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MANAGEMENT OF EXTERNAL CONTROL IN LABORATORIES OF MEDICAL ANALYSIS

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CONTENTS

INTRODUCTION

In various regulations (standards, laws), external control has been given different names: competence testing schemes, competence testing schemes, EQA, Proficiency Testing (PT) [7].
OMS 2071 of 2007 on MS Notification of Proficiency Testing Providers establishes similar terms for competence testing schemes: external quality control scheme, external quality assessment scheme [21] and SR EN ISO CEI 17043 : 2010 "Conformity Assessment .General Criteria for Competence Testing" defines the competence test, the interlaboratory comparison - the skill test scheme but also uses the terms "interlaboratory comparison schemes" and the "external quality evaluation program - EQA" with reference to medical laboratories [26].

Proficiency Testing (PT) is also a common term or "external quality control" especially used to describe skill testing schemes within the clinical / medical sector [7].
Other terms used in clinical laboratory practice are: external quality assessment scheme, external quality control scheme.

1. DEFINITION OF EXTERNAL CONTROL OF QUALITY

By control according to the explanatory dictionary of the Romanian language we understand "permanent or continuous verification of an activity, situations, etc., in order to follow its course and to take improvement measures" [10].

In the standards and legislation applicable to the medical analysis laboratory there are several definitions of external quality control;
SR EN ISO CEI 17043: 2010 Conformity assessment General requirements for competence tests;
- Organizing, conducting and evaluating measurements or attempts on identical or similar objects by two or more laboratories under predetermined conditions [26].

OMS 2071/2008 Interlaboratory comparison
- Organizing, conducting and evaluating the results of analyzing, measuring or examining the same samples or similar samples by several laboratories in accordance with predetermined conditions [21].

SR EN ISO CEI 17043: 2010 Competence test
- Evaluating a participant's performance through interlaboratory comparisons against predetermined criteria [26].

OMS 2071/2008 Competence Test Scheme
- Interlaboratory comparison method, designed and developed to evaluate laboratory performance in a specific area of analysis, measurement, or examination [21].

2. STANDARDS WHICH REQUEST AND BE USED IN IMPLEMENTING INTERNAL AND EXTERNAL QUALITY CONTROL

The standard according to dex is "Standard or set of rules governing quality, characteristics, shape,

etc. of a product; document in which these rules are recorded "[10].

Standards are developed by the International Organization for Standardization (ISO), a worldwide federation of national standardization bodies (ISO member committees). The development of international standards is entrusted to ISO technical committees. Each member interest committee on a topic for which a Technical Committee has been created has the right to be part of that committee. International, governmental and non-governmental organizations that have links with ISO also participate in papers [2, 7].

ISO collaborates closely with the International Electrotechnical Commission (IEC) for standardization in the electrotechnical field.

International standards are developed according to the rules of the ISO / IEC Directives, Part Two.

The main task of the technical committees is the development of international standards.

Draft international standards adopted by the Technical Committees are subject to the vote of the member committees. Their publication as an international standard requires the approval of at least 75% of the member committees that voted [2].

The main standards used by medical laboratories are:

- SR ISO / IEC Guide 99 International Methodology Vocabulary. Fundamental and general concepts and associate terminals (VIM) [24];
- EN ISO 15189: 2013 [25]
- SR EN ISO CEI 17043: 2010 [26].

3. QUALITY OF ACTIVITY OF MEDICAL LABORATORIES

The quality assurance of the services they provide has to be a permanent concern of the medical laboratories.

Quality control is represented by a complex system of administrative measures, working procedures, measuring techniques / observing different analytical parameters, resulting in a higher probability that the analytical result will be valid [9].

Standard SR EN ISO 15189 "Medical Laboratories. Requirements for Quality and Competence: in Section 5.6 "Quality Assurance Examination" states that "the laboratory must ensure the quality of the examinations" by performing them under defined conditions. "Appropriate pre-post and post-review processes need to be implemented. The lab should not invent any results "[25]. For good laboratory performance, the errors that may occur during the activity and the measures required to limit them should be known. Types of errors leading to quality control failures in the medical analysis lab:

- the release of results of patients with mistakes of transcription of the correct patient name, correct patient results due either to incorrectly used or unadjusted measuring units, or to mistakes in transcribing the figures, the release of results of a patient to another patient .
- the use of non-updated or non-updated biological reference intervals with the laboratory's own measurement or examination instruments or methods, or not specified on the analysis bulletin.
- The lack of quality control by the medical laboratory staff (internal and external)
- Non-analysis by the medical laboratory staff of the results obtained in performing the internal and external quality control or non-implementation of the corrective measures that are imposed (in time or not at all).
- Use by the medical laboratory of reagents with reduced sensitivity and specificity;
- failure by the medical laboratory to perform the calibration of the equipment according to the manufacturer's recommendations;
- non-maintenance of equipment according to manufacturers' recommendations [3,4];

The way in which the medical laboratory can prevent, detect and correct the release of mistaken results to the patient is represented by participation in an interlaboratory comparison program (s) (such as an external quality assessment program or aptitude test program) (s) for examining and interpreting the examination results "- requirement 5.6.3. Interlaboratory comparisons of the standard SR EN ISO 15189 [6,25].

Participation in competence testing schemes provides medical laboratories with a means to meet the requirement 5.6.4 "Examination Comparability" of the standard SR EN ISO 15189: 2013 "Medical Laboratories. Requirements for Quality and Competence "to assess the comparability of patient outcomes by medical laboratories participating in external quality control irrespective of equipment endowment, qualification and number of employees, labs, calibrators, internal controls or measurement and examination methods used by medical laboratories [2,11,25].

4. THE LABORATORY CHECK OF THE EXTERNAL QUALITY CONTROL

The Head of the Medical Analysis Laboratory must request "External Quality Assessment ...". to institutions providing external quality evaluation services, notified to the Ministry of Public Health for this area of activity "according to par. 2 art.24 of WHO 1301 of 2007. [12,20]

The Head of the Medical Analysis Laboratory together with the specialists must establish the requirements for the selection of the external quality control provider, taking into account the legislation, Standards, Standards, Policies of the bodies and institutions with responsibility in the respective field, Ministry of Health, National Accreditation Body (RENAR) National House of Health Insurance (CNAS) [16,17,20] .

Providers of competence tests for medical analysis laboratories must meet the legal requirements provided by the Ministry of Health according to Order no. 2071 of 16 December 2008 approving the procedure for notification of competence testing schemes for medical analysis laboratories:

- be notified by the Ministry of Health;
- to have "a medical and scientific advisory committee, made up of professionals with technical knowledge and experience in the field where the scheme" lit. e);
- to be able to provide the Ministry of Public Health, the National Health Insurance House and the county health insurance houses with "information regarding the results of the global statistical evaluations of the participating laboratories in Romania" [23].

Medical analysis laboratories that are accredited or wish to obtain accreditation from the National Accreditation Body (RENAR) according to the SR EN ISO 15189: 2013 standard. Laboratories Requirements for quality and competence must meet the requirement of this standard [29].

Interlaboratory comparison programs "that meet the relevant requirements of ISO CEI 17043" are provided by international quality or international quality control organizers who have implemented ISO 17043: 2010, are accredited by the national accreditation body in the country where the organizer of the external quality control is based - according to the standard SR EN ISO CEI 17043: 2010 "Conformity assessment General requirements for the competence tests [23].

The Government of Romania through the Ministry of Health establishes annually, together with the National Health Insurance House, through the Joint Order of the Ministry of Health and the President of CNAS, the Framework Contract on the Conditions of Health Care Provision within the Social Health Insurance System and the Methodological Rules for Application of the Framework Contract on the conditions for providing healthcare within the health insurance system for the respective year where the compulsory periodicity of the participation of the medical laboratories to the external quality control for the medical laboratories wishing to enter into a contractual relationship with CNAS for the settlement of the medical analyzes from the fund of the social health insurance system [14,15,17,18].

CNAS reimburses from the insured money in the social health insurance system the minimum number of 4 annual participations in the external quality control, but the laboratory may decide a higher number of parties to the external quality control depending on the medical laboratory field, the offer of the external control organizers of quality and other criteria established by the laboratory [17].

The number of external quality control participations is relevant to increasing the quality of medical analysis results for patients only if the performance reports of the medical laboratory are submitted by the organizer in a timely manner for the laboratory's specialists to analyze them and, until the next participation, in order to eliminate the causes that led to the appearance of the non-conformities due to the non-compliance with the external quality control against the criteria and procedures of the medical laboratory according to the requirement 5.36.4. of the international standard SR EN ISO 15189: 2013 [2,25].

5. STATISTICS USED FOR QUANTITATIVE RESULTS

The statistical data obtained at the external quality control are useful only together with and closely related to the medical service offered in the medical laboratories and represented by the results of the medical analyzes of the patients being statistical calculations based on the reported values declassifying the medical laboratories to the measurement of the subject submitted to the competence test in similar to how patient analyzes perform (using the same equipment, calibrators, internal controls, specialist, supplies, etc.) [5,6].

According to B.3.1.3 of the SR EN ISO CEI 17043: 2013 standard for the evaluation of the performances of the medical laboratories participating in the external quality control "The statistics currently used for quantitative results" are:

a) Difference D is calculated using equation (B.1):

$D = (x - X)$ where x is the result of the participant and X is the assigned value.

b) Difference in percent, D%, is calculated using the equation (B.2):

$D\% = (x-X) / X \times 100$

c) Z values are calculated using equation (B.3):

$Z = (x-X) / \sigma$ where, σ is the standard deviation for competence assessment [1]

Performance evaluation reports of the participants in the quantitative data competence test rounds provided by a national external quality control provider contain a summary table with the following information:

M - the measurement subjected to the round of attempts to cope;

U.M. - unit of measurement;

E - measurement equipment reported to the proficiency testing provider;

R.R (xi) - the result related to participation in the round of competence tests;

X * - assigned value (consensus values from participation in the round of competency tests);

CV - coefficient of variation;

σ / S * - robust standard deviation

Um (u (x *) - the standard uncertainty of the assigned value;

D - difference (bias, estimated deviation of the participant in the skill test scheme);

D% - percentage difference (percentage bias);
Z - Z score;
DOM. -The domain of the acceptable results (the range of values between the robust average of the results reported by the participant after the OIC measurement - consecutive values with a set of data - minus 2DS (S *) and plus 2DS (S *) for identical or equivalent equipments technically if there are at least 3 different values reported for participants in the Competence Scheme Round) [1,2].

6. ASSESSING THE PERFORMANCE OF MEDICAL LABORATORIES

The decisive factor for providing quality medical services is the performance of medical laboratories.

SR EN ISO 15189 specifies in section 5.6.3.4. Laboratory Performance Assessment as: Performance in interlaboratory comparisons needs to be reviewed and discussed with relevant staff. When the predefined performance criteria are not met, staff must participate in the implementation and registration of corrective actions. The effectiveness of corrective actions should be monitored and in section 5.6.4. Comparability of Examination Results: "There must be a defined means of comparing the procedures, equipment and methods used and establishing comparability of patient sample outcomes across the appropriate clinical range." [25].

"Evaluation of performance of medical laboratories for specific measurements" and "establishing the effectiveness and comparability of measurement methods used by medical laboratories" are two of the purposes for interlaboratory comparisons defined by SR EN ISO CEI 17043: 2010 " of competence "[26].

Competency testing providers "that substantially meet the relevant requirements of ISO / IEC 17043: 2010 compute" performance statistics "as described in SR EN ISO CEI 17043: 2010 and ISO13528: 2005 (E) [2].

The evaluation of the performances of the participating medical laboratories is done through interlaboratory comparisons.

Interlaboratory comparison is defined by the SR EN ISO CEI 17043: 2010 standard as "the organization, performance and evaluation of measurements or tests on identical or similar objects by two or more laboratories under predetermined conditions" [26].

According to the standard SR EN ISO CEI 17043: 2010, the performance assessment of medical laboratories for quantitative data analysis is usually done through z score value:
a. $| z | \leq 2.0$ shows "satisfactory" performance and does not generate any signal;
b. $2.0 <| z | <3.0$ shows the "questionable" performance and generates an alarm signal;
c. $| z | \geq 3.0$ shows "unsatisfactory" performance and generates a signal of action.

According to the SR EN ISO CEI 7043: 2010 standard, the performance assessment of medical laboratories for analyzes with qualitative and semiquantitative data is done "usually by comparing the participant's result with the assigned value. If they are the same, performance is acceptable. If they are not the same, then the reasoning of an expert is necessary to determine if the result suits his intentional use "[2,4].

7. ACCREDITATION OF MEDICAL LABORATORIES IN ROMANIA

Accreditation according to SR EN ISO 15189, definitions 3.1 is "the procedure by which an authorized body formally recognizes that an organization is competent to carry out specific tasks" [8,25].

There is only one national accreditation body in each country. Applicants for accreditation according to a certain standard may apply to another accreditation body from a country other than that where the applicant is based only if the national body does not provide the service - according to Regulation (EC) No. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation and market surveillance relating to the marketing of products [2,27].

7.1. International recognition of accreditation

International recognition agreements facilitate access to the export market. Accreditation bodies may become signatories to the following types of agreements:
- at the European level of the EA-MLA (Multilateral Agreement)
- international IAF-MLA, respectively, ILAC-MRA (Multilateral Reggnition Arrangement) [2,27,30].
o Due to the signatory state of these agreements, an accreditation obtained from a signatory accreditation body of one of the mentioned agreements is recognized in Europe and worldwide for the areas covered by the agreement.
o an EA-MLA is an agreement at European level whereby the signatory parties mutually recognize the accreditations granted and the reports / certificates issued by the entities accredited by them. This agreement is concluded for different domains and has as a principle the periodic mutual evaluation. , an international MRA, between IAF members and ILAC respectively.
o an IAF-MLA confers trust in accreditation bodies and in their empowerment to determine the competence of certification bodies. The accreditations granted by IAF-MLA signatories are

recognized globally on the basis of equivalent accreditation programs, thus reducing costs and adding value to industry and consumers.

o an ILAC-MRA confers trust in the accreditation bodies and their ability to determine the competence of a laboratory in conducting trials and calibrations. Reliability facilitates the acceptance of test results and calibrations between countries where results can be demonstrated as coming from accredited laboratories. The latter helps to reduce technical barriers in trade.

o Accreditation contributes to increasing the competitiveness of products and services in the context of the globalization of markets [2,27,30].

o Accreditation:

- Provides confidence in the technical competence, impartiality and integrity of bodies and laboratories that perform conformity assessment.
- Contributes to increasing the competitiveness of products and services in the context of globalization of markets.
- Contributes to promoting the principle of free movement of products and services.
- Promotes the protection of the life, health and safety of individuals, the environment and the protection of consumers' interests.

o The accreditation activity follows the basic principles:

- Transparency and public availability
- Representation of public interests
- Voluntary character
- Independence from the possible predominance of any specific interests
- Participation of the specialized bodies of the public administration
- Impartial treatment of appeals
- Harmonization with European and international accreditation rules
- Free access to accreditation without discrimination

o Accreditation offers various advantages to economic actors:

- Minimizing risks
- Avoiding multiple evaluations
- Increasing customer confidence
- Reducing the cost of recognizing products on foreign markets
- Reduce general expenses

o Accreditation is essential for:

- Functioning of a market oriented towards quality
- Public authorities
- Conformity assessment bodies [2,8].

7.2. Accreditation of medical laboratories

Each EU Member State has an accreditation body that uses certain standards, generally the SR EN ISO 15189 standard, for the accreditation of medical laboratories in that country [8].

The national accreditation body in Romania is RENAR (Romanian Accreditation Association). The accreditation of laboratories in Romania has been undertaken since 2007 [2]. Medical laboratories in Romania are accredited by RENAR according to the standard SR EN ISO 15189: 2013 "Medical Laboratories. Requirements for Quality and Competence "[29].

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation and market surveillance relating to the marketing of products specifies in Art. 15 Reasons why each EU member country:

- must not hold more than one accreditation body;
- should ensure that this body is organized so as to protect the objectivity and impartiality of its activities [2,27].

Romania has the largest number of medical laboratories accredited in a relatively short period of time (2008-2015) respectively 915, a significant number of medical laboratories in the respective accreditation process 280 [2].

The national legislation in 2008 stipulates that all medical laboratories wishing to liaise with the National House of Santas Insurance (CNAS), so that they are health care providers decontracted from the social health insurance fund, should be accredited according to ISO EN 15189. The Norms to the Framework Contract on the Provision of Health Care Insurance under the Health Insurance Scheme and OMS 1301/2007 stipulate that "as of January 1, 2008 in all medical laboratories I have to be connected with CNAS a management system of quality according to ISO EN15189 ", so medical laboratories require accreditation mainly to access CNAS funds [14,17,19].

The number of tests for which the medical laboratory requires accreditation is different from one country to another [2].

In France, a medical laboratory must have all the accredited tests in order to function [13, 28].

In Romania the number of tests to be accredited by the medical laboratory to enter into relationship with CNAS differs from one year to another according to the legislative provisions of the Co-Ca Norms of the year in question: in 2008 at least 10 tests were to be accredited in Romania, in 2011 at least 51 tests were to be accredited [2].

In accordance with the legislation and the requirements in force in Romania, the interest of the medical laboratories wishing to implement the quality management system according to SR EN ISO 15189 [2] has greatly increased.

CONCLUSIONS

The performance of medical laboratories is a decisive factor for providing quality medical services.

The external quality control service is performed by the Romanian medical laboratories according to the national legislation in force.

The utility of external control is that it checks the performance of medical laboratories to deliver the right results to patients as close to real value.

The external quality control service has a medical purpose and it is the responsibility of the head of the medical laboratory to take into account the criteria set by the Ministry of Health in its task of purchasing the external quality control service.

The minimum number of 4 participations per year for external quality control is provided by all external quality control organizers, national or international

The statistical data and calculations provided by the medical laboratory's participation in external quality control are of value only together and closely related to the patient's medical outcomes.

Medical laboratories should aim to implement a quality management system.

ABSTRACT

Patient safety is one of the important dimensions of quality, being extremely important for all healthcare activities, including the work of medical laboratories. 70-80% of medical diagnoses and medical conduct are based on tests performed by medical laboratory specialists [2]. External quality control as a medical service is a tool that measures the efficacy and comparability of measurement methods used by medical laboratories [4].

The role of external quality control for medical laboratories is to:

- contribute to providing reliable and comparable results to patients so that a patient is not healthy on the basis of an analytical report issued by a laboratory and ill on the basis of another analysis bulletin (issued by another laboratory or even by same laboratory at close times),
- save money in the public and private system by providing results of medical analyzes of patients leading to the most accurate and complex medical diagnosis [4].

REFERENCES

1. ALLEN L.C., 2013 - Role of quality management system in improving patient safety – Laboratiory aspects, Clinical Biochemistry 46, pg.1187-1193;
2. APETREI C., 2011 - Quality of analytical measurements - the guarantee of competent and reliable medical analyzes, article published in the "Romanian Journal of Medical Laboratory", year VI, no. December 24, ISSN 1841-866X;
3. ARMEAN P., 2002 - Evaluating and measuring the quality of hospital services, article published in the"Romanian Journal of Medical Laboratory", IMSS publication, no. 2, June 2002;
4. ARMEAN P.,POPA C., SORESCU G., VRANCEANU R., DINULESCU GD., 2011 - The role of human resources in implementing a quality control system in medical analysis laboratories, article published in the "Romanian Journal of Medical Laboratory" year VI, no. 22, June 2011, ISSN 1841-866X;
5. BECIU H., 2003 - Quality Management, National Institute for Research and Development in Health, Bucharest;
6. BONINI P., PLEBANI M., CERIOTTI F., RUBBOLI F., 2002 - Errors in laboratory medicine, Clin. Chem., 48, 691-698;
7. BUZOIANU M., 2006 - Current requirements and ways to ensure the traceability of measurements in clinical chemistry,article published in the "Romanian Journal of Medical Laboratory", year I, no. 4, november 2006, ISSN 1841-866X;
8. CRISTEA L., 2005 - Compliance of Quality Management, Bucharest;
9. FRONDAT F., DELAHAYE V., GOMEZ P.J., PODLUNSEK C., FARGES G.,CALISTE J.P., 2010 - Laboratories de analyses de biologie medicale: un outil deautodiagnostic base sur la norme NF EN ISO 15189, IRBM News, 31 (3), pg.1-6;
10. DOBRIN C., 2006 - Quality Management in Public Sector, ASE Publishing House, Bucharest;
11. DRAGOMIRESCU L., DRANE J.W., 2009 - Biostatstics for beginners, vol. I., Descriptive Biostatistics, VI-th Edition, CREDIS Publishing House, Bucharest, ISBN 978-973-734-4618;
12. FIELD MJ., LOHR K., , 1990 - Clinical practice guidelines: direction for a new program, National Academy Press, Washington DC;
13. GEORGESCU D., 2014 - Assess staff performance, article published in the "Romanian Journal of Medical Laboratory", year IX, no. 35, september 2014, ISSN 1841-866X;
14. GEORGESCU D., 2015 - The process of improving quality in medical laboratories, article published in the "Romanian Journal of Medical Laboratory", year X, no. 38, June 2015, ISSN 1841-866X;
15. GEORGESCU D., 2015 - Risk management in the medical analysis lab , article published in the "Romanian Journal of Medical Laboratory", year X, no. 40, december 2015, ISSN 1841-866X;
16. GEORGESCU S., POPA C., 2008 - Quality Audit - an important element in continuously improving the performance of medical analysis laboratories, public summary in "Romanian Journal of Medical Laboratory", year III, no.12, november 2008, ISSN 1841-866X;
17. GUZEL O.,GUNER E.I., 2009 - ISO 15189 Accreditation: Requirements for quality and

competence of medical laboratories, experience of a laboratory I, Clinical Biochemistry 42, pg. 274 -278;
18. KLEIN J.P., 2013 – L ´accreditation: un panorama des raisons et des d´raisons. Revue francophone des laboratories, nr.457, pg. 25-28;
19. LAZAR C., CULEA I., 2006 - The role of external quality control schemes in assessing the performance of clinical laboratories , article published in the "Romanian Journal of Medical Laboratory", year I, no. 4, november 2006, ISSN 1841-866X;
20. LIONEL A., VARNADOE, 1996 - Medical laboratory management and supervision, F.A. Davis Company, Philadelphia, 1996;
21. LIPPI G.,BLANCKAERT N., BONINI P., GREEN S., KITCHEN S., PALICKA V.et al., 2009 - Causes, consequences, detection and prevention of identification errors in laboratory diagnostics, Clin Chem lab med, 47,143-53;
22. LOHR KN., 1997 - The quality of practice guidelines and the quality of health care, Papers and reports of de WHO Conference on Guidelines in Health Care Practice;
23. LYNNES, GRACIA S., 2004 - Clinical Laboratory Mangement, ASM Press, Washington DC;
24. MIHAI C., 2000 - An approach to the quality of health services, article published in the Journal of Health Management, publication of IMSS, no.3;
25. NANCY R.TAGUE, 2005 - Quality Tools , 2nd edition- ASQ Quality Press, Milwaukee, Wisconsin;
26. PANAIT A., COJOCARU M., APETREI I., 2006 - Ensuring traceability of test results in laboratory medicine, article published in the "Romanian Journal of Medical Laboratory", year I, no. 4, november 2006, ISSN 1841-866X;
27. PASCAL P., BEYERLE F., 2006 - Les referentiels qualit applicables dans les laboratoires de analyses de biologie medicale, Pathologie Biologie 54, pg. 317-324;
28. PLEBANI M., 2006 - Errors in clinical laboratories or errors in laboratory medicine? Clin. Chem.Lab. Med. , 44, 750-759;
29. PLEBANI M., 2007 - Laboratory errors: How to improve pre- and post- analytical phases?, Biochem Med, 17,5-9
30. POPA C., 2015 - Specialists in medical laboratories, Bucharest, Copyright 2015;
31. POPA C., SORESCU G., 2008 - " Ensuring the quality of medical analyzes", article published in the "Romanian Journal of Medical Laboratory", no. 12/2008, ISSN 1841-866X;
32. POPA C., SORESCU G., POPA R.M.,VOICU I., DINULESCU S.L.V., 2015 - CALILAB study on external quality control in Romanian laboratories - 2008-2014, article published in the "Romanian Journal of Medical Laboratory", year X, no. 39, september 2015, ISSN 1841-866 X;
33. POPA C., SORESCU G., BORCAN E., POPA D., NEAGOE C., POPA R.M., GAMAN V., 2015 - The study on the role of specialists in medical laboratories in performing external quality control, article published in the "Romanian Journal of Medical Laboratory", year X, no.38, june 2015, ISSN 1841-866 X;
34. POPA C., SORESCU G., CHIFIRIUC C.M., POPA R.M., POPA D.,GAMAN V., BORCAN E., NEAGOE C., 2013 - CALILAB-, Study on external quality control in medical laboratories in Romania in the November 2014 round compared to 2008,2010, article published in the "Romanian Journal of Medical Laboratory", year X , no. 37, March 2015, ISSN 1841-866 X;
35. POPA C., POPA R.M., SORESCU G., 2015 - External quality control to support the quality of medical services, ppt presentation on the occasion of the World Accreditation Day, Bucharest, June 12;
36. POPA D., SORESCU G., 2016 - The main errors encountered in the biochemistry department of the medical analysis laboratory, article published in the "Romanian Journal of Medical Laboratory", year XI, no.43, October 2016, ISSN 1841-866 X;
37. RICOS C., GARCIA-VICTORIA M., 2004 - De la Fluente B.,Quality indicators and specifications for the extra-analytical phases in clinical laboratory management, Clin Chem Lab Med, 42, 578-582;
38. SILVERSTEIN MD., 2003 - An approach to medical errors and patient safety in laboratory sevices. A white paper, The Quality Institute Neeting, Atlanda, April 2003;
39. SORESCU G., 2009 - Improving the quality of the medical act in the healthcare system in Romania by implementing a quality management system, article published in the "Romanian Journal of Medical Laboratory", year IV , no.12, march 2009, ISSN 1841-866 X;
40. SORESCU G., PANTILIE CV., POPA C., 2009 - The Importance of the Implementation of an Integrated Quality- Environment Mamagement System in Romanian SMEs Active in the Medical Sector –Proceedings of the 2009 International Conference on Tourism, on " Sustainable Tourism within High Risc Areas of Environmental Crisis; Italy; April 22nd – 25 th, 2009; Italy (CD); ISSN 978-88-96116-20-3; baza de date international SCOPUS;
41. SORESCU G., POPA C., 2009 - Accreditation in the European Union, article published in the "Romanian Journal of Medical Laboratory", year IV , no.16, november 2009, ISSN 1841-866 X;
42. TAGUE N.R., 2005 - Quality Tools, 2nd edition, ASQ Quality Press, Milwaukee, Wisconsin;

43. TOCASE G., TOCASE A-M., 2010 - Quality control and validation of quantitative analytical methods for medical laboratories, Ed Tehnica, Bucharest;
44. TOACSE G., TOACSE A-M., 2008 - Uncertainty and Validation, Ed. Medicala, Bucharest, for medical laboratories;
45. VANAN MARCEL, 2009 - Quality control management in medical analysis laboratories, article published in the "Romanian Journal of Medical Laboratory", year IV , no.16, november 2009, ISSN 1841-866 X;
46. VLADESCU C., (coord.), 1998 - Management of Health Services, Efficient Edition, Bucharest;
*** Academia Romana Institutul de Lingvistica "Iorgu Iordan", Explanatory Dictionary of the Romanian Language - DEX, 2nd Edition, Encyclopedic Universe, Bucharest, 1998;
*** Regional Excellence Centers in the Improvement of Process Performance in the Health Care System in Romania- Research Report- Assessing the Current Situation on Organization and Implementation of Processes in the Field of Hospital Services Delivery and Identifying Training Needs in Quality Management and Process Improvement - Bucharest, 2011;
*** Clin Chem Lab Med: 2010 The European Register of Specialitis In Clinical Chemestry and Laboratory Medicine: Guide to the Register, version 3 -2010;
*** Labor Code (Law no.53 / 2003 completed and amended by Law no.40 / 2011)
*** Journal official de la Republique Francaise Law 2013-442 / 30.05.2013 on Reform in Medical Biology (France);
*** H.G.nr. 400/2014 on the approval of service packages and the framework contract that regulates the conditions for the provision of medical assistance within the framework of the health insurance system for the years 2014-2015;
*** Law no. 95/2006 on health reform;
*** Law no. 460/2003 regarding the exercise of biochemist, biologist and chemist in the Romanian health system, the establishment, organization and functioning of OBBCSSR.;
*** Quality management. Continuous Improvement of the Quality of Health Services, IMSS, Bucharest, 2000;
*** Methodological Norms for the Application of the Contract - Health Care Framework within the Health Insurance System;
*** OMS 119/2004 on the approval of the Norms regarding the authorization and functioning of laboratories conducting medical analyzes;
*** OMS 1301/2007 approving Norms on the operation of medical analysis laboratories;ize medicale;
*** OMS 1406/2006 for the approval of the Norms regarding the organization of the competition or the examination for taking the position of Head of Section, Labor Chief or Chief of Public Service Public Health Units;
*** OMS no.2071 / 2008 approving the Procedure for the notification of competency testing schemes for medical analysis laboratories;
***Order no. 360/2014 approving the methodological norms for the application in 2014 of H.G. no. 400/2014;
***Specific Regulation for Accreditation of Providers of Competence Tests according to SR EN ISO CEI 17043/2014;
*** SR EN ISO 9000: 2006 - Quality management systems. Fundamental and vocabulary principles;
*** SR EN ISO 9001:2001 - Quality management systems. Requirements;
*** SR EN ISO 9004:2001 - Quality management systems. Guidelines for Improving Performance;
*** The Romanian-pr standard SR. ISO / IEC Guide 99, International Metrology Vocabulary. Fundamental and general concepts and associated terms (VIM);
*** Standardul SR EN ISO 15189:2013 Medical laboratories. Requirements for quality and competence;
*** Standardul SR EN ISO 17043:2010 Conformity assessment. General requirements for competence tests;
*** The practice of chemical chemistry in the European Union –www.nvc.nl/ CCLM, Sanders, 2002;
*** www.sante.gouv.fr (Franta);
*** www.renar.ro;
*** www.unboundmedicine.com – The EC-4 Register of European clinical chemists and EC-4 activites.

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