: the acquisitions service, the supply service, the financial department, the accounting department, the legal 211 212 department, the human resources department and the IT (computing office) service. These 213 teams work every day. The principle is to avoid a breach in the supply. For this purpose, the chief pharmacist monitors the consumption dynamics, requiring the rapid engagement of 214 colleagues in the supply service whenever required. The above-mentioned sector prioritizes its 215 216 activities and actions so that supply remains continuous. The legal service promptly furnishes information concerning any legal change that has 217 occurred and needs to be known and applied by the pharmacy. 218 Collaboration with the computing office staff takes place on two levels: first, involvement in 219 the proper functioning of computing techniques in the pharmacy (quick and efficient 220 221 reactions); and second, involvement in obtaining information to be subsequently used by the pharmacy (e.g. the number of days of hospitalization corresponding to each section for the 222

calculation of DDD (Defined Daily Doses)/days of hospitalization, consumption of analgesics) (Daina et al., 2017). Activities specific to the control standard are presented in **Figure 8**.

During the period investigated in this study, the auditing and evaluation criterion included 2

#### 3.5. Auditing and Evaluation

- standards (**Figure 9**). The job description of the chief pharmacist includes duties and responsibilities related to exercising control over the activities of the subordinate staff (compliance with hygiene standards in the pharmacy, observance of functional circuits, and observance of professional deontology) (Order no. 1502/2016) (**Figure 10**).

  The internal audit does not apply to the pharmacy, but audit assignments as well as counselling activities are performed in the pharmacy by the Chief Authorizing Officer (Local Authority) and by the management (Law no. 672/2002; 500/2002; Ordinance no. 119/1999). This audit, through the audit mission of December 2016, had as its objectives the organizing and functioning of pharmacy activities, organizing the quantitative-value record of the medicines and medical materials within the pharmacy and determination and implementation in 2017 of the following recommendations:
  - Review of job descriptions and elimination of tasks that overlap for several employees
     or do not belong to specific employees;
- Setting performance indicators by category of personnel;
- Involving the staff of the pharmacy in the process of implementing the IMCS through
   the job description and annual evaluation process;
- Monthly verification, by the Heads of Section, through sampling, of the consistency
   between the amounts of medicinal products that left the pharmacy and those recorded

on the General Clinical Observation Sheet (GCOS) (implemented by codified procedure);

Monthly verification, by the Heads of Section, through sampling, of the consistency between the quantities of medicinal products registered in the GCOS, those recorded in the electronic records at the patient level, and payment statements (implemented by codified procedure).

Developed over time, the IMCS in the Oradea pharmacy is currently associated with eleven standards that have been complied with, three partially fulfilled (partial compliance) standards, and two standards not applicable to the pharmacy (**Table I**).

#### 4. Discussion

This study provides an overview of the development of internal, managerial quality control in a hospital pharmacy. The IMCS implemented in the Oradea County Emergency Clinical Hospital pharmacy is an ongoing process, constantly adapted to the requirements of the hospital. It is not a singular event, but rather a series of dynamic, permanent actions.

The IMCS was set up in the hospital in accordance with the Order of the Ministry of Public Finance no. 946/2005, updated and republished in the Official Gazette of Romania, Part I, no.469/5 July 2011, as subsequently amended and supplemented. Starting in 2012, the IMCS commission was updated by decision of the unit manager; a new president was named and all the heads of sectors and/or departments were included. For the proper organization and functioning of the Monitoring Committee, Coordination and Methodological Guidance of the IMCS Implementation/Development, a Commission Operating Regulation was developed. Sub-committees were set up to implement the IMCS at the hospital compartment level in order to empower the staff to identify specific activities, to develop written (formal and informal) procedures and to identify and analyze the risks associated with the specific activity.

These subcommittees also have the role of permanently pursuing and updating specific work 272 procedures, and developing new written and formal work procedures for specific activities, as 273 well as identifying and monitoring risks to employees. 274 The IMCS development program was updated with the observance of the structure stipulated 275 in art. 2, parts 2 and 3 of the updated OMFP no.946/2005, according to which the objectives, 276 actions, deadlines and responsibilities should be precise. In 2013, each department drafted the 277 list of activities, actions and objectives were defined to meet the SMART requirements 278 279 package. Performance indicators, associated with all objectives and activities in each service of the hospital, were established and defined. Particular attention was paid to the risk register, 280 the appointment of the risk register by the Heads of service, as well as the establishment and 281 Risk Monitoring Record. In March 2013, the IMCS's 282 management of the Monitoring/Coordination and Implementation/Development Guidance Commission requested 283 284 that a list of activities, both procedural and non-procedural, be drawn up at each entity level, and that all procedures be codified, verified by the committee chair and approved by the 285 286 manager. The chief pharmacist plays an important role in implementing the IMCS, but 287 ultimately the responsibility lies with each hospital employee who comes into contact or interacts with the hospital pharmacy. Implicitly, the responsibility and quality of the staff 288 serving the pharmacy is essential. 289 290 Given the current legislation (Decision nos. 1.148, 2008 and 68, 2012), each hospital must be accredited, accreditation being how it is demonstrated that a medical unit endeavors to 291 292 provide medical care services to meet patients' expectations, both in terms of results, and in terms of the conditions under which accreditation is granted. The accreditation assessment 293 visit, ensured by the National Authority for Quality of Health Management (ANMCS) in 294 295 2014, responded to eighteen indicators concerning the pharmacy, of which only one did not apply, the rest being in conformity. Notable among these indicators are: the decision as to the 296

person responsible for the pharmacy database; analysis, carried out by the pharmacy, of antibiotic use in the hospital; reports to be completed by the pharmaceutical service on monthly consumption and needs of medication, sent monthly to the hospital sectors; regular training of employee personnel who handle toxic substances; and procedures concerning the handling of volatile and dangerous substances. The Oraclea pharmacy completed the entire IMCS implementation process within the 2012-2013 period; therefore, in 2012, four codified procedures could be found at the pharmacy, to 303 which the risk register and two more coded procedures were added in 2013. The Ministry of Public Finance Order no. 400/2015, for the approval of the Internal Management Code of Public Entities, annexes 3 and 4.1, restricts the self-evaluation questionnaire to sixteen standards, two of which are not applicable to the Oradea hospital 307 pharmacy. In 2013, the ISO 9001: 2008 Certification "Quality Management Systems" made new improvements to the Quality Management System (QMS) in the hospital and thus to the 310 pharmacy also. During this period, the following were updated: internal hospital regulations, 312 job descriptions; courses were organized to continuously improve the professional performance in the hospital pharmacy. The evolutionary analysis of hospital pharmacy activity over time highlights the increase in complexity, achieved by the diversification of the products being managed (Figure 11). Within the time-span mentioned above, the drug nomenclature diversified, with new ICDs 316 made available to the medical staff. New therapeutic alternatives came to complete the group of antibiotics and analgesics. Medication for the cardiovascular system was supplemented 318 with new representatives annually, and the current parenteral and enteral nutrition meets the 320 requirements of the Intensive Care Unit.

297

298

299

300

301

302

304

305

306

308

309

311

313

314

315

317

319

Initially, the pharmacy managed only gauze, cotton or linen roller bandages, adhesive dressings and elastic roller bandages. Gradually it took over the entire range of sanitary materials and medical devices (except for osteosynthesis materials). Their management required a great effort on the part of the team which had to learn to assimilate them quickly, which represents a special professional challenge. The nomenclature of the sanitary materials and medical devices evolved slowly. The assortments diversified and their qualitative level increased. The medical staff of the hospital is in constant contact with the nominated pharmacy staff managing these goods. Any dissatisfaction or any hidden defect found, is brought to the attention of the pharmacy staff who periodically informs the health director about these issues via the sanitary materials monitoring committee. Information flow is quick and helps to prevent supply shortages as well as to improve the quality of purchased goods. Bringing sanitary materials and medical devices into the pharmacy's everyday activity has definitely contributed to an improvement in the quality of medical services provided to patients. After assuming management of medical supplies and devices, the pharmacy's activity was completed with management of reagents for the hospital's analysis laboratory. This new challenge led to a more regular supply system that is much appreciated. The diversification of the hospital pharmacy activity resulted in optimized managerial strategies of medical, sanitary, chemical waste, etc. This would be achieved only if all efforts are combined to make the disposal and storage of medical waste compatible with the legislative package in force (Bungau et al., 2015a). The hospital pharmacy becomes the main waste producer due to the various assortments along with the continuous increase of the quantities of products necessary for an optimal functioning and observance of all working protocols. Numerous studies have indicated the threats caused by pharmaceutical and sanitary residues (Bungau et al., 2015a b; Bungau et al., 2018; Daina et

321

322

323

324

325

326

327

328

329

330

331

332

333

334

335

336

337

338

339

340

341

342

343

344

345

al., 2017; Moisa et al., 2018; Tit et al., 2016) which are continuously released into the environment because they cannot be effectively removed by the wastewater treatment plants. In recent years, questions have been raised concerning the environmental risks related to these pollutants (Bourioug et al., 2017). For example, these emerging pollutants affect the hormonal system and, very importantly, contribute to antibiotic resistance (Bungau et al., 2018). Therefore, the wise management of the waste from the mentioned categories, as well as the implementation of a managerial system would weaken the environmental pollution and the prevalence of infections resulting most often from incorrect or deficient manipulation of hazardous wastes.

The involvement of the pharmacy through the Medicines Committee by analyzing the possibilities of modifying and optimizing specific therapeutic protocols along with analyzing drug consumption dynamics and correlating the antibiotic nomenclature of the hospital with the acquisition of antibiogram disks (Moisa et al., 2018), have led to a visible improvement in the management of drug or necessary pharmaceutical / sanitary products procurement. Moreover, a significant improvement was observed as to antibiotic use, on the one hand, and the corresponding management of existing drugs on the other hand. As a consequence no increase in the amount of medicinal waste has been observed following the diversification of the nomenclature and the change in the therapeutic protocols during the studied period.

The Pharmacy Management Team must propose the ways and solutions to reduce the amount of hazardous waste by implementing specific measures: 1) the reduction of waste from the source by purchasing mainly the materials which generate small quantities of waste; separating the resulting waste directly from the generating source by collecting them in specific categories; 2) providing training and continued professional development of staff

employed in the pharmacy or hospital who are directly involved in waste management; 3)

waste disposal in the collection and disposal of waste; 4) identifying the risks and proper 370 measures required to protect the personnel; 5) informing patients of the possible dangers 371 generated by the mismanagement of medical/sanitary waste and 6) the final disposal of 372 pharmaceutical wastes (known as the last stage of a pharmaceutical product) (Bungau et al, 373 2015a) should be carried out under appropriate conditions, only by authorized operators, so as 374 to ensure a minimum impact on the environmental health. 375 Another advantage to this new organization was the constitution of an active professional 376 377 team consisting of a physician, a laboratory physician, an epidemiologist and a pharmacist. The result of this cooperation led to a greater coherency between the pharmacy's antibiogram 378 disc nomenclature and that of the hospital's own nomenclature, thus leading to an 379 improvement in the hospital's antibiotic therapy strategy. The examples mentioned (related 380 only to hospital funding) clearly show that the implementation of internal quality management 381 382 was and remains highly necessary. Over time, the pharmacy managed to put the IMCS into practice and has currently complied 383 384 with 11 standards, and partially complied with other three standards, while two standards do 385 not apply to the Oradea hospital pharmacy. This situation was possible due to the implication and involvement of all the employees of the pharmacy, under the direction of the chief 386 pharmacist, but also thanks to the coordination by hospital management of the quality 387 388 management process. The best practice model demonstrated by the pharmacy in the development of the IMCS, with the involvement of the chief pharmacist, was adopted by all 389 390 sectors, services and departments in the hospital.

391

392

393

394

#### Conclusion

The existence of a specific organizational structure in the Oradea hospital pharmacy, adapted to the hospital's requirements, allows for clear assignments and responsibilities for each

employee, but also for the proper planning of the activity. Systemic and operational procedures, whether newly developed or revised, allow work to be properly conducted in the hospital and in its pharmacy. Collaboration between the pharmacy and hospital departments and services is essential, while at the same time the pharmacy's cooperation concerning human resources, financial, legal, procurement, IT and administrative services is also crucial. Specialized committees working in the hospital actively oversee activities as they are carried out, but they also modify, supplement and take corrective or preventive measures when required. The following aspects continue to be updated annually: work procedures, risk register, job descriptions and staff training.

## Acknowledgement

We express our appreciation to the editor, Dr. Damià Barceló, and to the anonymous reviewers for helping to improve our paper.

- **Conflicts of interest:** The authors declare no conflict of interest.
- **Contribution**: All authors had an equal contribution to this original article.

412	References						
413	Badulescu D, Bungau C, Badulescu A. Sustainable development through sustainable						
414	businesses. An empirical research among master students. J Environ Prot Ecol 2015;						
415	16(3):1101-1108.						
416	Bourioug M., Mazzitelli J.Y., Marty P., Budzinski H., Aleya L., Bonnafé E., Geret F. (2017).						
417	Assessment of Lemna minor (duckweed) and Corbicula fluminea (freshwater clam) as						
418	potential indicators of contaminated aquatic ecosystems: responses to presence of						
419	psychoactive drug mixtures. Environmental Science and Pollution Research.						
420	25:11192–11204.						
421	Bungau S, Bungau C, Tit, DM. Studies about last stage of product lifecycle management for a						
422	pharmaceutical product. J Environ Prot Ecol 2015a; 16(1):56-62.						
423	Bungau S, Suciu R, Bumbu A, Cioca G, Tit DM. Study on hospital waste management in						
424	medical rehabilitation clinical hospital, Baile Felix. J Environ Prot Ecol 2015b;						
425	16(3):980-987.						
426	Bungau S, Tit DM, Fodor K, Cioca G, Agop M, Iovan C, Nistor Cseppento DC, Bumbu A,						
427	Bustea C. Aspects regarding the pharmaceutical waste management in Romania.						
428	Sustainability 2018; 10(8):2788. doi:10.3390/su10082788.						
429	Ciuhureanu AT. Internal control and auditing - a necessity for responsible reporting and						
430	managerial usefulness of accounting information. Audit financiar XIV 2016;						
431	12(144):1349-1358.						
432	Crișan O, Iacob S. Codes of ethics of health professionals - a comparative analysis. Farmacia						
433	2016; 64(4):625-632.						
434	Daina L, Carp G, Neamțu C, Venter A, Armean A. Antibiotherapy in hospital – between the						

data L, Carp G, Neamţu C, Venter A, Armean A. Antibiotherapy în hospital – between the efficiency and quality of medical services. The role of the Drug Committee. Farmacia 2015; 63(3):407-412.

437	Daina L, Cioara F, Zaha D, Venter A, Daina CM, Bonta M. Developing internal/managerial							
438	inspections within the orthopaedics and traumatology wards. Osteoporos Int 2018							
439	29(1): P560.							
440	Daina LG, Neamțu C, Daina CM. Evaluating the analgesic consumption in a clinical							
441	emergency hospital. Farmacia 2017; 65(3):360-367.							
442	Decision no. 1.148 of September 18, 2008 (republished) regarding the composition,							
443	attributions and the way of organization and functioning of the National Accreditatio							
444	Commission of Hospitals, Romania's Official Gazette I no. 689 of 2008.							
445	Decision no. 68 of 1 February 2012 for amending and completing the Government Decision							
446	no. 1.148 / 2008 regarding the composition, attributions and the way of organization							
447	and functioning of the National Accreditation Commission of Hospitals, Romania's							
448	Official Gazette I no. 77 of 2012.							
449	Donabedian A, 2003. An Introduction to Quality Assurance in Health Care. Oxford University							
450	Press, Oxford.							
451	European Medicines Agency, Good practice guide on recording, coding, reporting and							
452	assessment of medication errors. 2015,							
453	https://www.ema.europa.eu/documents/regulatory-procedural-guideline/good-practice-							
454	guide-recording-coding-reporting-assessment-medication-errors_en.pdf /(accessed 10							
455	December 2017).							
456	European Medicines Agency, Good practice guide on risk minimisation and prevention of							
457	medication errors. 2015, https://www.ema.europa.eu/documents/regulatory-							
458	procedural-guideline/draft-good-practice-guide-risk-minimisation-prevention-							
459	medication-errors_en.pdf (accessed 12 December 2017).							
460	European Medicines Agency, Guideline on good pharmacovigilance practices (GVP), Modul							
461	V - Risk management systems (Rev1). 2017,							

462	https://www.ema.europa.eu/documents/scientific-guideline/guideline-good-
463	pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf/
464	(accessed 10 December 2017).
465	Floștoiu S, Internal/managerial control - subject of the public internal audit, International
466	Conference of Scientific Paper AFASES, 2012, Brasov, 24-26 May.
467	Furtunescu FL, Mincă DG, 2010. Managementul serviciilor de sănătate - Abordare prin
468	proiecte (The management of health services - Approach through projects), 2nd
469	edition revised and completed, "Carol Davila" University Publishing House,
470	Bucharest.
471	Iancu M, Bucșa C, Fărcaș A, Leucuța D, Dincu A, Mogoșan C, Dumitrașcu DL, Bojiță M.
472	Patient's counselling and management of adverse drug reactions and drug interactions
473	in the community pharmacy. Farmacia, 2015; 63(1): 80-85.
474	ISO certification: SR EN ISO 9001: 2015 Quality management systems. Requirements
475	Koczorowska-Cerbin M, Waszyk-Nowaczyk M, Odor K, Michalak M, Piotrowska S,
476	Matschay A, Simon M, Majchrzycki M. Pharmaceutical care as a chance of improving
477	health care in areas with an average level of urbanization. Farmacia 2017; 65(1):159-
478	166.
479	Law no. 500/2002 on public finances. Romania's Official Gazette no. 597 of 2002.
480	Law no. 672 of 2002 regarding the public internal audit. Romania's Official Gazette no. 953
481	of 2002.
482	Law no. 672/2002 on internal public audit. Romania's Official Gazette no. 953 of 2002.
483	Lombardi, N., Wei, L., Ghaleb, M., Pasut, E., Leschiutta, S., Rossi, P., Troncon, M. G., 2018.
484	Evaluation of the implementation of a clinical pharmacy service on an acute internal
485	medicine ward in Italy. BMC Health Serv Res., 18(1):259, doi:10.1186/s12913-018-
486	2988-y.

487	Ministry of Health, Order no. 75/2010 approving Rules for good pharmacy practice
488	Romania's Official Gazette I no. 91 of 2010.
489	Moisa, C, Vlad, AM, Teusdea, A, Cadar, O, Hoaghia, MA, Stan, RL, Taerel, A, Jurca, C
490	Vicas, LG. Randomized evaluation of the consumption of antibiotics in community
491	pharmacies. Farmacia, 2018; 66(6):1081-1090.
492	Mossialos E, Dixon A, Figueras J, Kutzin J, 2002. Funding health care: options for Europe
493	European Observatory on Health Systems and Policies Series, Open University Press
494	Bukingham, Philadelphia.
495	Order no. 1502/2016 for the approval of the composition and attributions of the Ethics
496	Council operating within public hospitals. Romania's Official Gazette no. 1 of 2017.
497	Order no. 200/2016 (Annex 2) amending and supplementing Order no. 400/2015 for the
498	approval of the Code of internal / managerial control of public entities art. 4 paragraph
499	(2). Romania's Official Gazette I no. 275 of 2016.
500	Order no. 201/2016 for the approval of Methodological Norms on Coordination
501	Methodological Guidance and Supervision of the Status of Implementation and
502	Development of the Managerial Internal Control System in Public Entities. Romania's
503	Official Gazette I no. 276 of 2016.
504	Order of the Minister of Public Finance no. 1702 of November 14, 2005 - Norms regarding
505	the organization and exercise of the counselling activity performed by the auditors
506	within public entities. Romania's Official Gazette I no. 154 of 2006.
507	Order of the Minister of Public Finance no. 252 of 2004 for the approval of the Code
508	regarding the ethical behaviour of the internal auditor. Romania's Official Gazette no
509	128 of 2004.
510	Order of the Minister of Public Finance no. 400/2015 for the approval of the Internal Control
511	Code, including internal management / control standards in public entities and for the

512	development of managerial control systems. Romania's Official Gazette no. 444 of
513	2015.
514	Order of the Minister of Public Finance no. 423 of March 15, 2004 regarding the amendment
515	of and the additions to The General Norms regarding the exercise of public internal
516	audit activities. Romania's Official Gazette no. 245 of 2004.
517	Order of the Ministry of Public Finances no. 946/2005 approving the Internal Control Code,
518	comprising the internal management/control standards at the public entities and for the
519	development of the managerial control systems. Romania's Official Gazette no. 675 of
520	2005, amended and completed through Order of the Minister of Public Finance no.
521	1389 of 2006. Romania's Official Gazette no.771 of 2006.
522	Ordinance no. 119/1999 on internal audit and preventive financial control. Romania's Official
523	Gazette no. 430 of 1999.
524	Tăerel AE, Soroceanu V, Rais C, Stancu E, Study of quality standards application in
525	Bucharest community pharmacies. Farmacia, 2014; 62(6):1082-1088.
526	Tit DM, Bungau S, Nistor Cseppento C, Copolovici DM, Buhas C. Disposal of unused
527	medicines resulting from home treatment in Romania. J Environ Prot Ecol 2016;
528	17(4):1425-1433.
529	Vera A, Kuntz L. Finance-oriented vs. operations-oriented management control in public
530	hospitals. J Hosp Adm 2014; 3(6):190-204.

531	List of figures
532	Figure 1. Control environment standards, 2012-2017
533	Figure 2. Control environment standards and activities in the hospital pharmacy
534	Figure 3. Performance and risk management standards, 2012-2017
535	Figure 4. Performance and risk management standards and activities in the hospital pharmacy
536	Figure 5. Information and communication standards, 2012-2017
537	Figure 6. Information and communication standards and activities in the hospital pharmacy
538	Figure 7. Control activities and standards, 2012-2017
539	Figure 8. Control activities, standards and strategies in the hospital pharmacy
540	Figure 9. Auditing and evaluation standards, 2012-2017
541	Figure 10. Auditing and evaluation standards and activities in the hospital pharmacy
542	Figure 11. Evolution of hospital pharmacy activity over time

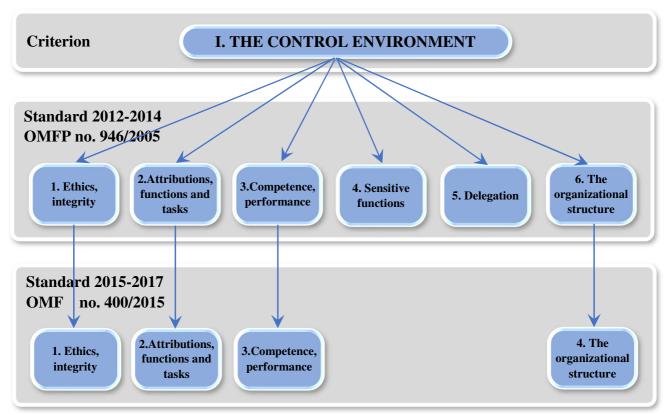


Figure 1.

#### **ETHICS AND INTEGRITY**

- Analyzing the way of promoting ethical values
- Revising the Contract Staff's Code of Ethics and Deontology
- Council monitoring ethics

# ATTRIBUTIONS, FUNCTIONS, TASKS

- The organizational structure
- The organigramme
- Internal regulations
- Regulations for organization and functioning
- The organizational chart
- Annual update of job descriptions
- Redistribution of work tasks
- Performance indicators for staff categories

# THE CONTROL ENVIRONMENT

# **COMPETENCE, PERFORMANCE**

- Contest for vacant jobs
- Knowledge and skills required for each job
- Distribution of tasks according to professional skills
- Nomination as holder for each activity sector
- Training plan
- Employee training including:
  - o holidays for vocational training
  - medical education coursed, paid by the hospital
- Annual evaluation of professional performance

# THE ORGANIZATIONAL STRUCTURE

- Organigramme
- Regulation for organization and functioning
- Internal regulation
- Internal organizational plan
- Definition of activity sectors, with nominated staff
- The delegation procedure
- Ensuring the informational flux and of the pharmacy circuits

#### SENSITIVE FUNCTIONS

• List of sensitive functions (administrators)

#### **DELEGATION**

- Internal regulations
- Decisions
- Form for changing/disposal of the on-call doctor, replacing staff between shifts

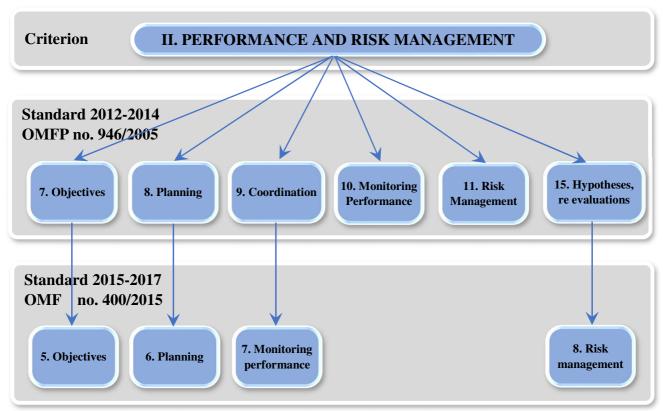


Figure 3.

#### **OBJECTIVES**

- The pharmacy's objectives are defined
- Complementary objectives are defined, in line with the hospital regulations (RI, ROF)
- The chief pharmacist has an administration contract
- The SMART objectives are set for each employee

#### **PLANNING**

- The Chief Pharmacist actively participates to the human, material and financial resources planning activity
- Planning days off and holidays
- Planning activity in terms of activity sectors
- Previous discussions for the coordination of activities
- The chief pharmacist makes the purchase plan for medicines, sanitary materials, reagents
- The Chief Pharmacist proposes hospital management to supplement or quantify pharmaceutical products in proportion to their hospital turnover
- Collaboration protocol between pharmacy and hospital sections

# PERFORMANCE AND RISK

#### MONITORING PERFORMANCE

- The Chief Pharmacist monitors the individual work performance of each employee through the Performance Indicators assumed in the Pharmacy Management Contract
- Individual self-evaluation is being implemented
- During the monthly meetings of the Medical Council, medical and economicfinancial indicators per department and medical service are analysed

### **RISK MANAGEMENT**

- Organigramme
- Regulation for organization and functioning
- Internal regulation
- Internal organizational plan
- Definition of activity sectors, with nominated staff
- The delegation procedure
- Ensuring the informational flux and of the pharmacy circuits

#### COORDINATION

- Executive board decisions
- Decisions
- Work meetings
- Internal notes
- Communications
- Protocols for collaboration among sections and departments
- Collaboration protocol with external structures

#### HYPOTHESES, REEVALUATIONS

- ROF
- Job descriptions
- Administration Contract for the Chief pharmacist
- Annual performance assessment

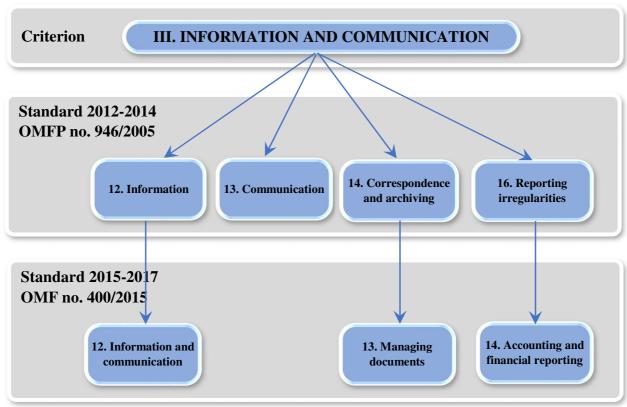


Figure 5.

# INFORMATION AND COMMUNICATION

- Integrated computer system
- Information-technology module in the pharmacy
- Restricted information technology module for sections
- Intranet
- Top-down written communication: Management -Pharmacy (Decisions, Internal Notes, Opinions, Information, Communicates)
- Bottom-up written communication: Pharmacy Management (periodic information, reports)
- Written communication: Pharmacy Sections
- Verbal phone communication

#### MANAGING THE DOCUMENTS

- Specific procedures for organizing, storing, using, identifying and archiving internal documents (forms, registers) and documents from outside the organization.
- Documents conforming to the hospital / pharmacy nomenclature

# INFORMATION AND COMMUNICATION

#### ACCOUNTING AND FINANCIAL REPORTING

• does not apply in the pharmacy

Figure 6.

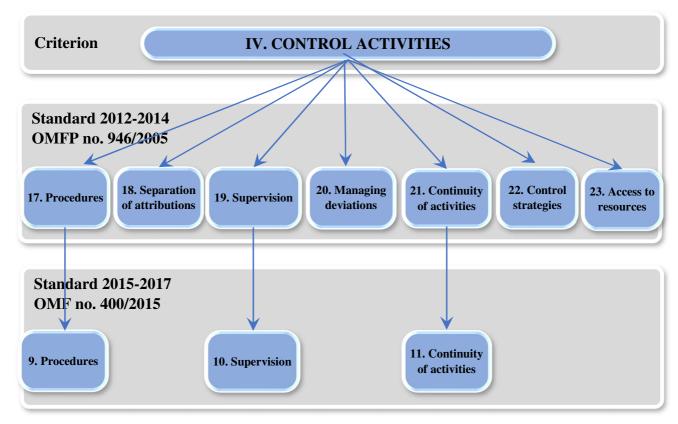


Figure 7.

#### **PROCEDURES**

- New procedures elaborated
- Old procedures revised
- Procedures archiving
- Decisions, Job description

#### **CONTROL ACTIVITIES**

#### **SUPERVISION**

- The Medicines Committee
- Pharmacovigilance Commission
- Pharmacovigilance files
- Centralizer of drugs involved in generating side effects
- Commission for Monitoring Sanitary materials
- Implementation of new procedures
- Implementation of working instructions
- Revision of procedures and working protocols
- Monitoring the medicines nomenclature

# THE CONTINUITY OF ACTIVITY

- Identifying situations that generate interruptions of activity
- Activity continuity measures: attendance schedule, vacation planning, equipment maintenance contracts, work safety, civil protection and emergency situations, fire prevention and extinguishing fire
- Hospital working teams with an active role of pharmacy: procurement, procurement, financial, accounting, legal, human resources, IT, computing office
- Implementing the hospital's financial policy by clearly establishing the funds allocated to medicines, medical devices, sizing of monthly orders
- Communications / Information from the Legal Service on any legislative change that has occurred
- Collaborating with the staff of the computing office for the proper functioning of pharmacy computing and generating various reports

#### SEPARATION OF ATTRIBUTIONS

- Job description
- Decisions

#### **DEALING WITH DEVIATIONS**

- Council of ethics
- General clinic observation sheet
- Committees for deviation from discipline

# **CONTROL STRATEGIES**

- Self-control
- Control by the Chief Pharmacist
- Inventory

# ACCESS TO RESOURCES

- Reports
- Decisions, Internal notes
- The information system
- ROF, RI

Figure 8.

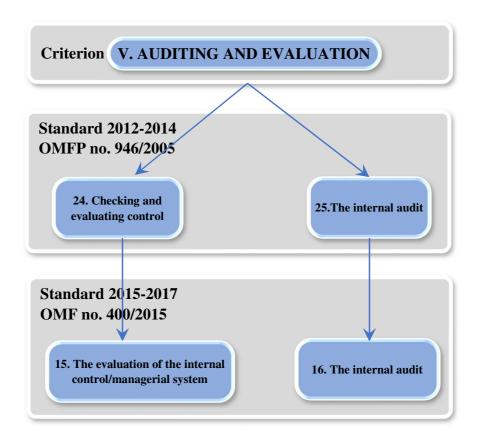


Figure 9.

# EVALUATION OF THE INTERNAL/ MANAGERIAL CONTROL SYSTEM

The job description of the Chief Pharmacist includes attributions and responsibilities relating to exercising control on the activities of the subordinated staff

- Questionnaires on employees' satisfaction
- Questionnaire on the staff's satisfaction
- Observance of functional circuits
- Observance of hygiene standards in the hospital
- Observance of ethics codes
- Observance of hospital regulations

# THE INTERNAL AUDIT

• Not applicable in pharmacy

## **AUDITING AND EVALUATION**

# **CONTROL CHECKING AND EVALUATION**

- The Chief Pharmacist performs unannounced controls with various goals
- The Chief Pharmacist's job description includes duties and responsibilities related to exercising control over the activities of the subordinate staff
- Employees have job descriptions that include control-related responsibilities at the work-level

Figure 10.

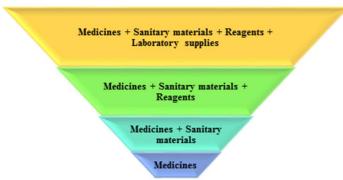
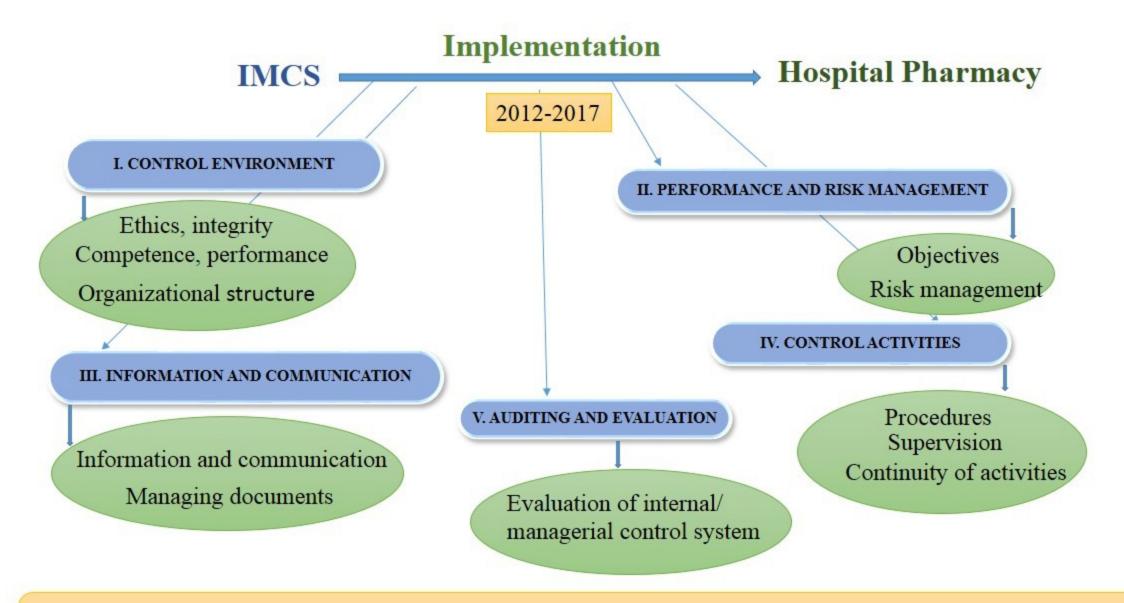


Figure 11

**Table I.** Implementation of SCMI standards in Oradea hospital pharmacy during 2012-2017

Standard	JCIVII	I/PI/NI	us III O	radea hospital pharmacy during 2012-2017  Standard I/PI/NI			
Year	2012	2013	2014	Year	2015	2016	2017
				- ***-			
Order of the Minister of Public Finance no. 946/2005 Order of the Minister of Finance no. 400/2015  I. CONTROL ENVIRONMENT							
Standard 1 Ethics and							
Standard 1. Ethics, integrity	I	I	I	integrity	I	I	I
Standard 2. Attributions, functions, tasks	PI	PI	PI	Standard 2. Attributions, functions, tasks	PI	PI	PI
Standard 3. Competence, performance	I	I	I	Standard 3. Competence, performance	I	I	I
Standard 4. Sensitive functions		NA		ı			
Standard 5. Delegation	I	I	I	1			
Standard 6. The organizational structure	I	I	I	Standard 4. The organizational structure	I	I	I
II. I	PERFOR	RMANCI	E AND F	RISK MANAGEMENT			
Standard 7. Objectives	I	I	I	Standard 5. Objectives	I	I	I
Standard 8. Planning	PI	PI	PI	Standard 6. Planning	PI	PI	PI
Standard 9. Coordination	I	I	I	-	•	•	
Standard 10. Monitoring performance	PI	PI	PI	Standard 7. Monitoring performance	PI	PI	PI
Standard 11. Risk management	I	I	I	Standard 8. Risk management	I	I	I
Standard 15. Hypotheses, re-evaluations	NI	PI	I	-			
III	. INFOR	RMATIO	N AND	COMMUNICATION			
Standard 12. Information	I	I	I	Standard 12. Information and communication	I	I	I
Standard13. Communication	I	I	I	1			
Standard 14. Correspondence and archiving	PI	PI	I	Standard 13. Managing documents	I	I	I
Standard 16. Signaling irregularities	PI	PI	PI	Standard 14. Accounting and financial reporting		NA	
	Γ	V. CONT	ROL A	CTIVITIES			
Standard 17. Procedures	I	I	I	Standard 9. Procedures	I	I	I
Standard 18. Separating attributions	I	I	I	1			
Standard 19. Supervision	I	I	I	Standard 10. Supervision	I	I	I
Standard 20. Managing deviance	PI	PI	PI				
Standard 21. Continuity of activities	PI	PI	PI	Standard 11. Continuity of activities	I	I	I
Standard 22. Control strategies	I	I	I	-			
Standard 23. Access to resources I I I I -							
V. AUDIT AND EVALUATION							
Standard 24. Control checking and evaluation	NI	NI	PI	Standard 15. Evaluation of the internal/managerial control system	PI	I	I
Standard 25. Internal audit		NA	l	Standard 16. Internal audit		NA	
	·				·		

I: implemented; PI: partially implemented; NI: not implemented; NA: not applicable.



IMCS has 11 annually updated compliance standards as follows: work procedures, risk register, job descriptions, staff training.