



# Rules for the Certification of Infection Prevention and Control Management Systems

*Effective from May 11<sup>st</sup> 2020*

RINA  
Via Corsica, 12  
16128 Genova - Italy

Tel.: +39 01053851  
Fax: +39 0105351000  
Web site: [www.rina.org](http://www.rina.org)

---

Technical rules



**CONTENTS**

CERTIFICATION OF INFECTION PREVENTION AND CONTROL MANAGEMENT SYSTEMS .....	3
CHAPTER 1 GENERAL .....	3
CHAPTER 2 REFERENCE STANDARD / CERTIFICATION REQUIREMENTS .....	3
CHAPTER 3 INITIAL CERTIFICATION .....	4
CHAPTER 4 MAINTENANCE OF CERTIFICATION .....	4
CHAPTER 6 PERFORMANCE OF AUDIT .....	4
CHAPTER 9 SPECIAL PROCEDURES FOR MULTI-SITE ORGANISATIONS .....	4
CHAPTER 10 TRANSFER OF ACCREDITED CERTIFICATES.....	5



## **CERTIFICATION OF INFECTION PREVENTION AND CONTROL MANAGEMENT SYSTEMS**

### **CHAPTER 1 GENERAL**

#### **1.1**

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Infection Prevention and Control Management System in relation to what is already defined in the General Rules for the Certification of Management Systems.

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

#### **1.2**

RINA issues certification in accordance with the requirements of ISO/IEC 17021:2011 and of ISO/IEC 17021-1:2015 to organizations whose Management System has been recognized as complying with all the requirements of the BIOSAFETY TRUST CERTIFICATION Normative Document, owned by RINA, in its latest version.

### **CHAPTER 2 REFERENCE STANDARD / CERTIFICATION REQUIREMENTS**

#### **2.1**

According to what is stated in the General Rules for the Certification of Management Systems, to obtain RINA certification an Infection Prevention and Control Management System must first and henceforth satisfy the requirements of the BIOSAFETY TRUST CERTIFICATION Regulatory Document, owned by RINA, in its latest version.

#### **2.3**

Conformity of the Management System with the reference standard is verified by means of an audit programme comprising:

- an initial audit in two stages,
- a surveillance audit within 6 months of the issue of the certificate;
- a surveillance audit in the first year;
- a surveillance audit in the second year;
- a certification renewal audit in the third year.



## **CHAPTER 3 INITIAL CERTIFICATION**

### **3.4**

In addition to what is stated in the General Rules for the Certification of Management Systems, together with or following the certification request, the Organization is to make available to RINA the general document that demonstrates compliance with all requirements of the Infection Prevention and Control Management System and the list and the evidence of the authorizations relevant to the Infection Prevention and Control Management System.

## **CHAPTER 4 MAINTENANCE OF CERTIFICATION**

### **4.2**

In addition to what is stated in the General Rules for the Certification of Management Systems, the organization must keep records of:

- accidents/emergencies in the site(s) and other events that could have potentially led to infection;
- any complaints regarding infection management and control;
- any comments or reports received from national or local authorities proposed to health surveillance;

and must make them available to RINA together with the relative corrective action implemented during the periodic audits.

The organisation must keep RINA informed of any observations/remarks from national or local authorities responsible for sanitary control and of any situations of legislative non-compliance related to all the organisation's activities, regardless of the field of application of the Infection Prevention and Control Management System.

## **CHAPTER 6 PERFORMANCE OF AUDIT**

### **6.1.3**

In addition to what is stated in p. 3.6 of the General Rules for the Certification of Management Systems, the term non-conformity also refers to a situation such as to reduce the capacity of the management system to ensure prevention and control of infections and/or compliance with legislation.

## **CHAPTER 9 SPECIAL PROCEDURES FOR MULTI-SITE ORGANISATIONS**

### **9.1**

As well as the activities defined in the General Rules for the Certification of Management Systems, also the risk analysis and assessment of the sites is to be managed by the organisation's head office.



## 9.2

As well as what is stated in the General Rules for the Certification of Management Systems, the sampling must consider following factors:

- the level of risks associated to the nature of activities and processes carried out in each site included in the scope of certification;
- the differences between the operations of each site.

## **CHAPTER 10 TRANSFER OF ACCREDITED CERTIFICATES**

Not applicable.



Publication: RC/C 137  
English edition

RINA  
Via Corsica 12  
16128 Genova - Italy

Tel. +39 01053851  
Fax: +39 0105351000  
web site: [www.rina.org](http://www.rina.org)

---

Technical rules