

GENERAL OVERVIEW OF THE METHODOLOGY AND CRITERIA FOR DETERMINING THE RISK LEVELS OF RISK-BASED INSPECTIONS CONDUCTED BY THE HEALTH AND LABOR INSPECTION BODY OF THE REPUBLIC OF ARMENIA

I. GENERAL PROVISIONS

1. The present methodology regulates the general approaches regarding the application of the risk-based inspections system (hereinafter referred to as “the risk system”) implemented by the Health and Labor Inspection Body of the Republic of Armenia (hereinafter referred to as the Inspection Body); the risk and the method of measuring it are defined as well as economic entities are classified according to risk levels and other definitions related to the assessment of risks are provided.

2. The aim of the risk system is to:

- 1) define, identify and analyze the risks in the sectors subject to control by the Inspection Body;
- 2) classify economic entities into risk groups: high, moderate, low;
- 3) maintain a database on all economic entities operating in the sectors subject to control by the Inspection Body, according to the fields of activity and criteria determining the risk levels;
- 4) address through the risk system inspections conducted by the Inspection Body at the sectors and economic entities with the highest level of risk subject to control;
- 5) reduce the risk level of economic entities through risk-based inspections to the minimum extent possible.

3. From the perspective of control exercised by the Inspection Body, risk (“Hygienic and epidemic risk”, “Medicines circulation risk”, “Health risk”, “Labor risk”) is the likelihood of harm caused to human life and health as a result of an economic entity’s activities per sector (“Maintenance of sanitary and epidemiological

safety of the population”, “Medicines circulation and pharmaceutical activity”, “Medical care”, “Employee health protection and safety”), given the degree of severity of the harm and expected adverse effects.

4. For the purpose of risk assessment, a database of economic entities shall be created and periodically updated according to sectors and individual risk criteria.

II. DATABASE APPLIED IN THE RISK SYSTEM

5. The Inspection Body shall maintain a database on the assessment of the economic entities controlled by the Inspection Body, based on the criteria for determining risk levels in four sectors. The data required for creating the database shall be collected from the information obtained as a result of implementation of the statutory functions of the Inspection Body as well as from the relevant information available in the databases of governmental bodies not involved in the database of the Inspection Body but conducting inspection, on the basis of the data on economic entities, shared between them.

6. The purpose of the database is to identify and classify the risk levels of the economic entities controlled by the Inspection Body based on the available information and established standards.

7. The database shall periodically be updated, supplemented and exploited for the purposes of the risk-based inspection system implemented by the Inspection Body.

III. MEASUREMENT OF THE SECTORAL AND INDIVIDUAL RISK LEVELS AND CLASSIFICATION OF THE ECONOMIC ENTITIES BASED ON RISK LEVEL

8. The risk levels of economic entities shall be measured as the sum total of the sectoral and individual risks of the economic entity, which has a maximum total weight of 200 points.

9. Sectoral risk is a risk criterion associated with the sectors in which an economic entity implements activities, the measurement of which is based on the significance and danger of the economic entity’s field of activity, determined by the potential adverse effects arising from such activities considering the degree of severity of such harm. If the economic entity carries out activities in several sectors, the sectoral risk shall be measured based on the data of the riskiest sector.

10. Individual risk is a risk criterion associated with the sectors in which an economic entity implements activities, the measurement of which is based on violations of the requirements established by law, committed by the economic entity, frequency of violations, measures undertaken to eliminate them

as well as other criteria defining the activities of the economic entity. The individual risk shall be measured by the sum total of risk scores calculated on the basis of the individual risk criteria.

11. Application of the risk criterion measured on the basis of frequency of violations and measures undertaken to eliminate the violations, its measurement and assessment shall be defined as follows:

- if the economic entity committed 5 and more violations in the previous year, violation shall be considered periodic and the maximum score for the given individual risk component shall be assigned per sector. Otherwise, violation shall not be considered periodic and 0 point for the given individual risk component shall be assigned per sector;

- where violations committed by the economic entity are eliminated, 0 point for the given individual risk component shall be assigned per sector. Otherwise, the maximum score shall be assigned for the given individual risk component per sector.

12. In economic entities operating in four sectors, where inspection was conducted by the Inspection Body following the introduction of the risk system provided for by this Annex, the risk shall be fully assessed and categorized based on the sectoral and individual risk scores. The maximum possible risk score shall be 200.

13. In economic entities operating in four sectors, where no inspection was conducted by the Inspection Body following the introduction of the risk system provided for by this Annex, the risk shall be assessed and categorized only based on the maximum possible risk (by the sum total of the maximum possible sectoral risk score and the maximum possible individual risk score). In the absence of a relevant individual risk component (assessed by checklists) the risk level shall conventionally be assessed 0. The maximum possible risk shall be assessed 150.

14. Economic entities shall be classified on the basis of the measured risk pursuant to the following mechanism in accordance with Table N 1: the economic entity that has received up to 30 percent inclusive of the maximum possible risk score shall be categorized into the low risk group, the economic entity that has received from over 30 to 70 percent inclusive shall be included in the moderate risk group, and the economic entity that has received from over 70 to 100 percent inclusive shall be categorized into the high risk group, however the body conducting the inspection shall include in the high risk group in the decreasing order of risk level up to twenty percent of the economic entities subject to inspection.

Table N 1

Low	Moderate	High
(0, 30%]	(30%, 70%]	(70%, 100%]

15. The relevant (checklist) individual risk component of the economic entity is the risk score assessed by checklists, which shall be calculated on the basis of points obtained from checklists completed during inspections conducted in the same year, implementation of recommendations made following the inspections, and during inspections conducted as required.

16. Each supervisory question included in the checklist questionnaire shall have a risk score. Based on the results of the checklist completed following the inspection in the economic entity the relevant (checklist) individual risk component shall be assessed, which shall constitute the sum total of the risk scores assigned to those supervisory questions the requirements of which have been violated and the answer “No” has been checked in the relevant column and line of the checklist. The risk scores of all the checklists completed in a given year shall be processed.

17. The risk scores for the checklist questions completed as a result of inspection of the performance which have received the positive “Yes” answer, shall be subtracted from the risk score calculated by the previous checklist.

18. The relevant (checklist) individual risk component shall be assigned a maximum of 50 points, which shall be calculated by the proportion of the risk scores and weights assigned to the checklist questions so that the sum of the products of the risk scores and weights should equal 50 points.

IV. HYGIENIC AND EPIDEMIC RISK ASSESSMENT IN ECONOMIC ENTITIES

19. The sectoral risk shall be assessed in economic entities carrying out their functions based on categorization by the classifiers of types of economic activity (CTEA), pursuant to Table N 2, and its maximum possible score shall be 100.

Table N 2

Code	Type of Activity	Score
A	Agriculture, forestry and fishing	5
B	Mining industry and open pit mining	50
C	Manufacturing (except C21)	40
C21	Production of pharmaceutical products	40
D	Electricity, gas, steam and air conditioning supply	40
E	Water supply, sewerage, waste management and recycling	100
F	Construction	30

G	Wholesale and retail trade; repair of cars and motorcycles (except G46.46.2, G47.73)	50
G 46.46.2	Wholesale trade of medicines	5
G 47.73	Retail trade of medicines at pharmacies	10
H	Transportation and storage economy	40
I	Accommodation and catering	50
J	Information and communication	30
K	Financial and insurance activities	10
L	Real estate related activities	30
M	Professional, scientific and technical activities	5
N	Administration and auxiliary activities	20
O	Public administration and protection; compulsory social security	20
P	Education	45
Q 86	Healthcare	60
Q 87	Social service of the population	40
Q 88	Social service without provision of accommodation	20
R	Culture, entertainment and recreation	40
S	Other services	40
T	Activities of households in the capacity of employer; production of non-differentiated goods and services for own consumption in households	0
U	Foreign organizations activities	0

20. The individual risk of economic entities shall be assessed per the following components and shall constitute the sum total of their risk scores. The individual risk components are as follows:

- 1) The number of employees, which shall be assessed according to Table N 3:

Table N 3

Number of employees	Score
1-100	5
101-200	10

201-300	15
301-400	20
401-500	25
501 and more	30

2) The number of services provided in the previous year at the economic entities carrying out activities under classifier “Healthcare” (Q86) of the types of economic activities specified in Table N 2, the maximum score being 40 points, based on the sum total of the risk scores obtained from Tables N 4 and N 5:

Table N 4

Number of hospitalized patients	Score
1-5000	5
5001-10000	10
10001-20000	15
20001 and more	20

Table N 5

Number of visits	Score
1-5000	5
5001-10000	10
10001-20000	15
20001 and more	20

3) Violations periodically committed by economic entities, pertaining to the given sector, with a maximum score of 10;

4) measures undertaken by economic entities to eliminate the violations, with a maximum score of 10;

5) the risk score measured on the basis of checklists, with a maximum score of 50.

V. HEALTH RISK ASSESSMENT IN ECONOMIC ENTITIES

21. The sectoral risk of economic entities shall be assessed based on the types of medical care and services established by the Republic of Armenia Government Decree N 276-N of 27 March 2008, provided by them, as follows: the risk weight of one type of medical care and service shall be measured by the maximum score of 65 divided by the number of all the types of medical care and services. The sectoral risk of the economic

entity shall be the product of the number of types of medical care and services provided by the given economic entity and the risk weight of one type.

22. The individual risk of economic entities shall be measured by the following components and shall be the sum total of their risk scores, the maximum possible score being 135. The individual risk components are:

1) The number of patient visits, with a maximum score of 40, based on the sum total of the risk scores obtained from Tables N 6 and N 7:

Table N 6

Number of hospitalized patients	Score
1-5000	5
5001-10000	10
10001-20000	15
20001 and more	20

Table N 7

Number of visits	Score
1-5000	5
5001-10000	10
10001-20000	15
20001 and more	20

2) Number of in-hospital deaths that occurred during the previous year, with a maximum score of 5, pursuant to Table N 8:

Table N 8

Number of deaths	Score
1-5	1
6-10	2
11-20	3
21-30	4
31 and more	5

3) Number of medical workers, with a maximum score of 20, pursuant to Table N 9:

Table N 9

Number of medical workers	Score
1-20	5
21-50	10
51-100	15
101 and more	20

- 4) violations pertaining to the given sector, periodically committed by economic entities, with a maximum score of 10;
- 5) measures undertaken by economic entities to eliminate the violations, with a maximum score of 10;
- 6) the risk score measured on the basis of checklists, with a maximum score of 50.

VI. MEDICINES CIRCULATION RISK ASSESSMENT IN ECONOMIC ENTITIES

23. The sectoral risk is the type of activity related risk, the maximum score of which is 100. The sectoral risk shall be assessed for each of the three main fields of activity of economic entities (production, wholesale trade, pharmaceutical) pursuant to Table N 10. The sectoral risk components are:

- 1) According to the type of risk – violation of the expiration date of medicines, violation of storage and transportation conditions, drug counterfeiting and violation of the state registration procedure;
- 2) According to the impact on the final consumer – to what extent direct or indirect the economic entity's contact with the final consumer is;
- 3) According to the risk range - how broad or localized the risk range is.

Table N 10

Type of activity	Type of risk					Impact on the final consumer	Risk range	Total
	Expirati on date	Storage conditions	Counter feiting	State registration	Total			
Production	5	10	10	5	30	10	20	60
Wholesale trade	0	10	10	20	40	20	40	100
Pharmaceutical	10	10	10	10	40	20	10	70

24. The individual risk of economic entities shall be measured by the following components and shall constitute the sum total of their risk scores pursuant to Table N 11. The individual risk components are:

- 1) economic entity's annual turnover (sales) of the previous year, with a maximum score of 10;

- 2) preparation of medicines (applicable only in case of pharmaceutical activities), with a maximum score of 10;
- 3) circulation of drugs or medicines containing psychotropic (psychoactive) substances, with a maximum score of 20;
- 4) the number of pharmacies owned by the same economic entity (applicable only in case of pharmaceutical activities), with a maximum score of 10;
- 5) violations pertaining to the given sector periodically committed by economic entities, with a maximum score of 10;
- 6) measures undertaken to eliminate the violations in economic entities, with a maximum score of 10 points;
- 7) the risk score measured on the basis of checklists, with a maximum score of 50.

Table N 11

Sales of the previous year (mln AMD)			Preparation of medicines		Circulation of medicines containing psychotropic (psychoactive) substances		Number of pharmacies			Periodic violations	Measures to eliminate the violations	Based on the checklist results
Up to 50 inclusive	50-200-inclusive	More than 200	Yes	No	Yes	No	1	2-5	6 and more			
4	6	10	10	0	20	0	8	10	6	Maximum 10	Maximum 10	Maximum 50

VII. LABOR RISK ASSESSMENT IN ECONOMIC ENTITIES

25. The sectoral risk shall be assessed in economic entities carrying out their functions based on categorization by the classifiers of types of economic activity (CTEA), pursuant to Table N 12, and its maximum possible score shall be 100.

Table N 12

Code	Type of activity	Score
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A	Agriculture, forestry and fishing	40
B	Mining industry and open pit mining	100
C	Manufacturing (except C21)	80
C21	Production of pharmaceutical products	30
D	Electricity, gas, steam and air conditioning supply	50
E	Water supply, sewerage, waste management and recycling	70
F	Construction	60
G	Wholesale and retail trade; repair of cars and motorcycles (except G46.46.2, G47.73)	40
G 46.46.2	Wholesale trade of medicines	10
G 47.73	Retail trade of medicines at pharmacies	10
H	Transportation and storage economy	30
I	Accommodation and catering	30
J	Information and communication	50
K	Financial and insurance activities	10
L	Real estate related activities	10
M	Professional, scientific and technical activities	10
N	Administration and auxiliary activities	10
O	Public administration and protection; compulsory social security	10
P	Education	10
Q	Healthcare	10
R	Social service of the population	10
S	Social service without provision of accommodation	10
T	Culture, entertainment and recreation	10
U	Other services	0

26. The individual risk of economic entities shall be measured by the following components and shall constitute the sum total of their risk scores, the maximum possible score of which shall be 100. The individual risk components are:

- 1) The total number of employees, with a maximum score of 10, pursuant to Table N 13.

Table N 13

Number of employees	Score
1 - 10	1
11 - 100	3
101 - 200	5
201 and more	10

2) The overall gender and age profile of employees, with a maximum score of 5, pursuant to Table N 14. If more than one of the below mentioned conditions are simultaneously available, the economic entity's risk according to this criterion shall be measured by the maximum score envisaged for such cases. Those conditions are:

- if the number of male employees under the age of 18 does not exceed 25 percent inclusive of the total number of employees, the economic entity's risk according to this criterion shall be assessed 2 points, otherwise it shall be assessed 3 points;

- if the number of female employees under the age of 18 does not exceed 25 percent inclusive of the total number of employees, the economic entity's risk according to this criterion shall be assessed 4 points, otherwise it shall be assessed 5 points;

- if the number of female employees aged 18 and above exceeds 25 percent of the total number of employees, the economic entity's risk according to this criterion shall be assessed 3 points, otherwise it shall be assessed 0 point;

- if the number of male employees aged 18 and above does not exceed or exceeds 25 percent of the total number of employees, the economic entity's risk according to this criterion shall be assessed 0 point.

Table N 14

Gender and Age Profile				
Age	Gender			
	Male		Female	
	(0%, 25%]	(25%, 100%]	(0%, 25%]	(25%, 100%]
Under the age of 18	2	3	4	5
Above 18	0	0	0	3

3) Depending on the number of employees affected by accidents and (or) occupational diseases at workplace during the previous year as a consequence of the economic entity's activities, specified below, the sum total of risk scores may amount to a maximum of 10:

- in case of an accident and (or) occupational disease that resulted in death the risk shall be assessed in the maximum amount, i.e. 10 points;
- in case of an accident and (or) occupational disease that resulted in disability 5 points shall be assigned for each affected person, the maximum score being 10;
- in case of an accident and (or) occupational disease that did not result in disability 2 points shall be assigned for each affected person, the maximum score being 10;
- 4) the number of informal employees, with a maximum score of 5 points, 0,5 points assigned for each informal employee, and in case of 5 and more informal employees the maximum score being 5;
- 5) violations pertaining to the given sector, periodically committed by economic entities, with a maximum score of 10;
- 6) measures to eliminate violations by economic entities, with a maximum score of 10;
- 7) the risk score assessed on the basis of checklists, with a maximum score of 50.

VIII. ANNUAL INSPECTION PLAN

27. The annual inspection plan of the Inspection Body shall be prepared taking into consideration the risk level of economic entities in the below mentioned proportion and shall be established by December 1 of the year preceding the inspections. Amendments can be made to the annual inspection plan by the consent of the Prime Minister of the Republic of Armenia:

- 1) economic entities included in the high risk group shall constitute at least seventy percent of the economic entities subject to inspection within a given year;
- 2) economic entities included in the low risk group shall constitute at maximum five percent of the economic entities subject to inspection within a given year.

28. The annual inspection plan shall include the following information:

- 1) the full names of the economic entities subject to inspection;
- 2) the date of completion of the last inspection conducted at each economic entity;
- 3) the risk level of each economic entity;
- 4) the period of conducting each inspection.

29. The list of economic entities subject to inspection within a given year shall be compiled pursuant to paragraph 14 of this Methodology from economic entities assessed according to the risk level and classified according to the relevant sectors. In order to make a feasible selection, the Inspection Body shall calculate the maximum number of economic entities for a given year, where it is possible to conduct inspections based on the available human resources potential, economic, organizational and financial capacities. Within the limits of this number the economic entities included in the high, moderate, low risk groups shall be selected

based on the proportion of separate sectors. Moreover, the quantitative selection by proportion in each sector shall be made based on the principle of highest to lowest points scored by economic entities.