Rules for Inspection of Nuclear and Radiation Activity

Article 1. Scope of Regulation

1. The Rule for Inspection of Nuclear and Radiation Activity (hereinafter –the Rule) establishes preconditions and procedures for inspection of regulated activities under the Law of Georgia on "Nuclear and Radiation Safety".

2. This Rule determines basic requirements for inspection of authorized nuclear and radiation activities under the relevant legislation and detection of unauthorized nuclear and radiation activities to ensure nuclear and radiation safety by the Legal Entity of Public Law - Nuclear and Radiation Safety Agency (hereinafter referred to as the Agency) within the system of the Ministry of Environment and Natural Resources Protection.

3. For the inspection, the Agency shall be guided by the Georgian Law on "Nuclear and Radiation Safety", Georgian Laws, this Rule and other normative acts.

Article 2. Definition of Terms

1. Terms used in this Rule have the following meanings:

a) **Inspection** - Determination of compliance of the nuclear and radiation activities of the facility with the requirements of the Georgian legislation and relevant response;

b) **Observation** - Visual inspection and review of documentation and collect general information on activities of the facility that may be used for inspection and to ensure appropriate response;

c) **Administrative prescript** - Document signed by the head of the Agency on violations detected during inspection, reporting and activities in accordance with the Georgian legislation, which informs the Inspection Object to eliminate violations in the specified time or refrain from any actions, non-fulfillment of which shall lead to the relevant liability under the Georgian legislation

d) **Inspection object** – Nuclear and radiation facility under planned or current inspection.

2. Other terms used in the Rule have the same meaning as in the Georgian Laws on "Nuclear and Radiation Safety", Georgian Laws, this Rule and other normative acts.

Article 3. Goals and objectives of Inspection

1. The goals of inspection of nuclear and radiation activity are follows:

a) To protect humans, personal involved in Nuclear and Radiation activities and the environment from harmful exposure to ionizing radiation;

b) To determine the conformity of the activities implemented by a physical or legal person with the requirements of the Georgian legislation in the area of nuclear and radiation safety.

2. Objectives of inspection are as follows:

a) To control over license conditions implementation by authorized physical or legal person or/and detect violations in nuclear and radiation safety and security by the license holder during implementation of nuclear and radiation activities

b) To detect unauthorized nuclear and radiation activities by a physical or legal person

c) To execute relevant measures in case of detecting violations of the requirements of the Georgian legislation in the area of nuclear and radiation safety and security

Article 4. Types of Inspection

Inspection of nuclear and radiation activity can be either planned or unplanned.

Article 5. Planned Inspection

1. Planned inspections are carried out in compliance with the annual inspection program, which is submitted for approval by head of the Agency to the Minister of Environment Protection and Agriculture of Georgia at the end of each year. The inspection program shall be carried out by considering the periodicity specified in paragraph 3 of this Article. The Resolution determines the list of inspection objects for the next year.

2. During elaboration of the annual inspection program, human resources and technical means required for the inspection shall be taken into account, as well as results of previous inspection and the periodicity of performed inspection stipulated by paragraph 3 of this Article.

3. The periodicity of the planned inspections is derived from the radiation risk of specific activities and graded approach and is determined as follows:

a) Application of radioactive sources in Medicine, Industry and Science (I, II, III Category sources) – at least once per year;

b) Application of Nuclear Material in Medicine, Industry and Science – at least once per year;

c) Handling with radioactive waste - at least once per 2 a year;

d) Application of Accelerators in Medicine, Industry, Science, Service providing - at least once in a year;

e) Application of radioactive sources in Medicine, Industry and Science (IV and V Category sources) – at least once per 3 years;

f) Application of Radiopharmpreparates for diagnostic and treatment purposes - at least once per 2 years;

g) Medical diagnostic radiology (computer tomography, angiography, x-ray diagnostics of general profile, mammography etc.) - at least once per 2 years;

h) Dental radiography and service delivery using ionizing radiation sources - at least once per 5 years;

j) Other types of licensed activities - at least once per 5 years.

4. Planned inspections are carried out through selection of the facilities. In this case, sequence of the inspection sites set out in the inspection program shall not be taken into consideration.

5. The planned inspection shall be carried out based on a prior warning to the license holder or his authorized representative which shall be sent to the addressee at least 7 calendar days prior to the inspection.

6. By the decision of the Agency Head, a complex inspection may be conducted with the joint participation of the Agency employees and other, invited specialists.

Article 6. Unplanned Inspection

1. Unplanned inspection shall be implemented:

a) By the decision of Head of the Agency based on the analysis of the existing information;

b) Based on decision of Head of the Agency based on notifications (complaints) from the state agencies, organizations, citizens;

c) Based on collected information on contingency or alleged violation of safety and security of nuclear and radiation activity, the licensing conditions and and/or violations of the Georgian legislation;

d) For the on-site verification of information presented in annual reporting of an authorized physical or legal person;

e) To prevent violation of the license conditions and to review the conditions set out for the implementation of specific activities, through on-site verification of the information confirming implementation of administrative prescription with-in the period.

f) For the detection of unauthorized nuclear and radiation activities by a physical or legal person;

g) Based on information collected on the violations as a result of observation of the Object;

2. If result of nuclear and radiation activity (radiation emergency, contingency, alleged violation of the law) may cause an immediate and direct threat to human life, health or environment, then it is possible to carry out operational unplanned inspection

3. Pre-license inspection is carried out on the basis of a graded approach to determining compliance with the current state of the documents applied for authorization, taking into account the risk and specificity of nuclear and radiation activity;

4. Unplanned inspection may be carried out in the facility provided by the inspection program, as well as at other facilities which are not included in the list established by this program

5. By the decision of the Agency Head, a complex inspection may be conducted with the joint participation of the Agency employees and other, invited specialists.

Article 7. Inspection of physical or legal persons, owners of Nuclear Material

- 1. Inspection of physical or legal persons, owners of Nuclear Material may be planned or unplanned.
- Inspection provide by responsible person for implementation of Agreement between the Republic of Georgia and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-proliferation of Nuclear Weapons and its Additional Protocol, with designated person for accountancy and control of Nuclear Material from inspection object.
- 3. During the inspection verified declared to the of the International Energy Agency safeguards department nuclear material, its inventory status, physical inventory reports, information about nuclear materials inventory changes, the documentation required of the Additional Protocol, nuclear materials of physical security and its compliance with National legislation.

Article 8. Observation of Object

1. Site visit may be carried out without the prior notification of the authorized or unauthorized physical or legal person.

2. Prior to observation, authorized person of the Agency is obliged to submit the identity card to the head of the object or to his authorized person.

3. The observation may include:

a) Collection of general information on nuclear and radiation activity, including visual observation of the activity, equipment and installations;

b) Requesting any documentation that may confirm fulfillment of the requirements and obligations of the Georgian legislation in the area of nuclear and radiation safety and security;

c) Collecting additional information on the measures taken to eliminate the violations identified by administrative prescript during the inspection of the inspection object.

4. In the course of observation, information collected on the activities by a physical or legal person may be used to make a decision on implementation of the planned or unplanned inspection.

5. Observation of the activities of a physical or legal person does not require issuance of an individual administrative-legal act.

Article 9. Individual administrative-legal act on inspection

1. Individual administrative-legal act on planned or unplanned inspection is issued by Head of the Agency.

2. In case of implementing the operational inspection and/or unplanned inspection based on a observation, a written individual administrative-legal act shall be issued within no more than three days after completion of the inspection.

3. An individual administrative-legal act issued by Head of the Agency on implementation of the inspection shall determine:

a) Type of inspection;

b) Persons performing inspection/Inspector (position, name, last name, identity of the head of inspection team);

c) Inspection object / objects and their addresses;

d) Date and duration of inspection.

Article 10. Implementation of inspection of Nuclear and Radiation Activities

1. Inspection provide only a person authorized by the Agency, for which any area of nuclear and radiation inspection object should be available, where appropriate activities are underway.

2. Before planned inspection the head of the relevant service of Agency is developing:

a) A group of authorized persons for specific inspection. The group must consist of at least two persons. One of them is appointed as the head of the inspection group. Based on the nuclear and radiation risks and the activities of the inspection object, the group may consist of more than two people.

b) Duration of inspection, which is determined based on inspection object nuclear and radiation activity(ies) risks, used sources, existing nuclear security and radiation safety situation. Duration of inspection may be extended by decision of the head of Agency, by issuing corresponding changes in the inspection order.

3. The head of Inspection group shall develop an individual inspection plan and agree with the head of the relevant service of Agency. An individual inspection plan includes delegation of rights and obligations between the members of the group, a list of necessary technical equipment and main activities during inspection.

4. The members of the inspection group should familiarize themselves with the authorization documentation of the object of inspection, previous inspection acts, revealed violations, administrative prescripts and information about their implementation in the electronic database.

5. Radiometric and dosimetric instruments should be selected that are relevant to the inspection object's activity, check their performance and calibration certificates. Inspection group should be equipped by personal dosimeters. Taking into account the specifics of the inspection object, the Inspection group may be additionally equipped with personal protective equipment (clothing, shoes, glasses, etc.);

6. prepared copyies of all documents necessary for inspection implementation.

3. Inspection shall start from submitting the Agency ID and order by head of the Agency on the inspection to the manager of the inspection object, to a RPO and / or other authorized employee

4. Inspection group member shall authorized to:

a) Review all documentation related to nuclear and radiation activity (radiation protection program, physical protection system, emergency preparedness and response plan, radiation monitoring results, quality control, calibration- testing of equipment and other documentation);

b) Interview to the organization's personnel and other competent persons for collecting the information necessary for inspection;

c) Take radiological (dosimetry) measurements and collect necessary information in order to determine compliance with the requirements of nuclear and radiation safety

d) Assess radiation emergency and / or incident preparedness;

e) Take samples for laboratory radiological evaluation;

f) If necessary, take photo and audio/video footage of the inspection object, if it may be used as material evidence of certain violations;

g) Based on the individual plan and inspection questionary verify fulfillment of the requirements of the Law of Georgia on Nuclear and Radiation Safety and other normative acts

- h) Protect confidentiality of commercial information related to nuclear and radiation activity.
- j) Perform other measures that are necessary for inspection purposes.

5. For implementation of authority specified in paragraph 3 of this Article, inspector is entitled to carry communication equipment, portable personal computers, laboratory sample collection and measuring devices, as well as individual dosimeters and any other equipment or materials for the purpose of inspections.

Article 11. Inspection Act and Act of Administrative Offenses

1. After completion of inspection, head of the inspection group or the group other member:

1.1 should conduct an exit briefing with the inspection object senior management/authorized person and should share the details about the inspection activities, observations, good practices, deficiencies and deviations

1.2 should develop the Inspection Act (based on the Annex 1 questionaries corresponding to the inspection object activity(ies)) describing the actions undertaken during the inspection process. Inspection Act shall be signed by the persons involved in this process.

2. One copy of the Inspection Act shall be forwarded to the representative of the Inspection object. Head of the inspection object or his authorized person shall confirm receipt of the Inspection Act through its signing.

3. In case of refusal to sign the Inspection Act by head of the inspection object or his authorized person, the relevant record shall be made in the Inspection Act.

4. In case of refusal to sign the Inspection Act, the Inspection Act shall be sent to the head of the inspection object within no later than ten working days after composition of the Inspection Act.

5. Refusal to sign the Inspection Act by head of the inspecting object or his authorized person shall not suspend the implementation of further procedures provided by the legislation of Georgia.

6. The results of the inspection with the attached Inspection Act and other materials of the case (if any) shall be submitted to the head of the Agency within the next five days after completion of the inspection.

7. The head of Agency, based on Inspection group members developed administrative prescripts, shall sent it to inspection object to eliminate the violations identified during the inspection process in a reasonable timeframe;

8. In case of detection of offenses, inspectors shall developed a act of administrative offenses following the procedure prescribed by law and send them to corresponding of inspection object court along with the attached materials.

9. Within 10 days after development of act of administrative offenses, the relevant structural subdivision (Unified Informational Bank) of the Ministry of Internal Affairs of Georgia shall be notified on this case.

Article 12. Record information into inspection register

- 1. Inspection group member shall upload all information concerned to the inspection to the Departmental registry database Inspection module:
- 2. In the database should recorded next information:

a) Inspection object name, Inspection time, group members, inspection tipe, Agency head order about inspection.

b) Individual plan and inspection act

c) Administrative prescripts with dates of elimination of violations, information from the inspection object on the implementation of administrative prescripts and the protocol(s) on the administrative violation;

d) Court decision (After receiving it in the Agency)

Article 13. Rights and Responsibilities of the Head of Nuclear and Radiation Facility

1. The head (authorized person) of the nuclear and radiation organization has the right to prevent an inspection group from entering the object without confirmation of authorization.

2. During inspection, head of an authorized or unauthorized organization and/or his authorized person shall:

a) Present all requested documents required for inspection;

b) Provide uninterrupted access to all areas of the object and do not restrict implementation of inspection activities;

c) Do not allow intentional interruption in operations of equipment and devices;

d) Do not restrict implementation of actions necessary for radiological measurements;

e) If required, provide the appropriate competent personnel during the inspection process. Failure to comply with this obligation does not exclude verification

f) Comply with other requirements set forth in the legislation.

g) Perform the actions in administrative prescript

h) Inform Agency about the fulfillment of the measures set out within the Administrative prescript, before the expiry of the mentioned term.

Article 14. Coercive measures

1. The Agency shall have the right to use compulsory measures envisaged by the Law of Georgia on "Nuclear and Radiation Safety" during the inspection.

2. In the course of inspection or summarizing the results of the inspection, after examining all the case materials and identification of violations, an administrative offense protocol shall be executed and forwarded to the Court in accordance with the rules established by the Georgian legislation.

3. In order to perform the coercive measures to prevent violation of the Georgian legislation in the area of nuclear and radiation safety, administrative prescript shall be sent to head of the organization.

4. Inspection object manager is obliged notify in written form the Agency about fulfillment of the Administrative prescript until the expiration of the deadline.

5. In case of non-compliance with the requirements defined in the Administrative prescript, the Agency shall act in accordance with the procedure established by the legislation of Georgia.

6. If during inspection (planned, unplanned) and observation there were found violations, including the circumstances which may have an immediate threat to human life, health, environment and evidence authorized person of the Agency shall carry out the necessary measures for obtaining evidence (including evidences, devices and s.o. sealing, sampling, etc.), as well as the legislation of response measures.

7. 7. The deliberate damage of the seal is regulated by the Administrative Offenses Code of Georgia.

8. The procedure of sealing and removal of seals of the Nuclear and Radiation Safety Agency, shall be determined by the relevant order of the Head of the Agency.

9. In case of detecting a criminal offense, the Inspection Act shall be forwarded to the Ministry of Internal Affairs of Georgia for further response.