



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

## **PROTOCOL**

# **FOR THE AUTHORIZATION AND AUDITING OF COLONOSCOPY CENTRES AND ENDOSCOPISTS**

NATIONAL SCREENING PROGRAMME FOR BOWEL CANCER

June 2012



## **PREFACE**

This is the Protocol for the authorization and auditing of colonoscopy centres and endoscopists. It was created within the scope of the national screening programme for bowel cancer that will be introduced in phases starting in September 2013. It offers an overview of the quality requirements laid down for organizations and professionals who wish to perform colonoscopies after a referral from the national screening programme. In addition it describes how the procedures for authorization and auditing will work.

Through this new national screening programme we aim to eventually prevent 2,400 deaths as a result of bowel cancer. A maximum health benefit is only possible if the quality of the execution of the entire sequence of the national screening programme and the subsequent care is high. We contribute to this attempt through national uniform quality requirements for colonoscopy centres and endoscopists.

RIVM, National Institute for Public Health and the Environment  
NVMDL (Netherlands Association of Gastroenterohepatologists)  
The five regional screening organizations

## DOCUMENT MANAGEMENT

### Version management

Version	Date	Author	Notes
2.1	May 2013	RIVM-CvB	Definitive interim version on the basis of questions and comments from the field and supplemented with the colonoscopy intake. Additions and changes have been put forward to the Work Group for Quality requirements for colonoscopy and the National Committee for the implementation of the national screening programme for bowel cancer and set on 23 April 2013.
2.2	December 2013	RIVM-CvB	Interim version, available in digital format via the website, in which changes in quality requirements were processed.
3.0	January 2014	RIVM-CvB	Third definitive version, distributed to colonoscopy centers at the commencement of the national screening programme.

### Amendments compared to version 2.1

Page	Amendment
17	Quality requirement 6.1 Endoscopy under work agreement was found to be multi-interpretable. It has been added to the requirement that it involves endoscopists 'working in a colonoscopy center'.
19	A new quality requirement in relation to assuring continuity in service provision (requirement 6.10) has been added to prevent waiting times. The colonoscopy center can assure continuity in service provision by ensuring a replacement is available for endoscopists.
21	A comment has been added to quality requirement 7.1 Professional registration in which more detail is provided on the professional re-registration of endoscopists.
24	In the overview of guidelines in section 8.3, the European guideline and the National guideline on colorectal liver metastasis have been removed. The Dutch guideline colonoscopy surveillance has been added to the overview.
26	In quality requirement 8.6 Risk management, the comment that the relevant protocol is currently being developed, has been removed. The first (concept) version of the protocol is available in digital format at: <a href="http://www.bevolkingsonderzoekdarmkanker.nl/downloads">www.bevolkingsonderzoekdarmkanker.nl/downloads</a> .
26	In quality requirement 8.7 Handling of incidents, a comment has been incorporated that the RCMDL receives confirmation of processing by the IGZ in case of IGZ notification.
26	In relation to notification of incidents, a new quality requirement has been added (requirement 8.9). As part of its role as referrer, the RCMDL should be able to assess if referral is sensible in the case of a calamity/incident.
28	A comment has been incorporated in quality requirement 9.2 Expertise in which more detail is provided on the content expertise of the care provider who is performing the colonoscopy intake.

Page	Amendment
30	The text clarifies in which cases during the intake interview the participant can be referred for a CT colonography.
30	The text clarifies how to deal with participants who indicate never to want to undergo a colonoscopy or alternative, after they have been thoroughly informed about this during the intake.
32	The aim of discussing the risk of interval carcinomas is further clarified in the text.
34	A comment has been added to quality requirement 9.18 Timely registration, clarifying when the registration of the intake must be complete, if this has been put 'on hold'.
38	A comment has been added to quality requirement 10.8 about possible future monitoring of the PDR and SPDR.
39	The calculation of the removal figures has been adjusted in quality requirements 10.10 and 10.11.
39	A few exceptions have been added to the quality requirement for tattooing (10.13) and the audit requirement of 95% has been deleted for the time being and converted to monitoring.
40	A comment has been added to quality requirement 11.1 Complication record, clarifying where endoscopists should record complications (for now) after commencement of the national screening programme.
41	In quality requirement 11.3, subdivision on the basis of severity of the complication has been amended to current practice.
41-43	In the quality requirements regarding complications (11.3 through to 11.6), the audit requirements have been removed and converted to monitoring.
47	Chapter 12 Issuing the report and aftercare and the associated quality requirements have been added. The proceeding chapters have been renumbered.
47-51, 53	The technical dataset colonoscopy does not provide for data on issuing the report for colonoscopy. This means that monitoring of turnaround time and the quantitative quality requirements in relation to issuing the colonoscopy report is not possible via ColonIS. The relevant requirements should be able to be demonstrated in the periodic audit of the RCMDL.
51	The quality requirement Follow-up (was 11.2) has moved from Chapter 11 to the new Chapter 12 on issuing the report and aftercare and has been incorporated here as quality requirement 12.8.
52	The turnaround times in quality requirements 13.1 and 13.4 have both been extended with 5 working days. Clients in the pilot in the screening region South-west often found the interval between receiving the letter with an unfavourable result and the invitation for the intake too short.
53	The quality requirements 13.6 and 13.9 (12.6 and 12.9 in the previous version) have been removed from the chapter on turnaround times and incorporated in the new chapter 12 on issuing the report and aftercare.
57	The Dutch guideline colonoscopy surveillance was made available by the NVMDL in 2013. This guideline is aligned with the national screening programme for bowel cancer. The quality requirement that any (potential) surveillance is conducted according to this guideline has been added to Chapter 15 (quality requirement 15.2).
69-76	Changes in quality requirements have been processed in Appendices 1 and 2 Admission and audit requirements for the colonoscopy centre and endoscopists.
77	Appendix 3 Structured data capture and Appendix 4 Checklist intake have been removed from the protocol. The technical dataset for colonoscopy is being managed in digital format. The checklist intake has been incorporated in the procedures for the colonoscopy intake. The most recent versions of the dataset and procedures can be found at:



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[www.bevolkingsonderzoekdarmkanker.nl/downloads](http://www.bevolkingsonderzoekdarmkanker.nl/downloads).

A new Appendix 3 with result letters for colonoscopy have been added.

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## 1. INTRODUCTION

### 1.1 Cause

On June 1, 2011, the Minister of Health, Welfare and Sport decided to implement the national screening programme for bowel cancer as of 2013. Population screening programmes that are offered to people who are not experiencing any complaints must meet a high performance quality. This applies to any part of the activity, from invitation to possible treatment, such that the desired effect of the national screening programme (health improvement) is achieved. In addition, the participant should expect national uniform quality. To obtain and assure such high quality, national quality requirements are set for the professionals who perform the national screening programme and the subsequent diagnostics after referral.

### 1.2 Goal and scope

This protocol informs the involved individuals about the quality requirements set for the execution of the national screening programme for bowel cancer and the subsequent diagnostics. The protocol is specifically aimed at the organizations and professionals for the performance of colonoscopies after referral due to a positive iFOBT result (an iFOBT is a self-administered test). The protocol contains information about the registration for participation, the prescribed admissions and audit requirements and the method of testing. Part of the requirements is based on scientific publications. This protocol provides the backgrounds and justification.

### 1.3 Realization and accountability

This version of the protocol was drawn up during the preparation of the national screening programme for bowel cancer. The members of the Work Group for Quality requirements for colonoscopy provided advice about the quality requirements to be set, and the layout of the protocol. The protocol was created under the authority of the RIVM, and with advice from the National Committee for the implementation of the national screening programme for bowel cancer. The names of the members of the workgroup and of the national committee are listed in Appendix 6. On the basis of questions and comments from the field and on recommendation of the National Committee, a few changes have been made to the quality requirements and the quality requirements have been added to issuing the report in this version of the protocol.

### 1.4 Reading guide

The protocol assumes that the reader possesses a general knowledge of the issue. Background information about the national screening programme is included in the implementation framework for the national screening programme for bowel cancer. A digital version of the implementation framework is available at: <http://www.bevolkingsonderzoekdarmkanker.nl/professionals> (only in Dutch).

### 1.5 Distribution and upkeep

The RIVM handles the editing and distribution of this protocol. Modifications are determined by the National Committee for the implementation of the national screening programme for bowel cancer. This protocol was issued as a paper version and sent to hospitals/independent care units in an information packet at the commencement of the national screening programme. The digital version of this protocol and the brochure can also be consulted at: [www.bevolkingsonderzoekdarmkanker.nl/downloads](http://www.bevolkingsonderzoekdarmkanker.nl/downloads) (only in Dutch).



The protocol is updated regularly. The (digital) newsletter on the National screening programme for cancer and news reports on the website referred to above will mention when a new version of this protocol becomes available.

## 2. NATIONAL SCREENING PROGRAMME FOR BOWEL CANCER

### 2.1 Design of the national screening programme



Figure 1 Diagram of the national screening programme including subsequent care (translation to follow).

The national screening programme for bowel cancer will invite all men and women from the ages of 55 through 75 years old to participate in the programme every two years. When the national screening programme has been completely implemented, about 2.2 million people will be approached annually. It is expected that about 60% of these will participate in the national screening programme. It is expected through this national screening programme that, in time, 2,400 deaths from bowel cancer will be prevented annually.

Everyone who is eligible will be sent a self-administered test (iFOBT). After taking a sample of faeces, the participant will send this test to a laboratory for analysis. In case of a positive result the participant will be referred for further diagnosis (a colonoscopy) and treatment if necessary.

The national screening programme for bowel cancer will be performed by the five regional screening organizations. They are responsible for the invitation and sending of the self-administered test. They also handle the notification of the result. In case of a positive result they first inform the family physician of the involved individual, and plan an appointment for an intake for a colonoscopy at a colonoscopy centre that is qualified for referrals from the national screening programme.

After an intake interview, a colonoscopy will be performed in the colonoscopy centre. The findings of this colonoscopy will be immediately shared orally. In case of a negative colonoscopy, the patient will again be invited to participate in the national screening programme after ten years. In case of a positive colonoscopy, additional diagnostics (pathology) take place. The colonoscopy centre will share this result with the patient involved. If it appears during the intake interview that a qualitatively good colonoscopy is not possible, but a CT colonography for example is possible, the colonoscopy centre will make a referral to the radiologist and will forward the information. The radiologist provides the result of the examination to the referring MDL physician of the colonoscopy centre. The colonoscopy centre will share the result with the patient involved.

Follow-up care may consist of a treatment. It is also possible that the patient will enter surveillance. When the patient can participate again in the national screening programme after surveillance, the colonoscopy centre will forward this information to the screening organization.

## 2.2 Quality assurance

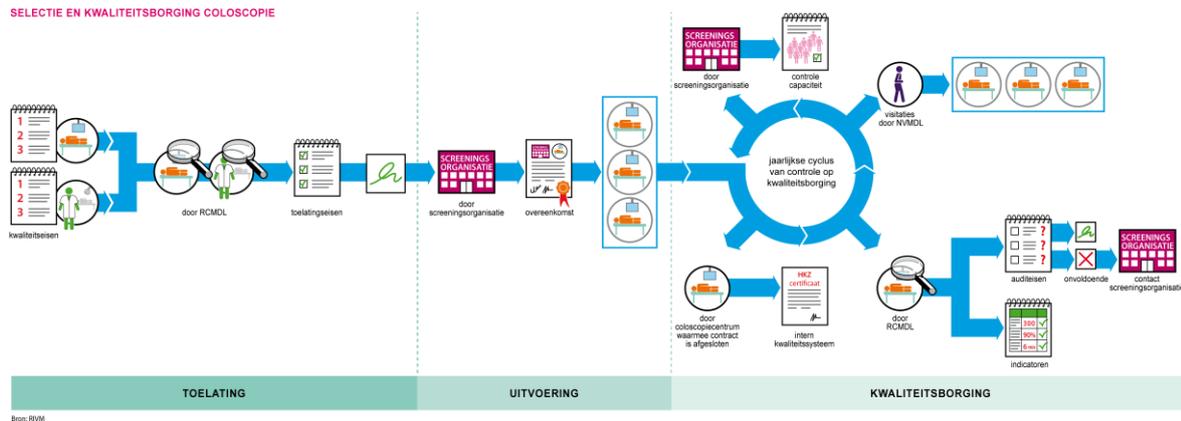


Figure 2 Admission and quality assurance in regard to the performance of screening colonoscopies (translation to follow).

A population screening programme requires good organization of the quality assurance, such that a qualitatively justified and useful performance of the population screening programme is guaranteed. Every partner in the chain, from invitation through and with possible treatment and surveillance, is responsible for the quality in their section of the chain. The responsibility for quality and quality assurance lies therefore at various levels and throughout the entire process, from invitation through possible treatment and surveillance.

An admission system is used in regard to the assurance of quality of the performing of screening colonoscopies. Only colonoscopy centres and endoscopists that satisfy the nationally defined quality requirements will receive referrals from the national screening programme and can perform screening colonoscopies. The examination for admission is performed by a Regional Coordinating MDL official (RCMDL) by authority of the screening organizations. When the admission requirements are met, the screening organization and the colonoscopy centre enter into an agreement for screening colonoscopies.

The quality assurance for the performance of screening colonoscopies pursuant to the national screening programme has a cycle of continuous improvement that consists of four parts. The colonoscopy centre has designed an internal quality system that is maintained by performing internal audits by the centre itself. In addition, the NVMDL makes periodic visits to test the quality of the activities of the colonoscopy centre and the endoscopist. If a colonoscopy centre has an agreement for performing screening colonoscopies, the centre must participate in the periodic audits by the screening organizations. Once every three years the RCMDL will perform a complete audit to check compliance with the agreement. In addition the RCMDL performs an intermediate audit on sectional aspects on an annual basis, where interval carcinomas, benchmark reporting and possibilities for improvement are discussed. The audit can also be a reason to adjust the national quality requirements and target numbers. A short-cycle capacity monitor (national and regional) will be established during the introduction of the national screening programme. The screening organizations and the RIVM will monitor, based on a number of critical parameters, if possible bottlenecks are (could be) created in available capacity.

### 3. ADMISSION

#### 3.1 Request

All organizations and professionals who wish to perform colonoscopies subsequent to a referral from a positive iFOBT result (screening colonoscopies) can submit a request to that effect. Interested colonoscopy centres can apply for this through the application form on the website of the regional screening organization.

The contact persons by screening region are:

Screening organization	Name of contact person	Telephone	E-mail address
National screening programme South	Yvonne Oosterhout	088-0001300	<a href="mailto:y.vanoosterhout@bevolkingsonderzoekzuid.nl">y.vanoosterhout@bevolkingsonderzoekzuid.nl</a>
National screening programme South-West	Annemieke van der Steen	088-2482125	<a href="mailto:a.vandersteen@bevolkingsonderzoekzuid-west.nl">a.vandersteen@bevolkingsonderzoekzuid-west.nl</a>
National screening programme Mid-West	André van Peppen	020-4096600	<a href="mailto:a.v.peppen@bevolkingsonderzoekmidden-west.nl">a.v.peppen@bevolkingsonderzoekmidden-west.nl</a>
National screening programme East	Alice Olde Reuver of Briel	088-1186243	<a href="mailto:a.oldereuver@bevolkingsonderzoekoost.nl">a.oldereuver@bevolkingsonderzoekoost.nl</a>
National screening programme North	Loes Dunning	050-5208882	<a href="mailto:dkscreening@bevolkingsonderzoeknoord.nl">dkscreening@bevolkingsonderzoeknoord.nl</a>

#### 3.2 Examination

If a colonoscopy centre and one or more endoscopists have applied for performing screening colonoscopies, an examination will take place for admission. This examination will be performed by a Regional Coordinating MDL official (RCMDL) under the authority of the screening organization in the involved region.

The examinations for admission will be performed by the RCMDL as of January 1, 2013. The screening organization makes an appointment for a visit if a colonoscopy centre has applied. The RCMDL will send a questionnaire prior to the examination of the colonoscopy centre that must be completed and returned. Based on this questionnaire and the prescribed requirements, the RCMDL will perform the examination for admission during the visit. Verification is made during the examination if the colonoscopy centre meets the admission requirements for participation in the national screening programme. The screening organization will also contact the colonoscopy centre for the examination of the endoscopists who applied. The examination for admission of endoscopists concerns an examination of knowledge (e-learning) and skills (evaluation of colonoscopies, polypectomies and registration information). Colonoscopy centres and endoscopists will receive more detailed information about the method of registration and the delivery of the necessary information for the purpose of the examination for admission as of September 2012. The admission requirements that colonoscopy centres and endoscopists must satisfy are listed in this protocol.

### 3.3 Agreement

The results of the examination are incorporated in an evaluation report. The colonoscopy centre receives the report from the RCMDL within two weeks after the examination. This report also includes the recommendation to the screening organization about the admission. The available colonoscopy capacity of the organization is discussed as well. In the case of sufficient capacity and a positive recommendation from the RCMDL, the colonoscopy centre receives an agreement from the screening organization for the performance of screening colonoscopies (see appendix 4.1). The endoscopists registered at the colonoscopy centre, if they satisfy the prescribed requirements, receive a quality agreement as an appendix to the cooperation agreement between the colonoscopy centre and the screening organization. Digital versions of example agreements can be found at: [www.bevolkingsonderzoekdarmkanker.nl/downloads](http://www.bevolkingsonderzoekdarmkanker.nl/downloads).

The agreement with the screening organization only pertains to contracting on the basis of quality. Just as in the case of colonoscopies that take place while not in the scope of the national screening programme, a contract is needed with the health insurer for the financing. It is recommended that colonoscopy centres that have applied to the screening organizations for the performance of screening colonoscopies make it known in the negotiations with the health insurers that they have applied for the admission on the basis of quality aspects.

If a colonoscopy centre or endoscopist does not meet the admission requirements, the colonoscopy centre can submit a new request for admission to the screening organizations. The time period determined by the RCMDL applies in this case, such as stated in the evaluation report. A re-evaluation for admission is performed by the RCMDL from the pertinent screening region together with an RCMDL from a different screening region. The colonoscopy centre will be tested on whether they have executed the necessary improvement measures. Upon a positive recommendation from the audit team, the colonoscopy centre or the endoscopist will as yet receive an agreement for the performance of screening colonoscopies. In case of a negative recommendation from the audit team, the colonoscopy centre can submit a new request for admission to the screening organization after one year. The RCMDL will then again perform an evaluation for admission.

## 4. AUDITING

### 4.1 Periodic audit

When a colonoscopy centre has received an agreement for the performance of screening colonoscopies, the centre participates in the periodic audits of the screening organizations. The RCMDL performs an audit on sectional aspects on an annual basis, where interval carcinomas, benchmark reporting and possibilities for improvement are discussed. Once every three years, a complete audit is performed to examine the observance of the agreements and to discuss possibilities for improvement. In time, a review will be made to see if there is a reason to adjust this period. The RCMDL performs these periodic checks by auditing on the basis of the nationally defined audit requirements. The audit requirements that are being examined are listed in this protocol.

### 4.2 Renewing agreement

The results of the audits are incorporated in an audit report. The colonoscopy centre receives the report from the RCMDL within two weeks after the audit. If this were a complete audit, this report also includes the recommendation to the screening organization about the renewal of the activities. Based on the results of the audit and the recommendation from the RCMDL the screening organization decides whether the agreements with the colonoscopy centre and the endoscopists can be renewed.

When a colonoscopy centre or endoscopist does not meet the audit requirements during a periodic (the first time, triennial) audit, the colonoscopy centre will be granted a period of time prescribed by the RCMDL to implement the necessary improvement measures. After this period, the RCMDL from the screening region involved, together with an RCMDL from a different screening region, will perform a re-audit. Upon a positive recommendation from the audit team, the screening organization renews the agreements for the colonoscopy centre and the endoscopists. In the case of a negative recommendation from the audit team to the screening organization, the agreement is not renewed. The colonoscopy centre can then after a year submit a supported request for renewed admission to the screening organizations. The RCMDL will then perform an evaluation for admission again.

If it appears during intermediate audits that the performing organization or professional no longer meets the quality requirements, this can also be accompanied by modifications to the agreement (see appendix 4.1 and 4.2).

## 5. CRITERIA

### 5.1 Quality requirements

The goal of the national screening programme for bowel cancer is to obtain health gains through the prevention or timely discovery of bowel cancer in individuals who have no complaints. Health gains can only be achieved if the quality of performance is high for the entire chain of the national screening programme and subsequent care. By setting quality requirements, an attempt is made for as great as possible an effectiveness of the national screening programme.

The quality requirements for the colonoscopy are defined by the national workgroup quality requirements colonoscopy, in which members of the NVMDL, NVVH, NIV, V&VN and the screening organizations are represented. The National Committee for the implementation of the national screening programme for bowel cancer has agreed with these requirements. The development of the quality requirements dovetails as much as possible with the existing quality processes of the NVMDL. This pertains, among other things, to inspections and the new HKZ certification schedule. In addition, the experience with the existing national screening programmes and the available information from national trial screening programmes for bowel cancer and international screening programmes are used.

### 5.2 Admission and audit requirements

The quality requirements are used for admission to (admission requirements) as well as quality assurance of (audit requirements) the performance of colonoscopies after a referral from the national screening programme for bowel cancer. By admission requirements are meant the requirements which colonoscopy centres and endoscopists must satisfy in order to be allowed to perform screening colonoscopies. Audit requirements are understood to be the requirements on the basis of which the colonoscopy centres and endoscopists are audited at pre-determined moments. The periodic (the first time being after three years) and intermediate audits have as purpose to test the observance of the agreements and to discuss possibilities for improvement.

An overview of the quality requirements for the colonoscopy centre and the endoscopist are provided in the tables in chapters 6 through 13 of this protocol. The following layout is maintained in these tables:

- The objective to be achieved in each area of activity;
- The indicator used to evaluate whether that objective is being achieved;
- The description of the content of the indicator;
- The admission requirement that must be met for participation in performing the national screening programme;
- The audit requirement that must be met for extending the participation in performing the national screening programme.

A part of the quality requirements are quantitative, and can be calculated based on registered indicators. The standards connected to these quality requirements for admission and auditing are supported scientifically, and will be justified in this protocol. The remaining quality requirements are qualitative in nature, and must generally be made evident. The RCMDL will make an estimate to which degree these requirements can be made sufficiently evident by the colonoscopy centre and/or endoscopist. The quality requirements can be subject to changes. For this reason, continuous monitoring for feasibility takes place. If necessary, the requirements will be adjusted to the modified circumstances.

## 6. ORGANIZATION

### 6.1 Agreements

The colonoscopy centre performs intake interviews with participants from the national screening programme with a positive iFOBT result that are referred to them and then performs the colonoscopy. The colonoscopy centre is responsible for the coordination and performance of the diagnostics, surveillance and transfer to treatment. A national screening programme requires a good organization of the quality assurance; such that a qualitatively justified and useful performance of the population screening programme is guaranteed.<sup>1</sup> The colonoscopy centre is responsible that qualified endoscopists perform the screening colonoscopies. Endoscopists employed by the colonoscopy centre that performs colonoscopies in the scope of the national screening programme for bowel cancer, must satisfy the nationally prescribed quality requirements of the national screening programme. In addition, the colonoscopy centre is responsible for the quality assurance of the pathology of the removed material and of the CT colonography if a qualitatively good colonoscopy is not possible. The colonoscopy centre therefore enters into agreements with pathology and radiology laboratories that satisfy the nationally prescribed quality requirements of the national screening programme.

Referrals from the national screening programme are made to colonoscopy centres that satisfy the quality requirements and that have entered into a cooperation agreement with a screening organization.

<b>Objective</b>		<b>Uniform quality for the performance of the national screening programme and subsequent diagnostics</b>	
<b>Indicator</b>	<b>Description</b>	<b>Admission requirement</b>	<b>Audit requirement</b>
6.1 Endoscopy under work agreement	Endoscopists employed by the colonoscopy centre that performs screening colonoscopies, satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
6.2 Pathology agreements	Agreements with pathology laboratories that satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
6.3 Radiology agreements	Agreements with radiology laboratories that satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
Responsible	Colonoscopy centre (6.1 through 6.3)		
Comments	6.1 If the screening colonoscopies are being performed by specialists from outside the colonoscopy centre that satisfy the quality requirements of the national screening programme, the colonoscopy centre has entered into an agreement with these specialists.		
Reference(s)	<sup>1</sup> RIVM. Implementation framework national screening programme for bowel cancer. 2012.		

## 6.2 Facilities

Users of a healthcare facility experience a building as pleasant, safe and functional if it is possible for good care to be delivered there. A good medical-technical layout along with the accompanying logistics of the healthcare facility is of essential importance in achieving this. Experience and functionality must be optimal. In addition, the functional layout of the facility must satisfy the prescribed requirements. A colonoscopy centre must have such facilities that all the functions on behalf of the national screening programme can be performed as required.

Objective		Such facilities that all the functions on behalf of the national screening programme can be performed as required		
Indicator	Description	Admission requirement	Audit requirement	
6.4	Location, construction, size and equipment	The location, construction, size and equipment of the colonoscopy centre satisfy the prescribed requirements.	demonstrable	demonstrable
6.5	Layout	The layout of the colonoscopy centre meets the prescribed requirements.	demonstrable	demonstrable
6.6	Equipment	The equipment of the endoscopy rooms and washing area meets the prescribed requirements.	demonstrable	demonstrable
Responsible	Colonoscopy centre (6.4 through 6.6)			
Comments	6.4 In conformance with the applicable ARBO legislation. In-home as well as by clinical care pathways are permitted here. 6.5-6.6 In conformance with the inspection requirements of the NVMDL (see appendix 5).			
Reference(s)	-			

## 6.3 Capacity

The national screening programme is part of the continuity of healthcare chain. Upon a positive result within the national screening programme, a referral to the next link in the healthcare chain follows for further diagnostics and possible treatment. The introduction of the national screening programme for bowel cancer has consequences for the processes that are invested in healthcare. The number of referrals for colonoscopy will continue to increase. Through this increase of the demand for healthcare, bottlenecks can develop in available capacity.<sup>2</sup>

In the fall of 2012, the available capacity for colonoscopies at the colonoscopy centres will be inventoried through a questionnaire. A short-cycle capacity monitor (national and regional) will be established during the introduction of the national screening programme. Based on a number of critical parameters for quality and accessibility, such as wait times and turn-around times for colonoscopy, the implementation of the national screening programme can be adjusted if necessary.<sup>2</sup> To be able to monitor the available capacity, the colonoscopy centre must periodically submit the necessary information.

In addition, a national appointment module will be designed, where the screening organizations manage all appointments for the intake interviews prior to the colonoscopy. The screening organizations have agreements with colonoscopy centres in their region, and have access to the appointment module. Moreover, it is possible for the screening organizations to plan appointments at colonoscopy centres within and outside their own region. This way the available capacity can be optimally utilized. The colonoscopy centres have access to the appointment module where they

indicate when they have what number of time slots available for intake interviews, based on the colonoscopy capacity available (endoscopist and assistant) and based on the assumption that a colonoscopy will be performed in 85% of the participants with a positive iFOBT.

Objective		Prevention of waiting times	
Indicator	Description	Admission requirement	Audit requirement
6.7 Capacity	Periodic submission of the necessary information about the available capacity.	demonstrable	demonstrable
6.8 Appointments for intake interview	Following up on the appointments made by the referring person for the intake interview.	-	demonstrable
6.9 Timeslots	Providing insight into the available timeslots for a certain period.	-	demonstrable
6.10 Continuity in service provision	Ensuring continuity in service provision	demonstrable	demonstrable
Responsible	Colonoscopy centre (6.7 through 6.10)		
Comments	-		
Reference(s)	<sup>2</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011.		

#### 6.4 Internal quality assurance

In its recommendation about the implementation of the national screening programme for bowel cancer, the Health Council has asked for attention to be paid specifically to the quality of the follow-up diagnostics.<sup>3</sup> It is known that the performance of endoscopists can differ substantially.<sup>4,5</sup> A recent study of indicators for the quality of endoscopists shows that if an endoscopist has a low adenoma detection rate this is an independent risk factor for interval carcinomas.<sup>6</sup> Research shows that a systematic quality assurance of colonoscopy and having colonoscopies carried out by endoscopists who perform well in tests can result in a major improvement in the quality of implementation.<sup>7</sup> The NVMDL organizes periodic inspections to improve the quality of work done by endoscopists.

In addition it is important that colonoscopy centres periodically show the strong and weak points of the work being done through performing internal audits, and calling attention to the possibilities for improvement. An internal audit is a systematic inspection that is performed to verify if activities correspond with what has been planned and agreed upon, if they are being performed in the correct manner and if they are suitable to achieve the intended goal and satisfy the requirements. In terms of the national screening programme for bowel cancer, the critical activities around performing the screening colonoscopies are of particular interest.

At the request of the NVMDL, HKZ has developed an interpretation document with the HKZ certification outline Client-/Patient safety for endoscopy departments ('Certification outline Patient safety for endoscopy departments'). The document is based on the existing HKZ certification outline Patient safety (version for hospital care) that is specified by the Expertise Centre on Quality Review in Healthcare in 2009. The interpretation document is compatible with the NTA 8009 (version 2011) for Hospitals. The Certification outline Patient Safety for endoscopy departments applies to the safety management system of endoscopy departments in hospitals as well as to independent treatment centres. The endoscopy department itself decides if and when to switch to an external evaluation on the basis of this certification outline.<sup>8</sup>

Objective		Internal assurance of the quality of the work to be performed	
Indicator	Description	Admission requirement	Audit requirement
6.11 Periodic inspections	Participation in periodic inspections by the professional group.	demonstrable	demonstrable
6.12 Accreditation	Satisfying the inspection requirements from the professional group.	demonstrable	demonstrable
6.13 Internal audits	Annual internal audit pertaining to the critical activities to be performed.	-	demonstrable
6.14 Certification	HKZ certification in a year to be determined later by the NVMDL.	-	demonstrable
Responsible	Colonoscopy centre (6.10 through 6.13)		
Comments	<p>6.12 In conformance with the inspection requirements of the NVMDL (see appendix 5).</p> <p>6.13 Performed by the colonoscopy centre on those critical activities that are performed in the scope of the national screening programme for bowel cancer.</p> <p>6.14 Certification will become an admission requirement in a year to be determined later by the NVMDL for (participation in the performance of) the national screening programme.</p>		
Reference(s)	<p><sup>3</sup> GR. National screening programme for bowel cancer. 2009.</p> <p><sup>4</sup> <i>Gastroenterology</i>. 2004;126(5):1247-1256.</p> <p><sup>5</sup> <i>Gut</i>. 2005;54(6):807-813.</p> <p><sup>6</sup> <i>N. Eng. J. Med.</i> 2010;362:1795-803.</p> <p><sup>7</sup> <i>BMJ</i>. 2004;329(7467):665-667.</p> <p><sup>8</sup> HKZ certification outline Patient safety for endoscopy departments. 2011.</p>		

## 7. PERSONNEL

### 7.1 Qualifications

The national screening programme generates a demand for care for a part of the participants through referral to further diagnosis. As a result, the introduction of the national screening programme for bowel cancer creates responsibilities in the availability of adjunctive care and treatment of high quality. This quality of the national screening programme and adjunctive care is connected to the knowledge and skills of the individual care providers. This assumption legitimizes a role for the national screening programme by setting requirements for training and improvement of expertise for the (ancillary) medical personnel that work within the national screening programme as well as those working in the directly adjuvant diagnostics. If these are not in order, the assumed health gains for the participant are not achieved. Care providers involved in the implementation of the national screening programme and adjuvant care must satisfy the final attainment levels and (re)registration pertaining to professional practice.<sup>9</sup>

Physicians who perform endoscopies must remain competent and authorized in conformance with the Wet op de beroepen in de individuele gezondheidszorg (Wet BIG) [Individual Health Care Occupations Act]. They must comply with the requirement for re-registration with their scientific association, in regard to schooling as well as in regard to the number of procedures performed.<sup>10</sup>

Objective		Qualified employees for the implementation of the national screening programme and subsequent diagnostics		
Indicator	Description	Admission requirement	Audit requirement	
7.1 Professional registration	Employees are responsible for professional and re-registration.	demonstrable	demonstrable	
7.2 Accreditation	Accreditation conforming to the final attainment levels for an endoscopist.	demonstrable	demonstrable	
Responsible	7.1 Colonoscopy centre 7.2 Endoscopist			
Comments	7.1 Endoscopists who perform colonoscopies after a referral via the national screening programme should be BIG and RGS registered. 7.2 The final attainment levels for an endoscopist are set by the NVMDL.			
Reference(s)	<sup>9</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011. <sup>10</sup> HKZ certification outline Patient safety for endoscopy departments. 2011.			

### 7.2 Expertise

A care provider is him/herself responsible for improvement of his/her expertise such that qualitative good care is provided. Improvement of expertise only succeeds when the care provider is prepared to critically evaluate his own performance (together with others) and to evaluate new developments and fit such into the existing care provided. Professional associations are responsible for the quality level of the pertinent professional group and colonoscopy centres for the quality of the performance by the employees.<sup>11</sup>

With references from the national screening programme, 'healthy' individuals without complaints that are not under surveillance or treatment will be offered a colonoscopy. This colonoscopy is not entirely

without risks. An RCMDL will therefore test the quality of the endoscopists beforehand and during the implementation.

<b>Objective</b>		<b>Expert employees for the implementation of the national screening programme and subsequent diagnostics</b>	
<b>Indicator</b>	<b>Description</b>	<b>Admission requirement</b>	<b>Audit requirement</b>
7.3 Competencies	Employees possess the required competencies.	demonstrable	demonstrable
7.4 Knowledge and skill	The completion of the screening module with good result.	demonstrable	demonstrable
Responsible	7.3 Colonoscopy centre 7.4 Endoscopist		
Comments	7.4 The knowledge and skills of the endoscopist are tested in the admissions test with the aid of, among others, e-learning, through the evaluation of colonoscopies to be performed, demonstrable images of polypectomies performed and the evaluation of registration data.  The proof of competence of the screening module will be periodically (every three years) extended by satisfying a renewal training as yet to be specified by the NVMDL.		
Reference(s)	<sup>11</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011.		

### 7.3 Staffing

To be able to run an endoscopy programme, at least three assistants must be present within the colonoscopy centre: one for support during the colonoscopy, one to deliver the necessary materials and one for activities in the recovery room.

<b>Objective</b>		<b>Sufficient employees for the implementation of the national screening programme and subsequent diagnostics</b>	
<b>Indicator</b>	<b>Description</b>	<b>Admission requirement</b>	<b>Audit requirement</b>
7.5 Staffing	The number of assistants present within the colonoscopy centre.	≥ 3	≥ 3
Responsible	Colonoscopy centre (7.5)		
Comments	In conformance with the inspection positions of the NVMDL (see appendix 5). The total need is 2 fte per 1000 colonoscopies.		
Reference(s)	-		

## 8. FRAMEWORKS

### 8.1 Legislation

The national screening programme for bowel cancer is a programme under the Wet op het bevolkingsonderzoek (WBO) [Population Screening Act] and in that sense is a programme that requires a license. The screening organizations are licensees on behalf of all care providers who have entered into an agreement for the national screening programme. This concerns a permit in the WBO framework.

All legislation that applies to health care, such as the Wet op de geneeskundige behandelingsovereenkomst (WGBO) [Medical Treatment Contracts Act], the Wet op de beroepen in de individuele gezondheidszorg (Wet BIG) [Individual Health Care Occupations Act] and the Wet bescherming persoonsgegevens (WBP) [Personal Data Protection Act] apply to the national screening programme for bowel cancer. Every healthcare provider that is involved in the implementation of this screening programme must satisfy the Wet klachtrecht cliënten zorgsector (WKCZ) [Health Service Clients ((Right of Complaint)) Act] and the Kwaliteitswet zorginstellingen (KWZi) [Care Institutions ((Quality)) Act].<sup>12</sup>

Objective		Implementation of the activities within the defined frameworks	
Indicator	Description	Admission requirement	Audit requirement
8.1 Legislation	Satisfying and working in conformance with the applicable laws and regulations.	demonstrable	demonstrable
Responsible	Colonoscopy centre (8.1)		
Comments	-		
Reference(s)	<sup>12</sup> RIVM. Policy framework for National Screening Programmes for Cancer 2013. 2012.		

### 8.2 Implementation framework

Through the creation of implementation frameworks, the RIVM-CvB provides guidance to the various national screening programmes which it directs. An implementation framework has also been created for the national screening programme for bowel cancer to which all parties are committed.<sup>13</sup> The goal of this implementation framework is to allow the national screening programme to run effectively within the qualitative frameworks and to ensure national uniformity. The implementation framework describes what is needed. The implementation framework is intended for all parties in the implementation (screening and subsequent diagnostics). The implementation framework is first issued as a paper version at the start of the national screening programme and sent to professional organizations and involved professionals. The most recent version of the implementation framework can be consulted at: <http://www.bevolkingsonderzoekdarmkanker.nl/professionals> (only in Dutch).

Objective		Implementation of the activities within the defined frameworks	
Indicator	Description	Admission requirement	Audit requirement
8.2 Implementation framework	Satisfying and working in conformance with the agreements in the nationally defined implementation framework for the national screening programme for bowel cancer.	-	demonstrable
Responsible	Colonoscopy centre and endoscopist (8.2)		
Comments	-		
Reference(s)	<sup>13</sup> RIVM. Implementation framework national screening programme for bowel cancer. 2014.		

### 8.3 Guidelines

Great significance is attached in the layout and implementation of the national screening programme for bowel cancer to the close involvement of the various professional groups that play a role in the entire chain of the national screening programme, subsequent diagnostics and treatment. This is accompanied by recognition of the professional standards, values and working methods.

Guidelines and protocols also define the professional standards and proper care. In terms of content, guidelines are the responsibility of the professional and his professional association. The professional organizations are responsible for the development and implementation of guidelines. Thus they also define them in terms of content. In terms of health law, each care provider is obligated on the basis of the WGBO to act corresponding to his responsibilities stemming from the professional standards.<sup>14</sup>

The most important guidelines for performing screening colonoscopies are listed in the overview below. For the remaining applicable guidelines, please consult the website of the NVMDL: <http://www.mdl.nl/richtlijnen2> (only in Dutch).

#### **Guideline on Sedation and/or Analgesia by Gastroenterohepatologists in Endoscopic Operations<sup>15</sup>**

This guideline has been developed by the Dutch Society of Gastroenterohepatology based on the Guideline on Sedation and/or Analgesia by Non-Anaesthetists issued in 1998 by the CBO [Dutch Institute for Healthcare Improvement].<sup>4</sup>

#### **Draft Guideline on Sedation and/or Analgesia outside the Operating Theatre<sup>16</sup>**

This draft guideline is a revised edition of the Guideline on Sedation and/or Analgesia by Non-Anaesthetists issued in 1998 by the CBO [Dutch Institute for Healthcare Improvement].<sup>18</sup> The appendix to the guideline deals with the procedures for the specialism, including those of gastroenterohepatologists.

#### **National Guideline on Colon Carcinoma<sup>18</sup>**

This guideline on policy on colon and rectal cancer has been developed by the National Working Group on Gastrointestinal Tumours of the Association of Comprehensive Cancer Centres (VIKC). It makes recommendations on diagnostic, treatment and follow-up procedures for adult patients with bowel cancer.

#### **National Guideline on Polypectomy Follow-up<sup>19</sup>**

This guideline provides a timetable for follow-up intervals after polypectomy.

#### **Dutch guideline on colonoscopy surveillance<sup>20</sup>**

The Guideline is developed by the Dutch Association of Gastroenterohepatologists (NVMDL) in collaboration with the Dutch Pathology Association (NVVP). The guideline is an update of the MDL guideline 'Follow-up after poliepectomy' and the sections of the guidelines 'Hereditary bowel cancer' and 'Colon carcinoma' that concern colonoscopy surveillance. Regular surveillance and timely removal of polyps results in a reduced incidence and mortality of bowel cancer. The current guideline involves all patients who have an indication for colonoscopy surveillance due to an increased risk of polyps.

#### **National Guideline on Hereditary Bowel Cancer<sup>21</sup>**

This guideline makes recommendations on diagnosis, treatment, follow-up, regular tests and prophylactic operations in cases of hereditary and familial bowel cancer.

#### Multidisciplinary guideline

The Health Council recommends developing integrated multidisciplinary guidelines for the screening programme, including diagnosis, treatment and surveillance. This guideline should be drafted by the professional groups involved after the start of the national screening programme.

Objective		Implementation of the activities within the defined frameworks	
Indicator	Description	Admission requirement	Audit requirement
8.3 Guidelines	Satisfying and working in conformance with the applicable guidelines as created by the professional group.	demonstrable	demonstrable
Responsible	Colonoscopy centre and endoscopist (8.3)		
Comments	At the start of the national screening programme the colonoscopy centre and the endoscopist must work in conformance with the guidelines as defined at that moment by the professional groups.		
Reference(s)	<sup>14</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011. <sup>15</sup> NG-MDL. Guideline on Sedation and/or Analgesia in Endoscopic Operations. 2001. <sup>16</sup> CBO. Consensus on Sedation and/or Analgesia by Non-Anaesthetists. 1998. <sup>17</sup> NVA/NVK. Draft Guideline on Sedation and/or Analgesia outside the Operating Theatre. 2008. <sup>18</sup> VIKC. National Guideline on Colon Carcinoma. 2008. <sup>19</sup> CBO. Reviewed Guideline on Polypectomy Follow-up. 2002. <sup>20</sup> NVMDL. Dutch guideline on colonoscopy surveillance. 2013. <sup>21</sup> VKGN. National Guideline on Hereditary Bowel Cancer. 2008.		

#### 8.4 Protocols

It is desirable for a national screening programme with a uniform methodology that national protocols are drawn up in addition to the applicable guidelines.<sup>23</sup> A part of these protocols are, to a greater or lesser degree, already applied locally. Uniform agreements about specific parts of performing screening colonoscopies are formulated in the national protocols. Where desired there is room for a regional interpretation for sections. The RIVM-CvB supports the development of the national protocols by the NVMDL through formulating the minimum requirements for the content together with experts from the involved professional groups.

The colonoscopy centre has developed and implemented a procedure for the preparation of colonoscopies.

Objective		Implementation of the activities within the defined frameworks	
Indicator	Description	Admission requirement	Audit requirement
8.4 Protocols	Satisfying and working in conformance with the nationally established, applicable, (requirements of) protocols.	demonstrable	demonstrable
8.5 Preparation for colonoscopy	An implemented procedure for the preparation of colonoscopies.	demonstrable	demonstrable
Responsible	8.4 Colonoscopy centre and endoscopist		



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Comments	8.5 If a procedure is not yet available, the colonoscopy centre needs to be able to demonstrate the methodology (that is yet) to be implemented to the RCMDL during the admission examination.
Reference(s)	<sup>23</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011.

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## 8.5 Risk management

Risk management is the entirety of effective measures to ensure that the national screening programme for bowel cancer is resumed and performed as intended as quickly as possible after an incident or calamity and that risks (that are foreseeable) are prevented. A broad national screening methodology has been developed for handling calamities in which the tasks and responsibilities of the parties involved are outlined.<sup>23</sup> The colonoscopy centre has developed and implemented a procedure for handling incidents.

In accordance with the Wet klachtrecht cliënten zorgsector (WKCZ) [Health Service Clients ((Right of Complaint)) Act], every care provider puts into place a procedure for the treatment of complaints about a conduct of theirs or persons working for them towards a client.<sup>24</sup> The care provider brings the relevant procedure to the attention of his clients in a fitting manner (section 2, paragraph 1 WKCZ).

The procedure covers handling of complaints by clients by a complaints committee. Clients may complain about any conduct by the care provider and those working for the care provider. No limitations may be placed on the grounds for complaint.

The colonoscopy centre discusses incidents and complaints that may lead to improvement in the national screening programme, in the period audit with the RCMDL.

Objective		Performing work activities within the set framework	
Indicator	Description	Admission requirement	Audit requirement
8.6 Risk management	Satisfies and is in accordance with the risk management protocol for the national screening programme for bowel cancer.	-	demonstrable
8.7 Handling incidents	An implemented procedure for handling incidents.	demonstrable	demonstrable
8.8 Evaluation of incidents	Incidents that may lead to improvement in the national screening programme are discussed in the periodic audit with the RCMDL.	-	demonstrable
8.9 Reporting incidents	Incidents/calamities that may pose a threat to the safety and quality of the national screening programme for the participant, are reported immediately to the RCMDL.	-	demonstrable
8.10 Handling complaints	An implemented procedure for handling complaints.	demonstrable	demonstrable
8.11 Evaluation of complaints	Complaints that may lead to improvement in the national screening programme are discussed in the periodic audit with the RCMDL.	-	demonstrable
Responsible	Colonoscopy centre (8.6 through 8.11)		
Comments	<p>8.7 If a procedure is not yet available, the colonoscopy centre needs to demonstrate the methodology (that is yet) to be implemented to the RCMDL during the admission examination.</p> <p>If it was reported to the IGZ, the colonoscopy centre sends a copy of confirmation of processing by the IGZ to the RCMDL.</p> <p>8.9 In its role as referrer, the RCMDL should be able to assess if referral is sensible in the case of a calamity/incident. In addition, the RCMDL should also be informed about handling of the incident.</p> <p>8.10 If a procedure is not available, the colonoscopy centre needs to be able to demonstrate the methodology (that is yet) to be implemented to the RCMDL during the admission examination.</p>		
Reference(s)	<p><sup>23</sup> RIVM. Risk management protocol. 2013.</p> <p><sup>24</sup> RIVM. Note on handling complaints. 2013.</p>		

## 9. INTAKE

The objective of the intake is to evaluate if further examination is required and if there are no obstacles or objections to performing this examination. In addition, the intake has the objective of informing the participant about the planned colonoscopy and collecting information relevant to the examination, especially the health status of the participant. The intake forms part of further diagnostics, which starts with the result of a positive iFOBT and continues through to the colonoscopy and issuing the report.

### 9.1 General aspects

An intake should always be conducted prior to the colonoscopy. This intake is face-to-face. The patient must be informed about the possible risks and the physician must be able to test if the patient has understood this information (which must also be recorded). The intake is conducted by a staff member with content expertise and who is authorized and competent, such as a nurse, NP/PA or specialist. A physician must be available for supervision and consultation. The colonoscopy centre can determine the duration of the intake themselves via the recording of time slots. The colonoscopy centre can make use of their own electronic hospital information system to record the patient history data. For the primary process of the national screening programme, the colonoscopy centre should additionally register some information in ColonIS.

If the iFOBT is positive, the result letter asks the participant to contact their general practitioner so that they can pass relevant (medical) information to the colonoscopy centre (if required). If the participant has a relevant medical history and has had contact with the general practitioner, the general practitioner is responsible for sending the required medical information to the colonoscopy centre for the intake. During the intake interview the participant is asked if they have had contact with the general practitioner and it is verified, where required, if the required information has been received by the general practitioner. If a participant has not had contact with the general practitioner and/or it becomes apparent during the intake that the colonoscopy centre requires further medical information, it is the responsibility of the colonoscopy centre to request this extra data from the general practitioner or other care professional.<sup>25</sup>

A number of aspects should be addressed during the intake for colonoscopies following referral from the national screening programme. This chapter provides further details of and references for these aspects. An Intake work guide for colonoscopy has also been formulated.<sup>26</sup> This work guide informs those involved about the possible contents of the intake for colonoscopy and can be used by the intaker as a guide for the intake interview. The work guide contains a checklist with all items/topics that should be addressed during the colonoscopy intake within the framework of the national screening programme.

Objective		Uniform quality in colonoscopy intake	
Indicator	Description	Admission requirement	Audit requirement
9.1 Personal contact	The intake takes place face-to-face.	-	demonstrable
9.2 Expertise	The intake is conducted by a staff member with content	-	demonstrable

	expertise who is authorized and competent.		
9.3 Responsible	If the patient has a relevant medical history and has not had contact with the general practitioner prior to the intake, it is the responsibility of the colonoscopy centre to request this information from the general practitioner or other care professional.	-	demonstrable
Responsible	Colonoscopy centre (9.1 through 9.3)		
Comments	<p>9.2 This concerns BIG-registered care providers, such as a nurse, NP/PA, physician. In consultation with the RCMDL, an exception is made at the commencement of the national screening programme for hospitals in which the intake is conducted by non-BIG registered care providers in the existing practice. During the first complete audit, which takes place three years after the national screening programme commences, all care providers who conduct an intake must be BIG-registered.</p> <p>New staff members who are going to conduct intakes within the context of the national screening programme for the first time, should be BIG registered.</p>		
Reference(s)	<p><sup>25</sup> RIVM. Implementation framework for bowel cancer. 2014.</p> <p><sup>26</sup> RIVM. Intake work guide for colonoscopy. 2014.</p>		

## 9.2 Patient history

The objective of taking the patient history is to determine if a colonoscopy can be conducted with the relevant patient. At a minimum, at least the below (general) aspects should be included when taking the patient history:

- case history
- family history
- medication use
- lifestyle
- allergy
- current health status

The national screening programme for bowel cancer has a specific target group and a different population than for colonoscopy on indication. For this reason, specific attention should be given to anti-coagulation and familial burden when taking the patient history.

In the NG-MDL guideline on Endoscopic interventions for patients with anti-coagulation and platelet aggregation inhibition, separate attention is given to dealing with anticoagulants in patients based on risk qualification of the intervention.<sup>27</sup> The chance of abnormalities due to colonoscopies after referral from the national screening programme is greater than with other colonoscopies. In order to limit the burden on the participant as much as possible, detected polyps are removed during the primary colonoscopy where possible.

It is checked during the colonoscopy intake if hereditary bowel cancer may be relevant to the patient. If it is determined that the extent of the familial burden is such that intensive monitoring is desirable, the guideline surveillance is followed.<sup>28</sup>

Any adjustments in medication (diabetes, anti-coagulation) and preparation are considered when the patient history is taken and agreed with the patient during the intake (if applicable).

Objective		Determining if a colonoscopy can be conducted	
Indicator	Description	Admission requirement	Audit requirement
9.4 Patient history	(At a minimum) the aspects outlined in the Colonoscopy admission and auditing protocol are checked during the intake.	-	demonstrable
9.5 Anticoagulation	An adjusted methodology is used if the patient is on anticoagulants.	-	demonstrable
9.6 Familial burden	It is checked during the colonoscopy intake if hereditary bowel cancer may be relevant to the patient.	-	demonstrable
Responsible	Colonoscopy centre (9.4 through 9.6)		
Comments	9.5 The adjusted methodology is outlined in the guideline Endoscopic interventions for patients with anti-coagulation and platelet aggregation inhibition. 9.6 If it is determined that the extent of the familial burden is such that intensive monitoring is desirable, the guideline surveillance is followed.		
Reference(s)	<sup>27</sup> NG-MDL. Guideline Endoscopic interventions for patients with anti-coagulation and platelet aggregation inhibition. 2005. Note: It has been indicated to the NVMDL that this guideline is not sufficient for the target group within the context of the national screening programme. An amended guideline will be issued in 2014. <sup>28</sup> NVMDL. Dutch guideline for colonoscopy surveillance. 2013.		

### 9.3 Treatment decision

Based on the outcome of the patient history, a decision is made whether a colonoscopy is necessary and whether there are no obstacles to conducting one. The national screening programme for bowel cancer has a specific target group and a different population than for colonoscopy on indication. Within this framework there are specific exclusion criteria for colonoscopies after referral by the national screening programme. Aside from any obstacles arising from the patient history, a colonoscopy should not be conducted if the patient:

- has a life expectancy of five years or shorter, in which abnormalities found will not be of clinical consequence
- has undergone a proctocolectomy
- is under treatment for bowel cancer (referral to/consultation with the treating physician)
- is under monitoring for an inflammatory disease of the bowel at the time of the fecal test (referral to/consultation with the treating physician)
- does not wish to (distinguishing between short-term (this round) or definitive)

The colonoscopy centre has made work agreements concerning responsibilities surrounding the treatment decision, from which it must be clear who (intaker or physician) is authorized to make the treatment decision on the basis of the outcome of the patient history.

Patients who cannot undergo a colonoscopy, but for whom a detected abnormality may have therapeutic consequences, are offered an alternative. The colonoscopy centre is responsible for a good transfer of patient data to the relevant specialist.

Only in highly exceptional cases it may already be determined during an intake interview that a complete colonoscopy is not possible. In this case, the participant can be referred for a CT colonography. For the purpose of monitoring, one of the below reasons is registered in the care provider portal of ColonIS by the intaker:

- earlier colonoscopy that could not be conducted fully due to a persisting reason
- other physical-medical reason
- psychological-medical reason (e.g. anxiety disorder, a history of sexual abuse)
- patient absolutely does not wish to undergo a colonoscopy
- other, namely ...

For participants who indicate they never wish to undergo a colonoscopy or alternative after they have been thoroughly informed about this during the intake, participation in the national screening programme is no longer of benefit. In this case, the intaker can point out that the participant can deregister from the national screening programme in writing via the screening organisation. If the participant does not do this, he/she will receive another invitation from the screening organisation after two years to make an appointment for an intake.

Objective		Determining if a colonoscopy is necessary	
Indicator	Description	Admission requirement	Audit requirement
9.7 Decision-making authority	The colonoscopy centre has made work agreements concerning responsibilities surrounding the treatment decision.	-	demonstrable
9.8 Exclusion criteria	Exclusion for colonoscopy takes place on the basis of the patient history and the exclusion criteria established within the framework of the national screening programme for bowel cancer.	-	demonstrable
9.9 Alternative for colonoscopy	Offering an alternative to patients who cannot undergo a colonoscopy, but for whom detection of an abnormality may have therapeutic consequences.	-	demonstrable
9.10 Transfer to specialist	A good transfer of patient data to the relevant specialist, if a qualitatively good colonoscopy is not possible.	-	demonstrable
Responsible	Colonoscopy centre (9.7 through 9.10)		
Comments	9.7 For example, by creating a family tree.		
Reference(s)	-		

### 9.4 Pre-sedation

Use of sedation and/or analgesics is not necessary with all colonoscopies, but is becoming more common. On the one hand, because patients may be anxious about an endoscopic procedure, and on the other hand, an increasing number of patients are indicating in advance that they would like to undergo the examination in a comfortable manner. Intravenous sedation and possibly analgesics are chosen in most cases because this allows a maximum effect to be achieved in a simple manner at the right moment in time.

The endoscopist must be alert for factors that may increase the risk of sedation. A form of screening should take place prior to the examination. The possibility of sedation with the colonoscopy can be discussed with the patient during the intake. A decision is then made on the basis of the patient history (use of medication, any comorbidities and general condition of the patient) if sedation is (not) possible for the relevant participant.

TABLE I. Classification for the evaluation of the anesthesia risk, formulated by the American Society of Anesthesiologists (ASA classification)<sup>2</sup>

Class	Description
I	a healthy patient
II	a patient with a light to moderate systemic abnormality that does not result in a limitation in function
III	a patient with a severe function-limiting systemic abnormality
IV	a patient with a systemic abnormality that is constantly associated with a threat to the patient's life
V	a patient who will probably die within 24 hours with or without surgery

The risk of sedation of the patient can (partly) be determined on the basis of the above ASA classification.<sup>29</sup> There are sufficient indications in literature that sedation of ASA III patients can be safely performed if the preconditions adequate monitoring and adequately trained staff are adhered to.<sup>30</sup>

If sedation is indicated, the aim for a colonoscopy is light or moderate sedation, in which the patient still responds to being spoken to or light stimulation. In the case of sedation, the guideline of the professional group is followed.<sup>31</sup>

Objective	Performing activities within the frameworks set		
Indicator	Description	Admission requirement	Audit requirement
9.11 Sedation	In the case of sedation, the guideline of the professional group is followed.	-	demonstrable
Responsible	Colonoscopy centre (9.11)		
Comments	-		
Reference(s)	<sup>29</sup> <i>Ned Tijdschr Geneeskd.</i> 1998;142:701-5. <sup>30</sup> <i>Gastroenterol.</i> 2007;133:675-701. <sup>31</sup> Guideline sedation and/or analgesics at locations outside the operation room (2010). Note: the NVMDL is currently working on amending this guideline.		

## 9.5 Informing the patient

It is important to provide the patient with clear information about the planned intervention during the intake. The information provided during the intake should at least cover the following aspects:

- the objective of the intervention
- the procedure (colonoscopy)
- risks and possible complications
- the chance of finding bowel cancer or polyps
- sedation options
- the approach if there are special circumstances (stoma, diabetes, patients who use medication)
- preparation
- instructions for the day of the examination/intervention
- information about aftercare

In addition, the patient receives written information about the preparation for a colonoscopy and about the colonoscopy itself.

Interval colon carcinomas are more common than previously thought, especially in the proximal colon.<sup>32,33</sup> The risk of interval carcinomas after colonoscopy should therefore be specifically covered during the intake interview. No matter how carefully the fecal test and colonoscopy test are performed, there is no guarantee that there are no malignant tumours or that these do not develop in the period prior to the next screening or colonoscopy. It is important that patients consult their general practitioner if complaints develop during this period. The protocol Interval carcinomas will be issued in 2014 with agreements and methodology for the monitoring of programmatic cancers within the national screening programme for bowel cancer and associated diagnostics.

Objective		Performing the activities within the frameworks set	
Indicator	Description	Indicator	Description
9.12 Providing information	At a minimum, the patient is provided with the information outlined in the protocol for the Admission and auditing of colonoscopy during the intake.	-	demonstrable
9.13 Written information	During the intake, the patient receives written information about the preparation for the colonoscopy and the procedure (colonoscopy) itself.	-	demonstrable
9.14 Interval carcinomas	During the intake, the patient is informed about the risk of interval carcinomas after colonoscopy.	-	demonstrable
Responsible	Colonoscopy centre (9.12 through 9.14)		
Comments	-		
Reference(s)	<sup>32</sup> <i>Gastroenterol.</i> 2011;140(1):65-72. <sup>33</sup> <i>Nature Reviews Gastroenterol &amp; Hepatol.</i> 2012;9:550-554.		

## 9.6 Informed consent

A broad scale of legislation applies to the organisation of the national screening programme for bowel cancer. An important category is legislation surrounding patient rights and, as an extension to this, legislation regarding careful handling of personal data in healthcare. Privacy laws state conditions that must be met by planned data flows for the purpose of screening, diagnostics, quality control and monitoring/evaluation of the programme and scientific research. In all cases, participants in the national screening programme receive a letter with the result of the iFOBT. If the result is positive, the letter also contains information on referral to the colonoscopy centre and a brochure with information about follow-up care. A new treatment agreement arises with the colonoscopy centre. If it becomes apparent from the intake interview that instead of a colonoscopy, an alternative is required, this falls within the same treatment agreement. The participant needs to provide informed consent within this new treatment agreement with the colonoscopy centre; this is subsequently the informed consent for the medical intervention(s) in that phase.<sup>34</sup>

Data from diagnostics are entered in the recording system of the centre and fall within the privacy policy of the relevant institution. However, part of this data should flow back to ColonIS for quality control, monitoring and evaluation and (possibly) scientific research. This data is also an information source for possible exclusion from subsequent rounds of the national screening programme. During the intake the participant is asked if he/she objects to this data exchange with the screening organisation. This concerns both data from the intake and the colonoscopy.

The colonoscopy centre and the centre where the patient may be treated, also have their own standard data processing and possible exchange with others, independent of data processing within the framework of the national screening programme. These all fall within the privacy policy of the relevant institution (hospital policy). For this reason, the patient is asked during the intake to provide consent to the colonoscopy centre for additional (medical) information to be requested from the general practitioner or other care provider (if required), if he/she has not had contact with the general practitioner prior to the intake. Issuing the colonoscopy report to the general practitioner after referral from the national screening programme also falls under the applicable hospital policy.

Objective		Careful handling of personal data	
Indicator	Description	Admission requirement	Audit requirement
9.15 Informed consent	Informed consent for medical interventions and consent for the recording and exchange of data with care providers external to the screening, takes places in accordance with the applicable hospital policy.	-	demonstrable
9.16 Consent for data exchange	During the intake, the patient is asked for consent for the exchange of data from the intake and colonoscopy with the screening organisation.	-	demonstrable
Responsible	Colonoscopy centre (9.15 through 9.16)		
Comments	-		
Reference(s)	<sup>34</sup> RIVM. Note on Admission and objection. 2012.		

## 9.7 Structured data recording

Execution of the national screening programme for bowel cancer involves the recording and exchange of data, such as examination results. Aside from this operational data, data is also recorded

and exchanged for the purpose of quality control, monitoring and evaluation. Monitoring and evaluation contribute to a continuous improvement process of the national screening programme. In doing so, both monitoring the quality of the primary execution processes (quality control) and national evaluation of the effectiveness and efficiency are important.

The colonoscopy centre can make use of their own recording system when recording the data (for patient history) during the intake for colonoscopy. However, for the purpose of continuity of the selection process through to referral and monitoring of the national screening programme, a limited amount of data from the uptake should be fed back to the IT system of the national screening programme. To this end, the colonoscopy centre registers the required data in a timely manner, in accordance with the technical dataset for intake<sup>35</sup> in the care provider portal that has been made available.

If a participant does not turn up for the colonoscopy intake, despite the appointment made, the colonoscopy centre registers the result of the intake interview as a 'no show' in the portal. On the basis of this entry, the screening organisation sends the participant a reminder letter, in which the participant is requested to schedule a new appointment themselves for the intake.

Objective		Supporting the primary process	
Indicator	Description	Indicator	Description
9.17 Recording the intake	Structured data recording of the required intake information in the care provider portal, made available for this purpose.	-	demonstrable
9.18 Timeliness of registration	The maximum time duration for registration of the required data from the intake after the interview.	-	≤ 5 working days
Responsible	Colonoscopy centre (9.17 through 9.18)		
Comments	9.17 In accordance with the technical dataset for intake. 9.18 If the intake is put on hold, registration of the intake must be completed within five working days after the medical data has been received.		
Reference(s)	<sup>35</sup> RIVM. Technical dataset for intake. 2014.		

## 10. COLONOSCOPY

The colonoscopy is accepted as the most effective method for the examination of the colon for lesions in patients ages 50 and older.<sup>36</sup> The effectiveness of the colonoscopy depends on the quality of the performance of the colonoscopy. The optimization of the quality and along with that also the effectiveness of the colonoscopy is a continuous process. Various important indicators have been defined during the past decade to measure the quality of (the performance of) colonoscopies.<sup>37</sup> Participants in the national screening programme for bowel cancer should expect a high and nationally uniform quality of the performance of their colonoscopy. It has been demonstrated through the indicators below that attaining a certain target value assures a good quality colonoscopy.

### 10.1 Experience

The quality of a colonoscopy depends to a large degree on the experience and skill of the endoscopist who performs the procedure. The European Guideline recommends that every endoscopist who participates in a screening programme for bowel cancer performs at least 300 colonoscopies on an annual basis.<sup>38</sup> The occurrence of adverse events is also dependent on the experience of the endoscopist. Rabeneck et al. has demonstrated that the chance of colonoscopy-related perforations and bleeding decreases with an increase of the number of colonoscopies performed annually.<sup>39</sup>

To limit the stress for the participant as much as possible, it is important that the endoscopist is skilled in performing polypectomies. Detected polyps and adenomas must be removed as much as possible during the primary colonoscopy.

Objective		Sufficient experience in colonoscopy and polypectomy		
Indicator	Description	Admission requirement	Audit requirement	
10.1 Number of colonoscopies	Number of (screening) colonoscopies performed per year.	≥ 300	≥ 300	
10.2 Number of polypectomies	Number of polypectomies performed per year.	≥ 50	-	
10.3 New colonoscopy	The percentage of the colonoscopies performed by the endoscopist where a new colonoscopy takes place for the removal of polyps.	-	monitoring	
Responsible	Endoscopist (9.1 through 9.3)			
Comments	10.1 Admission requirement: at least 300 colonoscopies in the year prior to the admission to the implementation. Audit requirement: at least 300 colonoscopies per year in the scope of the national screening programme for bowel cancer. A further review will be done in particular for the university medical centres if this requirement pertains to colonoscopies performed by self and/or supervised colonoscopies. 10.2 At least 50 polypectomies in the year prior to the admission to the implementation. 10.1 These (experience) requirements apply to all endoscopists who perform colonoscopies 9.2 in the scope of the national screening programme for bowel cancer (MDL physicians, surgeons, internists, nurse endoscopists). 10.3 Monitoring through the benchmark. In time the audit requirement will be determined and implemented on the basis of benchmark information.			
Reference(s)	<sup>38</sup> European Guidelines for Quality Assurance in colorectal cancer screening and diagnosis. 2010. <sup>39</sup> <i>Gastroenterology</i> . 2008;135:1899-1906.			

## 10.2 Completeness of exam

The degree of detection of polyps and adenomas is strongly dependent on the completeness of the examination.

A proper preparation of the colon is the key to a detailed inspection of the colon. Poor bowel preparation inhibits the detection of lesions and can result in the caecum not being reached.<sup>40</sup> To protect participants from the negative effects of the preparation, good hydration is essential. In practice there are various methods to prepare the colon for inspection, such as diet, catharsis and gut lavage. The method used must be acceptable to the participant and satisfy the guidelines for hygiene. The quality requirements for bowel preparation will be made available in the course of the preparation for the national screening programme.

A complete inspection of the colon (caecal intubation) can demonstrably prevent more deaths as a result of bowel cancer and is therefore an important indicator for the quality of the colonoscopy.<sup>41</sup> In a cohort study of patients with a previous incomplete colonoscopy, 4.3% advanced neoplasia turned out to be present in the follow-up of the section of the colon that was not seen previously.<sup>31</sup> The audit requirement of a 95% completion rate conforms to the standard that is applied in the screening programmes in the United States and Canada.<sup>43, 44</sup> The admission requirement is adjusted for colonoscopies in a non-screening population.

Two major studies have shown that the withdrawal time of a negative colonoscopy (in other words, no pathology detected) should take a minimum of 6 minutes.<sup>45, 46</sup> The studies show a clear correlation between the inspection time and the detection of small as well as large adenomas. Barclay et al. demonstrates that endoscopists with a withdrawal time of more than 6 minutes have a higher detection rate of neoplasia (28.3% versus 11.8%), with a significant difference in the detection of advanced neoplasia (6.4% versus 2.6%). Both studies support the position that longer withdrawal times translate to the detection of more lesions.

Objective		Complete examination of colon	
Indicator	Description	Admission requirement	Audit requirement
10.4 Bowel preparation	The percentage of colonoscopies where the colon is sufficiently clean to be able to inspect it well.	≥ 90%	≥ 90%
10.5 Caecal intubation rate	The percentage of colonoscopies with a complete caecum intubation.	≥ 90%	≥ 95%
10.6 Withdrawal time	The percentage of negative colonoscopies with a withdrawal time of at least 6 minutes.	-	≥ 90%
Responsible	10.4 Colonoscopy centre 10.5 Endoscopist 10.6 Endoscopist		
Comments	10.4 The colonoscopy centre is responsible for the preparation of the patient, which includes the bowel preparation. The degree of bowel preparation is recorded by the endoscopist during the colonoscopy according to the Boston Bowel Preparation Scale (BBPS). In doing so, the endoscopist works in accordance with the technical dataset for colonoscopy.		

Comments	<p>10.4 According to the Boston Bowel Preparation Scale (BBPS)<sup>47,48</sup></p> <p>The BBPS is a four point scoring system applied to the three largest parts of the colon: the right colon (including the cecum and ascending colon), the transverse colon (including the hepatic and splenic flexures), and the left colon (including the descending colon, sigmoid colon, and rectum). The points are assigned as follows:</p> <p>0 = Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared.</p> <p>1= Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid.</p> <p>2 = Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well.</p> <p>3 = Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid.</p> <p>Each region of the colon receives a "segment score" from 0 to 3 and these segment scores are summed for a total BBPS score ranging from 0 to 9. Therefore, the maximum BBPS score for a perfectly clean colon without any residual liquid is 9 and the minimum BBPS score for an unprepared colon is 0.</p> <p>A sufficiently clean colon has a BBPS score of 6 or higher.</p> <p>10.5 In accordance with the technical dataset for colonoscopy:</p> <ul style="list-style-type: none"> <li>- appendix-orifice, ileo-caecal valve, terminal ileum</li> <li>- photographic documentation of 2 of the 3 landmarks</li> </ul> <p>10.6 Withdrawal time from caecum to anus of at least 6 minutes in case of negative colonoscopies.</p>
Reference(s)	<p><sup>40</sup> <i>Gastrointest Endosc.</i> 2003;58:76-79.</p> <p><sup>41</sup> <i>Ann Intern Med.</i> 2009;150(1):1-8.</p> <p><sup>42</sup> NHS BCSP Endosc Qual Assurance group. 2011.</p> <p><sup>43</sup> <i>Gastroenterology.</i> 2008;134:1570-1595.</p> <p><sup>44</sup> <i>Can J Gastroenterol.</i> 2007;21(Suppl D):5-24.</p> <p><sup>45</sup> <i>N Engl J Med.</i> 2006;355:2533-2541.</p> <p><sup>46</sup> <i>Aliment Pharmacol Ther.</i> 2006;24:965-971.</p> <p><sup>47</sup> <i>Gastrointest Endosc.</i> 2010;72(4):686-692.</p> <p><sup>48</sup> <i>Gastrointest Endosc.</i> 2009;69(3 Pt 2):620-625.</p>

### 10.3 Detection rates

The primary goal of the national screening programme is to reduce deaths from bowel cancer by detecting cancer earlier, at an asymptomatic stage rather than on symptomatic presentation. The cancer detection rate however is a less accurate indication of the quality of the colonoscopy than the adenoma detection rate. The screening pilots in Great Britain endorse the point that cancer detection rates can vary by region and sex. In addition, it is the expectation that the rates will significantly vary per endoscopist, due to the small number of cancer cases in the population. For this reason it is important that a sound monitoring programme first takes place in regard to the cancer detection rate, before an audit requirement can be associated with it.

The adenoma detection rate is one of the most accepted quality indicators within the current screening programmes for bowel cancer.<sup>49</sup> The putative purpose of adenoma removal is to prevent the progression of benign lesions into bowel cancer. From the study by Kaminski et al. there appears to be a significant relationship between the adenoma detection rate and the chance for interval cancers.<sup>50</sup> The risk for interval cancer was significantly higher in participants that underwent a colonoscopy by endoscopists with a detection rate less than 20% than in participants that were examined by endoscopists with a detection rate of 20% or more. In a screening programme with healthy participants in the age category of 50 years and older, a minimum adenoma detection rate of 30% is desirable.<sup>49</sup>

With that, the adenoma detection rate is a significant indicator for the quality of the colonoscopy. It does however have the limitation that it does not measure the total number of detected adenomas. The mean number of adenomas per procedure (MAP) and the mean number of adenomas per positive procedure (MAP+) provide additional information about the skills of the endoscopist.<sup>51</sup> MAP and MAP+ are relatively new indicators. Good monitoring is necessary before audit requirements can be defined for these indicators.

Objective		Determining cancers and adenomas present in the screening population	
Indicator	Description	Admission requirement	Audit requirement
10.7 Cancer detection rate	The percentage of colonoscopies where (more than) one cancer has been detected.	-	monitoring
10.8 Adenoma detection rate	The percentage of colonoscopies where (more than) one adenoma has been detected.	≥ 20%	≥ 30%
10.9 MAP	The mean number of adenomas per procedure (colonoscopy).	-	monitoring
10.10 MAP+	The mean number of adenomas per positive procedure (colonoscopy).	-	monitoring
Responsible	Endoscopist (10.7 through 10.10)		
Comments	10.8 The PDR and SPDR may be added in the future as indicator if it becomes clear they are of added value in predicting the occurrence of interval carcinomas. 10.9/ Monitoring through the benchmark. In time the audit requirement will be 10.10 determined and implemented on the basis of benchmark information.		
Reference(s)	<sup>49</sup> <i>Gastrointest Endosc.</i> 2006;63:16-28. <sup>50</sup> <i>N Engl J Med.</i> 2010;362(19):1795-1803. <sup>51</sup> <i>Gut.</i> 2012;61:1050-1057.		

#### 10.4 Removal rates

Data from the National Polyp Study Workgroup point to a prevention of interval cancers of 76-90% by colonoscopy and polypectomy.<sup>52</sup> In the removal of polyps it is first and foremost necessary to perform the polypectomy as safe as possible. Colonoscopic adverse events are unusual, but are associated with a high morbidity.<sup>53</sup> In addition it is important that a polyp is completely removed during a polypectomy in order to prevent local regrowth. Two studies show that a quarter of all interval cancers subsequent to a colonoscopy possibly developed from tissue remaining after a polypectomy.<sup>54,55</sup> The retrieval of polyps for pathology analysis is important to exclude invasive carcinomas in addition to be able to determine the interval for surveillance.<sup>56</sup>

Objective		Prevention of interval cancers /availability of polyps for pathology analysis	
Indicator	Description	Admission requirement	Audit requirement
10.11 Polyp removal rate	The percentage of polyps removed of the total number of detected polyps during the colonoscopy.	≥ 90%	≥ 90%
10.12 Polyp retrieval rate > 5 mm for pathology analysis	The percentage of retrieved polyps for pathology analysis of the total number of polyps retrieved during the colonoscopy with a size > 5 mm.	monitoring	≥ 90%
Responsible	Endoscopist (9.11 through 9.12)		
Comments	<p>10.11 The audit requirement is corrected for colonoscopies with higher numbers of polyps. Colonoscopies in which more than 10 polyps are detected, are not included in the calculation of the retrieval rate.</p> <p>10.12 Monitoring via the benchmark. In time, the admission and audit requirement will be determined and implemented on the basis of the benchmark data.</p> <p>For retrieved polyps that are not provided for pathology analysis, the reason is provided on a colonoscopy level. The following reasons may be chosen:</p> <ul style="list-style-type: none"> <li>- long procedure</li> <li>- a burden on the patient</li> <li>- polyp not found again</li> <li>- many polyps</li> <li>- other</li> </ul>		
Reference(s)	<p><sup>52</sup> <i>N Engl J Med.</i> 2006;63(4 Suppl):16-28.</p> <p><sup>53</sup> <i>Arch Surg.</i> 2008;143:701-706.</p> <p><sup>54</sup> <i>Gastrointest Endosc.</i> 2005;61:385-391.</p> <p><sup>55</sup> <i>Clin Gastroenterol Hepatol.</i> 2006;4:1259-1264.</p> <p><sup>56</sup> <i>Nat Rev Gastroenterol Hepatol.</i> 2011;8:554-564.</p>		

## 10.5 Tattooing

Tattooing during colonoscopy is an important technique for the marking of lesions that are to be removed with a following (new) treatment. It is recommended to tattoo the involved area with a permanent marker. Studies show that there are various safe products available with which the chance of complications is limited.<sup>57, 58</sup>

Objective		Planning surgery	
Indicator	Description	Admission requirement	Audit requirement
10.13 Tattooing	The percentage of detected cancers given a tattoo, with the exception of those located in: <ul style="list-style-type: none"> <li>- cecum</li> <li>- distal 4 cm of the rectum</li> </ul>	-	monitoring
Responsible	Endoscopist (10.13)		
Comments	-		
Reference(s)	<p><sup>57</sup> <i>Am J Gastroenterol.</i> 1996;91:1804-1808.</p> <p><sup>58</sup> <i>Gastrointest Endosc.</i> 2002;56:339-342.</p>		



## 11. WELLBEING OF PATIENTS

### 11.1 Adverse events

#### *Recording and follow-up*

In general, a colonoscopy is a safe and reliable procedure for the detection and simultaneous treatment of colon polyps. Notwithstanding the fact that colonoscopic adverse events are unusual, they can be life-threatening. It is therefore imperative to limit morbidity and mortality related to the screening as much as possible. To monitor the safety of colonoscopy programmes, each institution should have to systematically record the occurrence of adverse events and mortality up to 30 days following the colonoscopy.<sup>59</sup> The accurate recording and continuous monitoring of adverse events is an integral part of the national screening programme, and takes place during as well as after the colonoscopy.

Objective	Minimizing the (chance of) harm to the screening population		
Indicator	Description	Admission requirement	Audit requirement
11.1 Complication record	Keeping a complication record.	demonstrable	demonstrable
Responsible	11.1 Endoscopist		
Comments	Endoscopists register complications in ColonIS at the endoscopist level (for now) after the national screening programme commences, until a connection to the complication register by the NVMDL is ready. Only the RCMDL has access to this information.		
Reference(s)	<sup>59</sup> <i>Nat Rev Gastroenterol Hepatol.</i> 2011;8:554-564.		

#### *Number of adverse events*

An adverse event is an unintended and undesired outcome during or following the actions of a care provider, that it has an adverse effect on the health of the patient such that an adjustment of the treatment is necessary or that there is irreparable damage. Adverse events occur in about 2 of every 1000 colonoscopies, and the risk increases when a biopsy or polypectomy is performed during the procedure.<sup>60-66</sup> Adverse events can occur during the colonoscopy itself or several to a number of days later (recording of complications that occur up to 30 days after the procedure).

Objective		Minimizing the (chance of) harm to the screening population	
Indicator	Description	Admission requirement	Audit requirement
11.2 Complications during colonoscopy	The percentage of colonoscopies performed by the endoscopist where a complication occurs (up to 30 days after the procedure).	-	≤ 0.3%
Responsible	Endoscopist (11.2)		
Comments	In accordance with the technical dataset for colonoscopy: <ul style="list-style-type: none"> <li>- with a distinction based on type of complication: perforation, haemorrhage, remnant group</li> <li>- with a distinction based on seriousness of the complication:               <ul style="list-style-type: none"> <li>minor (no admission, no transfusion, no intervention)</li> <li>mild ((extra) admission &lt; 4 days)</li> <li>moderate (admission 4-10 days, &lt;4 transfusions, endoscopic or percutaneous interventions)</li> <li>serious (admission &gt; 10 days, &gt;4 transfusions, angiographic or surgical intervention or IC admission)</li> <li>fatal (death)</li> </ul> </li> </ul>		
Reference(s)	<sup>60</sup> <i>Clin Gastroenterol Hepatol.</i> 2010;8:166-173. <sup>61</sup> <i>Gastroenterology.</i> 2008;135:1899-1906. <sup>62</sup> <i>Gastrointest Endosc.</i> 2009;69:665-671. <sup>63</sup> <i>Ann Intern Med.</i> 2006;145:880-886. <sup>64</sup> <i>N Engl J Med.</i> 2006;355:1863-1872. <sup>65</sup> <i>Gastrointest Endosc.</i> 2001;53:620-627. <sup>66</sup> <i>Intern Med J.</i> 2003;33:355-359.		

### Colonic perforation

A perforation of the bowel wall can occur due to mechanical injury during the insertion, over-insufflation of the colon or as a result of a medical procedure, such as a biopsy or polypectomy. Studies into adverse events with colonoscopy show a wide variety in perforation rates. Results from an early study during the seventies revealed a perforation rate of 0.2% for diagnostic colonoscopy and 0.32% for polypectomy.<sup>67</sup> A study published in 2008 among over 95,000 persons in the age range of 50 to 75 years old revealed a perforation rate for colonoscopy of 0.6%.<sup>68</sup>

A study among almost 40,000 patients, ages 65 years and older, gives a good indication of perforation rates in screening programmes.<sup>69</sup> The total risk for perforation in this study came to 1:500, with an incidence in the screening group of 1:1000. In connection with the high number of polyps anticipated in iFOBT positive participants in the Dutch screening population, the incidence of 1:1000 for colonoscopies with polypectomy must be corrected. For example, an evaluation of the BCSP screening programme in England has pointed out that during this programme over 35% of the FOBT positive patients had a polypectomy performed.<sup>70</sup>

Perforations occur more often during the removal of larger right-sided sessile polyps.<sup>71</sup> The most perforations occur as a result of thermal injury during a polypectomy. Submucosal injection to raise polyps is potentially protective by limiting thermal injury from electrocautery. A clear understanding of technique and equipment is therefore essential for an endoscopist.

Objective		Minimizing the (chance of) harm to the screening population	
Indicator	Description	Admission requirement	Audit requirement
11.3 Perforation rate colonoscopy	The perforation rate for colonoscopies performed by the endoscopist (up to 30 days after the procedure).	-	< 0.1%
11.4 Perforation rate polypectomy	The perforation rate for colonoscopies with polypectomy performed by the endoscopist (up to 30 days after the procedure).	-	< 0.5%
Responsible	Endoscopist (11.3 through 11.4)		
Comments	In conformance with the National Protocol for Structured Data Recording and Image Storage: - with a distinction based on seriousness of the perforation: NVMDL definition		
Reference(s)	<sup>67</sup> JAMA. 1976;235:928-903. <sup>68</sup> Gastroenterology. 2008;135:1899-1906. <sup>69</sup> J Natl Cancer Inst. 2006;95:230-236. <sup>70</sup> NHS BCSP Endosc Qual Assurance group. 2011. <sup>71</sup> Dis Colon Rectum. 1993;36:1126-1131.		

### Bleeding

Bleeding is the most frequent adverse event following polypectomy. Post polypectomy bleeding due to the removal of small polyps is the most frequent cause of bleeding and is usually related to complications of electrocautery.<sup>72</sup> In order to prevent post polypectomy bleeding small polyps that are not pedunculated should be cold snared. Bleeding associated with cold snaring is usually immediate and allows the endoscopist the opportunity for endoscopic management.

In conformance with the complication record of the NVMDL, bleeding only needs to be recorded as an adverse event if there is a change in the policy normally followed after the conclusion of the endoscopy. Therefore bleeding that can be resolved peri-procedural endoscopically is not considered as a complication. Should a patient for example for safety's sake be admitted for a night of observation, this does count as a complication.

A variety of studies have reported bleeding rates of 0.3 to 6.1% for polypectomies.<sup>73, 74</sup> The risk for bleeding increases with the size of the polyp and the location where the polyp is found. Early bleeding can be limited by the placement of removable snares on pedunculated polyps. In addition adrenaline injection into the polyp base may decrease immediate bleeding.

Endoscopists must be familiar with the possible interventions to prevent bleeding and with the techniques to manage these.

Objective		Minimizing the (chance of) harm to the screening population	
Indicator	Description	Admission requirement	Audit requirement
11.5 Polypectomy bleeding	The percentage of colonoscopies with polypectomy performed by the endoscopist, where a complicated bleeding occurs (up to 30 days after the procedure).	-	monitoring
Responsible	Endoscopist (11.5)		
Comments	<p>A complicated bleeding is a bleeding that occurs during or after the actions of an endoscopist, that has such an adverse effect on the health of the patient that an adjustment of the treatment is necessary or that there is irreparable damage. Bleeding that is resolved peri procedural endoscopically, is not considered as a complicated bleeding.</p> <p>In conformance with the technical dataset for colonoscopy:</p> <ul style="list-style-type: none"> <li>- with a distinction based on seriousness of the bleeding: NVMDL definition</li> </ul>		
Reference(s)	<p><sup>72</sup> <i>Gastrointest Endosc.</i> 2000;51:676-681.  <sup>73</sup> <i>Dis Colon Rectum.</i> 1993;36:1126-1131.  <sup>74</sup> <i>Gastrointest Endosc.</i> 2002;55:307-314.</p>		

## 11.2 Patient safety

### *Acting professionally*

Patient safety is understood as: the (near) absence of (the chance for) injury inflicted to the patient that is a result of the care providers not following the professional standard and/or shortcomings of the healthcare system.<sup>75</sup>

To ensure professional conduct, the endoscopy department must have decided on and implemented a protocol, guideline or procedure for certain aspects pertaining to patient safety. It is explicitly not the intention here that everything is described. By 'decided on' the only intention is that there is agreement within the organization about the way in which something is executed. The procedure has then been determined and known to the relevant employees.<sup>76</sup> Aside from this, the employees are and continue to be authorized and competent and they work in conformance with the most current insights and agreements regarding the risky actions that are applicable to the endoscopy field.

The endoscopy department itself determines how it designs the testing of the professional actions, for example by testing between colleagues, examination or as part of the internal audit programme. During testing between colleagues and examination it is possible to evaluate if employees treat patients correctly, if they observe the agreements made within the professional association and if they perform medical/nursing acts according to the guideline, protocol or procedure. This last point can also be tested during the internal audits.<sup>76</sup>

Objective		Minimizing the (chance of) harm to the screening population	
Indicator	Description	Admission requirement	Audit requirement
11.6 Working according to protocol	Employees work according to protocols, guidelines and procedures, as far as required for patient safety.	demonstrable	demonstrable
11.7 Risky actions	Employees are authorized and competent to perform risky actions.	demonstrable	demonstrable
11.8 Testing actions	Professional actions by employees in regard to risky procedures are tested according to a defined method.	-	demonstrable
Responsible	Colonoscopy centre (11.6 through 11.8)		
Comments	-		
Reference(s)	<sup>75</sup> You must organize patient safety, Quality in Care. 2008. <sup>76</sup> HKZ certification outline Patient safety for endoscopy departments. 2011.		

### Hygiene

One in ten patients who are admitted to a hospital in the Netherlands will contract an infection while in the hospital. That is about 65,000 people per year. Unfortunately hospital infections cannot always be prevented, but through certain preventive measures, the number can be significantly reduced. In the first place it is important that the employees observe the requirements set for personal hygiene. In addition, proper cleaning and disinfection of the materials used is a significant factor in the prevention of infections. The Steering Committee for Cleaning and Disinfecting Flexible Endoscopes (SFERD) has translated the existing regulations in the area of cleaning and disinfecting of flexible endoscopes to a practice standard.<sup>77</sup> During the periodic inspections by the NVMDL various aspects in the area of hygiene and measures taken to that effect are tested.

The Workgroup for Infection Prevention (WIP) sets up national guidelines for the prevention of infections in healthcare institutions in the Netherlands, with the goal of providing guidance to actions in the practice setting. The guidelines are professional standards that are created in cooperation with professionals and professional groups. Institutions can use the WIP guidelines as a starting point for determining their policy in this area. It is recommended that endoscopy departments work in conformance with the WIP guidelines for hospital.<sup>78</sup>

Objective		Prevention of infection	
Indicator	Description	Admission requirement	Audit requirement
11.9 Personal hygiene	Employees abide by the prescribed requirements for personal hygiene.	demonstrable	demonstrable
11.10 Endoscopes	Cleaning, disinfection and (microbiological) checking of endoscopes takes place in conformance with the prescribed requirements.	demonstrable	demonstrable
Responsible	Colonoscopy centre (11.9 through 11.10)		
Comments	11.9 - 11.10 In conformance with the inspection requirements of the NVMDL (see appendix 5).		
Reference(s)	<sup>77</sup> SFERD. Cleaning and disinfection of Flexible Endoscopes. 2010. <sup>78</sup> HKZ certification outline Patient safety for endoscopy departments. 2011.		

### 11.3 Patient satisfaction

#### Comfort

Colonoscopies performed in the scope of the national screening programme must be safe and of high quality during which the participant experiences as little discomfort as possible. The discomfort of the patient during the colonoscopy must be measured and recorded. The adjusted Gloucester Comfort Scale, running from no discomfort to severe discomfort, can be used to quantify the discomfort experienced by patients.<sup>79</sup>

The experience of discomfort during and after the colonoscopy can be caused by the retention of air in the colon. To reduce the accumulation of air, CO<sub>2</sub> can be used. Various studies have shown that insufflation of CO<sub>2</sub> in de colon can significantly decrease abdominal pain and discomfort for the patient.<sup>80-82</sup>

Objective		Optimizing patient experiences	
Indicator	Description	Admission requirement	Audit requirement
11.11 Comfort score	The percentage of colonoscopies where the participant experiences moderate or severe discomfort.	-	monitoring
11.12 CO <sub>2</sub> insufflation	The percentage of colonoscopies where CO <sub>2</sub> insufflation is utilized.	equipment present	100%
Responsible	11.11 Endoscopist 11.12 Colonoscopy centre		
Comments	<p>11.11 Pain and discomfort for the participant during and after the colonoscopy are monitored and documented in conformance with the National Protocol for Structured Data Recording and Image Storage. The assistant present during the colonoscopy records the necessary data (during the procedure).</p> <p>According to the (adjusted) Gloucester Comfort Scale:</p> <ul style="list-style-type: none"> <li>- no no discomfort, resting comfortably throughout</li> <li>- minimal one or two episodes of mild discomfort, well tolerated</li> <li>- mild more than two episodes of discomfort, adequately tolerated</li> <li>- moderate significant discomfort, experienced several times during the procedure</li> <li>- severe extreme discomfort, experienced frequently during the procedure</li> </ul> <p>Monitoring through the benchmark. In time the audit requirement will be determined and entered on the basis of benchmark information.</p> <p>11.12 At the start of the national screening programme, the colonoscopy centre possesses the necessary equipment for the administration of CO<sub>2</sub> for each colonoscopy room.</p>		
Reference(s)	<p><sup>79</sup> <i>Nat Rev Gastroenterol Hepatol.</i> 2011;8:554-564.</p> <p><sup>80</sup> <i>Gut.</i> 2002;50:604-607.</p> <p><sup>81</sup> <i>Gastrointest Endosc.</i> 2002;56:190-194.</p> <p><sup>82</sup> <i>Dis Colon Rectum.</i> 2003;46:322-326.</p>		

*Providing care*

Patient experiences are important in the determination of the quality of the colonoscopy.<sup>83</sup> Patients with a high (pain) tolerance and much satisfaction will be more open to receiving medical care.<sup>84</sup> Dissatisfied patients will change physicians more quickly or be more quickly inclined to appeal to the right to complain.<sup>85-88</sup> The study by De Jonge, Sint-Nicolaas et al. shows that patient satisfaction can be considered as a significant indicator for the quality of colonoscopies.<sup>89</sup> It is a measurement for the acceptance by the patient of the procedure and possibly a factor in complying with advice for the follow-up.

Pursuant to the Health Service Clients (Right of Complaint) Act (WKCZ) each care provider must take measures for handling complaints about his behaviour of the behaviour of persons employed by him towards a client. The care provider brings the measures taken in a fitting manner to the attention of his clients (article 2, lid 1 WKCZ). The measure provides for complaints of clients to be addressed by a complaint committee. The clients can complain about all behaviours of the care provider and of those by the persons employed by him. No limitations may be applied to the grounds for complaints. The colonoscopy centre discusses those complaints with the RCMDL which can lead to an improvement of the national screening programme.

Objective		Optimizing patient experiences	
Indicator	Description	Admission requirement	Audit requirement
11.13 Satisfaction measurement	The measuring of the satisfaction of the participant and how the participant has experienced the quality, safety and comfort of the care provided.	-	demonstrable
11.14 Language usage	Employees are able to speak to participants in the Dutch language.	-	demonstrable
Responsible	Colonoscopy centre (11.13 through 11.14)		
Comments	11.13 Based on a nationally frequency and method (questionnaire) determined in advance.		
Reference(s)	<sup>83</sup> <i>Gastrointest Endosc.</i> 2002;52:827-30. <sup>84</sup> <i>Med Care Rev.</i> 1993;50:49-79. <sup>85</sup> <i>Psychiatry Med.</i> 1971;2:31-54. <sup>86</sup> <i>J Health Soc Behav.</i> 1976;17:329-39. <sup>87</sup> <i>Eval Programme Plann.</i> 1983;6:291-7. <sup>88</sup> <i>Gastrointest Endosc.</i> 2001;53:703-10. <sup>89</sup> <i>Endoscopy.</i> 2012;44(5):462-472.		

## 12. ISSUING THE REPORT AND AFTERCARE

To make sure the participant is not left in a state of uncertainty for too long, he/she should be informed about the result of the colonoscopy as soon as possible. This information should be provided in a nationally uniform manner. If the iFOBT result is positive, the participant has received information about the colonoscopy and the possible associated consequences so that he/she can make a considered choice about the next step. To avoid confusion by the participant, it is important that the information provided by the colonoscopy centre after the colonoscopy is consistent with the information received by the participant during the national screening programme about the colonoscopy. The information after the colonoscopy should at least cover the following aspects: (significance of the) result, aftercare and consequences of the result for the national screening programme.

### 12.1 Information provided after the colonoscopy

After completing the colonoscopy, the result/findings, aftercare and consequences of the result for the next step in the national screening programme are discussed with the participant. Paragraphs 12.2 through 12.4 provide further detail on issuing the report after a negative and positive colonoscopy. In relation to aftercare (paragraph 12.5), the participant is informed verbally and in writing about what he/she is (not) allowed to do after the colonoscopy. It is also indicated which complaints and complications may occur as a result of the colonoscopy and what the participant must do if complaints worsen. In the brochure about the examination, received by the participant with the invitation, this is worded as follows:

#### Complaints after the examination

Many people continue to have some complaints for a while after undergoing a colonoscopy, such as abdominal pain, intestinal cramps, a bloated feeling and flatulence. This is normal and disappears after a few days. It is possible you may lose some mucus and fluid via your anus up to a few days after the colonoscopy. If your physician has removed a polyp or piece of tissue, you may also lose some blood via the anus. This stops of its own accord within a few days. If the loss of blood continues or the bleeding becomes heavier, it is important that you contact the colonoscopy centre where the colonoscopy was conducted. If complaints worsen, or if you get a fever, contact the MDL specialist on duty via the Emergency department of the hospital.

This text is based on information that, in alignment with the NVMDL, can be found on the website of the MLDS (<http://www.mlds.nl>).

In addition, the participant is informed after the colonoscopy that the colonoscopy centre will approach him/her after a negative colonoscopy by telephone to check if there have been any complications.

**Objective**

**Providing uniform information after the colonoscopy**

Indicator	Description	Indicator	Description
12.1 Uniform information	After the colonoscopy and result of the pathology analysis have been shared with the participant, the participant receives verbal and written information about the findings and aftercare.	-	demonstrable
12.2 Consistent information	The verbal and written information is consistent with the information from the brochure 'If blood is found in your stool'.	-	demonstrable
Responsible	Colonoscopy centre (12.1 through 12.2)		
Comments	12.1 Written information is provided in accordance with a national results form, which also outlines the consequences for the national screening programme or follow-up care (see Appendix 3). If the colonoscopy result is negative, patients receive this form; if the colonoscopy is positive, it is provided after the pathology analysis.		
Reference(s)	-		

## 12.2 Issuing the report after a colonoscopy without pathology analysis

A colonoscopy without pathology analysis means that no tissue or polyps were found during the colonoscopy that were sent in for pathology analysis. This usually means that the screening organisation will invite the participant again after ten years for the national screening programme unless he/she is older than 75 years of age.

After the procedure, the endoscopist provides the following verbal information to the participant:

- that despite the iFOBT, no relevant abnormalities have been found
- what the possible reasons could be for the positive iFOBT
- if applicable: that the participant will receive another invitation from the national screening programme and what the reason for the 10 year period is
- that the participant should remain alert for complaints such as blood in their stool and a persistent change in bowel movement and to contact their general practitioner if these complaints occur

If (it is suspected that) there are big abnormalities or secondary findings during the intake or colonoscopy, such as a positive family history for bowel cancer, the endoscopist informs the participant about this and ensures there is a good transfer of the participant.

Aside from verbal information, the participant also receives written confirmation of this (see Appendix 3a).

<b>Objective</b>			
<b>Issuing the report in a uniform manner after colonoscopy without pathology analysis</b>			
Indicator	Description	Indicator	Description
12.3 Verbal information in case of colonoscopy without pathology analysis	Verbal information about the findings after a colonoscopy without pathology analysis addresses (at least) those aspects that are outlined in the protocol Admission and auditing for colonoscopy.	-	demonstrable
12.4 Result letter in case of colonoscopy without pathology analysis	The percentage of participants receiving the national results and aftercare letter after a colonoscopy without pathology analysis.	-	≥ 95%

Responsible	Colonoscopy centre (12.3 through 12.4)
Comments	<p>12.3 If the participant has objected to data exchange with the screening organisation, he/she should be made aware that he/she needs to inform the screening organisation himself/herself that he/she would like an invitation for the national screening programme after ten years.</p> <p>12.4 In accordance with a national aftercare and result letter, in which the consequences for the national screening programme are also outlined, to be provided by the colonoscopy centre (see Appendix 3a). Monitoring of the percentage is not possible in ColonIS. The relevant audit requirement should be able to be demonstrated by the colonoscopy centre in the periodic audit of the RCMDL.</p>
Reference(s)	-

### 12.3 Issuing the report after a colonoscopy with pathology analysis

A colonoscopy with pathology analysis means that tissue or polyps were removed during the colonoscopy that were sent in for pathology analysis.

After completion of the procedure, the endoscopist verbally provides the following information:

- that tissue and/or polyps have been removed. The endoscopist covers the size, expectations etc.
- in the case of polyps, the endoscopist indicates in accordance with the brochure ‘If blood is found in your stool’ that there may be starting or advanced polyps and that pathology analysis will provide more insight about this and the management plan to follow
- that the patient will be informed within five working days about the pathology result

Objective		Issuing the report in a uniform manner after colonoscopy with pathology analysis	
Indicator	Description	Indicator	Description
12.5 Verbal information if there are abnormalities	Verbal information about the findings after a colonoscopy with pathology analysis addresses (at least) those aspects that are outlined in the protocol Admission and auditing for colonoscopy	-	demonstrable
Responsible	Colonoscopy centre (12.5)		
Comments	-		
Reference(s)	-		

### 12.4 Issuing the report after the pathology analysis result

After a maximum of five working days, the participant receives verbal information about the following aspects:

- result of the pathology analysis
- the meaning of the colonoscopy result for the next step (treatment, surveillance or return to national screening programme). To this end, the colonoscopy centre organises a good transfer.

- if a participant is eligible for treatment or surveillance, it is indicated that they will not be invited for the national screening programme for the time being
- if (it is suspected that) there are secondary findings during the intake or colonoscopy, such as a positive family history for bowel cancer, the endoscopist informs the participant about this and ensures there is a good transfer of the participant

In addition, the colonoscopy centre asks the participant during the consult if there have been any complications as a result of the colonoscopy and to report any complications in the next few weeks to the colonoscopy centre.

It is up to the colonoscopy centre whether this consult takes place by telephone or at the outpatient clinic.

A maximum of 5 working days after the verbal consult, the participant receives written confirmation of the result, in which a distinction is made between:

- a colonoscopy with pathology analysis result with a return to the national screening programme (see Appendix 3b)
- a colonoscopy with pathology analysis result with surveillance after 3 or 5 years (see Appendix 3c)

If cancer is diagnosed, the participant does not receive written confirmation of the result.

<b>Objective</b>			
<b>Issuing the report in a uniform manner after colonoscopy with pathology analysis</b>			
<b>Indicator</b>	<b>Description</b>	<b>Indicator</b>	<b>Description</b>
12.6 Consult	The consult in which the participant receives verbal information about the pathology analysis result, addresses (at least) those aspects that are outlined in the protocol Admission and auditing for colonoscopy.	-	demonstrable
12.7 Result letter after colonoscopy with pathology analysis	The percentage of participants with pathology analysis after colonoscopy that receive written confirmation of this after the pathology analysis result, including information on the follow-up care.	-	≥ 95%
Responsible	Colonoscopy centre (12.6 through 12.7)		
Comments	<p>12.6 It is up to the colonoscopy centre whether this consult takes place by telephone or at the outpatient clinic.</p> <p>12.7 This concerns a national result letter with a distinction in return to the national screening programme (see Appendix 3b) or surveillance (see Appendix 3c), in which the surveillance period can vary.</p> <p>Monitoring of the percentage in ColonIS is not possible. The relevant audit requirement should be able to be demonstrated by the colonoscopy centre in the periodic audit of the RCMDL.</p>		
Reference(s)	-		

## 12.5 Aftercare

After the colonoscopy, the participant is informed about possible physical complaints as a result of the colonoscopy and what to do if complaints worsen or new complains develop. In addition, the

participant is informed after the colonoscopy without pathology analysis that the colonoscopy centre will approach him/her by telephone to check if there have been any complications.

During contact with the patient, which takes place within a month, the following are addressed:

- if there have been complications after the colonoscopy and if so, which
- if the patient has understood the information after the colonoscopy

Objective		Minimising the (chance of) harm in the screening population	
Indicator	Description	Indicator	Description
12.8 Follow-up	The percentage of participants for whom the time interval between a colonoscopy without pathology analysis and the contact with the patient in which they are asked about complications is <i>1 month at the most</i> .	-	≥ 95%
Responsible	Colonoscopy centre (12.8)		
Comments	In the case of a colonoscopy with pathology analysis, questions about possible complications are combined with the verbal consult about the pathology analysis result. Monitoring of the percentage in ColonIS is not possible. The relevant audit requirement should be able to be demonstrated by the colonoscopy centre in the periodic audit of the RCMDL.		
Reference(s)	-		

## 13. TURNAROUND TIMES

### 13.1 Colonoscopy

Various studies have demonstrated that national screening programmes for bowel cancer can cause anxiety in the participants. Lindholm et al. shows that this is applicable for a small part of the participants at the moment they receive the invitation for participation in the national screening programme.<sup>90</sup> The anxiety among the participants increases when the result of the iFOBT is determined to be positive. In a study among over 6000 persons, the degree of anxiety appeared to increase by 60% in the group with a positive result for the faeces test, where in 15% their daily life was negatively influenced. Parker et al. also shows that the anxiety among the participants is greatest after the result of a positive test and the invitation for a colonoscopy examination.<sup>91</sup> In general, the degree of anxiety is greater among women and participants with a lesser amount of education than under men and participants with a higher education.

To limit the anxiety among participants with a positive iFOBT, the turnaround times must be as short as possible. This applies to the intake interview as well as for the colonoscopy to be performed.

Objective		Minimizing the anxiety among participants	
Indicator	Description	Admission requirement	Audit requirement
13.1 Turnaround time result letter through intake colonoscopy	The percentage of participants for whom <i>the time interval between the sending of the result letter (with a referral) based on a positive iFOBT and the intake for colonoscopy lasts a maximum of 10 working days.</i>	-	≥ 95%
13.2 Turnaround time appointment for intake colonoscopy through performance of colonoscopy	The percentage of participants for whom the time interval between the (primary) planned appointment for the intake for colonoscopy and the colonoscopy to be performed lasts <i>a maximum of 10 working days.</i>	-	≥ 95%
13.3 Turnaround time for intake colonoscopy through appointment for colonoscopy	The percentage of participants for whom the time interval between the intake for the colonoscopy and the (primary) planned appointment for the colonoscopy to be performed lasts <i>a maximum of 10 working days.</i>	-	≥ 95%
13.4 Turnaround time result letter through performance of colonoscopy	The percentage of participants for whom the time interval between the sending of the result letter (with a referral) based on a positive iFOBT and the performance of the colonoscopy lasts <i>a maximum of 15 working days.</i>	-	≥ 95%
Responsible	Colonoscopy centre (13.1 through 13.4)		
Comments	13.2 The assumption is that an appointment for intake is only made if a colonoscopy can be scheduled within 2 weeks. 13.2-13.4 Turnaround times are corrected if a postponement takes place at the request of the participant.		
Reference(s)	<sup>90</sup> <i>Scand J Gastroenterol.</i> 1977;32(3):238-45. <sup>91</sup> <i>J Med Screen.</i> 2002;9(1):7-10.		

### 13.2 Issuing the report

The studies by Lindholm and Parker indicate that the anxiety among participants with a positive iFOBT result significantly decreases after the colonoscopy has taken place.<sup>92, 93</sup> In order not to leave the participant too long in a state of anxiety, he or she must be informed as quickly as possible about the result of the colonoscopy. If no abnormalities are found during the colonoscopy, the participant is informed orally immediately following the procedure, and will receive a follow-up care form which also contains the result. If a polypectomy or a biopsy has been performed, the result of the pathology analysis is discussed orally with the participant. If major abnormalities are noted during a colonoscopy, the participant is informed about this orally immediately following the procedure. In addition, the definitive result of a positive colonoscopy, including the result from pathology, will be confirmed in writing with the participant.

Objective		Minimizing the anxiety among participants	
Indicator	Description	Admission requirement	Audit requirement
13.5 Turnaround time intake colonoscopy through result letter	The percentage of participants for whom the time interval between the appointment for an intake for colonoscopy and the sending of the definitive result letter (after colonoscopy and subsequent pathology) by the MDL physician to the participant lasts a <i>maximum of 25 working days</i> .	-	≥ 95%
13.6 Turnaround time colonoscopy with polypectomy/biopsy through oral consult	The percentage of participants for whom the time interval between a colonoscopy with a polypectomy or biopsy and the subsequent oral consult lasts a <i>maximum of 5 working days</i> .	-	≥ 95%
13.7 Turnaround time for a colonoscopy with polypectomy/biopsy between oral consult through result letter	The percentage of participants for whom the time interval after a colonoscopy with a polypectomy or biopsy between the oral consult and the sending of the definitive result letter to the participant by the MDL physician lasts a <i>maximum of 5 working days</i> .	-	≥ 95%
Responsible	Colonoscopy centre (13.5 through 13.7)		
Comments	13.5-13.7 Monitoring of the turnaround time in ColonIS is not possible. The relevant audit requirements should be able to be demonstrated by the colonoscopy centre during the periodic audit of the RCMDL.		
Reference(s)	<sup>92</sup> <i>Scand J Gastroenterol.</i> 1977;32(3):238-45. <sup>93</sup> <i>J Med Screen.</i> 2002;9(1):7-10.		

## 14. DATA MANAGEMENT

### 14.1 Structured data recording

In order to be able to perform the national screening programme, the data necessary for this programme must be determined, and a data exchange will take place between the parties involved in the chain. To be able to test and monitor the quality of the performance of the national screening programme and follow-up care, it is necessary that structured data pertaining to the screened persons be able to be kept up and analysed. A complete recording of the activities in the scope of the national screening programme are eminently important in this process.

Colonoscopy is the golden standard for the prevention of bowel cancer. The preventive effect of a colonoscopy is to a high degree dependent on the quality of the procedure.<sup>94</sup> A periodic evaluation of indicators makes it possible to ensure and improve the quality of colonoscopies.<sup>84</sup> One condition for this is the recording of data by a structured method. Without accurate and complete records, no reliable comparison can take place, and monitoring of the quality is not possible.<sup>96</sup>

An overview of the variables to be recorded in the scope of the national screening programme for bowel cancer is included in the technical dataset for colonoscopy.<sup>97</sup>

Objective		Support of the primary process/monitoring and evaluation of the quality	
Indicator	Description	Admission requirement	Audit requirement
14.1 Data recording & image storage	A structured recording of data and storage of images.	up-to-date system	demonstrable
14.2 Reporting of activities	Complete reporting of the activities performed in the scope of the national screening programme.	-	100%
14.3 Registration of colonoscopies	The share of the colonoscopies performed by the endoscopist with a complete registration.	≥ 100	100%
Responsible	14.1 Colonoscopy centre 14.2 Colonoscopy centre 14.3 Endoscopist		
Comments	14.1-14.3 In conformance with the National Protocol for Structured Data Recording and Image storage. 14.1 When testing for admission to the implementation, an up-to-date registration system must be present. 14.3 At least 100 consecutive colonoscopy reports in the year preceding the admission for the implementation. At least 100 registered colonoscopies are required to be able to make a reliable calculation of the indicators.		
Reference(s)	<sup>94</sup> <i>Gastrointest Endosc.</i> 2006;63:16-28. <sup>95</sup> <i>Gastrointest Endosc.</i> 2012;75 (1):98-106. <sup>96</sup> <i>Gastrointest Endosc.</i> 2007;65:757-66. <sup>97</sup> RIVM. Technical dataset for colonoscopy. Most recent version available on-line.		

## 14.2 Structured data supply

For the purpose of quality assurance, monitoring and evaluation, data are needed that are recorded during a colonoscopy. It is very important that these data are recorded in the same manner by all colonoscopy centres. The defined set of data that are recorded during the colonoscopy in conformance with the protocol for structured data recording and image storage, are submitted back to the screening organizations for the purpose of the follow-up registration. In the IT system, these data are linked to the participant and used for quality assurance and monitoring.<sup>98</sup> Having the necessary data available and a structured delivery of this data are necessary for a good analysis and evaluation of the data.

Objective		Support of the primary process/monitoring and evaluation of the quality	
Indicator	Description	Admission requirement	Audit requirement
14.4 Data delivery	Having the necessary data available and a structured delivery of said data.	up-to-date system	demonstrable
14.5 Data exchange	Access to a secure internet connection for electronic data exchange.	demonstrable	demonstrable
Responsible	Colonoscopy centre (14.4 through 14.5)		
Comments	<p>14.4 When testing for admission to the implementation, an up-to-date registration system must be present.</p> <p>14.5 The colonoscopy centre should have access to an UZI pass. The URA code from the UZI register is used to identify the care provider in the digital connection of messages. The UZI pass is also required to gain access to ColonIS for the manual input of data when colonoscopy centres are not (yet) able to send an electronic message to ColonIS at the start of the national screening programme.</p>		
Reference(s)	<sup>98</sup> Adviesrapport IT-infrastructuur Darmkankerscreening. 2010.		

## 14.3 Managing data

Solid agreements about the ownership and use of the data are a precondition for a good IT infrastructure that facilitates a good data interface within the chain of screening and patient care. The joint screening organizations are the administrators of the IT system that facilitates the registration and interfacing of data for the national screening programme for bowel cancer. They have entered into a cooperation agreement with the provider for this purpose. A user regulations document secures the access to and use of the registered data. To be able to secure the data interface between the local registration systems and the IT system of the national screening programme, the colonoscopy centre must make periodic updates and backups of the (data in) the registration systems that it uses for the national screening programme.

Objective		Support of the primary process/monitoring and evaluation of the quality	
Indicator	Description	Admission requirement	Audit requirement
14.6 Data management	Periodic updates and backups of (the data in) the applicable registration systems.	up-to-date system	demonstrable
14.7 Access to data	Managing the access to the (privacy-sensitive) data in the ColonIS intake module.	-	demonstrable
Responsible	Colonoscopy centre (14.6 through 14.7)		



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Comments	14.6 When testing for admission to the implementation, an up-to-date registration system must be present. 14.7 Pursuant to the nationally defined user regulations.
Reference(s)	-

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## 15. FOLLOW-UP CARE

### 15.1 Treatment

Various medical professionals can be involved in the treatment and follow-up care in the hospital, such as surgeons, radiation therapists and oncologists. In line with the Guide to Division of Responsibilities for Teamwork in Healthcare<sup>99</sup> it is recommended for follow-up care to have one care provider responsible for the process of subsequent treatment (after a positive colonoscopy).<sup>100</sup> It is the responsibility of the colonoscopy centre to have a good transfer of the patient and data to the pertinent specialist.

Objective		Assuring the transfer to follow-up care	
Indicator	Description	Admission requirement	Audit requirement
15.1 Transfer to follow-up care	Good transfer of patient and data to the pertinent specialist, if treatment is necessary.	-	demonstrable
Responsible	Colonoscopy centre (15.1)		
Comments	-		
Reference(s)	<sup>90</sup> Guide to Division of Responsibilities for Teamwork in Healthcare. 2010. <sup>100</sup> RIVM. Feasibility study into population screening for bowel cancer. 2011.		

### 15.2 Surveillance

Surveillance is understood to be a periodic check-up with colonoscopy for persons in high-risk groups. The guideline on surveillance defines what the diagnoses are that would include the patients in a high-risk group and which surveillance policy would be followed at that time. After a positive result of the iFOBT and colonoscopy, individuals can be assigned to a surveillance programme, where the participant would have to return periodically to the hospital for check-up. To this end, the colonoscopy centre follows the Dutch guideline colonoscopy surveillance.<sup>101</sup> After the completion of the surveillance programme, those individuals who have not yet reached the maximum age can again participate in the screening programme. This means that the involved individuals would again be invited for the national screening programme after the last surveillance colonoscopy. After having performed a surveillance colonoscopy, the colonoscopy centre (through electronic message) reports the result of the colonoscopy and the follow-up measures (completion of surveillance with return to the national screening programme, or date of next surveillance colonoscopy) to the screening organization.

Objective		Assuring the return to the national screening programme	
Indicator	Description	Admission requirement	Audit requirement
15.2 Surveillance	In the case of surveillance, the guideline for the professional group is followed		
15.3 Return to national screening programme	Electronic notification if a participant, after a surveillance colonoscopy, can return to the national screening programme.	-	demonstrable
Responsible	Colonoscopy centre (15.2 and 15.3)		



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Comments	-
Reference(s)	<sup>101</sup> NVMDL. Nederlandse richtlijn coloscopie surveillance. 2013.

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## NOTES

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## ABBREVIATIONS

AGB	General Data Management (healthcare providers) (Algemeen GegevensBeheer ((zorgverleners))
BIG (act)	Individual Health Care Occupations Act (Wet op de beroepen in de individuele gezondheidszorg)
BVO	National Screening Programme (Bevolkingsonderzoek)
BSCP	Bowel Cancer Screening Programme (UK)
CSA	Central Sterilization Department (Centrale Sterilisatie Afdeling)
CT (-colonography)	Computer tomograph (-colonography)
CvB	Centre for Population Screening of the RIVM (Centrum voor Bevolkingsonderzoek van het RIVM)
FSB	Facility Collaboration for National Screening Programmes (Facilitaire Samenwerking Bevolkingsonderzoeken)
FTE	Full time equivalent
GR	(National) Health Council (Gezondheidsraad)
HKZ	Harmonization of Quality Review in Health Care (Harmonisatie Kwaliteitsbeoordeling Zorgsector)
IBD	Inflammatory Bowel Disease
iFOBT	Immunological Faecal Occult Blood Test (Immunologische Fecaal Occult Bloed Test)
IGZ	Health Care Inspectorate (Inspectie voor de Gezondheidszorg)
IKNL	Comprehensive Cancer Centre Netherlands (formerly VIKC) (Integraal Kankercentrum Nederland (voorheen VIKC))
IT	Information Technology (Informatie Technologie)
KWZi	Care Institutions (Quality) Act (Kwaliteitswet zorginstellingen)
LHV	National Association of General Practitioners (Landelijke Huisartsen Vereniging)
MAP	Mean number of adenomas per procedure
MAP+	Mean number of adenomas per positive procedure
MDL (-arts)	Gastroenterohepatologist (Maag-Darm-Lever (-arts))
NFK	Dutch Federation of Cancer Patients' Organizations (Nederlandse Federatie van Kankerpatiëntenorganisaties)
NFU	Dutch Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra)
NHG	Dutch College of General Practitioners (Nederlands Huisartsen Genootschap)
NHS	National Health Service
NIV	Dutch Association of Internists (Nederlandse Internisten Vereniging)
NTA	Dutch Technical Agreement (Nederlandse Technische Afspraak)
NVKC	Dutch Society for Clinical Chemistry and Laboratory Medicine (Nederlandse Vereniging voor Klinische Chemie)
NVMDL	Dutch Association of Gastroenterohepatologists (Nederlandse Vereniging van Maag-Darm-Leverartsen)

NVVH	Dutch Surgical Association (Nederlandse Vereniging voor Heelkunde)
NVVP	Dutch Pathology Association (Nederlandse Vereniging voor Pathologie)
NVvR	Dutch Radiology Association (Nederlandse Vereniging voor Radiologie)
NVZ	Dutch Hospitals Association (NVZ vereniging van ziekenhuizen)
RCMDL	Regional Coordinating MDL official (Regionaal Coördinerend MDL-functionaris)
RIVM	National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu)
SFERD	Steering Committee for Cleaning and Disinfecting Flexible Endoscopes (Stuurgroep flexibele endoscopen reiniging en desinfectie)
SO	Screening organization (Screeningsorganisatie)
SPKS	Foundation for Patients with Cancer of the Alimentary Canal (Stichting voor Patiënten met Kanker aan het Spijsverteringskanaal)
VKGN	Dutch Society for Clinical Genetics (Vereniging Klinische Genetica Nederland)
V&VN	Dutch Nurses & Care Providers (Verpleegkundigen & Verzorgenden Nederland)
VWS	(Ministry of) Health, Welfare and Sport (Volksgezondheid, Welzijn en Sport)
WBO	Population Screening Act (Wet op het bevolkingsonderzoek)
WBP	Personal Data Protection Act (Wet bescherming persoonsgegevens)
WGBO	Medical Treatment Contracts Act (Wet op de geneeskundige behandelingsovereenkomst)
WIP	Workgroup for Infection Prevention (Werkgroep infectie preventie)
WKCZ	Health Service Clients (Right of Complaint) Act (Wet klachtrecht cliënten zorgsector)
ZN	Umbrella organization of health insurers (Zorgverzekeraars Nederland)

## APPENDIX 1 ADMISSION AND AUDIT REQUIREMENTS FOR COLONOSCOPY CENTRE

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Organization	Uniform quality for the performance of the national screening programme and subsequent diagnostics	Endoscopy under work agreement	Endoscopists employed by the colonoscopy centre that perform screening colonoscopies, satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
		Pathology agreements	Agreements with pathology laboratories that satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
		Radiology agreements	Agreements with radiology laboratories that satisfy the nationally prescribed quality requirements for the national screening programme.	demonstrable	demonstrable
	Such facilities that all the functions on behalf of the national screening programme can be performed as required	Location, construction, size and equipment	The location, construction, size and equipment of the colonoscopy centre satisfy the prescribed requirements (ARBO legislation).	demonstrable	demonstrable
		Layout	The layout of the colonoscopy centre meets the prescribed requirements (inspection requirements of the NVMDL).	demonstrable	demonstrable
		Equipment	The equipment of the endoscopy rooms and washing area meets the prescribed requirements (inspection requirements of the NVMDL).	demonstrable	demonstrable
	Prevention of waiting times	Capacity	Periodic submission of the necessary information about the available capacity.	demonstrable	demonstrable
		Appointments for intake interview	Following up on the appointments made by the referring person for the intake interview.	-	demonstrable
		Time slots	Providing insight into the available time slots for a certain period.	-	demonstrable
		Continuity in service provision	Ensuring continuity in service provision		
	Internal assurance of the quality of the work to be performed	Periodic inspections	Participation in periodic inspections by the professional group.	demonstrable	demonstrable
		Accreditation	Satisfying the inspection requirements from the professional group.	demonstrable	demonstrable
		Internal audits	Annual internal audit pertaining to the critical activities to be performed.	-	demonstrable
		Certification	HKZ certification in a year to be determined later by the NVMDL.	-	demonstrable
Personnel	Qualified employees	Professional registration	Employees are responsible for professional and re-registration.	demonstrable	demonstrable

**Protocol for the Authorization and auditing of colonoscopy**

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	Expert employees	Competencies	Employees possess the required competencies.	demonstrable	demonstrable
	Sufficient employees	Staffing	The number of assistants present within the colonoscopy centre.	≥ 3	≥ 3

## Protocol for the Authorization and auditing of colonoscopy

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Frameworks	Implementation of the activities within the defined frameworks	Legislation	Satisfying and working in conformance with the applicable laws and regulations.	demonstrable	demonstrable
		Implementation framework	Satisfying and working in conformance with the agreements in the nationally defined implementation framework for the national screening programme for bowel cancer.	demonstrable	demonstrable
		Guidelines	Satisfying and working in conformance with the applicable guidelines as created by the professional group.	demonstrable	demonstrable
		Protocols	Satisfying and working in conformance with the nationally established, applicable, (requirements of) protocols.	demonstrable	demonstrable
		Colonoscopy preparation	An implemented procedure for the preparation of colonoscopies	demonstrable	demonstrable
		Risk management	Satisfy and work in accordance with the national risk management protocol for the national screening programme for bowel cancer.	demonstrable	demonstrable
		Handling incidents	An implemented procedure for handling incidents.	-	demonstrable
		Evaluating incidents	Incidents that may lead to improvement in the national screening programme are discussed in the periodic audit with the RCMDL.		demonstrable
		Reporting incidents	Incidents/calamities that may pose a threat to the safety and quality of the national screening programme for participants, are reported immediately to the RCMDL.		demonstrable
		Handling complaints	An implemented procedure for handling complaints.	demonstrable	demonstrable
		Evaluating complaints	Complaints that may lead to improvement in the national screening programme are discussed in the periodic audit with the RCMDL.		demonstrable
Intake	Uniform quality in the intake interview for colonoscopy	Personal contact	The intake takes place face-face		
		Expertise	The intake is conducted by a staff member who is a content expert, authorized and capable.		
		Responsibility	Complaints that may lead to improvement in the national screening programme are discussed in the periodic audit with the RCMDL.		
	Determining if a colonoscopy can be performed	Patient history	When asking about the patient history during the intake, (at least) those aspects are addressed that are outlined in the protocol Admission and auditing for colonoscopy.		
		Anticoagulation	An amended procedure is followed if anticoagulants are used		
		Family history	It is checked during the intake if the patient has a family history of hereditary bowel cancer.		

## Protocol for the Authorization and auditing of colonoscopy

Intake (continued)	Determining if a colonoscopy is required	Authority to make decisions	The colonoscopy centre has made work agreements about the responsibilities in relation to making the treatment decision.			
		Exclusion criteria	Exclusion for colonoscopy takes place on the basis of the patient and family history and the exclusion criteria that have been determined within the framework of the national screening programme for bowel cancer.			
		Alternative to colonoscopy	Offering an alternative to patients who cannot undergo a colonoscopy, but for whom a detected abnormality may have therapeutic consequences.			
		Transfer to specialist	Good patient data transfer to the relevant specialist, if a good colonoscopy is not possible.			
	Conducting the work activities within the set frameworks		Sedation	In the event of sedation, the guideline of the professional group is followed.		
			Providing information	At a minimum, the patient is provided with the information outlined in the protocol for the Admission and auditing of colonoscopy during the intake.		
			Written information	During the intake, the patient receives written information about the preparation for the colonoscopy and the procedure (colonoscopy) itself.		
			Interval carcinomas	During the intake, the patient is informed about the risk of interval carcinomas after colonoscopy.		
			Informed consent	Informed consent for medical interventions and consent for the recording and exchange of data with care providers external to the screening, takes places in accordance with the applicable hospital policy.		
			Consent for data exchange	During the intake, the patient is asked for consent for the exchange of data from the intake and colonoscopy with the screening organisation.		
	Supporting the primary process		Recording the intake	Structured data recording of the required information from the intake in the care provider portal made available for this purpose.		
Timeliness of the registration			The maximum time duration for registration of the required data from the intake after the interview.			
Colonoscopy (high quality)	Complete examination of colon	Bowel preparation	The percentage of colonoscopies where the colon is sufficiently clean to be able to inspect it well.	≥ 90%	≥ 90%	
Wellbeing of patients	Minimizing the (chance of) harm to the screening population	Follow-up	The percentage of participants for which the time span between a colonoscopy during which no abnormalities were found and the telephone contact in connection with possible complications amounts to <i>at the most 1 month</i> .	-	≥ 95%	

## Protocol for the Authorization and auditing of colonoscopy

		Working according to protocol	Employees work according to protocols, guidelines and procedures, as far as required for patient safety.	demonstrable	demonstrable
		Risky actions	Employees are authorized and competent to perform risky actions.	demonstrable	demonstrable
		Testing actions	Professional actions by employees in regard to risky procedures are tested according to a defined method.	-	demonstrable
	Prevention of infection	Personal hygiene	Employees abide by the prescribed requirements for personal hygiene.	demonstrable	demonstrable
		Endoscopes	Cleaning, disinfection and (microbiological) checking of endoscopes takes place pursuant to the prescribed requirements.	demonstrable	demonstrable
	Optimizing patient experiences	CO <sub>2</sub> insufflation	The percentage of colonoscopies where CO <sub>2</sub> insufflation is utilized.	equipment present	100%
		Satisfaction measurement	The measuring of the satisfaction of the participant and how the participant has experienced the quality, safety and comfort of the care provided.	-	demonstrable
		Complaints	An implemented procedure for the processing of complaints.	demonstrable	demonstrable
		Language usage	Employees are able to speak to participants in the Dutch language.	-	demonstrable

## Protocol for the Authorization and auditing of colonoscopy

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Turnaround times	Minimizing the anxiety among participants	Turnaround time result letter through intake colonoscopy	The percentage of participants for whom the time interval between the sending of the result letter (with a referral) based on a positive iFOBT and the intake for colonoscopy lasts a <i>maximum of 10 working days</i> .	-	≥ 95%
		Turnaround time appointment for intake colonoscopy through performance of colonoscopy	The percentage of participants for whom the time interval between the (primary) planned appointment for the intake for colonoscopy and the colonoscopy to be performed lasts a <i>maximum of 10 working days</i> .	-	≥ 95%
		Turnaround time for intake colonoscopy through appointment for colonoscopy	The percentage of participants for whom the time interval between the intake for the colonoscopy and the (primary) planned appointment for the colonoscopy to be performed lasts a <i>maximum of 10 working days</i> .	-	≥ 95%
		Turnaround time result letter through performance of colonoscopy	The percentage of participants for whom the time interval between the sending of the result letter (with a referral) based on a positive iFOBT and the intake for colonoscopy lasts a <i>maximum of 15 working days</i> .	-	≥ 95%
		Turnaround time intake colonoscopy through result letter	The percentage of participants for whom the time interval between the appointment for an intake for colonoscopy and the sending of the definitive result letter (after colonoscopy and subsequent pathology) by the MDL physician to the participant lasts a <i>maximum of 25 working days</i> .	-	≥ 95%
		Turnaround time colonoscopy without abnormalities & confirmation of result	The percentage of participants that after a colonoscopy during which no abnormalities have been found receives an oral explanation immediately after the procedure and a written confirmation of the result.	-	≥ 95%
		Turnaround time colonoscopy with polypectomy/biopsy through oral consult	The percentage of participants for whom the time interval between a colonoscopy with a polypectomy or biopsy and the follow-up oral consult lasts a <i>maximum of 5 working days</i> .	-	≥ 95%
		Turnaround time for a colonoscopy with polypectomy/biopsy between oral consult through result letter	The percentage of participants for whom the time interval between the oral consult and the sending of the definitive result letter by the MDL physician to the participant lasts a <i>maximum of 5 working days</i> .	-	≥ 95%
		Turnaround time for colonoscopy with major abnormalities & informing participant	The percentage of participants that after a colonoscopy during which major abnormalities are found are informed immediately after the procedure.	-	≥ 95%

Protocol for the Authorization and auditing of colonoscopy

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Data management	Support of the primary process/monitoring and evaluation of the quality	Data recording & image storage	A structured recording of data and storage of images.	up-to-date system	demonstrable
		Reporting of activities	Complete reporting of the activities performed in the scope of the national screening programme.	-	100%
		Data delivery	Having the necessary data available and a structured delivery of said data.	up-to-date system	demonstrable
		Data management	Periodic updates and backups of (the data in) the applicable registration systems.	up-to-date system	demonstrable
		Access to data	Managing the access to the (privacy-sensitive) data in the ColonIS intake module.	-	demonstrable
Follow-up care	Assuring the transfer to follow-up care	Transfer to follow-up care	Good transfer of patient and data to the pertinent specialist, if treatment is necessary.	-	demonstrable
	Assuring surveillance and the return to the national screening programme	Surveillance	In the case of surveillance, the guideline of the professional group is followed.	-	demonstrable
		Return to national screening programme	Electronic notification if a participant, after a surveillance colonoscopy, can return to the national screening programme.	-	demonstrable

## APPENDIX 2 ADMISSION AND AUDIT REQUIREMENTS FOR ENDOSCOPIST

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Personnel	Qualified employees	Accreditation	Accreditation conforming to the final attainment levels for an endoscopist.	demonstrable	demonstrable
	Expert employees	Knowledge and skill	The completion of the screening module with good result.	demonstrable	demonstrable
Frameworks	Implementation of the activities within the defined frameworks	Implementation framework	Satisfying and working in conformance with the agreements in the nationally defined implementation framework for the national screening programme for bowel cancer.	demonstrable	demonstrable
		Guidelines	Satisfying and working in conformance with the applicable guidelines as created by the professional group.	demonstrable	demonstrable
		Protocols	Satisfying and working in conformance with the nationally established, applicable, (requirements of) protocols.	demonstrable	demonstrable
Colonoscopy (high quality)	Sufficient experience in colonoscopy and polypectomy	Number of colonoscopies	Number of (screening) colonoscopies performed per year.	≥ 300	≥ 300
		Number of polypectomies	Number of polypectomies performed per year.	≥ 50	-
		New colonoscopy	The percentage of the colonoscopies performed by the endoscopist where a new colonoscopy takes place for the removal of polyps.	-	monitoring
	Complete examination of colon	Caecal intubation rate	The percentage of colonoscopies with a complete caecum intubation.	≥ 90%	≥ 95%
		Withdrawal time	The percentage of negative colonoscopies with a withdrawal time of at least 6 minutes.	-	≥ 90%
	Determining cancers and adenomas present in the screening population	Cancer detection rate	The percentage of colonoscopies where (more than) one cancer has been detected.	-	monitoring
		Adenoma detection rate	The percentage of colonoscopies where (more than) one adenoma has been detected.	≥ 20%	≥ 30%
		MAP	The mean number of adenomas per procedure (colonoscopy).	-	monitoring
		MAP+	The mean number of adenomas per positive procedure (colonoscopy).	-	monitoring
	Prevention of interval cancers/ availability of polyps for pathology analysis	Polyp removal rate	The percentage of polyps removed of the total number of detected polyps during the colonoscopy.	≥ 90%	≥ 90%
		Polyp removal rate > 5 mm for the purpose of pathology	The percentage of polyps removed for pathology analysis of the total number of polyps removed during the colonoscopy > 5 mm.	monitoring	≥ 90%

	Planning surgery	Tattooing	The percentage of detected cancers given a tattoo, excluding those located in the cecum or 4 cm distal from the rectum		Monitoring
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## Protocol for the Authorization and auditing of colonoscopy

Subject	Objective	Indicator	Description	Admission requirement	Audit requirement
Wellbeing of patients	Minimizing the (chance of) harm to the screening population	Complication record	Keeping a complication record.	demonstrable	demonstrable
		Complications during colonoscopy	The percentage of colonoscopies performed by the endoscopist where a complication occurs (up to 30 days after the procedure).	-	≤ 0.3%
		Perforation rate colonoscopy	The perforation rate for colonoscopies performed by the endoscopist (up to 30 days after the procedure).	-	≤ 0.1%
		Perforation rate polypectomy	The perforation rate for colonoscopies with polypectomy performed by the endoscopist (up to 30 days after the procedure).	-	≤ 0.5%
		Polypectomy bleeding	The percentage of colonoscopies with polypectomy performed by the endoscopist where a complicated bleeding occurs (up to 30 days after the procedure).	-	≤ 1%
	Optimizing patient experiences	Comfort score	The percentage of colonoscopies where the participant experiences moderate or severe discomfort.	-	monitoring
Data management	Support of the primary process/monitoring and evaluation of the quality	Registration of colonoscopies	The share of the colonoscopies performed by the endoscopist with a complete registration.	≥ 100	100%

## APPENDIX 3 COLONOSCOPY RESULT LETTERS

### 3a Option Colonoscopy without pathology analysis result with return to the national screening programme after 10 years

Dear Sir/Madam,

You underwent an internal bowel examination today, also called a colonoscopy. This examination has been conducted because blood was found in your stool in the national screening programme for bowel cancer. No abnormalities were found during the colonoscopy that may indicate bowel cancer or a precursor of bowel cancer (polyps). Blood in the stool can also be caused by hemorrhoids or fragile blood vessels, for example. Sometimes no reason is not found for blood in the stool.

#### **What does the result mean?**

You will receive another invite for the national screening programme for bowel cancer in ten years. Because you underwent a colonoscopy today, there is no reason to examine you until ten years time. The chance that you will develop bowel cancer within this period is very small. If you will be over 75 years of age in ten years, you will no longer receive an invitation for the national screening programme.

#### **Complaints after the examination**

Many people continue to have some complaints for a while after undergoing a colonoscopy, such as abdominal pain, intestinal cramps, a bloated feeling and flatulence. This is normal and disappears after a few days. It is possible you may lose some mucus and fluid via your anus up to a few days after the colonoscopy.

You will receive a call in the coming month to see if any complaints developed after the examination.

Immediately warn your general practitioner or report to the Emergency department if the following complaints develop after the colonoscopy:

- Sudden heavy abdominal pain, or if the pain does not disappear within a few days
- Fever
- Sudden heavy bloodloss from the intestines, or if the blood loss does not disappear within a few days



You develop complaints, such as blood in your stool or a persistent change in bowel movement such as constipation or diarrhea in the next ten years? Do not wait for the next invitation for the national screening programme but immediately make an appointment with your general practitioner.

### 3b Option Colonoscopy with pathology analysis result with return to national screening programme

Dear Sir/Madam,

You underwent an internal bowel examination recently, also called a colonoscopy. This examination was conducted because blood was found in your stool in the national screening programme for bowel cancer.

Polyps were found in your bowel during the colonoscopy and these have been removed immediately. The result of this has already been discussed with you.

#### **What does the result mean?**

You will receive another invite for the national screening programme for bowel cancer in ten years. The chance that you will develop bowel cancer within this period is very small. If you will be over 75 years of age in ten years, you will no longer receive an invitation for the national screening programme.

You develop complaints, such as blood in your stool or a persistent change in bowel movement such as constipation or diarrhea in the next ten years? Do not wait for the next invitation for the national screening programme but immediately make an appointment with your general practitioner.

### 3c Option Colonoscopy with pathology analysis result with surveillance after 3 or 5 years

Dear Sir/Madam,

You underwent an internal bowel examination recently, also called a colonoscopy. This examination was conducted because blood was found in your stool in the national screening programme for bowel cancer.

Polyps were found in your bowel during the colonoscopy and these have been removed immediately. The result of this has already been discussed with you.

#### **What does the result mean?**

Polyps can develop again. For this reason, we recommend you have a follow-up colonoscopy in [fill in 3 or 5] years.

To this end, please [action: to be filled in by colonoscopy centre]

This means that you will not receive an invitation for the national screening programme between now and the follow-up colonoscopy.

## APPENDIX 4.1 MODEL COLONOSCOPY COOPERATION AGREEMENT

# DRAFT Model Colonoscopy Cooperation Agreement

### The Parties,

The Foundation for National Screening -..... (*name*) based in ..... (address, place), WBO permit holder in the scope of the national organization for bowel cancer screening, here legally represented by (name), (function), from hereon to be referred to as "The screening organization",

and

The ..... (name) at (address and place), here acting as the performing centre for colonoscopies within the framework of the national organization for bowel cancer screening, here legally represented by (name), (function), from hereon to be referred to as "The colonoscopy centre",

### Considering:

1. That on June 1, 2011 the Ministry of Health, Welfare and Sport decided to a phased implementation as of 2013 of a national screening programme for bowel cancer in all persons ages 55-75 years, through means of a biennial self-administered test;
2. That the Centre for Population Screening of the RIVM (RIVM-CvB) is charged with the direction of the (preparations for the) implementation of the national screening programme for bowel cancer, and to that effect has created a national organization;
3. That the Screening Organizations (SO's) have been given the assignment from the RIVM-CvB for implementation and regional coordination of the national screening programme for bowel cancer, will receive financing for that purpose from the subsidy policy on public health and are permit holders within the framework of the Act for the National Screening Programme;
4. That individuals with an unfavourable (positive) result of the test named under point 1 will be referred by the screening organization and invited for a colonoscopy.

### Declare

That they wish to cooperate in the framework of the national organization of the national screening programme for bowel cancer within the nationally defined frameworks for said purpose.

### And declare to have agreed as follows:

#### Article 1 The screening organization

1. The screening organization carries out the following tasks, among others, in the framework of the national screening programme for bowel cancer:
  - 1.1. the selection and the (repeated) invitation of the target group including providing the self-administered test;
  - 1.2. informing the family physician in case of an unfavourable (positive) result;
  - 1.3. communication of the result of the self-administered test to the participant, referral of participants with an unfavourable (positive) result and invite them for an intake interview at a colonoscopy centre with which this cooperation agreement has been entered into;

- 1.4. perform the reference function in regard to the quality of performance of screening and subsequent diagnostics, among which the colonoscopy centres. To this effect, a Regional Coordinating Gastroenterohepatology official (RCMDL) will be associated with every screening organization, who permits and supervises the quality of the colonoscopy centres (see also article 4.5);
- 1.5. together with the other screening organizations purchase the testing method and services of laboratories for the analysis of the self-administered tests.
2. The screening organization assures that the screening is performed in the (nationally) uniform manner in its own region, among which by
  - 2.1. conforming to the decisions of the RIVM-CvB concerning the implementation of the national screening programme for bowel cancer;
  - 2.2. assuring there is cooperative understanding through agreements with all involved parties.
3. The screening organization handles the management and maintenance of ColonIS, the IT system for the facilitation of the primary process, quality assurance, monitoring & evaluation and (in time) supplementing research of the national screening programme for bowel cancer.

## Article 2 The Colonoscopy Centre

1. The Colonoscopy Centre carries out the following tasks, among others, in the framework of the national screening programme for bowel cancer:
  - 1.1. the at least weekly communication of available time slots for intake interviews for a colonoscopy in the framework of the national screening programme to the screening organization. This is done through the ColonIS appointments module, such that the number of time slots is aligned with the available colonoscopy capacity so as to make sure that the turnaround time is achievable;
  - 1.2. the intake of participants in the national screening programme for bowel cancer with an unfavourable (positive) result of the self-administered test, on referral from the regional coordinating MDL official associated with the screening organization;
  - 1.3. the performance of a colonoscopy or, if necessary, multiple colonoscopies and/or a request for performing CT colonography in a centre that meets the quality requirements set pursuant to the national screening programme for bowel cancer, by endoscopists that meet the quality requirements prescribed to them pursuant to the national screening programme for bowel cancer, as apparent from a valid quality agreement (appendix x);
  - 1.4. if necessary, order additional diagnostics from a pathology laboratory that meets the quality requirements prescribed by the national screening programme for bowel cancer;
  - 1.5. informing the participant (and his/her family physician) about the result of the colonoscopy, and possibly about the CT colonography and/or additional diagnostics;
  - 1.6. in case of an unfavourable (positive) result, making appointments with the participant for surveillance and/or referral for further treatment;
  - 1.7. feedback of the results to the regional coordinating MDL official named in article 1-1.4;
  - 1.8. the performing of a surveillance programme and providing data about the result of this programme and the follow-up measures to the screening organization through ColonIS.
2. The colonoscopy centre conforms to the national Implementation Framework (appendix x), the quality requirements and directions of the RIVM-CvB, established after advise from the National Committee.
3. The colonoscopy centre maintains a registration of the procedures performed and provides the nationally agreed-upon data to the screening organization while observing the Personal Data Protection Act. The data is provided digitally such that when using ColonIS these data can be used for performing the national screening programme, quality assurance, monitoring and evaluation, and possibly scientific research.

### Article 3 Implementation Framework

1. After recommendation by the National Committee, the RIVM-CvB determines a national Implementation Framework (appendix x) for the implementation of the national screening programme for bowel cancer.
2. The Parties are obligated to abide what is stated in paragraph 1 of the Implementation Framework and the accompanying protocols.
3. The colonoscopy centre may not apply any modifications in (the method of performing) its tasks without informing the Screening organization about this in advance. The Screening organization will determine if permission for the modification is required.

### Article 4 Quality

1. The RIVM-CvB will set national quality requirements for the national screening programme for bowel cancer, with consideration for the recommendations by the National Committee in this regard.
2. The quality requirements pertain to various parts that are important for the national screening programme for bowel cancer and the subsequent diagnostics and care.
3. The determined quality requirements form an appendix to this agreement.
4. The Parties are obligated to observe the quality requirements stated in paragraph 1.
5. The screening organization is responsible for maintaining the quality requirements stated in paragraph 1.
6. By entering into this agreement, the screening organization has ascertained that the colonoscopy centre meets the quality requirements as applicable at that time.
7. In September of each year, the RIVM-CvB determines the quality requirements for the following calendar year with consideration for the recommendation in this regard by the National Committee, and communicates these to the screening organizations and through the website for the national screening programme for bowel cancer of the RIVM.

### Article 5 Quality Audit

1. The activities and procedures of the colonoscopy centre are evaluated by the RCMDL and screening organization according to the national protocol.
2. The colonoscopy centre is required to actively participate in the audits mentioned in the previous paragraph, and to make the information requested for this audit available.
3. If the quality audit leads to an observation of deviations from the quality requirements or shortcomings, the screening organization will report these in writing to the colonoscopy centre. Depending on the seriousness of the deviation, an improvement period is determined.
4. The colonoscopy centre is obligated in case of the circumstances mentioned in the previous paragraph to implement such improvements within the determined period after the date of the written notification that it meets the quality requirements respectively that the observed shortcomings have been resolved.
5. The screening organization will satisfy itself within six months after the date of the written notification that the improvements have been implemented, unless a different time period has been agreed upon.

### Article 6 Duration and termination of the agreement

1. The agreement is entered into by the parties for 1 year, effective [DATE] and after the expiration of this period is implicitly renewed, each time for a period of 1 year.
2. The Parties can terminate this agreement for reasonable and fair grounds as of the first day of a full calendar year through a registered and justified letter and observing a period of notice of three months.
3. The agreement is dissolved effective immediately without judicial intervention if:

- 3.1. the screening organization no longer possesses a valid permit for the national screening programme for bowel cancer pursuant to the Act for the National Screening Programme as intended in Article 1.1;
- 3.2. the colonoscopy centre does not cooperate in the quality audits;
- 3.3. the colonoscopy centre has not instituted any improvements in the case of observed abnormalities of the quality requirements or shortcomings within the procedure and time periods listed in Article 5.

Article 7 Disputes

- 1. This agreement and all agreements that are created as a result are governed by the laws of the Netherlands.
- 2. If in case of a dispute the parties cannot come to agreements after consultations, they will preferably attempt to resolve such a dispute by means of mediation pursuant to the regulations of the Dutch Mediation Institute in Rotterdam, such as that reads on the starting date of the mediation. If it has appeared to be impossible to resolve a dispute as indicated above with the aid of mediation, the parties will be able to submit the dispute to the civil court. If mediation is not deemed fitting given the nature and/or seriousness of the dispute, the parties can submit the dispute to the civil court as well.

Article 8 Final clauses

- 1. The appendices mentioned in this agreement, among which the quality agreements with the endoscopists employed at the pertinent colonoscopy centre, are an integral part of this agreement.
- 2. If any clause of this agreement is null or void, the remaining clauses of this agreement will continue to fully remain in effect, and the parties will formulate new clauses for the replacement of the null and/or void clauses, where the purpose and meaning of the null and/or void clause is observed as much as possible.
- 3. Deviations from and/or supplements to this agreement are only applicable insofar these are agreed up by the parties in writing. This also applies to modifications that the RIVM-CvB adopts in the model agreement.
- 4. This agreement replaces all oral as well as written agreements that have been entered into between the parties pursuant to the subject of this agreement.

Signature:

<i>Place and date:</i>	<i>Place and date:</i>
The Screening Organization (name) at (address and place) on its' behalf,	The Colonoscopy Centre (name) at (address and place) on its' behalf,
<i>(name and function of the legal representative)</i>	<i>(name and function of the legal representative)</i>
Signature	Signature

## APPENDIX 4.2 ENDOSCOPIST QUALITY AGREEMENT

### DRAFT

### Quality Agreement between the screening organization and endoscopists who perform colonoscopies in the framework of the national screening programme for bowel cancer

This agreement is an appendix to the cooperation agreement between the colonoscopy centre where the endoscopist is employed and the screening organization.

#### *The Undersigned,*

#### Has taken notice of:

##### General

1. That on June 1, 2011 the Ministry of Health, Welfare and Sport decided to a phased implementation as of 2013 of a national screening programme for bowel cancer in all persons, ages 55-75 years, through means of a biennial self-administered test.
2. That the Centre for Population Screening of the RIVM (RIVM-CvB) is charged with the direction of the (preparations for the) implementation of the national screening programme for bowel cancer, and to that effect has created a national organization.
3. That the Screening Organizations (SO's) have been given the assignment for implementation and regional coordination of the national screening programme for bowel cancer, will receive financing for that purpose from the subsidy policy on public health and are permit holders within the framework of the Act for the National Screening Programme.
4. That individuals, with an unfavourable (positive) result of the test named under point 1 will be referred by the screening organization and invited for a colonoscopy.
5. That for the purpose of the national screening programme for bowel cancer, fine-tuning on the national level in a Programme Committee is warranted and coordination at the regional level by the permit holder, the screening organization.
6. That all the parties involved with the direct care provided to the referred participant from the national screening programme for bowel cancer must meet the Health Service Clients (Right of Complaint) Act.

##### The screening organization

1. The screening organization provides a valid permit pursuant to the Act for the National Screening Programme for the national screening programme for bowel cancer, and is thereby the permit holder.
2. The screening organization carries out the following tasks, among others, in the framework of the regional organization of the national screening programme for bowel cancer:
  - a. the selection and the (repeated) invitation of the target group including providing the self-administered test;
  - b. informing the family physician in case of an unfavourable result;
  - c. communication of the result of the self-administered test to the participant, referral of participants with an unfavourable (positive) result and invite them for an intake interview at a colonoscopy centre with which a cooperation agreement has been entered into and which therefore meets the nationally prescribed quality requirements;

- d. perform the reference function in regard to the quality of performance of screening and subsequent diagnostics, among which the colonoscopy centres. To this effect, a Regional Coordinating MDL official (RCMDL) will be associated with every screening organization, who permits and supervises the quality of the colonoscopy centres and the endoscopists;
  - e. together with the other screening organizations purchase the testing method and services of laboratories for the analysis of the self-administered tests;
  - f. the signalling to colonoscopy centres of clients who are approaching their invitation moment in their surveillance programme.
3. The screening organization assures that the national screening programme for bowel cancer is performed in the (nationally) uniform manner in its own region, among which by
    - a. conforming to the decisions of the RIVM-CvB concerning the implementation of the national screening programme for bowel cancer;
    - b. assuring there is cooperative understanding through agreements with all involved parties.
  4. The screening organization handles the management and maintenance of ColonIS, the IT system for the facilitation of the primary process, quality assurance, monitoring & evaluation and (in time) supplementing research of the national screening programme for bowel cancer.

#### Agrees with:

##### 1 Training

1. Has successfully completed a training course that meets the national quality requirements that have been set for the national screening programme for bowel cancer (appendix x).
2. Follows demonstrable new developments in the professional area.

##### 2 Performance of the colonoscopy, including the preceding intake interview

1. Holds an intake interview and performs a colonoscopy on the participant referred through the national screening programme according to the nationally applicable quality requirements.
2. During the intake interview and colonoscopy adheres to the national Implementation Framework as determined by the RIVM-CvB (appendix x) and the accompanying protocols and guidelines.
3. Commits in the framework of the national screening programme for bowel cancer to cooperate with a pathology laboratory and a radiology centre for CT colonography that meet the quality requirements as determined by the RIVM-CvB for the national screening programme for bowel cancer.
4. Keeps a record of the procedures performed for the participants referred by the national screening programme and provides the nationally agreed upon data of these through ColonIS to the screening organizations while observing the WGBO and the Personal Data Protection Act in the manner nationally agreed upon.

##### 3 Quality

1. Commits to adhering to the national quality requirements for the national screening programme for bowel cancer as determined by the RIVM-CvB with regard for the recommendation in this regard by the National Committee. The actual version of these quality requirements are published on the web site of the RIVM ([www.bevolkingsonderzoekdarmkanker.nl](http://www.bevolkingsonderzoekdarmkanker.nl)).
2. Actively participates in the quality audits performed by the RCMDL from the screening organization and makes the necessary information for this audit available.
3. Commits himself to follow relevant continuing and refresher courses.

**4 Duration and termination of the agreement**

1. The quality agreement is entered into for 1 year, effective [DATE] and after the expiration of this period is implicitly renewed, each time for a period of 1 year.
2. The quality agreement can be terminated on reasonable and fair grounds with the observation of a period of notice of three months.
3. The quality agreement is dissolved effective immediately without judicial intervention if:
  - 3.1 the screening organization no longer possesses a valid permit for the national screening programme for bowel cancer pursuant to the Act for the National Screening Programme;
  - 3.2 the provider no longer meets the quality requirements or appears to no longer meet the training requirements as stated in article 1.

**5 Disputes**

If in case of a dispute the parties cannot come to agreements after consultations, they will preferably attempt to resolve such a dispute by means of mediation pursuant to the regulations of the Dutch Mediation Institute in Rotterdam, such as that reads on the starting date of the mediation. If it has appeared to be impossible to resolve a dispute as indicated above with the aid of mediation, the parties will be able to submit the dispute to the civil court. If mediation is not deemed fitting given the nature and/or seriousness of the dispute, the parties can submit the dispute to the civil court as well.

**6 Final Clauses**

1. The treatment agreement for a colonoscopy is effected between the undersigned and the referred participant in the national screening programme for bowel cancer.
2. The protocols, quality requirements and the like as stated in articles 2 and 3 of the Implementation Framework are an integral part of this quality agreement.
3. If any clause of this quality agreement is null or void, the remaining clauses of this quality agreement will continue to fully remain in effect, and the parties will formulate new clauses for the replacement of the null and/or void clauses, where the purpose and meaning of the null and/or void clause is observed as much as possible.

Name:
Address:
Place:
Employed by:
AGB code (?)

**For agreement**

## APPENDIX 5 INSPECTION REQUIREMENTS OF THE NVMDL (applicable to the national screening programme)

This table includes the requirements of the inspection committee of the NVMDL that apply to the national screening programme for bowel cancer.

Inspection requirements	
<b>1. Personnel</b>	
1.1	The assistance during endoscopies must be performed by nurses trained for this function who have followed the "Endoscopy Course".
1.2	At least 3 assistants must be present to be able to run an endoscopy programme (the total need is 2 fte per 1000 colonoscopies).
1.3	Around the clock emergency care for possible complications must be guaranteed. To this end, there must be a schedule for evening, night and weekend for twenty-four hour availability services or clear agreements must have been made with another centre/hospital.
1.4	The endoscopy department must have sufficient secretarial support.
1.5	All employees involved with the cleaning and disinfecting of scopes are professionals and qualified in this area.
<b>2. Endoscopy Department</b>	
2.1	The endoscopy department must consist of: <ul style="list-style-type: none"> <li>a. waiting area</li> <li>b. preparation area</li> <li>c. endoscopy room with a surface of at least 25 m<sup>2</sup> (1 endoscopy room for every 1500 scopes per year; the more scopes are performed, this number can be reduced to 1000 per year)</li> <li>d. recovery area with at least 3 monitored beds</li> <li>e. bathrooms</li> <li>f. the possibility to carry out "private" conversations</li> <li>g. space for reporting</li> </ul>
2.2	For each endoscopy room the following are necessary <ul style="list-style-type: none"> <li>a. a changing area</li> <li>b. a complete endoscopy unit</li> </ul>
2.3	Complete cleaning procedures have been defined for the department.
2.4	The storage for sterile medical aids is not located in the washing area.
<b>3. Equipment in the endoscopy rooms</b>	
3.1	There are sufficient endoscopies available to be able to run a continuous programme.
3.2	Argon coagulation equipment is available.
3.3	There is sufficient monitoring equipment present to meet the consensus of the NVMDL.
3.4	Agreements have been defined at the management level about the use of disposable and re-usable materials.
3.5	An investment and replacement budget has been defined at the management level.

## Inspection requirements

### 4. Personal hygiene

- 4.1 Everyone who (possibly) comes in contact with the microbial flora of a patient wears gloves.
- 4.2 While performing every scope, glasses and/or aprons are worn in addition to gloves.
- 4.3 The endoscopist and assistants wash and/or disinfect their hands after every colonoscopy.
- 4.4 During the initial cleaning of the scopes, all pertinent personal protective measures are to be taken (skirt, nose/mouth mask/glasses, gloves).
- 4.5 While exchanging the cans of the cleaning and disinfectant materials, all pertinent personal protective measures are taken.

### 5. Washing area and cleaning equipment

- 5.1 The situation in the washing area is such that there
  - a. is a clearly visible route during the cleaning and disinfection of the scopes
  - b. is a visible 'clean' and 'dirty' side
  - c. is an adequate ventilation system present
  - d. are sufficient facilities for the washing of hands
- 5.2 There are operating instructions present for the scope disinfectors and the drying cabinets.
- 5.3 There are logbooks for all equipment.
- 5.4 The logbook/software is used to track if, and if yes, how often error messages (malfunctions) occur in the cleaning and disinfection process.
- 5.5 There is a clear malfunction procedure for the equipment.
- 5.6 The logbook is used to record malfunctions in the equipment and who resolved the malfunction.
- 5.7 The functioning for each piece of equipment is checked after a malfunction has been resolved.
- 5.8 The critical information of that check is registered in the logbook.
- 5.9 Equipment is released for use if the proper functioning has been determined during the check.
- 5.10 A contract for periodic preventive maintenance has been entered into with the suppliers of the equipment.
- 5.11 Work and checks performed by technical services and/or the supplier are recorded in their logbook by the technical service.
- 5.12 Preventive maintenance takes place by employees of the department.
- 5.13 A technical validation of the equipment takes place periodically.
- 5.14 In the scope of the validation of the disinfection process, a residue determination will be made of disinfectants once per year.
- 5.15 The cleaning and disinfectant fluids used have a CE marking.
- 5.16 A double check is done during the change-out of the cleaning and disinfectant fluids.
- 5.17 A technical validation is done when placing a new scope disinfectant into operation.
- 5.18 A technical validation is done after maintenance/repair of a scope disinfectant.

### 6. Cleaning and disinfection of scopes

- 6.1 A procedure has been created which defines the cleaning and disinfection process of scopes and accessories.
- 6.2 Scopes are transported in a closed bin.
- 6.3 An obvious distinction is made between the transport bins for clean and dirty scopes.

## Inspection requirements

- 6.4 The outside cover of the scope is always removed immediately after use with dry gauze.
- 6.5 Valves and other removable parts are taken from the endoscope.
- 6.6 When cleaning manually, all the channels of the scope are perfused immediately after use with a tepid enzymatic cleanser.
- 6.7 After cleaning with the enzymatic cleanser the instruments are first rinsed with water before placing them in the disinfectant.
- 6.8 The water and air channels are cleaned by flushing with a water pistol.
- 6.9 The channels of all scopes for mechanical cleaning are brushed and checked for open passages.
- 6.10 A leak test is performed on all scopes prior to the cleaning and disinfection process.
- 6.11 A protocol defines the actions to be taken if a leak is discovered in the scope.
- 6.12 All scopes are mechanically cleaned and disinfected after use.
- 6.13 All re-usable accessories are cleaned and disinfected in the scope disinfectant.
- 6.14 Accessories that must be sterile go to the CSA.
- 6.15 A scope is first cleaned and disinfected before and after repairs.
- 6.16 The disinfection of endoscopes and equipment is done according to the current guidelines from the workgroup for infection prevention (WIP).
- 6.17 The critical points (process parameters) of the cleaning and disinfection process are recorded.
- 6.18 The endoscopes and accessories are cleaned and disinfected in the scope disinfectant according to the programme established by the supplier.
- 6.19 The scope disinfectant checks whether all the channels are properly connected.
- 6.20 The scope disinfectant checks if the cleaning and disinfection fluid flow through all the channels.
- 6.21 The programme indicates if the cleaning and disinfection process does not run according to the correct procedure.

### 7. Drying and storage of scopes

- 7.1 There are enough places in the drying cabinet(s) to dry all scopes with filtered compressed air.
- 7.2 All the channels of the scopes are connected in the drying cabinet.
- 7.3 The endoscopes are dried for at least 30 minutes in the drying cabinet.
- 7.4 The scopes are stored dry and dust-free in a closed cabinet.

### 8. Microbiological check

- 8.1 The effectiveness of the cleaning and disinfection process is determined through microbiological study.
- 8.2 There is a culture procedure.
- 8.3 A microbiological validation of the equipment takes place periodically.
- 8.4 A microbiological validation is done when placing a new scope disinfectant into operation.
- 8.5 A microbiological validation is done after maintenance/repair of a scope disinfectant.
- 8.6 The results of the microbiological testing are recorded in the logbook of the endoscopy disinfectant.
- 8.7 There is a procedure for dealing with contaminated scopes.



## Inspection requirements

### 9. Endoscopic examination and/or endoscopic treatment

- 9.1 Obtaining an informed consent is required for all therapeutic procedures and endoscopic examination.
- 9.2 The sedation and monitoring must take place according to the NVMDL guidelines.
- 9.3 Time must be scheduled into the scoping programme for performing emergency scopes.

### 10. Reporting and registration

- 10.1 With each endoscopy, registration takes place of:
  - a. the patient
  - b. the endoscopist
  - c. the assistant(s)
  - d. the scope used
  - e. date and time of the scoping
  - f. scope disinfectant used
  - g. assistant who handled the placement into the disinfectant
- 10.2 The registration of the actions of the MDL practice must be centrally recorded.
- 10.3 The reporting must be automated and be immediately available.
- 10.4 A complication registration must be provided.

## APPENDIX 6 WORKGROUP QUALITY REQUIREMENTS FOR COLONOSCOPY AND NATIONAL COMMITTEE

Below is an overview of all the members of the Work Group for Quality Requirements for Colonoscopy and the National Committee for the Implementation of the national screening programme for bowel cancer who are involved in the creation of this protocol.

### Members of the Work Group for Quality Requirements for Colonoscopy

Organization	Name	Function
Boersma personnel services (Boersma personeelsdiensten)	Mr. T. Boersma	Chairman
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. M. van Wieren	Project employee, secretary
National screening programme East	Mrs. A. Olde Reuver of Briel	Policy employee national screening programme
Dutch Association of Gastroenterologists (NVMDL)	Mr. W. Moolenaar (until 2-1-2012)	Gastroenterohepatologist (MCA)
Dutch Association of Gastroenterologists (NVMDL)	Mr. M. van Haastert	Gastroenterohepatologist Martini Hospital Groningen (Martini Ziekenhuis Groningen)
Erasmus MC	Mr. J. Sint-Nicolaas	AIO PhD Student (Erasmus MC)
Dutch Association of Gastroenterologists (NVMDL)	Mrs. E. Dekker	Gastroenterohepatologist (AMC)
Erasmus MC	Mr. V. de Jonge	AIO PhD Student (Erasmus MC)
Dutch Association of Internists (NIV)	Mr. R. Loffeld	Internist
Dutch Association of Gastroenterologists (NVMDL)	Mr. J.W. Poley	Gastroenterohepatologist (Erasmus MC)
Netherlands Surgical Association (NIVVH)	Mr. C. Rosman	Surgeon, Canisius-Wilhelmina Hospital (CWZ)
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mr. A.J.J. Lock	Medical Advisor
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. E. Brouwer	Project employee for quality
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. H. van Veldhuizen	Project leader implementation bowel cancer screening
V&VN MDL	Mrs. M. Wissink	Registered Nurse (MC de Veluwe)
V&VN MDL	Mrs. E. van der Heide	Registered Nurse (UMCG)
Screening organization/FSB	Mrs. A. Vos (until 5-1-2012)	Programme leader implementation bowel cancer screening at the screening organizations
Dutch Association of Gastroenterologists (NVMDL)	Mrs. A. van der Sluys-Veer (as of 2-1-2012)	Gastroenterohepatologist (OLVG)
Dutch Association of Gastroenterologists (NVMDL) (replacement)	Mr. M. Groenen (as of 2-1-2012)	Gastroenterohepatologist (Alysis)
<b>Observation members</b>		
Screening organization/FSB	Mr. M. Schouten (as of 5-1-2012)	Programme leader implementation bowel cancer screening at the screening organizations

## Members of the National Committee for the implementation of the national screening programme for bowel cancer

Organization	Name	Function
Rehabilitation Centre De Hoogstraat (Revalidatiecentrum De Hoogstraat)	Mr. R. Beuse	Chairman, National Committee
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. H. van Veldhuizen	Project leader implementation bowel cancer screening, secretary
Screening organizations	Mr. W. Spijker	Director, Screening Organization South-west
Screening organizations (until 6-1-2012)	Mrs. A. Bartels	Director, Screening Organization West Central
Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC)	Mr. H. Bonfrèr	Professor Emeritus, Clinical Geneticist
Dutch Association of Gastroenterologists (NVMDL)	Mr. E.J. Kuipers	President, Netherlands Association of Gastroenterohepatologists, Gastroenterohepatologist (Erasmus MC)
Dutch Association of Internists (NIV)	Mr. R. Loffeld	Internist (Zaanstad MC)
Netherlands Surgical Association (NIVH)	Mr. C. Rosman	Surgeon, Canisius-Wilhelmina Hospital (CWZ)
Netherlands Surgical Association (NIVH) (replacement)	Mrs. H. van Veldhuizen	Surgeon (VUMC)
Dutch Pathology Association (NVVP)	Mr. G.A. Meijer	Pathologist (VUMC)
Dutch Pathology Association (NVVP) (replacement)	Mrs. I.D. Nagtegaal	Pathologist (UMCN)
Dutch College of General Practitioners (NHG)	Mr. N.J. de Wit	Professor, General Practice Medicine (UMCU)
NHG (replacement)	Mr. A.J.M. Drenthen	Team leader, prevention and patient information of the NHG
National Association of General Practitioners (LHV)	Mrs. E.C. Romijn	General Practitioner, Sr. Policy Officer
Foundation for Patients with Cancer of the Alimentary Canal; Colorectal Cancer Patients Group	Mrs. J.C.M. Pon	President, Colorectal Cancer Patients Group
Health Insurers Umbrella Organization (ZN)	Mr. G. Salemink	Medical Advisor
Dutch Federation of Cancer Patients (NFK)	Mrs. A. Snijders	Policy Officer, Quality of Care
Dutch Federation of Cancer Patients (NFK) (replacement)	Mrs. L. van Loon	Project Leader, Quality of Care
Dutch Society for Clinical Genetics (VKGN)	Mr. R.H. Sijmons	Clinical Geneticist (UMCG)
Comprehensive Cancer Centre of The Netherlands (IKNL)	Mr. N.J.H. Hoefsmit	Director
Dutch Radiology Association (NVvR)	Mr. J. Stoker (as of 4-1-2012)	Radiologist (AMC)
Dutch Radiology Association (NVvR) (replacement)	Mr. G.J. den Heeten (as of 4-1-2012)	Radiologist (UMCN), Director National Expert and Training Centre for Breast Cancer Screening (LRCB)
Comprehensive Cancer Centre of The Netherlands (IKNL) (replacement)	Mrs. M.L.E.A. Jansen-Landheer	Director of Networks
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. M.L. Heijnen	Sr. Project employee bowel cancer
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mr. J. van Delden	Financial advisor
Screening organization/FSB	Mrs. A. Vos (until 5-1-2012)	Programme leader implementation bowel cancer screening at the screening organizations
V&VN	Mrs. W. Kok	Registered Nurse



Observation members		
Observation member: VWS	Mrs. A. Bartels	Sr. Policy Officer
Observation member: IGZ	Mr. J. Remmen	Sr. Inspector
Dutch Hospital Association/Dutch Federation of University Medical Centres (NVZ/NFU)	Mr. Weijnenborg	Sr. Policy Advisor
National Institute of Public Health and the Environment (RIVM)/Centre for Population Screening (CvB)	Mrs. M. van Wieren	Project employee
Screening organization/FSB	Mr. M. Schouten (as of 5-1-2012)	Programme leader implementation bowel cancer screening at the screening organizations