Accred Qual Assur (2006) 10: 583–589
DOI 10.1007/s00769-005-0066-8

GENERAL PAPER

Matthias Rossbach
Jane Gerardo-Abaya
Aleš Fajgelj
Peter Bode
Peter Vermaercke
Michael Bickel

Quality system implementation in Member States of the IAEA

Received: 23 October 2005
Accepted: 19 November 2005
Published online: 18 January 2006

M. Rossbach (✉)
Industrial Applications and Chemistry Section, Division of Physical and Chemical Sciences, Department of Nuclear Sciences and Applications, International Atomic Energy Agency, IAEA Wagramerstr. 5, PO Box 100, 1400 Vienna, Austria
e-mail: m.rossbach@iaea.org
Tel.: +43-1-2600-21750
Fax: +43-1-26007-21750

J. Gerardo-Abaya
Latin American Section, Department of Technical Co-operation, IAEA, Vienna, Austria

A. Fajgelj
Agency's Laboratories Seibersdorf, IAEA, Vienna, Austria

P. Bode
Delft University of Technology, Interfaculty Reactor Institute, Mekelweg 15, 2629 JB Delft, The Netherlands

P. Vermaercke
SCK-CEN, The Belgian Nuclear Research Centre, Boeretang 200, 2400 Mol, Belgium

M. Bickel
European Commission, Joint Research Centre, Institute for Reference Materials and Measurements, Retieseweg 111, 2440 Geel, Belgium

Abstract The International Atomic Energy Agency (IAEA), through its Technical Co-operation Programme, has supported the establishment of many nuclear analytical and complementary laboratories in Member States. This included the development of capabilities for the use of various nuclear analytical techniques that include alpha, beta, and gamma spectrometry; radiochemical analysis; neutron activation analysis; energy dispersive X-ray fluorescence analysis; and total reflection X-ray fluorescence. As economic, ecological, medical, and legal decisions are frequently based on laboratory results, they need to be based on accepted national and international standards.
The IAEA has taken up this important issue to enhance and foster the competitiveness of nuclear analytical laboratories with the consideration that non-nuclear capabilities are equally important. The projects aim at enhanced quality awareness, a concise system for documentation, establishment of standard operating procedures, procedures for validation of methods, surveillance of method performance, systems for sample management, regular qualification of personnel, client liaison and safety. These projects follow the ISO/IEC 17025 standard and promote participating laboratories to maintain a self-sufficient quality system by which they might be able to obtain national accreditation. This contribution describes the general concept of these projects and discusses some of the results achieved.

Keywords Technical cooperation · Quality systems · Accreditation · IAEA · Member States

Introduction

As an independent intergovernmental, science and technology-based organization in the United Nations family, the International Atomic Energy Agency (IAEA), provides assistance in the use of nuclear science and technology for peaceful applications and facilitates the transfer of nuclear technology and knowledge in a

sustainable manner to its Member States (see inserted textbox). Substantial support has been directed towards establishing or upgrading the use of nuclear analytical techniques in laboratories in the framework of national and regional development programs. The capabilities that have been developed can be grouped as follows:

– Determination of radionuclides by alpha, beta, and gamma spectrometry for environmental and man-made radioactivity investigations in e.g., food commodities; and
– Determination of trace, minor and major elements using nuclear and related analytical techniques such as neutron activation analysis (NAA) and X-ray fluorescence spectrometry (XRF).

IAEA mechanisms to support QA/QC development in Member States

One of the IAEA's programs offers technical support via Coordinated Research Projects (CRPs), a mechanism enabling scientists from developing and developed countries to work on a specific research topic for an average duration of 3 years. This covers a limited funding that complements the developing countries' existing resources to carry out investigations. Proven technologies usually resulting from a conclusive research are adapted for practical applications through the Technical Cooperation (TC) program with Member States. The support through the TC program complements the existing resources in the Member State where a national or regional program exists.

The IAEA TC support has been delivered through national and regional projects in nuclear institutions in governmental laboratories in various sectors and universities of Member States. These laboratories are in charge of monitoring public health and safety; they support the management of natural resources and the protection of the environment; they provide product certifications for export or import; their analytical data contribute to maintain a safe agriculture, to preserve crops, and to maximize nutritional value.

The recent initiatives were carried out through the regional projects in Europe, Latin America, Africa and Asia, through the formal mechanism of regional agreements like ARCAL (Regional Agreement for Latin America), RCA (Regional Agreement for Asia) and AFRA (Regional Agreement for Africa), as well as regional and national projects in these regions and in Europe. Some of the specific objectives of the TC program in these mechanisms are to:

– Increase and improve capabilities to analyze polluted air and water samples for toxic trace elements.
– Support industrial applications of nuclear techniques, such as "non-destructive testing", use of radiotracers in process control and process optimization, mineral prospecting and use of geothermal energies.
– Investigate the environmental impact of the use of insecticides and fertilizers.
– Determine transport and fate of contaminants from the continent through the rivers and estuaries and coast due to industrial and agrochemical pollution of fluvial and marine sediments, soil, and water.
– Improve the awareness of the participants for good analytical practice and enhancing capabilities in the use of reference materials for quality control purposes.

Through TC support, equipment is provided and manpower is developed via training courses, fellowships, expert missions, or scientific visits in the Member States under either the national or regional project umbrella. It needs to be assured that the equipment component complements existing facilities and conditions related to the project with an end in view of sustaining the capabilities of the Member States after the project completion (http://www-tc.iaea.org/tcweb/default.asp).

By supporting the efforts of various Member States to enhance the quality of their analytical capabilities, the IAEA also contributed to their general development level such as:

– Improvement in trace element analysis laboratory for routine determination of samples collected from lakes and seawater, as well as geological and agricultural samples.
– Production of reference materials for food and environmental matrices that support the verification requirements at the national service laboratories
– Strengthened analytical capabilities for mineral prospecting and environmental control of industrial pollution.
– Improved radioactivity measurement capability and assessment of radioactive contamination in food, environment, and waste.
– Enhancement of exports like minerals and foodstuffs that strengthen the national economy.
– Remediation of pollution problems to improve the environment.

In time, the support of the IAEA has progressed from simple establishment of capabilities to a responsive action to the demands for ensuring the quality of the services. Developing countries are heavily affected by constraints in trade due to stricter regulations on the concentration of agrochemicals, trace elements, and radionuclides in exported goods in importing countries. With increasing globalization of trade, a growing need has been observed for laboratories using nuclear analytical techniques to provide their beneficiaries objective evidence of the accuracy and reliability of the results. Huge financial losses have occurred due to the poor quality of analytical results of the producing country, identified by the receiving country upon re-analysis of the consignment. Nuclear analytical

laboratories providing export certificates are increasingly confronted with the request of formal accreditation so as to ensure international acceptance.

While quality assurance has always been important to the IAEA for safety, as can be seen in its Code of Practice for Safety in Nuclear Power Plants and ensuing documents [1], the recognition of various challenges to the socio-economic programs of Member States initiated the inclusion of quality assurance components in its programs. Although the IAEA is not the organization to provide accreditation, it supports in this way the preparation of the laboratories towards this goal through the quality assurance projects. The assistance of laboratories in their attempt to set up quality systems up to a point where they can seek formal national accreditation or certification helps them to become more self-sustainable and is satisfying their customers (beneficiaries) in their request for demonstrated quality of results.

The support for quality management in laboratories is guided by the following general targets: (1) determining the general levels of knowledge and application of quality assurance principles (as delineated in ISO/IEC 17025:1999) in the responding laboratories; (2) selecting a trial group of laboratories; (3) enhancing the levels of understanding and application via a defined set of steps introduced through training and consultative services; (4) implementing what has been learnt, and, (5) measuring the difference in compliance levels of the participating laboratories with the requirements of the ISO/IEC 17025 before and at the conclusion of the project. The quality projects are characterized by intensive support on the part of the agency staff, with the assistance of a group of external experts in QC, QA, and nuclear techniques. They provide rapid feedback to the participant laboratories on the results obtained at scheduled milestones, encourage them to make further progress, and show them how to achieve improvements.

The implementation of a quality system – approach

Link with beneficiaries

Several regional projects have been implemented through Technical Co-operation mechanisms by the IAEA to enhance the application of quality standards, mainly with participation of national nuclear institutions. A case study was made in Brazil, Argentina, and Chile on the demands of customers of participating laboratories with respect to the required quality and performance. In addition, national bodies in these countries were scouted on the countries' policies and programs with respect to certification and accreditation. This assessment showed that industries and other beneficiaries of nuclear analytical laboratories welcomed support from the IAEA that will enable them to provide objective evidence on the quality of their results, which might eventually lead to the formal certification or accreditation of their quality assurance systems. The Latin American organizations on metrology and accreditation welcomed the IAEA's projects in support of their policies as an additional opportunity for implementing their national training schemes.

Project structure

The structure of the 2–3 year TC projects on QC/QA implementation has been refined over the years but still follows the same basic mechanism:

The number of participants in each of the projects is limited to 12–15 nuclear analytical laboratories from a particular region. Selection criteria are (i) the method of analysis: first choice is be given to laboratories which use α, β, and γ-ray spectrometry, second choice to those using neutron activation analysis, and third choice to those employing X-ray fluorescence spectrometry; (ii) participants must be able to identify their existing and potential customers; (iii) preference is given to laboratories that have participated in related TC projects; (iv) participant's executive officer and, if different, the laboratory manager must indicate and demonstrate explicit commitment; and, (v) if necessary, preference is given to participants that process a large number of samples of high priority to their national economy. Another criterion could be that the laboratory under question is a partner of the IAEA's international network of Analytical Laboratories for the Measurement of Environmental Radioactivity (ALMERA network) and, therefore, might be requested to provide measurement data to the IAEA.

1. Following a general coordination meeting, the participants are trained in 3–4 workshops to establish quality procedures and documents conforming to the requirements of the ISO/IEC 17025 standard. For the purpose of the project, the basic requirements for quality assurance and quality systems have been arranged in three groups for successive implementation:
   - The first group includes the requirements for internal quality control and the first basic principles of quality assurance;
   - The second group includes the requirements for quality assurance and some of the basic requirements for quality management;
   - The third group includes the requirements of quality management and suggestions for additional practices to realize a self-sustainable quality system, fit for inspection for accreditation.
2. Participants submit six monthly progress reports for evaluation according to an established rating system. These reports are reviewed by a group of QA/QC experts, familiar with the techniques and the ISO/IEC 17025 requirements. The participants are allowed to provide the evidence in their native language. The contents of a progress report are outlined in Table 1.
3. Teams of two external experts (preferably from the same region as the participants) are assigned to take care of laboratories from the respective countries. These experts assess the progress reports, provide "on-line" assistance for further improvement, and carry out mock-up audit

Table 1 Quality indicators and evidence to be provided in progress reports

Quality indicator	Form of Evidence
1. Management commitment	Text
2. Mission statement	Text
3. Sources of error, technical and organizational	Text
4. Critical technical variables	Lists
5. Environmental factors	Lists
6. Quantified criteria for variables and factors	Lists
7. Use of control charts for critical variables and environmental factors	Control chart
8. Use of standards, reference materials, blanks etc	Measurement/analysis report
9. Performance checks of equipment, chemicals etc	Logbook pages
10. Calibration	Forms
11. Trackability of operations	Administrations, user lists
12. Equipment plus lab management	Administration, labeling
13. Documentation control (documents, computers, archives)	Descriptive text, lay-out of documents control of schemes, manuals
14. Sample custody	Example
15. Coding system(s)	Example
16. Standard operating procedures	List and Example
17. Statistical analysis	Example
18. Uncertainty budget	Text and example
19. Status of traceability	Text
20. Laboratory intercomparisons and proficiency testing	List and results
21. Method validation	Report
22. Definition of responsibilities	Descriptive text
23. Qualification of personnel	Records and training scheme
24. Authorization of reports, certificates etc	Example
25. Internal audits	Audit scheme plus example
26. Quality manual	Table of contents
27. Quality manager	Tasks

inspections that are intended more as technical assistance rather than as mere auditing.

4. Additional expert assistance and fellowship training can be provided if requests for in-depth training are expressed by the participants.
5. Two proficiency-testing rounds are carried out for the duration of the project tailored to the needs of the participants to assess any improvement of the analytical performance of the group.

Rating system for quality management

A checklist addressing all the items of the ISO standard was prepared for the assessment of the laboratories during the audit inspections. A rating system was developed specifically for these TC projects. Scores of 0 to 5 (Table 2) are attributed on the basis of documentary and operational evidence of compliance to the requirements of the ISO/IEC 17025. The ratio of the scores obtained by the participating laboratories to the maximum obtainable scores, expressed as percent, indicates the level of implementation of the quality system in a particular laboratory according to the evaluation by the experts assigned to that specific laboratory.

Subsequent results from the different progress reports and/or ratings from the audit inspections provide an indication of the progress of quality system implementation with time.

Rating and auditors' advice are transferred for information and guidance to the staff to improve their quality systems.

The laboratories' feedback and several successful accreditations (see below) after receiving the support of the Agency TC projects prove that this concept developed for quality system implementation is working, and can help improve quality output substantially in developing countries (Table 3).

The typical budget for a QA/QC regional project involving 12–15 laboratories for 3 years currently (2005) lies between US$ 350,000 and 400,000 and is distributed almost equally for expert visits, workshops, and training courses. Less than 5% of the total is allocated for equipment and consumables to improve certain QC abilities (reference materials, standards, calibrations, etc.).

The IAEA's activities in the implementation of quality systems started in 1994–1996 in Latin American Member States in projects operating under the ARCAL (Acronym of: Acuerdo Regional de Cooperación para la Promoción de la Ciencia y Tecnología Nucleares en América Latina y el Caribe) framework. In 1997, a 3-year Regional Model Project on "Quality Control and Quality Assurance for Nuclear Analytical Techniques" provided expertise for QC and QA to those Member States enabling a rapid feedback to the participant laboratories on methodologies for improvement of techniques and analysis results at scheduled milestones. Subsequently, similar initiatives were taken in Europe, East Asia, and West Asia, covering 54 Member States in those regions. To date, the largest regional project for quality management is on-going until 2007 in Africa under AFRA agreement with the participation of 19 countries.

Results

The conformity to the ISO/IEC 17025 of the participating laboratories in the East European project (RER/2/004) is reflected in Fig. 1. An increase from 30 to 92% in compliance was obtained in a period of 3 years, reflected by the averaged scores of the progress reports evaluations.

This indication of improvement in quality system implementation is confirmed by the scores in the audit inspections (Fig. 2). It demonstrates the representativeness of the scores of the progress reports, which, after all, is

Table 2 Graduations in the assessment; final scores are obtained by combining the individual scores for the level of documentation and operational status[a]

Documentation	Score	Operationality	+ Score
No documentation exists	0	Not operational	+0
Some documentation exists in the form of a logbook, a draft form, a preliminary spreadsheet, a draft procedure	1	Operational, but there are critical remarks	+1
All necessary documentation is available: a logbook or a form, a spreadsheet, a fully validated procedure does exist	2	Operational, but still a few non-critical remarks do exist	+2
		Fully operational	+3

[a]If, e.g., a draft standard operating procedure exists (score 1) but the quality control/quality assurance mechanism is well operational (score 2), the laboratory will receive a score of 3 for this item

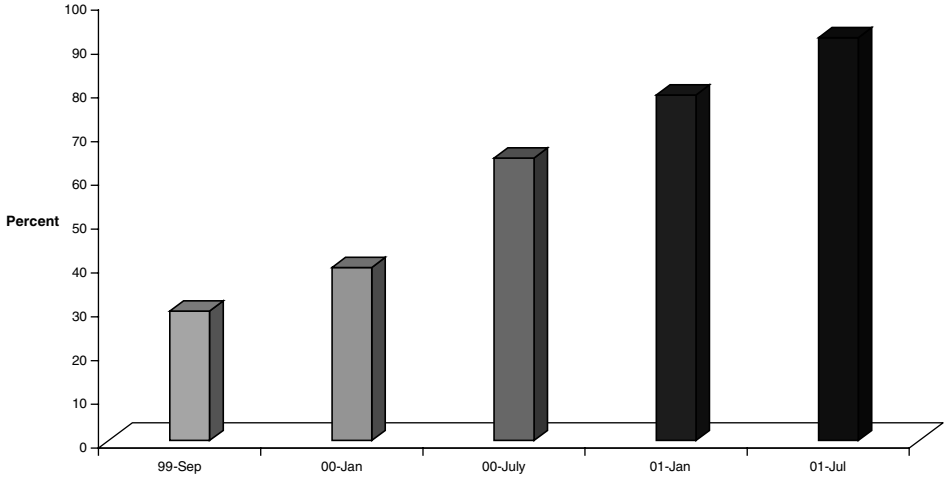

Fig. 1 Averaged scores of progress report evaluation for 12 laboratories in nuclear analytical measurements within the regional European project RER/2/004 (1999–2002). The increase in scores reflects the increase in compliance with the requirements of the International Standard ISO/IEC 17025:1999

Table 3 TC regional projects under implementation or finalized and countries involved (countries underlined received IAEA assistance in the final step to apply for accreditation)

Region	Project	Duration	Countries involved
Latin America	RLA/4/013	1997–1999	Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Mexico, Paraguay, Peru, Uruguay, Venezuela
	RLA/2/011	2003–2005	
Europe	RER/2/004	1999–2002	Armenia, Belarus, Croatia, Estonia, Hungary, Latvia, Poland, Romania, Slovakia, Slovenia, Turkey
East Asia	RAS/2/010	2001–2003	China, Indonesia, Republic of Korea, Malaysia, Mongolia, Pakistan, Philippines, Sri Lanka, Thailand, Vietnam
West Asia	RAW/2/005	2003–2005	Islamic Republic of Iran, Jordan, Kazakhstan, Kuwait, Lebanon, Syrian Arab Republic, Uzbekistan, Yemen
Africa	RAF/4/018	2003–2007	Algeria, Burkina Faso, Cameroon, DRCongo, Egypt, Ethiopia, Ghana, Kenya, Libyan Arab Jamahiria, Madagascar, Mauritius, Morocco, Niger, South Africa, Sudan, Tanzania, Tunisia, Uganda, Zambia

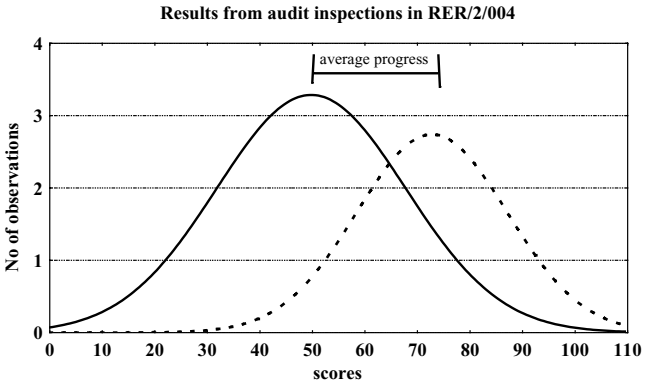

Fig. 2 Average progress in implementation of ISO 17025 requirements by participants from RER/2/004 as scored during audit inspections

a remote verification mechanism. Figures 1 and 2 further reflect that the progress of quality system implementation in such a project can actually be quantified. Moreover, the scores from the first progress report indicate that many laboratories have already adapted quality control and quality assurance measures before actually starting to think about ISO compliance.

Similar figures exist for other completed projects in Latin America and in Asia, RLA/4/13 and RAS/2/010, respectively. Other projects (Table 3) that are still (2005) in progress are expected to show similar results after completion.

Supporting activities

Participants in the regional TC projects are encouraged to develop into national centers of competence for further dissemination of the quality management ideas. There has been already a considerable spin-off in some countries following the training in QA/QC of the selected participants. Some of the participants initiated national training courses on QA/QC and lectures in native language reaching many more people then could be achieved by the IAEA projects alone. Additional supporting material was prepared by the IAEA for backing-up such activities, like technical documents (TECDOCs) on, e.g., the design of clean rooms and clean laboratories [2], use of reference materials for micro analytical techniques [3], development and use of reference materials and quality control materials [4], quantifying uncertainty in nuclear analytical measurements [5], and a training guide book on "Quality System Implementation for Nuclear Analytical Techniques" [6]. A textbook, CD ROM, and related materials are under development and will be distributed to Member States as an aid for Quality Managers to present certain aspects of a quality system and quality management. This modular training material can also be used for awareness building or as marketing material of managers and/or customers.

Table 4 Countries with nuclear analytical laboratories participating in IAEA TC projects that obtained ISO/IEC 17025 accreditation as a result of these projects[a]

Country	Year
Chile	1997
Argentina	1998
Hungary	2004
Romania	2004
Slovakia	Before start of project
Slovenia	2003
Armenia	Before start of project
South Korea	Before start of project
Indonesia	2003
Brazil	
Peru	
Pakistan	2005
Malaysia	2005

[a]In *italic*: countries that applied for accreditation (2005)

The IAEA envisioned that, in order to facilitate the sustainability of accreditation of (nuclear) analytical laboratories, each region would require expertise on preparation of suitable materials and organization and evaluation of proficiency testing rounds. As these special skills are hardly present in developing countries, a new interregional project, "Production of Reference Materials and Organization of Proficiency Tests", was initiated in 2003 and completed in 2004 (INT/1/054). Together with an enhanced metrology and accreditation infrastructure in the respective developing countries, these activities help to improve considerably the reliability of the analytical output from laboratories, which have been supplied for many years with valuable equipment and training but are still lacking appropriate infrastructure and quality culture. It is expected that the IAEA can contribute through these activities to a harmonization of analytical results, in particular those achieved via measurement of radioactivity and other trace constituents, and hence strengthen the economic situation of some of the Member States willing to face the international competition.

Conclusions

The International Atomic Energy Agency support for quality management practices for nuclear analytical laboratories in the past 10 years has been valuable for the ISO/IEC 17025 accreditation of laboratories (Table 4) in Chile, Argentina, South Korea, Indonesia, Armenia, Hungary, Romania, Slovenia, Slovakia and Pakistan and ISO-9001 certification of institutions in Cuba, and Brazil. Participating laboratories in other countries (e.g., Poland, Sri Lanka, Philippines, Syria, and Mauritius) are already close to the point where they can apply for accreditation. The degree of ISO/IEC 17025 compliance as measured by the performance indicators increased in Eastern European and East Asia laboratories from approximately 25%

to approximately 75% during the project time of 2–3 years.

Since the IAEA seems to be the only international organization that provides technical analytical support to its Member States' end-user laboratories in nuclear and nuclear-related techniques, it is within its mandate and apt that the IAEA initiated these QA/QC projects. As one of the few initiatives that enable quantification of results, such an effort will be continued. The close monitoring in combination with well-designed training course activities, the on-site audit inspections with immediate feedback and assistance to resolve problems proved to be a successful concept for quality system implementation. The reputation of IAEA and the demonstration of its expertise on-site appealed a strong management commitment and staff cooperation in the laboratories participating to the projects.

Acknowledgements Implementation of the QA/QC projects would not been feasible without the strong and continuous support by many external experts and IAEA staff knowledgeable in quality assurance matters as well as in the technical details of the nuclear techniques. Steady development of the concept for these projects was also an achievement mainly by the auditors (in alphabetical order) (H. Aigner, P. Arikan, B. Bayat, J.F. Boas, K. Burns, P. Doherty, M. ElBidaoui, K. Hopstock, B. Innes, J. Kucera, Kwang Yong Jee, S. Nakamura, A.V.R. Reddy, P.P. de Regge, P. Robouch, A. Shakhashiro). The authors are grateful to the project officers involved in the cited projects (Mr. Samiei, Mr. G. Malich, Mr. Jan Stuller, Mr. N. Lutfi, Mr. M. Maksoudi, Mr. F. Khangi, Ms. M. Zednik) and to the management of TC and NA for the opportunity to publish a collaborative work between the two departments.

References

1. Quality management of nuclear power plant operations, a manual. TECDOC No. 315 (1990) IAEA Vienna, Austria
2. IAEA (2003) Clean laboratories and clean rooms for analysis of radionuclides and trace elements, IAEA-TECDOC-1339, IAEA Vienna, Austria
3. IAEA (2002) Reference materials for microanalytical nuclear techniques, IAEA-TECDOC-1295, IAEA Vienna, Austria
4. IAEA (2003) Development and use of reference materials and quality control materials, IAEA-TECDOC-1350, IAEA Vienna, Austria
5. IAEA (2004) Quantifying uncertainty in nuclear analytical measurements, IAEA TECDOC-1401, IAEA Vienna, Austria
6. IAEA (2004) Quality system implementation for nuclear analytical techniques, Technical Report Series, IAEA-TCS-24, IAEA Vienna, Austria
7. Bode P, Van Dalen JP (1994) J Radioanal Nucl Chem 179: 141–148