

APPROACH FOR ASSESSING THE EFFECTIVENESS OF REGULATORY CONTROL IN PERU USING PERFORMANCE INDICATORS

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Abstract

The paper is intended to make an approach for assessing the effectiveness of *regulatory activities in Peru by using of performance indicators for each of the activities developed pursuant their responsibilities. So inspections, authorizations, enforcement and regulation activities are qualified by levels of attainments and then assessed independently to rise specific issues. The general conclusion is that regulatory activities seems to be acceptable but some improvements are needed in order to reach a good level of performance.*

1. Introduction

The regulatory functions in Peru, are under responsibility of Instituto Peruano de Energía Nuclear – IPEN, as prescribed by law. The technical and administrative requirements are established on the Radiological Safety Rule [1] this being the top level regulation.

The regulatory activities comprise the issuing of rules and authorizations, performing of inspections and the enforcement.

It has been felt that both the program and staffing have helped to develop all of these regulatory activities in an acceptable manner. However, a verification of effectiveness is always required from time to time in order to make improvements to the current level of control.

The assessment includes the inspection activities, authorizations, enforcement actions and regulations.

2. Setting up the performance indicators

Some performance indicators, taken from reference [2], have been set up for each assessed aspect accordingly the following:

- a) Inspection: following actions, assessment of results, solution of findings
- b) Authorizations: procedures for granting authorizations, supervision of procedural actions.
- c) Enforcement: appropriate and timely actions and the achieving of proposed safety and protection goals.
- d) Regulations: sufficiency and clearness of rules.

Qualifications are set for three levels:

- **Favorable:** action has appropriate contributed to fulfill the regulatory function and the required measures help to maintain a good protection and safety level.
- **Fair:** undertaken actions are acceptable but not enough appropriate.
- **Unfavorable:** actions are not sufficient to assure that regulatory functions are fulfilled.

3. Assessment of activities

All of the indicators have been derived from existing data in regulatory records – coming from users under control. These indicators are grouped and then reviewed to make the qualification.

3.1. Inspections Rutinary inspections are performed over medical and industrial facilities using radiation sources. Data comes from almost 1500 inspections performed along 5 years. At first, data from inspection results are grouped to show the extent of verifications performed. These indicators are displayed in the Table 1 below.

Table 1. Qualification of indicators derived from inspections

INDICATOR	FAVORABLE	FAIR	UNFAVORABLE
Correct use of devices	50% good	25%	30% poor
Good safety engineering	96% good	3%	1% poor
Following of procedures	60% good	5%	35% poor
Staffing	50% good	30%	20% poor
Staff turnover	48% low	35% medium	17% high
Record retrieval system	10% good	10%	80% poor
House keeping	45% good	23%	32% poor
Financial stability	35% good	48%	17% poor
Average performance	45,5%	27,3%	27,2%

These results are used to define the effectiveness of the inspections through the indicators shown in Table 2. In this particular case, the words Favorable, Fair and Unfavorable match with Action, Only Recording and Non Action respectively.

Table 2. Indicators qualified in the inspection activity

INDICATOR	FAVORABLE	FAIR	UNFAVORABLE
Following actions	10%	80%	10%
Assessment of results	5%	80%	15%
Solution of findings	5%	---	95%
Average performance	6,67%	53,33%	40%

The low average performance is due to that qualification took into account just what directly is result from inspection, but it is necessary to state that the other results are linked with enforcement actions or authorization procedures (e.g. solution of findings are a previous condition for licenses renewal).

3.2. Authorizations: Licenses or registers granted to all of the users of radiation sources non exempted. The kind of authorization – license or register – depends on the signification of risk arose by practice. Authorizations are granted linked to specific conditions and limitations and become the framework of protection and safety to the practice granted. The procedure for granting authorizations must be clear and concise in order to determine that the technical requirements are met by the requesting facility. Indicators assessed to determine the effectiveness of the activity are shown in Table 3.

Table 3. Qualified indicators for authorizations activity.

INDICATOR	FAVORABLE	FAIR	UNFAVORABLE
Procedures available for all practices	16%		84%
Procedural actions	60%	35%	5%
Supervision of procedural actions	20%	56%	24%
Average performance	32%	30,33%	37,67%

The average performance trends to an acceptable level, if Favorable and Fair percentages are added up, but the procedures need to be improved.

3.3. Enforcement. The regulatory requirements are fulfilled by all of the users of radiation sources however, due to that some users do not fulfill their obligations it is necessary to apply coercive measures, here called enforcement. This activity includes procedures for previous notices and for sanctioning in order to achieve that users accomplish the laws and rules. Four

indicators of effectiveness are assessed from data collected in records of the regulatory body. In the table 4 are shown the qualifications of these indicators.

Table 4. Qualified indicators for enforcement activity

INDICATOR	FAVORABLE	FAIR	UNFAVORABLE
On time notification	30%	33%	37%
Control of deadlines	50%	25%	25%
Sanction on time	73%	15%	12%
Following of users responses	25%	22%	53%
Average performance	44,5%	23,75%	23,75%

The average performance is deemed appropriate and a few efforts will be needed to achieve an excellent level.

3.4. Regulations. In order to make clear the requirements of regulatory body to users of radiation sources, performance and prescriptive rules are prepared and approved. It is considered that not all of the practices will need prescriptive rules and the general criteria may be enough suitable. The effectiveness of this activity may be assessed taking into account the opinions and needs stated by users of radiation sources, when they found not easy understand what the regulatory body wants. The choosen indicators are related to quantity and suitability of rules existing and to the lack of some others. In the Table 5 are shown these indicators and the qualification for them.

Table 5. Qualified indicators for regulatory activities

INDICATOR	FAVORABLE	FAIR	UNFAVORABLE
Enough prescriptive rules	10%	23%	67%
Suitable criteria to meet requirements	60%	18%	22%
Clearness of rules	37%	26%	37%
Easy to understand requirements	26%	25%	49%
Average performance	33,25%	23%	43,75%

In spite of general performance is appropriate, as this field is linked with authorization activities, it would need to rise the level of performance.

4. Conclusions

In a general view, the performance of regulatory activities seems to be acceptable for fulfilling the commissioned functions. However, the specific results show too that it is necessary to improve the effectiveness of these activities. Some of these identified needs are:

- lack of more prescriptive rules addressed to some practices (X ray diagnostic, nuclear medicine, brachithery and radiotherapy).
- improving of authorization procedures, specifically for those practices with high potencial risk, and stressing a more in-depth assessment.
- lack of additional requirements to improve the protection and safety.
- lack of re-assessment of inspection schedules.

It is expected that an improvement in the regulation and authorization activities will cause a general improvement in the whole performance of the regulatory body. This will help to fulfill both national and international [3] safety and radiation requirements.

6. References

[1] INSTITUTO PERUANO DE ENERGIA NUCLEAR, Reglamento de Seguridad Radiológica, Decreto Supremo No.009-97-EM, Perú 1997.

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and implementation of a regulatory infrastructure governing protection against ionizing radiation and the safety of radiation sources. IAEA 7th Draft (Provisional Standard Series), Vienna, 1997.

[3] ORGANISMO INTERNACIONAL DE ENERGIA ATOMICA, Normas básicas internacionales de seguridad para la protección contra la radiación ionizante y para la seguridad de las fuentes de radiación, Colección Seguridad No.115, Viena, Austria, 1997.