

Protocol for the admission and auditing of pathology laboratories
Bowel Cancer Screening Programme
December 2013 (version 3.0)

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FOREWORD

This document is the Acceptance and Auditing Protocol for Pathology Laboratories. This protocol was drawn up within the framework of the bowel cancer screening programme that is being implemented in stages from January 2014. It provides an overview of the quality requirements set for organisations and professionals wishing to assess the pathology from colonoscopies performed after referral from the screening programme. It also describes the procedures for acceptance and auditing.

With this new screening programme we aim in the long term to prevent 2,400 deaths caused by bowel cancer. It is only possible to achieve the maximum health benefit if the implementation of the entire chain from the screening programme to the subsequent care is of high quality. Uniform national quality requirements for the pathology laboratories will contribute towards this goal.

RIVM, *Centrum voor Bevolkingsonderzoek* (Centre for population studies)

NVVP (*Nederlandse Vereniging voor Pathologie* - Dutch Association for Pathology)

The five regional screening organisations

DOCUMENT MANAGEMENT

Version management

Version	Date	Author	Explanatory notes
1.0	February 2013	RIVM-CvB	First definitive version: made available in digital form in February 2013.
2.0	May 2013	RIVM-CvB	Second definitive version: made available in digital form and sent to all the pathology laboratories in printed form at the end of May 2013.
2.1	June 2013	RIVM-CvB	Definitive interim version: made available in digital form in June 2013 because of a change in the application for a UZI pass.
3.0	December 2013	RIVM-CvB	Definitive version for the start in 2014: made available in digital form in December 2013.

Changes compared to version 2.1

Page	Change
14, 16-19, 21	A comment was added to a number of the requirements stating that it could also be an equivalent. A comment to this effect has been introduced to requirements 6.2, 6.5, 7.1, 7.2 and 8.5. In the case of requirement 8.1, the equivalent has been incorporated into the description of the quality requirement: The pathology laboratory complies with and works in accordance with the applicable <i>European</i> legislation and regulations.
17	Quality requirement 7.1: Pathologists must be MSRC registered. MSRC has now been superseded by RGS. MSRC has been replaced by RGS in the comments related to the quality requirement.
21	In the case of quality requirement 8.4 Risk Management, the comment stating that the protocol is currently being formulated has been removed. The initial draft version of the protocol has been made available in digital form on: www.bevolkingsonderzoekdarmkanker.nl/downloads .
21	In the case of quality requirement 8.5 Dealing with Incidents, a comment has been added stating that in the case of an IGZ report, the RCP will receive a copy of the final decision made by the IGZ.
33	Annex 2, the structured recording of pathology data has been removed from the protocol. The technical dataset for pathology is maintained digitally. The most recent version of the dataset is available at: www.bevolkingsonderzoekdarmkanker.nl/downloads . The following annexes have been renumbered.

CONTENTS

INTRODUCTION

1.	INTRODUCTION	7
1.1	Motivation	7
1.2	Goal and scope	7
1.3	Development and accountability	7
1.4	Document outline	7
1.5	Distribution and maintenance	7

BOWEL CANCER SCREENING PROGRAMME

2.	BOWEL CANCER SCREENING PROGRAMME	8
2.1	Organisation of the screening programme	8
2.2	Pathology reference function	9
2.3	Quality assurance	10

PROCEDURE

3.	ACCEPTANCE	11
3.1	Application	11
3.2	Assessment	11
3.3	Registration	11
4.	AUDITING	12
4.1	Periodic audit	12
4.2	Continuing the work	12

CRITERIA

5.	CRITERIA	13
5.1	Quality requirements	13
5.2	Acceptance and audit requirements	13

ACCEPTANCE AND AUDIT REQUIREMENTS

6.	ORGANISATION	14
6.1	Clinical practice	14
6.2	Internal quality assurance	14
6.3	External quality control	15
6.4	External quality assurance	16
7.	PERSONNEL	
7.1	Qualifications	17
7.2	Expertise	17

8.	FRAMEWORKS	19
8.1	Legislation	19
8.2	Implementation framework	19
8.3	Guidelines and protocols	20
8.4	Risk management	20
9.	PATHOLOGY	22
9.1	Colon biopsy assessment	22
9.2	Immunohistochemical investigation	23
9.3	High grade lesions	23
9.4	Review and consultation	23
9.5	Communicating the results	24
10.	PROCESS DURATIONS	25
11.	DATA MANAGEMENT	26
11.1	Structured data recording	26
11.2	Structured supply of data	26
11.3	Data management	27

REFERENCES

NOTES	28
CONSULTED LITERATURE	29
ABBREVIATIONS	30

ANNEXES

ANNEX 1	Pathology acceptance and audit requirements	31
ANNEX 2	Overview of relevant legislation and regulations	33
ANNEX 3	Working Party on Pathology Quality Requirements and the National Commission	34
ANNEX 4	Job description for the Regional Coordinating Pathologist (RCP)	36

1. INTRODUCTION

1.1 Motivation

The Dutch Minister of Health, Welfare and Sports decided on 1 June to implement the colon cancer screening programme. A screening programme that is offered to people with no symptoms requires a high quality implementation. This applies to every part of the programme, from the invitation to any required treatment, to be able to achieve the desired health benefit from the screening programme. The participant is also entitled to expect a uniform level of quality throughout the country. To achieve and safeguard this high level of quality, national quality requirements are being set for the professionals that will be implementing the screening programme and the subsequent diagnostics after referral.

1.2 Goal and scope

This protocol informs any concerned parties about the quality requirements that have been set for the implementation of the bowel cancer screening programme and the subsequent diagnostics. The protocol focuses specifically on the laboratories and professionals that assess the pathology from colonoscopies performed after referral because of a positive iFOBT result (an iFOBT is a self-sampling test). The protocol contains information about applying to participate in the programme, the acceptance and audit requirements and the method of assessment. Some of the requirements are based on scientific publications. This protocol also provides the conceptual foundations and background information.

1.3 Development and accountability

This third version of this protocol was developed during the preparations for the bowel cancer screening programme. The members of the Working Party on Pathology Quality Requirements provided recommendations regarding the quality requirements and the protocol set up. The protocol was developed under the responsibility of the RIVM and with advice from the board of the NVVP and the National Commission for the implementation of the bowel cancer screening programme. Annex 3 lists the names of the members of the Working Party and the National Commission. A number of changes were introduced into this third version of the protocol as a consequence of questions and remarks related to version 2.0 and with advice from the National Commission.

1.4 Document outline

The reader of this protocol is assumed to possess the relevant general knowledge. Background information about the screening programme is contained in the implementation framework for the bowel cancer screening programme. A digital version of the implementation framework is available from:

<http://www.bevolkingsonderzoekdarmkanker.nl/downloads>.

1.5 Distribution and maintenance

The RIVM is responsible for editing and distributing this protocol. Changes are submitted to the National Commission for the implementation of the bowel cancer screening programme. A paper version of this protocol will be produced and distributed, once-only, to the pathology laboratories during the implementation phase of the screening programme. The pathologists will be provided with digital access to the protocol via the newsletter from the NVVP and the RIVM. Hospitals, colonoscopy centres and health care insurance companies will also be informed. The digital version of this protocol is also available from:

<http://www.bevolkingsonderzoekdarmkanker.nl/downloads>.



The protocol will be updated regularly after the implementation of the screening programme. The digital newsletter for the cancer screening programme and the news items on the above mentioned website will state when a new version of this protocol is available.

2. BOWEL CANCER SCREENING PROGRAMME

2.1 Organisation of the screening programme



In the bowel cancer screening programme, all men and women aged from 55 to 75 will be invited to participate in the programme once every two years. When the screening programme is fully implemented, approximately 2.2 million people will be approached each year. Approximately 60% of these are expected to participate in the screening programme. In the long term, this screening programme is expected to prevent 2400 deaths from bowel cancer each year.

Each eligible person will be sent a self-sampling test kit (iFOTB). The participant will send this test kit with their faeces sample to a laboratory for analysis. If the test produces a positive result, the participant will be referred for further diagnosis (colonoscopy) and, if necessary, treatment.

The bowel cancer screening programme will be implemented by the five regional screening organisations. They are responsible for the invitations and for sending the self-sampling test kits. They will also communicate the test results. In the case of a positive result, they will first notify the participant's GP and plan an appointment for the pre-colonoscopy interview at a colonoscopy centre that qualifies for referrals from the screening programme.

The pre-procedure interview will be followed by a colonoscopy procedure in the colonoscopy centre. These colonoscopy findings will be communicated verbally at the time. In the case of a negative colonoscopy, the patient will be invited to participate in the screening programme again after ten years. In the case of a positive result, supplementary diagnostics will be performed (pathology). The colonoscopy centre will instruct a pathology laboratory to examine the material. The pathology laboratory will assess the material and send the results to the colonoscopy centre. The pathology results will be communicated to the patient by the colonoscopy centre. If the pre-procedure interview reveals that a good quality colonoscopy is not possible but that a CT colonography for example is possible, the colonoscopy centre will refer the participant to the radiologist and transfer their data. The radiologist will communicate the results of the investigation to the referring MDL doctor at the colonoscopy centre. The results will be communicated to the patient by the colonoscopy centre.

The follow-up policy may be comprised of treatment. It is also possible that the participant is placed under surveillance. The colonoscopy centre will inform the screening organisation when the participant is able return to the screening programme following surveillance or treatment.

2.2 Pathology reference function

A screening programme requires well organised quality assurance to guarantee the high quality, responsible and sustainable implementation of the screening programme. Each partner in the chain, from the invitation to any required treatment and surveillance, is responsible for the quality in their part of the chain. Consequently, the responsibility for quality and quality assurance is located at different levels and distributed throughout the entire process.

In addition to the existing guidelines and protocols from the professional bodies, national quality requirements have been set for referrals from the screening programme for subsequent diagnostics. These quality requirements are used in a system of testing and quality assurance of the pathology that results from colonoscopies performed after referral from the screening programme. A reference function has been set for this inspection and assurance.

The organisation of the pathology reference function is based on the following principles:

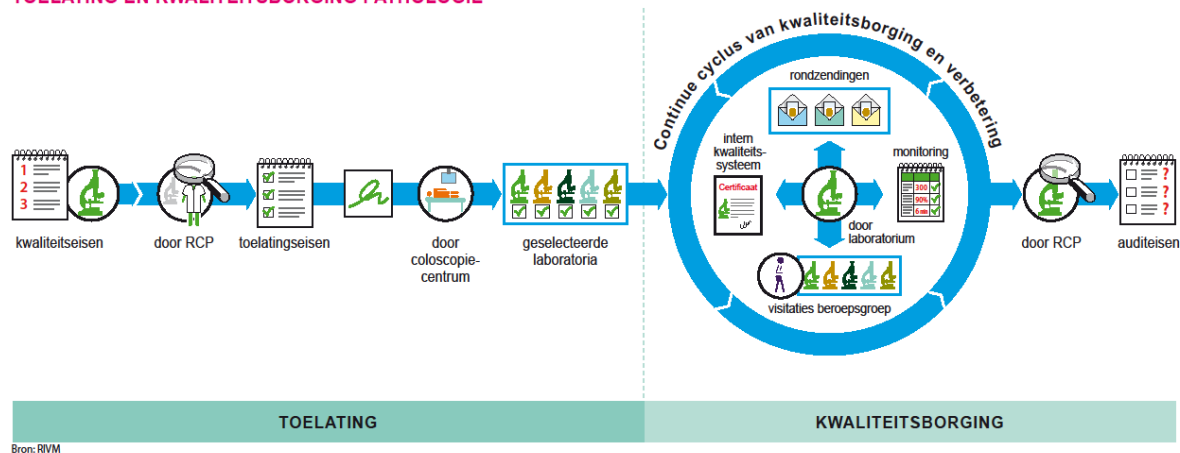
1. In compliance with the implementation framework for the bowel cancer screening programme, the pathology laboratories are responsible for assessing the histological material from colonoscopies performed after referral from the screening programme. They work in compliance with quality requirements set for the screening programme and the subsequent diagnostics.
2. In compliance with the implementation framework for the bowel cancer screening programme, the colonoscopy centres are responsible for the quality and coordination of the implementation of the subsequent diagnostics, including pathology. The colonoscopy centres are the commissioning parties for the pathology laboratories and consequently enter into contracts with them.
3. Histological material from colonoscopies performed after referral from the screening programme are only supplied by the colonoscopy centres to pathology laboratories that meet the quality requirements set for the screening programme and the subsequent diagnostics.
4. In compliance with the feasibility study and the implementation framework for the bowel cancer screening programme, the joint screening organisations are responsible for the quality assurance of the screening programme and the subsequent diagnostics (colonoscopy and pathology) and accordingly for organising and contracting the reference function.
5. The pathology reference function provides assistance to the colonoscopy centres in support of their responsibility, as the commissioner, for the quality of the pathology from colonoscopies performed after referral from the screening programme.

The reference function is fulfilled by regional coordinating pathologists (RCP). A single regional coordinating pathologist works for each screening organisation. The RCP is a BIG registered pathologist. Each screening organisation enters into a contract with a pathologist in the region for this purpose. The regional coordinating pathologists are supported in their duties by employees from the screening organisations. The RCP is accountable to the board of the screening organisation. The RCP also assists the colonoscopy centres in support of their responsibilities, as the commissioner, for the quality of the pathology from colonoscopies performed after referral from the screening programme.

Annex 4 contains the job description of the RCP which specifies the duties of the RCP in more detail.

2.3 Quality assurance

TOELATING EN KWALITEITSBORING PATHOLOGIE



The quality assurance of the assessment of pathology from colonoscopies performed after referral from the screening programme, includes an acceptance system. Pathology laboratories that wish to participate in the assessment of pathology from colonoscopies performed after referral from the screening programme are assessed by the regional Coordinating Pathologist (RCP) to determine whether they comply with the prescribed national acceptance criteria. If a laboratory meets the criteria, the RCP will advise the screening organisations to include this laboratory in the register of selected laboratories. Colonoscopy centres are required to only send histological material from colonoscopies performed after referral from the screening programme for assessment to pathology laboratories that are included in this register and consequently meet the specified quality requirements.

The quality assurance for the assessment of pathology from colonoscopies performed after referral from the screening programme involves a continuous cycle of improvement that is comprised of four stages. The pathology laboratory has set up an internal quality system that is maintained through the implementation of internal audits by the laboratory itself. An important part of this includes participation in the circulars that are designed to safeguard the uniformity of the techniques and the assessment method. The professional body will also perform periodic inspections to assess the quality of the work of the pathology laboratory and the pathologist. In addition to periodic inspections by the professional body, the results of the participating laboratories will be assessed annually by the RCP using the appropriate prescribed indicators (audit of specific aspects). During the annual consultation with the pathology laboratories, the RCP will discuss the results, interval carcinomas, benchmark data and opportunities for improvement.

The RCP will perform a full audit once every three years, to assess compliance with the prescribed national audit criteria.

The periodic audits may result in a need to adjust the national quality requirements and target figures. The RCP fulfils an advisory role in the quality assurance of the entire chain.

3. ADMISSION

3.1 Application

Any organisation or professional that wishes to assess pathology from colonoscopies performed after referral from the screening programme can submit an application to do so. Pathology laboratories that are interested in this can apply using the application form on the website of the regional screening organisation.

The contacts for each screening region are:

Screening organisation	Name of contact	Telephone	E-mail address
Bevolkingsonderzoek Zuid	Yvonne Oosterhout	+31 (0)88-0001374	y.vanoosterhout@bevolkingsonderzoekzuid.nl
Bevolkingsonderzoek Zuid-West	Annemieke van der Steen	+31 (0)88-2482125	a.vandersteen@bevolkingsonderzoekzuid-west.nl
Bevolkingsonderzoek Midden-West	Mieke Janssen	+31 (0)20-4096600	m.janssen@bevolkingsonderzoekmidden-west.nl
Bevolkingsonderzoek Oost	Alice Olde Reuver of Briel	+31 (0)88-1186243	a.oldereuver@bevolkingsonderzoekoost.nl
Bevolkingsonderzoek Noord	René C. Boom	+31 (0)50-5208888	rchboom@bevolkingsonderzoeknoord.nl

3.2 Assessment

When a pathology laboratory applies to assess pathology from colonoscopies performed after referral from the screening programme, an acceptance assessment will be performed. This assessment will be carried out by the Regional Coordinating Pathologist (RCP).

The acceptance assessments will be performed by the RCP from May 2013. The screening organisation will arrange a visit to the applicant pathology laboratory. Before the assessment takes place, the RCP will send the pathology laboratory a questionnaire, which must be completed and returned. The RCP will use this questionnaire alongside the prescribed requirements to perform the acceptance assessment during the visit. During the assessment, it will be determined whether the pathology laboratory meets the acceptance requirements for the assessment of colonoscopies performed after referral from the screening programme. In February 2013, pathology laboratories and pathologists were further notified of the application procedure and of how to supply the required data for the acceptance assessment. Version 2.0 of the protocol was sent to the pathology laboratories at the end of May 2013. This protocol contains the acceptance requirements that pathology laboratories must meet.

3.3 Registration

The results of the assessment will be incorporated into an assessment report. The pathology laboratory will receive the report from the RCP within two weeks of the assessment. This report will also contain the recommendation regarding acceptance. In the case of a positive recommendation from the RCP, the pathology laboratory will be included in the register of selected laboratories by the screening organisation. Colonoscopy centres that perform colonoscopies after referral from the

screening programme, will only offer the histological material from these colonoscopies for investigation to pathology laboratories that are included in the register of selected laboratories.

If a pathology laboratory does not meet the acceptance requirements, the pathology laboratory can submit a new application for acceptance to the screening organisation. This new application is subject to the applicable time limit as set by the RCP and specified in the assessment report. An acceptance reassessment will be performed by the RCP from the relevant screening region in cooperation with an RCP from a different screening region. This will also assess whether the pathology laboratory has implemented the required improvement measures. If the audit team issues a positive recommendation, the pathology laboratory will now be included in the register of selected laboratories. If the audit team issues a negative recommendation, the pathology laboratory can submit a new application for acceptance to the screening organisation after one year. The RCP will then perform a new acceptance assessment.

4. AUDITING

4.1 Periodic audit

When a pathology laboratory is registered in the overview of selected laboratories, it will participate in the periodic audits performed by the RCP. Each year the RCP will audit specific aspects and discuss interval carcinomas, benchmark data and opportunities for improvement. A full audit will be performed once every three years to assess compliance with the prescribed national audit criteria and discuss opportunities for improvement. The RCP will perform this periodic audit using the prescribed national audit criteria. The audit requirements are specified in this protocol.

4.2 Continuing the work

The results of the audits will be incorporated into an audit report. The pathology laboratory will receive the report from the RCP within two weeks of the audit. In the case of a full audit, the report will include a recommendation in respect of continuing the work. If the RCP issues a positive recommendation, the pathology laboratory will remain listed in the register of selected laboratories.

If a pathology laboratory does not meet the audit criteria during a periodic audit, the RCP will specify a time frame within which the pathology laboratory must implement the required improvement measures. After this time, the RCP from the relevant screening region will perform a re-audit in cooperation with an RCP from a different screening region. If the audit team issues a positive recommendation, the pathology laboratory will remain listed in the register of selected laboratories. If the audit team issues a negative recommendation, the pathology laboratory will be removed from the register of selected laboratories. After one year, the pathology laboratory can submit a request for renewed acceptance into the screening organisation. The RCP will then perform a new acceptance assessment.

If an interim audit shows that the pathology laboratory no longer meets the quality requirements, this can also result in a change to its registration in the register of selected laboratories.

5. CRITERIA

5.1 Quality requirements

The goal of the bowel cancer screening programme is to achieve health benefits through the prevention or early detection of bowel cancer in people with no symptoms. It is only possible to achieve the maximum health benefit if the implementation of the entire chain, from the screening programme to the subsequent care, is of a high quality. By setting quality requirements, we are striving to achieve the maximum possible effect from the screening programme.

The quality requirements for pathologist have been developed by the national working party on pathology quality requirements, which includes representatives from the NVVP and the screening organisation. The board of the NVVP and the National Commission for the implementation of the bowel cancer screening programme have approved these requirements. The quality requirements were developed to be as compatible as possible with the existing quality processes of the NVVP. This includes the inspections by the professional body and the system of circulars. Use was also made of the experience gained during the existing screening programmes as well as the information available from the trial bowel cancer screening programme and international screening programmes.

5.2 Acceptance and audit requirements

The quality requirements are used for both acceptance into (acceptance requirements) and the quality assurance of (audit criteria) the assessment of pathology from colonoscopies performed after referral from the bowel cancer screening programme. The term acceptance requirements means the requirements that pathology laboratories must meet to be permitted to assess the pathology from colonoscopies performed after referral from the screening programme. The term audit criteria means the requirements used as the basis for auditing pathology laboratories at predefined times. The goals of the periodic and interim audits is to assess continuing compliance with the quality requirements and to discuss opportunities for improvement.

The tables included in chapters 6 to 11 of this protocol contain an overview of the acceptance requirements and audit criteria for pathology laboratories. The tables include the following categories:

- the subject states the aspect of work that is to be performed;
- the goal that should be achieved by the respective work;
- the indicator that is used to determine whether the goal has been achieved;
- the description of the contents of the indicator;
- the acceptance requirement is, in the case of a $\sqrt{}$, applicable for participation in the programme;
- the audit criteria is, in the case of a $\sqrt{}$, applicable for continuing the work;

Three quality requirements are quantitative and can be calculated using registered index numbers. The other quality requirements are qualitative and must be met in a demonstrable manner. The RCP will have to evaluate the extent to which the pathology laboratory adequately meets these requirements in a demonstrable manner. Wherever possible the prescribed quality requirements have an empirical basis, which is justified in this protocol.

The quality requirements may be subject to change. Their practical viability is therefore continuously monitored. If necessary, the requirements will be modified to take into account the changed conditions.

6. ORGANISATION

6.1 Clinical practice

A screening programme that is offered to people with no symptoms requires a high quality implementation. This applies to every part of the programme, from invitation to any necessary treatment, and to all professionals that implement the screening programme and the subsequent diagnostics performed after referral. The parameters for this are created by good clinical practice.

The clinical practice in pathology laboratories is assessed by the professional body using quality inspections performed by the National Inspection Commission (LVP, *Landelijke Visitatie Commissie*) of the NVVP. These inspections take place in compliance with the quality inspection assessment system for pathology¹. The NVVP website contains the most recent overview of the inspection criteria used by the LVC to assess the pathology laboratories(<http://www.pathology.nl/kwaliteitsvisitatie>).

Quality inspections are performed once every five years. Participation is necessary to meet the RGS criteria for re-registration. A laboratory that wishes to assess the pathology from colonoscopies performed after referral from the screening programme must also participate in the periodic inspections by the LVC. The pathology laboratory must also have a positive recommendation from the LVC in respect of continuing the work.

Goal			
Good quality clinical practice			
Indicator	Description	Acceptance criteria	Audit criteria
6.1 Periodic inspections	Participation in periodic inspections by the professional body.	✓	✓
6.2 Recommendation to continue the work.	A positive recommendation from the National Inspection Commission, or an equivalent body, to continue the work.	✓	✓
Comments	6.2 The RCP performs the assessment to determine whether the laboratory meets the equivalent of the prescribed requirement. The RCP issues a recommendation about this to the screening organisation. It is for the screening organisation to decide whether the laboratory is accepted or, in the case of an audit criteria, may continue to work within the framework of the screening programme.		
Foundations	¹ LVC. Assessment system for quality inspections in pathology (http://www.pathology.nl/kwaliteitsvisitatie).		

6.2 Internal quality assurance

Safeguarding the quality of the screening programme and the subsequent diagnostics is important for the entire process within the chain. The responsibility for quality and quality assurance is located at different levels. The health care provider is responsible for the proper implementation of the screening programme and/or the subsequent diagnostics and complies with the associated, prescribed national guidelines and protocols. The health care provider or the organisation in which the health care provider works, must set up and maintain an internal quality system².

It is also important that the health care provider performs periodic internal audits to document the strong and weak aspects of their performance and to focus on opportunities for improvement. An internal audit is a systematic investigation that is performed to determine whether the activities

correspond with the planned and agreed activities, whether they are being performed correctly, are suitable for achieving the intended goal and comply with the requirements.

The most important activities for pathology laboratories, within the framework of the bowel cancer screening programme, are the critical activities related to assessing the pathology from colonoscopies performed after referral from the screening programme.

Goal		Internal quality assurance for the work that is to be performed	
Indicator	Description	Acceptance criteria	Audit criteria
6.3 Internal quality system	An organised and well-maintained quality system.	✓	✓
6.4 Internal audits	Annual internal audit of the critical activities that have to be performed.		✓
Comments	6.3 The pathology laboratory complies with the requirements set by the NVVP for accreditation. The NVVP intends to incorporate the compulsory character of an accreditation, such as the CCKL-RvA, as an item in the next five-year policy plan (2014-2018). However, the discussion on this policy plan has yet to take place within the association.		
Foundations	² RIVM. Feasibility study into population screening for colorectal cancer. 2011;53.		

6.3 External quality control

Participants in the screening programme must be able to assume that the pathology from colonoscopies performed after referral from the screening programme produce the same results irrespective of which laboratory or pathologist performs the assessment. A circular is an important aid to investigating the comparability of the laboratories and pathologists. The primary goal is to determine repeatability and reproducibility, but also accuracy and consistency. Circulars can also provide an understanding of the competence of the participating laboratories and pathologists as well as provide opportunities for improving quality.

To be able to compare the quality of the pathology from colonoscopies performed after referral from the screening programme with those from other laboratories and possibly with target values, the pathology laboratory must also participate in external quality control systems³. Furthermore, a distinction is made between:

- circulars of histological specimens for the assurance of uniformity in the applied techniques of embedding, sectioning and staining the biopsies
- digital circulars containing histological images of colon pathology for the assurance of uniformity of assessment and reproducibility between pathologists

The results of the circulars are made available by the pathology laboratory to the RCP.

Goal			
Assure uniformity in the applied techniques and assessment			
Indicator	Description	Acceptance criteria	Audit criteria
6.5 Circulars of histological specimens	Participation is a system of circulating histological specimens	✓	✓
6.6 Circulation of histological images	Participation is a system of digital circulation of histological images of colon pathology.		✓
Comments	<p>6.5 As used within the framework of the SKML, or an equivalent. The RCP performs the assessment to determine whether the laboratory meets the equivalent of the prescribed requirement. The RCP issues a recommendation about this to the screening organisation. It is for the screening organisation to decide whether the laboratory is accepted or, in the case of an audit criteria, may continue to work within the framework of the screening programme.</p> <p>6.6 The Pathology EQA system from the BCSP will be adopted for this purpose. During the acceptance procedure, the RCP will assess whether the laboratory is prepared to participate in these circulars.</p>		
Foundations	<p>³ CCKL Practical guidelines. 2005;109-110. Taking into account the transition from CCKL to RvA ISO15189.</p>		

6.4 External quality assurance

In addition to inspections by the professional body, internal quality assurance and external quality control, extra quality requirements can be set within the framework of implementing a screening programme. Possible reasons for this could be because it is desirable for there to be a uniform national implementation or that additional requirements are found to be desirable because a screening programme is being offered to people that have no symptoms⁴. The quality requirements are used in a system of inspection and assurance for the assessment of pathology from colonoscopies performed after referral from the screening programme. A reference function has been set up for this inspection and assurance (see section 2.2).

A system of acceptance and auditing is used to assure the quality of the implementation of the screening programme and the subsequent diagnostics. The quality requirements are used for both the acceptance into (acceptance requirements) and quality assurance of (audit criteria) the programme. Laboratories that assess pathology from colonoscopies performed after referral from the bowel cancer screening programme participate in the periodic audits performed by the Regional Coordinating Pathologist (RCP). The goal of the audits is to assess continuing compliance with the quality requirements and to discuss opportunities for improvement (see chapters 3 and 4).

Goal			
External quality assurance for the work that is to be performed			
Indicator	Description	Acceptance criteria	Audit criteria
6.7 Periodic audits	Participation in the periodic audits performed by the RCP within the framework of the screening programme.		✓
Comments	Each year the RCP performs an audit on specific aspects of colon pathology. A full audit will be performed once every three years, to assess compliance with the prescribed national audit criteria.		
Foundations	<p>⁴ RIVM. Feasibility study into population screening for colorectal cancer. 2011;48.</p>		

7. PERSONNEL

7.1 Qualifications

For some of the participants, the screening programme generates a need for care because of they are referred for additional diagnostics. The quality of the screening programme and subsequent care is related to the knowledge and skills of the individual health care providers. This starting principle establishes a role for the screening programme in setting requirements for the training and professional development of doctors and paramedics that work within the screening programme as well as in the subsequent diagnostics. If these are not well organised, the anticipated health benefits for the participant will not be achieved. Health care providers involved in the implementation of the screening programme and the subsequent care must comply with the attainment targets and the (re-)registration related to the execution of their professional duties⁵.

Employees that assess the pathology from colonoscopies performed after referral from the screening programme must remain proficient and competent in compliance with the Netherlands' Individual Health Care Professions Act (*Wet BIG, Wet op de beroepen in de individuele gezondheidszorg*). The pathology laboratory must ensure that employees properly manage their professional registration and re-registration. Pathologists must be RGS registered.

Goal			
Qualified employees for the implementation of the screening programme and the subsequent diagnostics			
Indicator	Description	Acceptance criteria	Audit criteria
7.1 Professional registration	Employees are responsible for their professional registration and re-registration.	✓	✓
Comments	7.1 Pathologists must be RGS registered, or equivalent. The RCP performs the assessment to determine whether the laboratory meets the equivalent of the prescribed requirement. The RCP issues a recommendation about this to the screening organisation. It is for the screening organisation to decide whether the laboratory is accepted or, in the case of an audit criteria, may continue to work within the framework of the screening programme.		
Foundations	⁵ RIVM. Feasibility study into population screening for colorectal cancer. 2011.		

7.2 Expertise

A health care provider is personally responsible for his or her professional development to ensure they provide good quality health care. Professional development can only succeed if the health care provider is prepared to perform a critical assessment of their actions, in cooperation with others, as well as assess new developments on their merit and incorporate them into the existing health care system. Professional associations are responsible for the level of quality of the relevant professional community and pathology laboratories are responsible for the quality of the work performed by the employees⁶.

The NVVP commission for continued professional development (*CBN, Commissie Bij- en Nascholing*) initiates and promotes professional development in pathology at a national level. Their principle activities involve programming and organising the annual national Pathology Days and the professional development evenings. Other focal points include providing information about professional development on the NVVP website and the accreditation of professional development activities.

Supplemental to the standard professional development activities provided by the CBN, the RCP organises professional development activities that focus specifically on colorectal pathology. The pathologist must accumulate at least five points of professional development in this area within the standard five-year cycle of professional development.

The pathologist's experience also contributes towards the degree of expertise available for the work performed in the screening programme and the subsequent diagnostics. In support of this the pathologist has successfully completed the assessment comprised of an e-learning module and an EQU of a yet to be defined number of sections.

Goal			
Expert employees for the implementation of the screening programme and the subsequent diagnostics			
Indicator	Description	Acceptance criteria	Audit criteria
7.2 Professional development	Number of professional development points attained by the pathologist in the area of colorectal pathology in five years.		≥ 5
7.3 Assessment	The successful completion of the assessment for pathologists.		√
Comments	<p>7.2 The half-day sessions of professional development in the field of colorectal pathology are compatible with the standard 5-year cycle of training for re-registration, or its equivalent. The RCP performs the assessment to determine whether the laboratory meets the equivalent of the prescribed requirement. The RCP issues a recommendation about this to the screening organisation. It is for the screening organisation to decide whether the laboratory is accepted or, in the case of an audit criteria, may continue to work within the framework of the screening programme.</p> <p>7.3 The assessment for pathologists is comprised of an e-learning module and a digital EQU of a yet to be defined number of sections. The results of the assessment will be assessed by the RCP.</p> <p>The e-learning module and the EQA will be made available to the pathologists on 1 January 2014. The pathologist can participate in the EQA after completing the e-learning module.</p> <p>Laboratories that assess the pathology from colonoscopies performed after referral from the screening programme are responsible for ensuring the pathologists that assess this pathology have successfully completed both parts of this assessment by 1 July 2014.</p>		
Foundations	<p>⁶ RIVM. Feasibility study into population screening for colorectal cancer. 2011;56.</p>		

8. FRAMEWORKS

8.1 Legislation

The bowel cancer screening programme is a study in compliance with the Population Screening Act (WBO, *Wet op het bevolkingsonderzoek*) and consequently requires a licence. The screening organisations are licence holders on behalf of all the health care providers that have entered into a contract related to the screening programme. This is a licence within the framework of the WBO.

All the legislation applicable to health care such, as the Medical Treatment Contracts Act (WGBO, *Wet op de geneeskundige behandelingsovereenkomst*), the Individual Health Care Professions Act (Wet BIG, *Wet op de beroepen in de individuele gezondheidszorg*) and the Personal Data Protection Act (WBP, *Wet bescherming persoonsgegevens*), are applicable to the bowel cancer screening programme. Each health care provider involved in the implementation of this screening programme must comply with the Client's Right of Complaint (Care Sector) Act (WKCZ, *Wet klachtrecht cliënten zorgsector*) and the Care Institutions (Quality) Act (KWZi, *Kwaliteitswet zorginstellingen*)⁷.

Annex 2 contains an overview of the principle relevant legislation and regulations.

Goal			
Perform the work within the specified frameworks			
Indicator	Description	Acceptance criteria	Audit criteria
8.1 Legislation	Compliance with and working in accordance with the applicable European legislation and regulations.	✓	✓
Comments	-		
Foundations	⁷ RIVM. Policy Framework for Cancer Screening Programmes 2013. 2012.		

8.2 Implementation framework

The RIVM-CvB has set up the implementation frameworks to provide guidance to the different screening programmes that are coordinated by the region. An implementation framework, to which all parties are committed, has been set up for the bowel cancer screening programme⁸. The goal of the implementation framework is to ensure the screening programme operates effectively within the quality frameworks and to ensure national uniformity. The implementation framework describes what is needed to achieve this. The implementation framework is intended for all parties involved in the implementation (screening and subsequent diagnostics). A paper version of this implementation framework will be produced and distributed, once-only, to the professional bodies and the involved professionals at the start of the of the screening programme. The most recent version of the implementation framework is available at: <http://www.bevolkingsonderzoekdarmkanker.nl/downloads>.

Goal Perform the work within the specified frameworks			
Indicator	Description	Acceptance criteria	Audit criteria
8.2 Implementation framework	Compliance with and working in accordance with the agreements contained in the prescribed national implementation framework for the bowel cancer screening programme.		✓
Comments	-		
Foundations	⁸ RIVM. Implementation framework for the bowel cancer screening programme. 2012.		

8.3 Guidelines and protocols

When setting up and implementing the bowel cancer screening programme, great importance was placed on the close involvement of the different professional bodies that play a role throughout the entire chain of the screening programme, subsequent pathology and treatment. This includes recognition of the professional standards, values and methods.

Guidelines and protocols help define the professional standard and best practices. They are a fundamental responsibility of the professional and his or her professional body. The professional bodies are responsible for the development and implementation of guidelines and protocols. In terms of health rights, every health care provider is required by the WGBO to act in accordance with his or her responsibilities in pursuance of the professional standard⁹.

The principle guidelines for assessing pathology are presented on websites of the NVVP¹⁰ and the IKNL¹¹.

Goal			
Perform the work within the specified frameworks			
Indicator	Description	Acceptance criteria	Audit criteria
8.3 Guidelines and protocols	Compliance with and working in accordance with the applicable guidelines and protocols as prescribed by the professional body.	✓	✓
Comments	The pathology laboratory and the pathologist must at the start of the screening programme work in compliance with the guidelines and protocols prescribed at that time by the professional body.		
Foundations	⁹ RIVM. Feasibility study into population screening for colorectal cancer. 2011. ¹⁰ http://www.pathology.nl/vakinhoudelijk/richtlijnen . ¹¹ http://www.oncoline.nl/ .		

8.4 Risk management

Risk management is the entire set of decisive measures to ensure the bowel cancer screening programme is resumed as intended as quickly as possible after an incident or calamity and that any foreseeable risks are prevented. A screening programme-wide method will be set up to deal with calamities that describes the tasks and responsibilities of the involved parties. The pathology laboratory has set up and implemented a procedure for dealing with incidents.

In compliance with the Client's Right of Complaint (Care Sector) Act (WKCZ) every health care provider must set up a procedure to deal with complaints about their conduct or that of a person working with a client on his or her behalf. The health care provider must notify the clients in a suitable manner of the procedure (Article 2, paragraph 1 of the WKCZ). The procedure provides for a client's complaint to be dealt with by a complaints commission. The clients can complain about any conduct of a health care provider or anyone working for the health care provider. No limitations may be applied to the grounds for complaint.

The pathology laboratory will discuss during the periodic audit with the RCP any incidents or complaints that could lead to improvements to the screening programme.

Goal		Perform the work within the specified frameworks		
Indicator		Description	Acceptance criteria	Audit criteria
8.4	Risk management	Compliance with and working in accordance with the prescribed national risk management protocol for the bowel cancer screening programme.		✓
8.5	Dealing with incidents	An implemented procedure for dealing with incidents.	✓	✓
8.6	Evaluation of incidents	Incidents that could lead to improvements in the screening programme are discussed with the RCP during the periodic audit.		✓
8.7	Dealing with complaints	An implemented procedure for dealing with complaints.	✓	✓
8.8	Evaluation of complaints	Complaints that could lead to improvements in the screening programme are discussed with the RCP during the periodic audit.		✓
Comments		<p>8.5 If there is no procedure in place, the pathology laboratory must be able to demonstrate to the RCP during the acceptance assessment, the method that will be implemented.</p> <p>In the case of a report to the IGZ, or equivalent, the pathology laboratory must send the RCP a copy of the final decision made by the Inspectorate. The RCP performs the assessment to determine whether the laboratory meets the equivalent of the prescribed requirement. The RCP issues a recommendation about this to the screening organisation. It is for the screening organisation to decide whether the laboratory is accepted or, in the case of an audit criteria, may continue to work within the framework of the screening programme.</p> <p>8.7 If there is no procedure in place, the pathology laboratory must be able to demonstrate to the RCP during the acceptance assessment, the method that will be implemented.</p>		
Foundations		-		

9. PATHOLOGY

Pathology has an important function in screening for bowel cancer because the treatment of the participants in the programme is dependent on the quality and accuracy of the diagnosis. The pathology influences the decision of whether to perform a local and/or a large resection as well as on whether to perform surveillance after the screening.¹²

9.1 Assessment of colon biopsy

The abnormalities that are biopsied or fully removed during a colonoscopy performed after referral from the screening programme are processed using standard procedures in the pathology laboratory. A diagnosis can generally be made using standard staining techniques. In its recommendations regarding the implementation of the bowel cancer screening programme, the Health Council of the Netherlands (GR, *Gezondheidsraad*) required special attention for the classification of adenomas for the surveillance programme, but in particular for the monitoring performed in the screening programme. The GR is of the opinion that protocol-based and standardised, nationally uniform reporting of abnormalities is a precondition and that this is facilitated by the availability in the Netherlands of the PALGA system, which is used by all pathology laboratories¹³. During the assessment of the pathology, the data is recorded in compliance with the format and the quality requirements * of the PALGA protocol module (PPM).

The professional(s) with primary responsibility for laboratory investigations must meet the training requirements as prescribed by the professional body for the relevant profession. The responsibility for the laboratory organisation, as well as the responsibility for certain analytical aspects, can be delegated to appropriately qualified employees by the professional(s) with primary responsibility. However, this does not mean that the primary professional responsibility has been delegated¹⁴. The histological specimens are then assessed under the responsibility of a registered pathologist.

Goal		Uniform assessment of colon biopsies		
Indicator		Description	Acceptance criteria	Audit criteria
9.1	Protocol-based working practices	When assessing the pathology, the data is recorded in compliance with the format and the quality requirements of the PALGA protocol module.	✓	✓
9.2	Responsibility	Histological specimens are assessed under the responsibility of a registered pathologist.	✓	✓
Comments		9.1 During the assessment for acceptance into the programme, the pathology laboratory must have demonstrable experience with recording data in compliance with the format and the quality requirements* of the PPM. 9.2 This assumes that task reconfiguration has not yet taken place. When a task reconfiguration is performed, the quality requirements will be reassessed and more broadly formulated. In this case, the certified assessor will be deemed to be equivalent to the pathologist within the prescribed quality requirements.		
Foundations		13 GR. Bowel cancer screening programme. 2009;119. 14 CCKL Practical guidelines. 2005;39.		

¹² European guidelines on quality assurance of colorectal cancer screening and diagnosis. 2010;209.

* This includes the integral conversion to SNOMED-CT, the required CDA structure for the report, the standardised and timely processing of updates to the structure of the protocol, validation and pre-validation studies where necessary, fully integrated electronic connections with the relevant MDL systems, and integration with the interface between the screening organisations and pathology laboratories. It is expressly forbidden to input data manually.

9.2 Immunohistochemical investigation

Within the framework of the bowel cancer screening programme, immunohistochemical investigation is not routinely performed in the pathology of polyps. It is expected that for most of the pathology from colonoscopies performed after referral from the screening programme, a diagnosis will be possible using standard staining. Immunohistochemical staining will then have no added benefit.

Goal			
Cost-effective colon biopsy assessment			
Indicator	Description	Acceptance criteria	Audit criteria
9.3 Immunohistochemical investigation	Within the framework of the bowel cancer screening programme, immunohistochemical investigation is not routinely performed in the pathology of polyps.		✓
Comments	Investigations performed in relation to possible hereditary cancer symptoms are not included within the scope of this indicator.		
Foundations	-		

9.3 High grade lesions

The European Directive for the quality assurance of bowel cancer screening and diagnostics recommends in the absence of evidence-based guidelines that the percentage of the pathology in an iFOBT screening programme with the outcome 'high grade lesion' must not be greater than 10%¹⁵. As it is not expected that the practical situation in the Netherlands will deviate from the European situation, this standard for the pathology has been adopted within the framework of the bowel cancer screening programme.

Goal			
Uniformity of assessment			
Indicator	Description	Acceptance criteria	Audit criteria
9.4 High grade lesions	The percentage of the pathology from colonoscopies performed after referral from the screening programme with the outcome 'high grade lesion'.		≤ 10%
Comments	High grade lesion is considered to be: adenoma with high grade dysplasia, (intramucosal) carcinoma in situ or suspected pre-carcinoma. An invasive carcinoma is not considered to be a high grade lesion.		
Foundations	¹⁵ European guidelines on the quality assurance of colorectal cancer screening and diagnosis. 2010;226.		

9.4 Review and consultation

Within the framework of quality assurance, a pathologist can employ a system of review and consultation for the assessment of histological material. If there is any uncertainty about a primary assessment, a pathologist can obtain advice from a fellow pathologist via a consultation. If there are any questions after a primary assessment or if a resection has been performed, it may be necessary for the original specimen to be re-assessed (reviewed) by, for example, a different hospital.

It is also important that the pathology laboratory has knowledge of the laboratories and pathologists that can be used for review and consultation. A register must also be maintained of all the histological

assessments for which a review or consultation was requested.¹⁶ This requires that reviews and consultations by the pathologist are registered in compliance with the format and quality requirements of the PALGA protocol module.

Goal			
Assuring the quality of the assessment			
Indicator	Description	Acceptance criteria	Audit criteria
9.5 Review	Reviews and consultations are registered by the pathologist in compliance with the format and the quality requirements of the PALGA protocol module.		✓
Comments	The registration of reviews and consultations in PALGA is not yet possible. This will be included in the new release of PALGA.		
Foundations	¹⁶ NEN-EN-ISO 15189:2007;8.		

9.5 Communicating the results

The responsibility for the laboratory organisation, as well as the responsibility for certain analytical aspects, can be delegated to appropriately qualified employees by the professional(s) with primary responsibility. However, this does not mean that the primary professional responsibility has been delegated¹⁷. The results of the pathology from colonoscopies performed after referral from the screening programme must be authorised by a qualified pathologist.

If the outcome of the iFOBT test on the faeces sample is positive, the participant in the bowel cancer screening programme will be referred for a colonoscopy. In the case of a positive result, supplementary diagnostics will be performed (pathology). The colonoscopy centre will instruct a pathology laboratory to investigate the material. The pathology results will be communicated to the participant by the colonoscopy centre. The results of the pathology will be supplied digitally to the colonoscopy centre that requested the investigation within the framework of the bowel cancer screening programme.

Goal			
Ensure the results are communicated in a uniform and high quality manner			
Indicator	Description	Acceptance criteria	Audit criteria
9.6 Authorisation	Results are authorised by a qualified pathologist.	✓	✓
9.7 Communicating the results	The pathology results will be supplied digitally to the colonoscopy centre that requested the investigation within the framework of the bowel cancer screening programme.		✓
Comments	-		
Foundations	¹⁷ CCKL Practical guidelines. 2005;39.		

10. PROCESS DURATIONS

Different studies have shown that bowel cancer screening programmes can cause anxiety amongst the participants. Lindholm *et al.* showed that this applies to a small percentage of the participants at the time they receive the invitation to participate in the screening programme¹⁸. The anxiety amongst the participants increases if the results from the faeces test proves to be positive. A study involving over 6000 people showed that the degree of anxiety increased by 60% in the group that had a positive result from the faeces test and that 15% experienced a negative effect on their daily life. In addition, Parker *et al.* showed that anxiety amongst participants was highest after a positive test and an invitation for a colonoscopy¹⁹. In general, the degree of anxiety was greater amongst women and participants with a lower level of education than amongst men and participants with a higher level of education.

The studies performed by Lindholm and Parker also show that anxiety amongst participants with a positive iFOBT result reduces considerably after the colonoscopy has been performed.^{18,19} To ensure the participant is not kept unnecessarily long in a state of uncertainty, he or she should be informed of the result of the colonoscopy as quickly as possible.

To limit anxiety amongst the participants with a positive iFOBT test, process durations should be as short as possible. This applies to the pre-procedure interview, the colonoscopy and the duration of the pathological investigation.

Goal			
Minimise anxiety amongst the participants			
Indicator	Description	Acceptance criteria	Audit criteria
10.1 Duration from the receipt of the material to authorisation of the PA results	The percentage of submissions for which the time interval between the arrival of the histological material at the pathology laboratory and the authorisation of the outcome by the pathologist is a maximum of five working days.		≥ 95%
Comments	-		
Foundations	¹⁸ <i>Scand J Gastroenterol.</i> 1977;32(3):238-45. ¹⁹ <i>J Med Screen.</i> 2002;9(1):7-10.		

11. DATA MANAGEMENT

11.1 Structured data recording

Good record keeping of the pathology of colon biopsies is very important to the health care provider treating the patient, the Dutch Cancer Register (*Nederlandse Kankerregistratie*), the primary process and the quality assurance of the screening programme. Different studies have shown that the introduction of a proforma template containing a minimum dataset, makes a uniform and more complete record possible compared to the interpretation of reports based on free text²⁰. The professional body has set up a PALGA protocol module for the structured recording of pathology data from colon biopsies.

To be able to implement the screening programme, the required data must be recorded and this data must be exchanged between the stakeholders in the chain. To be able to assess and monitor the quality of the implementation of the screening programme and the subsequent health care, it is essential that structured data related to the people being screened is recorded and can be analysed. A complete record of the work performed within the framework of the screening programme, in compliance with the format and the quality requirements of the PALGA protocol module, is essential to this²¹.

An overview of the variables that need to be registered within the framework of the bowel cancer screening programme is included in the pathology technical dataset. The most recent version of the dataset is available at: www.bevolkingsonderzoekdarmkanker.nl/downloads.

Goal			
Support for the primary process; monitor and evaluate quality			
Indicator	Description	Acceptance criteria	Audit criteria
11.1 Data recording	Structured data recording in compliance with the format and the quality requirements of the PALGA protocol module.	✓	✓
Comments	For acceptance into the programme, an up-to-date registration system must be present during the assessment. Connection to the national database (PALGA) is essential for this.		
Foundations	²⁰ European Guidelines on the quality assurance for colorectal cancer screening and diagnosis. 2011;226. ²¹ RIVM. Implementation framework for the bowel cancer screening programme. 2012;31.		

11.2 Structured supply of data

Data is required for quality control, monitoring and evaluation. This data is recorded alongside the pathology. It is very important that this data be registered in the same manner by all the pathology laboratories. The defined dataset that is recorded alongside the pathology is fed back to the screening organisations to be used in the follow-up registration. This data is used in the IT system (ColonIS) for quality control and monitoring²². For the proper analysis and evaluation of this data, the required data must be made available and supplied in a structured manner. The laboratory must supply the minimum dataset in messages that are consistent with the messages generated by the PALGA protocol module.

The pathology laboratory must have a secure internet connection for the electronic exchange of data within the framework of the screening programme.

Goal			
Support for the primary process; monitor and evaluate quality			
Indicator	Description	Acceptance criteria	Audit criteria
11.2 Supply of data	The provision of digital access to the required data and its structured digital delivery.	✓	✓
11.3 Data exchange	The availability of a secure internet connection for the electronic exchange of data.	✓	✓
Comments	<p>11.2 During the assessment for acceptance into the programme, an up-to-date system must be present for the exchange of data, within the framework of the screening programme, for the quality assurance, monitoring and evaluation of the screening programme.</p> <p>11.3 If at the start of the screening programme, the pathology laboratory is not yet able to send an electronic message to ColonIS, the laboratory must have an UZI pass. The UZI pass is necessary to be able to access ColonIS to enter data manually.</p>		
Foundations	<p>22 Advisory report on IT infrastructure for bowel cancer screening. 2010.</p>		

11.3 Data management

Good agreements about the ownership and use of data is a prerequisite for a good IT infrastructure that will facilitate the proper exchange of data within the chain of screening and health care. The screening organisations jointly manage the IT systems that facilitate the registration and exchange of data for the bowel cancer screening programme. They have entered into a partnership agreement with the processor for this purpose. A set of user regulations safeguards the access to and use of the registered data. To safeguard the data exchange between the local registration systems and the IT systems of the screening programme, the pathology laboratory must perform periodic updates and backups of the registration systems and its data that are used within the framework of the screening programme. The access necessary for the employees and the exchange of data with the colonoscopy centre must also be safeguarded.

Goal			
Monitor and evaluate quality; protect the data			
Indicator	Description	Acceptance criteria	Audit criteria
11.4 Data management	Periodic updates and backups of the relevant registration systems and its data.	✓	✓
Comments	<p>If results are communicated electronically with the colonoscopy centre, the required employee access and the exchange of data with the colonoscopy centre must be safeguarded.</p> <p>During the assessment for acceptance into the programme, an up-to-date system must be present for the exchange of data, within the framework of the screening programme, for the quality assurance, monitoring and evaluation of the screening programme.</p>		
Foundations	-		

NOTES

1. NVVP (LVC). Waarderingsystematiek voor kwaliteitsvisitatie Pathologie (*Assessment system for quality inspections in pathology*) (<http://www.pathology.nl/kwaliteitsvisitatie>).
2. Van Veldhuizen H, Carpay MEM, Van Delden JA, et al. Uitvoeringstoets bevolkingsonderzoek naar darmkanker. Opsporing van darmkanker in praktijk gebracht (*Feasibility study into a bowel cancer screening programme. The practical detection of colorectal cancer*). RIVM Report 225101003. 2011: 53.
3. CCKL. Praktijkrichtlijn voor een kwaliteitssysteem voor Laboratoria in de Gezondheidszorg (*Practical guidelines for a quality system for health care laboratories*). 2005; 109-110. (Taking into account the transition from CCKL to RvA ISO15189)
4. Van Veldhuizen H, Carpay MEM, Van Delden JA, et al. Uitvoeringstoets bevolkingsonderzoek naar darmkanker. Opsporing van darmkanker in praktijk gebracht (*Feasibility study into a bowel cancer screening programme. The practical detection of colorectal cancer*). RIVM Report 225101003. 2011: 65, 48.
5. Van Veldhuizen H, Carpay MEM, Van Delden JA, et al. Uitvoeringstoets bevolkingsonderzoek naar darmkanker. Opsporing van darmkanker in praktijk gebracht (*Feasibility study into a bowel cancer screening programme. The practical detection of colorectal cancer*). RIVM Report 225101003. 2011: 56.
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7. RIVM. Beleidskader Bevolkingsonderzoeken naar Kanker (*Policy framework for cancer screening programmes*). 2013.
8. RIVM. Implementation framework for the bowel cancer screening programme. Version 1.0 September 2012. (<http://www.bevolkingsonderzoekdarmkanker.nl/professionals>).
9. Van Veldhuizen H, Carpay MEM, Van Delden JA, et al. Uitvoeringstoets bevolkingsonderzoek naar darmkanker. Opsporing van darmkanker in praktijk gebracht (*Feasibility study into a bowel cancer screening programme. The practical detection of colorectal cancer*). RIVM Report 225101003. 2011: 48-51.
10. NVVP. Richtlijnen Nederlandse Vereniging voor Pathologie (*Guidelines of the Dutch Association for Pathology*). (<http://www.pathology.nl/vakinhoudelijk/richtlijnen>).
11. IKNL. Richtlijnen oncologische zorg (Guidelines for oncology health care). (<http://www.oncoline.nl/>).
12. European Commission. European Guidelines for quality assurance in colorectal cancer screening and diagnosis. Brussels. 3 February 2011; 209.
13. Gezondheidsraad. Bevolkingsonderzoek naar darmkanker (*Health Council of the Netherlands. Bowel cancer screening programme*). Publication number 2009/13. Den Haag. 2009; 119.
14. CCKL. Praktijkrichtlijn voor een kwaliteitssysteem voor Laboratoria in de Gezondheidszorg (*Practical guidelines for a quality system for health care laboratories*). 2005; 39.
15. European Commission. European Guidelines for quality assurance in colorectal cancer screening and diagnosis. Brussels. 3 February 2011; 226.
16. NEN-EN-ISO 15189:2007. Medical laboratories - Particular requirements for quality and competence. April 2007; 8.
17. CCKL. Praktijkrichtlijn voor een kwaliteitssysteem voor Laboratoria in de Gezondheidszorg (*Practical guidelines for a quality system for health care laboratories*). 2005; 39.

18. Lindholm E, Berglund B, Kewenter J, Haglund E. Worry associated with screening for colorectal carcinomas. *Scand J Gastroenterol*. 1977; 32(3): 238-45.
19. Parker MA, Robinson MH, Scholefield JH, Hardcastle JD. Psychiatric morbidity and screening for colorectal cancer. *J Med Screen*. 2002; 9(1): 7-10.
20. European Commission. European Guidelines for quality assurance in colorectal cancer screening and diagnosis. Brussels. 3 February 2011; 226.
21. RIVM. Implementation framework for the bowel cancer screening programme. Version 1.0 September 2012; 31
(<http://www.bevolkingsonderzoekdarmkanker.nl/professionals>).
22. Mekenkamp H, Schapendonk SWP. Adviesrapport IT-infrastructuur Darmkankerscreening ter ondersteuning van uitvoering, kwaliteitsborging & landelijke evaluatie (*Advisory report on the IT infrastructure for bowel cancer screening to support the implementation, quality assurance and national evaluation*). 2010.

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ABBREVIATIONS

BIG (wet)	<i>Wet op de beroepen in de individuele gezondheidszorg</i> (Individual Health Care Professions Act)
BSCP	Bowel Cancer Screening Programme (UK)
CBN	<i>Commissie Bij- en Nascholing van de NVVP</i> (NVVP commission for continued professional development)
CCKL	<i>Stichting voor de bevordering van het laboratoriumonderzoek en voor de accreditatie van laboratoria in de gezondheidszorg</i> (Foundation for the advancement of laboratory research and for the accreditation of laboratories in the health care sector)
ColonIS	Colon Information System
CT	Computed tomographic colonography
CvB	<i>Centrum voor Bevolkingsonderzoek van het RIVM</i> (The RIVM centre for population studies)
EQA	External Quality Assessment
FSB	<i>Facilitaire Samenwerking Bevolkingsonderzoeken</i> (Ancillary partnership for screening programmes)
GR	<i>Gezondheidsraad</i> (Health Council of the Netherlands)
ID	Identification
iFOBT	Immunological Faecal Occult Blood Test
IGZ	<i>Inspectie voor de Gezondheidszorg</i> (The Healthcare Inspectorate)
IKNL	<i>Integraal Kankercentrum Nederland</i> (formerly VIKC) (Dutch integrated cancer centre)
IT	Information Technology
KWZi	<i>Kwaliteitswet zorginstellingen</i> (Care Institutions (Quality) Act)
LCIBD	<i>Landelijke commissie invoering bevolkingsonderzoek darmkanker</i> (National Commission for the implementation of the bowel cancer screening programme)
LHV	<i>Landelijke Huisartsen Vereniging</i> (National association of general medical practitioners)
LVC	<i>Landelijke Visitatie Commissie van de NVVP</i> (NVVP national inspections commission)
MDL	<i>Maag-Darm-Lever</i> (literally 'stomach, bowel and liver' but also used to refer to a gastroenterologist)
NFK	<i>Nederlandse Federatie van Kankerpatiëntenorganisaties</i> (Dutch federation of cancer patient organisations)
NFU	<i>Nederlandse Federatie van Universitair Medische Centra</i> (Dutch federation of university teaching hospitals)
NHG	<i>Nederlands Huisartsen Genootschap</i> (Dutch college of general medical practitioners)
NHS	National Health Service
NIV	<i>Nederlandse Internisten Vereniging</i> (Dutch association of internal medicine)
NVKC	<i>Nederlandse Vereniging voor Klinische Chemie</i> (Dutch association of clinical chemistry)
NVMDL	<i>Nederlandse Vereniging van Maag-Darm-Leverartsen</i> (Dutch association of gastroenterologists)
NVVH	<i>Nederlandse Vereniging voor Heelkunde</i> (Dutch association for surgery)
NVVP	<i>Nederlandse Vereniging voor Pathologie</i> (Dutch association for pathology)
NVvR	<i>Nederlandse Vereniging voor Radiologie</i> (Radiological Society of the Netherlands)
NVZ	<i>Nederlandse Vereniging van Ziekenhuizen</i> (Dutch association of hospitals)
PA	Pathology
PALGA	<i>Pathologisch anatomisch landelijk geautomatiseerd archief</i> (nationwide network and registry of histology and cytopathology in the Netherlands)
PPM	PALGA protocol module
RCMDL	<i>Regionaal Coördinerend MDL-functionaris</i> (Regional coordinating administrator for



	gastroenterology)
RCP	<i>Regionaal Coördinerend Patholoog</i> (Regional coordinating pathologist)
RGS	<i>Registratiecommissie Geneeskundig Specialisten</i> (Registration commission for health specialists)
RIVM	<i>Rijksinstituut voor Volksgezondheid en Milieu</i> (National Institute for Public Health and the Environment)
SPKS	<i>Stichting voor Patiënten met Kanker aan het Spijsverteringskanaal</i> (Foundation for patients with cancer of the digestive tract)
UZI	<i>Unieke Zorgverleners Identificatie</i> (Unique health care provider identification)
VKGN	<i>Vereniging Klinische Genetica Nederland</i> (Association for clinical genetics in the Netherlands)
V&VN	<i>Verpleegkundigen & Verzorgenden Nederland</i> (Nurses and carers in the Netherlands)
VWS	<i>Volksgezondheid, Welzijn en Sport</i> (Dutch Ministry of Health, Welfare and Sport)
WBO	<i>Wet op het bevolkingsonderzoek</i> (Population Screening Act)
WBP	<i>Wet bescherming persoonsgegevens</i> (Personal Data Protection Act)
WCZ	<i>Wet cliëntenrechten zorg</i> (Rights of health care clients Act)
WGBO	<i>Wet op de geneeskundige behandelingsovereenkomst</i> (Medical Treatment Contracts Act)
WKZ	<i>Wet klachtrecht cliënten zorgsector</i> (Client's Right of Complaint (Care Sector) Act)
ZN	<i>Zorgverzekeraars Nederland</i> (Health care insurers in the Netherlands)

ANNEX 1 ACCEPTANCE REQUIREMENTS AND AUDIT CRITERIA FOR PATHOLOGY

Subject	Goal	Indicator	Description	Acceptance criteria	Audit criteria
Organisation	Good quality clinical practice	Periodic inspections	Participation in periodic inspections by the professional body.	✓	✓
		Recommendation to continue the work.	A positive recommendation from the National Inspection Commission, or an equivalent body, to continue the work.	✓	✓
	Internal quality assurance for the work that is to be performed	Internal quality system	An organised and maintained quality system.	✓	✓
		Internal audits	Annual internal audit of the critical activities that have to be performed.	✓	✓
	Assure uniformity in the applied techniques and assessment	Circulars of histological specimens	Participation is a system of circulating histological specimens	✓	✓
		Circulation of histological images	Participation is a system of digital circulation of histological images of colon pathology.		✓
	External quality assurance for the work that is to be performed	Periodic audits	Participation in the periodic audits by the RCP within the framework of the screening programme.		✓
Personnel	Qualified employees	Professional registration	Employees are responsible for their professional registration and re-registration.	✓	✓
	Employee expertise	Professional development	Number of professional development points attained by the pathologist in the area of colorectal pathology in five years.		≥ 5
		Assessment	The successful completion of the assessment for pathologists.		✓
Frameworks	Perform the work within the specified frameworks	Legislation	Compliance with and working in accordance with the applicable European legislation and regulations.	✓	✓
		Implementation framework	Compliance with and working in accordance with the agreements contained in the prescribed national implementation framework for the bowel cancer screening programme.		✓
		Guidelines and protocols	Compliance with and working in accordance with the applicable guidelines and protocols as prescribed by the professional body.	✓	✓
		Risk management	Compliance with and working in accordance with the prescribed national risk management protocol for the bowel cancer screening programme.		✓
		Dealing with incidents	An implemented procedure for dealing with incidents.	✓	✓
		Evaluation of incidents	Incidents that could lead to improvements in the screening programme are discussed with the RCP during the periodic audit.		✓



		Dealing with complaints	An implemented procedure for dealing with complaints.	✓	✓
		Evaluation of complaints	Complaints that could lead to improvements in the screening programme are discussed with the RCP during the periodic audit.		✓

Subject	Goal	Indicator	Description	Acceptance criteria	Audit criteria
Pathology	Uniform assessment of colon biopsies	Protocol-based working practices	When assessing the pathology, the data is recorded in compliance with the format and the quality requirements of the PALGA protocol module.	✓	✓
		Responsibility	Histological specimens are assessed under the responsibility of a registered pathologist.	✓	✓
	Cost-effective colon biopsy assessment	Immunohistochemical investigation	Within the framework of the bowel cancer screening programme, immunohistochemical investigation is not routinely performed in the pathology of polyps.		✓
	Uniformity of assessment	High grade lesions	The percentage of the pathology from colonoscopies performed after referral from the screening programme with the outcome 'high grade lesion'.		≤10%
	Assuring the quality of the assessment	Review and consultation	Reviews and consultations are registered by the pathologist in compliance with the format and the quality requirements of the PALGA protocol module.		✓
	Ensure the results are communicated in a uniform and high quality manner	Authorisation	Results are authorised by a qualified pathologist.	✓	✓
		Communicating the results	The pathology results will be supplied digitally to the colonoscopy centre that requested the investigation within the framework of the bowel cancer screening programme.		✓
Process durations	Minimise anxiety amongst the participants	Duration from the receipt of the material to authorisation of the PA results	The percentage of submissions for which the time interval between the arrival of the histological material at the pathology laboratory and the authorisation of the outcome by the pathologist is a maximum of five working days.		≥ 95%
Data management	Support for the primary process; monitoring and evaluating quality	Data recording	Structured data recording in compliance with the format and the quality requirements of the PALGA protocol module.	✓	✓
		Supply of data	The provision of digital access to the required data and its structured digital delivery.	✓	✓
		Data exchange	The availability of a secure internet connection for the electronic exchange of data.	✓	✓
	Monitor and evaluate quality; protect the data	Data management	Periodic updates and backups of the relevant registration systems and its data.	✓	✓



ANNEX 2 OVERVIEW OF THE RELEVANT LEGISLATION AND REGULATIONS

Population Screening Act (WBO, *Wet op het bevolkingsonderzoek*)

The purpose of the WBO is to protect participants against the risks of a screening. A cancer screening programme is subject to licensing. A licence can be issued by the WVS Minister to one or more screening programme providers. Conditions are attached to this licence regarding the quality of implementation of the screening programme.

Medical Treatment Contracts Act (*Wet op de geneeskundige behandelingsovereenkomst*)

This act regulates the relationship between the patient and the health care provider. When a patient calls on the assistance of a health care provider, a medical treatment contract is created between them. The patient commissions the health care, which is defined as: investigations, the provision of advice or treatment in the area of medicine, which is designed to cure someone of an illness, prevent an illness or to assess their state of health, or to provide obstetric assistance. The WGBO is an imperative law, which means it is not permitted to make any agreements between patients and health care providers or institutions that provide health care, that are contrary to the WGBO.

Client's Right of Complaint (Care Sector) Act (WKCZ, *Wet klachtrecht cliënten zorgsector*)

The Client's Right of Complaint (Care Sector) Act (WKCZ, *Wet klachtrecht cliënten zorgsector*) regulates procedures related to complaints from health care consumers, with the intention of making the threshold for submitting a complaint as low as possible. Another aim of the act is to use the complaints to improve the quality of the health care. The act applies to all health care institutions and all health care professionals.

Care Institutions (Quality) Act (KWZi, *Kwaliteitswet zorginstellingen*)

The Care Institutions (Quality) Act (KWZi, *Kwaliteitswet zorginstellingen*) is a typical framework act. This means that only general instructions are provided. The details are left to the professionals in the practical field, in consultation with the umbrella organisation. The purpose of the KWZi is to specify a number of criteria which health care providers must meet. The key concept in this act is "good health care practices".

Rights of health care clients Act (WCZ, *Wet cliëntenrechten zorg*)

The government wishes to replace a number of patient-related acts with a new Rights of health care clients Act (WCZ, *Wet cliëntenrechten zorg*). Acts that will be removed after the arrival of the WCZ include the Medical Treatment Contracts Act (WGBO, *Wet op de geneeskundige behandelingsovereenkomst*), the Client's Right of Complaint (Care Sector) Act (WKCZ, *Wet klachtrecht*) and the Care Institutions (Quality) Act (KWZi, *Kwaliteitswet zorginstellingen*).

Individual Health Care Professions Act (Wet BIG, *Wet beroepen in de individuele gezondheidszorg*)

The Individual Health Care Professions Act (Wet BIG, *Wet op de beroepen in de individuele gezondheidszorg*) is intended to improve the quality of care provided by the professionals. The act is also intended to protect patients or clients against incompetent or negligent treatment by the individual health care providers.

Personal Data Protection Act (WBP, *Wet bescherming persoonsgegevens*)

The Dutch Personal Data Protection Act specifies rules that protect personal privacy. The act is applicable to all forms of personal data processing, irrespective of whether the processing takes place on paper or in computer files. Processing is a very broad concept, which includes the entire process from the acquisition, combination, processing, storage and transmission of data, to its destruction. The full or partly automated processing of personal data must in principle be reported to the Data Protection Authority (CBP, *College bescherming persoonsgegevens*). The CBP then records these reports in a public register.

Code of Conduct

The Code of Conduct is an implementation of the statutory provisions contained in the WGBO and the WBP regarding the processing of data for medical scientific research. The statutory provisions and their implementation in this code of conduct originate from a consideration of the different interests. One side involves protecting the personal privacy of people involved in a study. The other side involves the interests of public health and of specific groups of patients that are served in the short and long term by this type of study. The privacy aspects form the limiting conditions for this type of study.

Code of Practice

The Code of Practice focuses on the responsible acquisition, use and storage of human tissue for scientific research, that becomes available for other purposes, such as diagnostics and surgical treatment, than the scientific research for which it was originally intended.

ANNEX 3 WORKING PARTY ON PATHOLOGY QUALITY REQUIREMENTS AND THE NATIONAL COMMISSION

The following is an overview of all the members of the Working Party for Pathology Quality Requirements and the National Commission for the implementation of the bowel cancer screening programme (LCIBD) that were involved in developing this protocol.

Members of the Working Party for Pathology Quality Requirements

Organisation	Name	Position
RIVM-CvB	Ms H. van Veldhuizen	Programme director for the implementation of the bowel cancer screening programme (chair)
RIVM-CvB	Ms M. van Wieren	Programme associate for the implementation of the bowel cancer screening programme (secretary)
Screening organisations	Ms A. Olde Reuver of Briel	Regional project leader for the bowel cancer screening programme (East)
NVVP	Ms I. Nagtegaal	Pathologist and professor (UMCN/St. Radboud), PALGA board member
NVVP	Mr M. Kliffen	Pathologist (Maastricht Ziekenhuis hospital)
NVVP	Ms E. Bloemena	Pathologist and professor (ACTA/VUmc)
RIVM-CvB	Mr A. Huisman	Senior consultant (MedicalPHIT)
RIVM-CvB	Ms E. Brouwer	Quality programme associate
Informal members		
FSB (screening organisations)	Mr M. Schouten	Project director for the implementation of the bowel cancer screening organisations

Members of the National Commission for the implementation of the bowel cancer screening programme

Organisation	Name	Position
De Hoogstraat revalidation centre	Mr R. Beuse	Chairman of the National Commission
RIVM-CvB	Ms H. van Veldhuizen	Programme director for the implementation of the bowel cancer screening programme (secretary)
Screening organisations	Mr W. Spijker	Screening programme (South West) board member
Screening organisations (replacement)	Ms E. Bongers (from 1 October 2013)	Screening programme (Mid West) board member
Screening organisations (replacement)	Ms A. Bartels (to 1 July 2012)	Screening programme (Mid West) board member
Screening organisations (replacement)	Ms S. Bentvelsen (1 July 2012 to 1 October 2013)	Screening programme (East) board member
IKNL	Mr N.J.H. Hoefsmit	Chair of the board of directors
IKNL (replacement)	Ms M. Jansen-Landheer	Director of networks
LHV	Ms L. Romijn	General Practitioner, Senior policy officer
NFK	Ms A. Snijders	Quality of Care policy officer

	(until 1 November 2012)	
NHG	Mr N.J. de Wit	General Practitioner and professor (UMCU)
NHG (replacement)	Mr A.J.M. Drenthen	Team Leader of Prevention and Patient Information
NIV	Mr R. Loffeld	Internist (Zaanstad MC)
NV KC	Mr H. Bonfrèr	Clinical Chemist, RIVM-CvB advisor

NVMDL (to 1 January 2013) NFU (from 1 January 2013)	Mr E.J. Kuipers	MDL doctor and professor (Erasmus MC) NVMDL chairman (to 1 January 2013) Chair of the board of directors (Erasmus MC) (from 1 January 2013)
NVMDL	Mr A. Masclee (from 1 January 2013)	NVMDL chairman and professor (MUMC)
NVMDL (replacement)	Mr J. Keller (from 01/09/2013)	MDL doctor (Haga hospital)
NVVH	Mr C. Rosman	Surgeon (CWZ)
NVVH (replacement)	Ms H. van Grevenstein	Surgeon (UMCU)
NVVP	Mr G.A. Meijer	Pathologist and professor (VUmc)
NVVP (replacement)	Ms I. Nagtegaal	Pathologist and professor (UMCN/St. Radboud), PALGA board member
NVVP (replacement)	Ms E. Bloemena	Pathologist and professor (ACTA/VUmc)
NVvR	Mr J. Stoker	Radiologist and professor (AMC)
NVvR (replacement)	Mr G.J. den Heeten	Radiologist and professor (LRCB/UMCN)
SPKS Bowel Cancer Patient Group	Ms J.C.M Pon	Patient Group chairwoman
NVZ	Ms M. van der Wel (from 1 October 2012)	Policy advisor
NVZ	Mr Weijnenborg (until 1 October 2012)	Senior policy advisor
RIVM-CvB	Ms M.L. Heijnen	Senior programme associate for the implementation of the bowel cancer screening programme
RIVM-CvB	Mr A. Klein (from 1 May 2013)	Financial Advisor
RIVM-CvB	Mr J. van Delden (to 1 October 2013)	Financial Advisor
VKGN	Mr R.H. Sijmons	Clinical Geneticist and professor (UMCG)
V&VN	Ms W. Kok-Kuipers	Nurse
ZN	Mr G. Saleminck	Medical advisor
FSB (screening organisations)	Ms A. Vos (to 1 May 2012)	Project director for the implementation of the bowel cancer screening organisations

Informal members

VWS	Ms A. Rendering	Senior policy officer
IGZ	Mr J. Remmen (to 1 January 2012)	Senior inspector
FSB (screening organisations)	Mr M. Schouten (from 1 May 2012)	Project director for the implementation of the bowel cancer screening organisations
NFK	Ms L. van Loon	Quality of Care project director
RIVM-CvB	Ms M. van Wieren	Programme associate for the implementation of the bowel cancer screening programme
RIVM-CvB	Ms E. Brouwer	Quality programme associate
V&VN MDL	Ms T. Korpershoek (from 1 April 2013)	V&VN MDL chairwoman

ANNEX 4 JOB DESCRIPTION FOR THE REGIONAL COORDINATING PATHOLOGIST (RCP)

1. Job environment

A screening programme that is offered to people with no symptoms requires a high quality of implementation. This applies to every part of the programme chain, from the invitation to any required treatment, to ensure the desired health benefit of the screening programme is achieved. The participant is also entitled to expect a uniform level of quality throughout the country. To achieve and safeguard this high level of quality, national requirements are set for the professionals implementing the screening programme and the subsequent diagnostics following referral.

In addition to existing guidelines and protocols, national quality requirements have been set in respect of referrals from the screening programme for subsequent diagnostics. These quality requirements are used in a system of inspection and quality assurance for the pathology that results from colonoscopies following referral from the screening programme. A reference function has been set for this inspection and assurance.

2. Position in the organisation

The reference function is fulfilled by regional coordinating pathologists (RCP). Funding for the RCP is obtained from the Public Health Subsidy Scheme. A single regional coordinating pathologist works within each screening organisation. The RCP is a BIG registered pathologist. Each screening organisation enters into a contract with a pathologist in the region for this purpose. The regional coordinating pathologists are supported in their duties by employees from the screening organisations. The RCP is accountable to the board of the screening organisation for performing the work.

Within the reference function, the RCP is responsible for:

- assessing the PA laboratories against the national acceptance requirements for the selection of colonoscopy centres
- the periodic assessment of PA laboratories against the national audit criteria, as required to assure the quality of the implementation and for opportunities for improvement
- the annual monitoring and discussion of interval carcinomas, in consultation with the RCMMDL
- the annual benchmarking and discussion of the performances of the PA laboratories, on the basis of the relevant national indicators
- the promotion and facilitation of professional development
- contributing towards the quality assurance of the screening programme chain

The RCP also supports the colonoscopy centres, as the commissioners of the pathology, in their responsibilities for the quality of the pathology from colonoscopies performed after referral from the screening programme.

3. Duties

3.1 Assessing pathology laboratories

A uniform national level of quality in the screening programme is achieved through a system of acceptance into the programme. It is a requirement for the colonoscopy centres to only send histological material from colonoscopies performed after referral from the screening programme for assessment to PA laboratories that meet the specified national criteria. The RCP performs this assessment by:

- assessing the PA laboratories against the national acceptance requirements in compliance with the Acceptance and Auditing Protocol for Pathology Laboratories
- preparing assessment reports in compliance with the prescribed format
- formulating recommendations for the screening organisation regarding the registration of PA laboratories in the overview of selected laboratories

If the PA laboratory does not meet with the prescribed requirements, they can submit a new assessment application to the screening organisation within the time limit set by the RCP. The RCP will then perform a reassessment².

3.2 Periodic audit

For each laboratory that assesses pathology, on the instructions of the colonoscopy centre, from colonoscopies performed after referral from the screening programme, a full audit is performed at least once every three years to assure the quality of the programme in compliance with the prescribed national requirements and to discuss opportunities for improvement. The RCP performs this periodic audit on the basis of the prescribed national audit protocol. The inspection will be comprised of:

- assessing the PA laboratories against the national audit criteria in compliance with the Acceptance and Auditing Protocol for Pathology Laboratories
- assessing the results of the assessment for pathologists (e-learning and EQA)
- discussing the opportunities for improvement on the basis of the findings
- preparing audit reports in compliance with the prescribed format
- performing any necessary re-audits, including reporting the findings
- formulating recommendations for the screening organisation regarding extending the registration of PA laboratories in the overview of selected laboratories

If a PA laboratory does not meet the prescribed criteria during an audit, the RCP will specify a time frame within which the PA laboratory must implement the required improvement measures. After this period, the RCP will perform a re-audit³. If the RCP issues a positive recommendation after an audit, and if necessary a re-audit, the screening organisation will extend the registration of the PA laboratory in the overview of selected laboratories. If the RCP issues a negative recommendation to the screening organisation, the laboratory will be removed from the overview. After a year, the PA laboratory can submit a request for renewed registration into the screening organisation. The RCP will then perform a new assessment. The RCP performs interim audits on specific aspects.

3.3 Monitoring interval carcinomas

An important part of the work of the RCP is monitoring the interval carcinomas in cooperation with the RCMDL officers. In consultation with the RCMDL, the RCP performs the following:

- the annual creation, either personally or by a third party, of summaries from the IT systems specifying the interval carcinomas per contracted colonoscopy centre and associated pathology laboratory
- an analysis of the specified overviews
- a discussion of the interval carcinomas with the relevant pathologists
- reports the findings and opportunities for improvement to the PA laboratory

² A reassessment will be performed by the RCP in the relevant screening region in cooperation with an RCP from a different screening region.

³ A re-audit will be performed by the RCP in the relevant screening region in cooperation with an RCP from a different screening region.

3.4 Benchmarking the performances

Benchmarking and indicators are used to compare the performance of the health care providers to each other. The RCP performs this benchmarking by:

- creating, either personally or by a third party, an annual benchmark report from the IT systems that contains the performance for each of the selected PA laboratories. The report must comply with the prescribed national protocol for the relevant national indicators
- analysing the specified benchmark reports
- discussing the benchmark reports with the PA laboratories.
- reporting the findings and opportunities for improvement to the PA laboratory

3.5 Professional development

The purpose of professional development is to share knowledge and expertise with each other and to ensure the relevant health care providers in the chain are familiar with each other and each other's work. In addition to the professional development already provided by the professional bodies, the RCP provides a contribution whenever this is desirable to the implementation and/or improvement of the programme. The RCP does this by:

- the general promotion and facilitation of professional development
- fulfilling a consultative function
- encouraging individual pathologists to continue professional development after an audit has shown particular aspects that require improvement
- keeping the PA laboratories informed of meetings, congresses and new developments
- organising regional referral meetings for pathologists to deal with difficult specimens (second opinion)
- contributing to the professional development of employees at, for example, screening organisations, colonoscopy centres and PA laboratories

3.6 Quality assurance of the chain

The RCP contributes to the quality assurance of the chain by:

- collecting, personally or by a third party, the required data from the IT system, periodic audits and benchmark reports and analysing the specified data
- formulating an accountability report for the screening organisation and the Centre for Population Screening (CvB, *Centrum van Bevolkingsonderzoek*)
- providing input for the national assessment that is performed each year on the instructions of the Centre for Population Screening
- participating in peer RCP consultations
- participating in national peer consultations with the other reference functions (clinical chemists and regional coordinating MDL administrators)
- recommending to the CvB possible aspects of the screening programme that require improvement
- provide advice to the CvB by drafting proposals for possible changes to guidelines, protocols or quality requirements



4. Scope

- The RCP is accountable to the screening organisation in respect of the contents and implementation of assessments, periodic audits, the monitoring of interval carcinomas, benchmarking and professional development.
- The frameworks are formed by the applicable legislation, regulations, guidelines, protocols and the implementation framework for the bowel cancer screening programme.
- The RCP advises the screening organisation about whether pathology laboratories meet the prescribed national requirements for registration on the overview of selected PA laboratories.
- The RCP advises the Centre for Population Studies about opportunities for improvement with respect to the quality of the screening programme chain and modifications to guidelines, protocols and quality requirements.
- The RCP informs the Centre for Population Studies on the quality of the chain by providing input for the national assessment that is performed annually on the instructions of the Centre for Population Studies.
- The RCP advises PA laboratories on the opportunities for improvement that emerge from periodic audits, the monitoring of interval carcinomas and performance benchmarking.
- The RCP engages another RCP in an assessment or audit, if:
 - the pathology laboratory does not accept the recommendation of the RCP
 - it involves an assessment or audit in the centre where the RCP is working or has worked
 - it is a reassessment or re-audit
- The RCP coordinates with the professional bodies about the inspections performed by them.

5. Knowledge and skills

- completed training as a pathologist
- applicable registration in compliance with the Individual Health Care Professions Act (Wet BIG)
- affiliated with the NVVP
- works in compliance with the guidelines and protocols of the NVVP and the quality requirements of the bowel cancer screening programme and the subsequent diagnostics
- minimum of five years' experience in diagnostics
- must formally perform 'sixteen hours of patient-related work a week
- extremely up-to-date on all aspects of the bowel cancer screening programme
- respected by the members of the professional bodies
- demonstrable knowledge of professional audits
- a minimum of one visit per year to a professional development day or congress

6. Competences

- reliable and transparent
- excellent communication skills
- quality-focused
- good judgement
- analytical
- diplomatic
- convincing
- independent