Description of the Inspectorates

	Swissmedic	RHI NW	RFS-OZ	IRM-S	ISOPTh
Official designation	Swissmedic, Bereich Bewilligungen, Abteilung Inspektorate und Bewilligungen	Regionales Heilmittelinspektorat der Nordwestschweiz (RHI)	Regionale Fachstelle der Ost- und Zentralschweiz (RFS-OZ)	Ispettorato regionale dei medicamenti della Svizzera del Sud (IRM-S)	Inspectorat de Suisse occidentale des produits thérapeutiques (ISOPTh)
English designation	Swissmedic, Licensing Sector, Division "Inspectorates" and Licences"	Regional Medicines Inspectorate of Northwestern Switzerland	Regional Medicines Inspectorate of Eastern and Central Switzerland	Regional Medicines Inspectorate of Southern Switzerland	Regional Medicines Inspectorate of Western Switzerland
Text reference	IoS	IoC	IoC	IoC	IoC
Address	Hallerstrasse 7, 3012 Bern	Marktgasse 4, 4051 Basel	Haldenbachstrasse 12, 8006 Zürich	Via Agostino Maspoli 6, 6850 Mendrisio	Route des Arsenaux 16, 1700 Fribourg
Homepage	www.swissmedic.ch	www.rhinw.ch	www.rfsoz.ch	http://www4.ti.ch/dss/dsp/ufc/chi-siamo/ispettorato-regionale-dei-medicamenti-della-svizzera-del-sud/	-
Cantons involved	All cantons and the Principality of Liechtenstein [1]	AG, BE, BL, BS, LU, SO	AI, AR, GL, GR, NW, OW, SG, SH, SZ, TG, UR, ZG, ZH, Principality of Liechtenstein[1]	TI	FR, GE, JU, NE, VD, VS

[1] The Swiss inspection system covers only the inspection process in Liechtenstein but not the issue of establishment licenses and of certificates.

	Swissmedic	RHI NW	RFS-OZ	IRM-S	ISOPTh
Legal form	Swissmedic is a public legal entity of the Swiss Confederation in the third circle of the administrative model. It has its own legal personality.	The RHI NW is an own legal entity in the public sector. The legal basis for the RHI NW is the convention of July 16th 2003 between the cantons mentioned above. A performance agreement ("Leistungsvereinbarung") with the cantons and rules of procedure derive from the convention.	The „Kantonale Heilmittelkontrolle" is part of the „Gesundheitsdirektion des Kantons Zürich" (Health Directorate of the canton Zurich). As the „Regionale Fachstelle für Heilmittelkontrolle" (Regional Competence Center for the Control of Therapeutic Products) this unit provides inspection services that are laid down in bilateral contracts with the partner cantons and the principality of Liechtenstein.	IRM-S is a unit of Dipartimento della Sanità e della Socialità del canton Ticino.	The legal basis for the ISOPTh is the convention of November 14th 2005 between the cantons mentioned above. The administration of the ISOPTh is affiliated to the administration of the canton Fribourg.
Organisation	The Agency is structured into four operational sectors and three administrative departments. Division "Inspectorates and Licences" is in the "Licensing Sector". The head of the division reports to the head of the "Licensing sector" who reports to the director-general of the Agency. The heads of the sectors form the management board of Swissmedic.	The supervisory organ is the Inspectorate Council (Inspektoratsrat, IR) that reports to a body formed by the directors of public health from the participating cantons ("Gesundheitsdirektorenkonferenz der Nordwestschweiz"). Administrative decisions by the IR are binding for the RHI NW. The RHI NW is structured into the following sectors: • Direction • Administration • Planning and infrastructure • Quality assurance • Inspections	The „Kantonale Heilmittelkontrolle Zürich" is divided in three operative units, i.e. inspectorate, laboratory, and administration (cf. current organisation chart on the homepage). The head of the unit reports to the director of public health of the canton of Zurich.	The head of the inspectorate hierarchically reports to the cantonal pharmacist of canton Ticino.	The ISOPTh is supervised by a directorial committee composed of the cantonal pharmacists of the participating cantons.

	Swissmedic	RHI NW	RFS-OZ	IRM-S	ISOPTh
Number of inspectors [2]:	about 11	5	about 11	1	3
Accreditation ISO/IEC 17020	since June 2006	since August 2001	since August 2000	since July 2005	since November 2006
Common inspection duties covered by the accreditation	Inspections of manufacturers (including contract laboratories) of finished dosage forms and/or of APIs and wholesalers, importers, exporters, traders abroad of finished dosage forms and/or APIs [3].				
Additional inspection duties (covered by the accreditation)	Inspection of blood establishments and rare pharmaceutical techniques. In certain cases such as for-cause inspections or delegation of an inspection, the IoS also inspects pharmaceuticals (possible scope see “common inspection duties”).	Storage of human blood and labile blood products, and other inspections delegated (narcotics) from an involved canton within its competence.	Storage of human blood and labile blood products, pharmacies, drug stores, pharmacies of self-dispensing doctors, aspects of the narcotic law.		Inspections of sites with a cantonal manufacturing license, on delegation from the canton concerned.
Other inspection duties (not covered by the accreditation)	Inspection of manufacturers and wholesalers of transplants products, transplant establishments and transplantation centers, microbiological and serological laboratories and laboratories performing genetic analyses on humans. GCP-, PV- and GLP-inspections.				

[2] An inspector is someone qualified to carry out inspections, irrespective whether inspections are only part of the tasks. The number given here is limited to persons involved in GMP/GDP inspections only.

[3] For details, see annex 2 to I-SMI.RL.02.