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3 **Guideline on good pharmacovigilance practices (GVP)**
4 **Module IV – Pharmacovigilance audits**

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42 IV.A. Introduction

43 Following the entry into force of the new legislation on pharmacovigilance in July 2012, there is a
44 requirement for marketing authorisation holders, competent authorities in the Member States and the
45 European Medicines agency (the Agency) to perform audits of their pharmacovigilance systems [DIR
46 Art 101(2), Art 104(2), REG Art 28f], including risk based audits of their quality systems [IR Art 13
47 (1), Art 17 (1).]

48 For the purposes of this module reference to pharmacovigilance audit(s) and pharmacovigilance audit
49 activity(ies) are deemed to include pharmacovigilance system audits and audit(s) of the quality system
50 for pharmacovigilance activities.

51 The minimum requirements of the pharmacovigilance systems and the quality system are set out in
52 the Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of
53 pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament
54 and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (IR). Risk-
55 based audits of the pharmacovigilance system contain all areas listed in Directive 2001/83/EC (DIR)
56 and Regulation (EC) 726/2004 (REG). The specificities of the risk-based audits of the quality system
57 [for pharmacovigilance activities] are as described in the Implementing Measures [IR Art 8,10,
58 11,12,13(1) for marketing authorisation holders, and IR Art 8,14,15,16,17(1) for national competent
59 authorities and the Agency.]

60 The overall description and objectives of pharmacovigilance systems and quality systems for
61 pharmacovigilance activities are referred to in **Module I**, while the specific pharmacovigilance processes
62 are described in each respective Module of GVP.

63 In this Module, all applicable legal requirements are referenced in the way explained in the **GVP**
64 **Introductory Cover Note** and are usually identifiable by the modal verb “shall”. Guidance for the
65 implementation of legal requirements is provided using the modal verb “should”.

66 This Module provides guidance on planning and conducting the legally required audits, and in respect
67 of the operation of the EU regulatory network, the role, context and management of pharmacovigilance
68 audit activity. This Module is intended to facilitate the performance of pharmacovigilance audits,
69 especially to promote harmonisation, and encourage consistency and simplification of the audit
70 process. The principles in this Module are aligned with internationally accepted auditing standards*,
71 issued by relevant international auditing standardisation organisations*¹ and support a risk-based
72 approach pharmacovigilance audits.

73 Section **IV.B.** outlines the general structures and processes that should be followed to identify the most
74 appropriate pharmacovigilance audit engagements and describes the steps which can be undertaken
75 by marketing authorisation holders, competent authorities in Member States and the European
76 Medicines Agency, to plan, conduct and report upon an individual pharmacovigilance audit
77 engagements. This Section also provides an outline of the general quality system and record
78 management practices for pharmacovigilance audit processes.

79 Section **IV.C.** provides and outline of the operation of the EU network in respect of pharmacovigilance
80 audits.

¹ More details regarding **The Institute of Internal Auditors (IIA)** www.theiia.org; the **International Organisation for Standardisation (ISO)** www.iso.org; **Information Systems Audit and Control Association (ISACA)** www.isaca.org; **The International Auditing and Assurance Standards Board (IAASB)** www.ifac.org; **The International Organisation of Supreme Audit Institutions (INTOSAI)** www.issai.org.

81 Note for public consultation: Terms marked with a star (*) are included in a glossary of terms that
82 defines terms and abbreviations in an annex at the end of the Module. After public consultation, this
83 annex will be deleted, as these definitions as finalised will be incorporated in the GVP Annex Definitions

84 **IV.B. Structures and processes**

85 ***IV.B.1. Pharmacovigilance audit and its objective***

86 Pharmacovigilance audit activities should verify, by examination and evaluation of objective evidence,
87 the appropriateness and effectiveness of the implementation and operation of a pharmacovigilance
88 system, including its quality system for pharmacovigilance activities.

89 In general, an audit is a systematic, disciplined, independent and documented process for obtaining
90 evidence and evaluating it objectively to determine the extent to which the criteria are fulfilled,
91 contributing to the improvement of risk management, control and governance processes. Audit
92 evidence consists of records, statements or other information, which are relevant to the audit criteria
93 and verifiable. Audit criteria are, for each audit objective, the standards of performance and control
94 against which the auditee and its activities will be assessed. In the context of pharmacovigilance,
95 audit criteria should reflect the requirements for the pharmacovigilance system, including its quality
96 system for pharmacovigilance activities, as found in the legislation and guidance.

97 ***IV.B.2. The risk-based approach to pharmacovigilance audits***

98 A risk-based approach is one that uses techniques to determine the high-risk areas, where risk is
99 defined as the probability of an event occurring that will have an impact on the achievement of
100 objectives, taking account of the severity of its outcome and/or likelihood of non-detection by other
101 methods. The risk-based approach to audits focuses on the areas of highest risk to the organisation's
102 pharmacovigilance system, including its quality system for pharmacovigilance activities. In the context
103 of pharmacovigilance, the risk to public health is of prime importance. Risk is assessed at the
104 following stages:

- 105 • strategic level audit planning resulting in an audit strategy (long term approach), which should be
106 endorsed by senior management;
- 107 • tactical level audit planning resulting in an audit programme, setting audit objectives, and the
108 extent and boundaries, often termed as scope, of the audits in that programme; and
- 109 • operational level audit planning resulting in an audit plan for individual audit engagements,
110 prioritising audit tasks based on risk and utilising risk-based sampling and testing approaches, and
111 reporting of audit findings in line with their relative risk level and audit recommendations in line
112 with the suggested grading system [see [IV.B.2.3.1.](#)]

113 In order to implement a risk-based approach to pharmacovigilance audits, the auditors should carry
114 out and document risk assessments as a basis for the strategic, tactical and operational planning of
115 pharmacovigilance audit activity in their organisation (see [IV.B.2.1.](#), [IV.B.2.2.](#) and [IV.B.2.3.](#)
116 respectively).

117 **IV.B.2.1.Strategic level audit planning**

118 The audit strategy is a high level statement of how the audit activities will be delivered over a period of
119 time, longer than the annual programme, usually for a period of 3-5 years. The audit strategy includes
120 a list of all possible audits that could be performed and an assessment of risk, resources and training

121 needs. The audit strategy is used to outline the areas highlighted for audit, the audit themes as well as
122 the methods and assumptions on which the audit programme is based.

123 The audit strategy should cover the governance, risk management and internal controls of all parts of
124 the pharmacovigilance system including:

- 125 • all pharmacovigilance processes and tasks;
- 126 • the quality system for pharmacovigilance activities;
- 127 • interactions and interfaces with other departments, as appropriate;
- 128 • pharmacovigilance activities conducted by affiliated organisations or activities delegated to another
129 organisation (e.g. regional reporting centres, MAH affiliates or third parties).

130 This is a non-prioritised, non-exhaustive list of examples of risk factors that could be considered for the
131 purposes of a risk assessment at the strategic audit planning level:

- 132 • changes to legislation and guidance;
- 133 • mergers, major re-organisation or other re-structuring of the pharmacovigilance system,
134 (specifically for marketing authorisation holders, this may lead to a significant increase in the
135 number of products for which the system is used);
- 136 • change in key managerial function(s);
- 137 • risk to availability of adequately trained and experienced pharmacovigilance staff, e.g. due to
138 significant turn-over of staff, deficiencies in training processes, recent re-organisation, recent
139 increase in volumes of work;
- 140 • significant changes to the system since the time of a previous audit, e.g. introduction of a new
141 database(s) for pharmacovigilance activities or of a significant upgrade to the existing database(s),
142 changes to processes and activities in order to address new or amended regulatory requirements;
- 143 • first medicinal product on the market (for a marketing authorisation holder);
- 144 • medicinal product(s) on the market with specific risk minimisation measures or other specific
145 safety conditions such as requirements for additional monitoring;
- 146 • criticality of the process, e.g.:
 - 147 – for competent authorities: how critical is the area/process to proper functioning of the
148 pharmacovigilance system and the overall objective of safeguarding public health;
 - 149 – for marketing authorisation holders: how critical is the area/process to proper functioning of
150 the pharmacovigilance system. When deciding when to audit an affiliate or third party, the
151 marketing authorisation holder should consider the nature and criticality of the
152 pharmacovigilance activities that are being performed by affiliate or third party on behalf of the
153 marketing authorisation holder, in addition to considering the other factors included in this list;
- 154 • outcome of previous audits, e.g. has the area/process ever been audited (if not, then this may
155 need to be prioritised depending on criticality); if the area/process has previously been audited,
156 the audit findings* are a factor to consider when deciding when to re-audit the area/process,
157 including the implementation of agreed actions;
- 158 • identified procedural gaps relating to specific areas/processes;
- 159 • other information relating to compliance* with legislation and guidance, for example:

- 160 – for competent authorities: information from compliance* metrics (as described in the
161 Commission Implementing Regulation on the Performance of Pharmacovigilance Activities
162 Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC), from complaints,
163 from external sources, e.g. audits/assessments of the competent authority conducted by
164 external bodies;
- 165 – for marketing authorisation holders: information from compliance* metrics (as described in the
166 Commission Implementing Regulation on the Performance of Pharmacovigilance Activities
167 Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC), from inspections see
168 Module III, from complaints, from other external sources, e.g. audits;
- 169 • other organisational changes that could negatively impact on the area/process, e.g. if a change
170 occurs to a support function (such as information technology support) this could negatively impact
171 upon pharmacovigilance activities.

172 **IV.B.2.2. Tactical level audit planning**

173 An audit programme is a set of one or more audits planned for a specific timeframe, normally for a
174 year. The audit programme should be approved by the head of the organisation.

175 The risk-based audit programme should be based on an appropriate risk assessment and should focus
176 on:

- 177 • the quality system for pharmacovigilance activities;
- 178 • critical pharmacovigilance processes (see for example Module I and IR Art 11, 15);
- 179 • key control systems relied on for pharmacovigilance activities;
- 180 • areas identified as high risk, after controls have been put in place or mitigating action taken.

181 The risk-based audit programme should also take into account areas with insufficient past audit
182 coverage, and high risk areas identified by and/or specific requests from management and/or persons
183 responsible for pharmacovigilance activities.

184 The audit programme document should include a brief description of the plan for each audit to be
185 delivered, including its scope and objectives.

186 The rationale for the timing, periodicity and scope of the individual audits which form part of the audit
187 programme should be based on the documented risk assessment. However, risk-based
188 pharmacovigilance audit(s) should be performed at regular intervals to assure that the system
189 complies with the legislative requirements.

190 **IV.B.2.3. Operational level audit planning and reporting**

191 ***IV.B.2.3.1. Planning and fieldwork***

192 The organisation should ensure that written procedures are in place regarding the planning and
193 conduct of individual audits that will be delivered. Timeframes for all the steps required for the
194 performance of an individual audit should be settled in the relevant audit related procedures, and the
195 organisation should ensure that audits are conducted in accordance with the written procedures.

196 Individual pharmacovigilance audits should be undertaken in line with the approved risk-based audit
197 programme (see IV.B.2.2.). When planning individual audits, the auditor identifies and assesses the
198 risks relevant to the area under review and employs the most appropriate risk-based sampling and
199 testing methods, documenting the audit approach in an audit plan*.

200 **IV.B.2.3.2. Reporting**

201 The findings* and audit recommendations* of the auditors should be documented in an audit report
202 and be communicated to management in a timely manner. The audit process should include
203 mechanisms for communicating the audit findings* to the auditee* and receiving feedback, and
204 reporting the audit findings* and audit recommendations to management and relevant parties,
205 including those responsible for pharmacovigilance systems, in accordance with legal requirements and
206 guidance on pharmacovigilance audits. Audit findings and audit recommendations* should be reported
207 in line with their relative risk level and should be graded in order to indicate their relative criticality to
208 risks impacting the pharmacovigilance system, processes and parts of processes. The grading system
209 should be defined in the description of the quality system for pharmacovigilance, and should take into
210 consideration the thresholds noted below which would be used in further reporting under the legislation
211 as set out in [section IV.C.2](#):

- 212 • **critical** is a fundamental weakness in one or more pharmacovigilance processes or practices that
213 adversely affects the whole pharmacovigilance system and/or the rights, safety or well-being of
214 patients, or that poses a potential risk to public health and/or represents a serious violation of
215 applicable legislation and guidelines. The audit recommendation aims at introducing mitigating
216 action that addresses the risk of the critical audit finding so that it is not detrimental at the level
217 assessed anymore; immediate action is required;
- 218 • **major** is a significant weakness in one or more pharmacovigilance processes or practices, or a
219 fundamental weakness in part of one or more pharmacovigilance processes or practices that is
220 detrimental to the whole process and/or could potentially adversely affect the rights, safety or
221 well-being of patients and/or could potentially pose a risk to public health and/or represents a
222 violation of applicable legislation and guidelines which is however not considered serious. The
223 audit recommendation aims at introducing mitigating action that addresses the risk of the major
224 audit finding so that it is not detrimental at the level assessed anymore; prompt action is required;
- 225 • **minor** is a weakness in the part of one or more pharmacovigilance processes or practices that is
226 not expected to adversely affect the whole pharmacovigilance system or process and/or the rights,
227 safety or well-being of patients. The audit recommendation aims at introducing mitigating action
228 that addresses the risk of the minor audit finding so that it is not detrimental at the level assessed
229 anymore; action within a reasonable timeframe is required.

230 Serious concerns that need to be urgently addressed should be communicated in an expedited manner
231 to the auditee*'s management and the senior management.

232 **IV.B.2.4. Actions based on audit recommendations* and follow-up of audits**

233 The management of the organisation is responsible for ensuring that the organisation has a mechanism
234 in place to adequately address the audit recommendations* arising from pharmacovigilance audits,
235 including the preparation of an action plan.

236 Senior management and those charged with governance, should ensure that effective action is
237 implemented to address the audit findings and audit recommendations* arising from
238 pharmacovigilance audits or formally accept the risk of not taking action. The implementation of
239 agreed actions should be monitored in a systematic way, and the progress of implementation should
240 be communicated on a periodic basis to senior management.

241 Evidence of completion of actions should be recorded in order to document that issues raised during
242 the audit have been addressed.

243 Capacity for follow-up audits should be foreseen in the audit programme. They should be carried out as
244 deemed necessary, in order to verify the completion of agreed actions. [IR Art 13(2), Art 17(2)]

245 ***IV.B.3. Quality system and record management practices***

246 **IV.B.3.1. Competence of auditors and quality management of audit** 247 **activities**

248 ***IV.B.3.1.1. Independence and objectivity of audit work and auditors***

249 The organisation should assign the specific responsibilities for the pharmacovigilance audit activities.
250 Pharmacovigilance audit activities should be independent and separate from routine quality control*
251 activities relating to pharmacovigilance.

252 In order to be independent, audits should be conducted by those who have no actual or potential
253 conflicts of interest and who are not operationally involved in the activities to be audited. [IR Art
254 13(1)] The organisation's management should ensure this independence and objectivity in a structured
255 manner and document this.

256 Auditors should be free from interference in determining the scope of auditing, performing
257 pharmacovigilance audits and communicating audit results. The main reporting line should be to the
258 level within the organisation that allows the auditor(s) to fulfil their responsibilities (for example the
259 auditor(s) may functionally report to the head of the organisation or an oversight body like an audit
260 committee or management board).

261 Auditors can consult with technical experts, personnel involved in pharmacovigilance processes, and
262 with the person responsible for pharmacovigilance; however auditors should maintain an unbiased
263 attitude that allows them to perform audit work in such a manner that they have an honest belief in
264 their work product and that no significant quality compromises are made. Objectivity requires auditors
265 not to subordinate their judgement on audit matters to that of others.

266 ***IV.B.3.1.2. Qualifications, skills and experience of auditors and continuing professional*** 267 ***development***

268 Auditors should demonstrate and maintain proficiency in terms of the knowledge, skills and abilities
269 required to effectively conduct and/or participate in pharmacovigilance audit. The proficiency of audit
270 team members will have been gained through a combination of education, work experience and
271 training and, as a team, should cover knowledge, skills and abilities in:

- 272 • audit principles, procedures and techniques;
- 273 • applicable laws, regulations and other requirements relevant to pharmacovigilance;
- 274 • pharmacovigilance activities, processes and system(s);
- 275 • management system(s);
- 276 • organisational system(s).

277 Adequate training for auditors should also be considered by the organisation (see **Module I**).

278 ***IV.B.3.1.3. Evaluation of the quality of audit activities***

279 Evaluation of audit work can be undertaken by means of ongoing and periodic assessment of all audit
280 activities, auditee* feedback and self-assessment of audit activities.

281 **IV.B.3.2. Audits undertaken by outsourced audit service providers**

282 Ultimate responsibility for the operation and effectiveness of the pharmacovigilance system resides
283 within the organisation (i.e. within the Agency, competent authority or marketing authorisation
284 holder). Where the organisation decides to use an outsourced audit service provider to implement the
285 pharmacovigilance audit requirements on the basis of this GVP module and perform pharmacovigilance
286 audits:

- 287 • the requirements and preparation of the audit risk assessment, the audit strategy and audit
288 programme and individual engagements should be specified to the outsourced service providers,
289 by the organisation, in writing;
- 290 • the scope, objectives and procedural requirements for the audit should be specified to the
291 outsourced service provider, by the organisation, in writing;
- 292 • the organisation should obtain and document assurance of the independence and objectivity of
293 outsourced service providers;
- 294 • the outsourced audit service provider should also follow the relevant parts of this GVP module.

295 **IV.C. Operation of the EU network**

296 ***IV.C.1. Pharmacovigilance audit policy framework and organisational*** 297 ***structure***

298 **IV.C.1.1. Marketing authorisation holders in the EU**

299 ***IV.C.1.1.1. Requirement to perform an audit***

300 The marketing authorisation holder in the EU is required to perform regular risk-based audit(s) of their
301 pharmacovigilance system [DIR Art 104(2)], including audit(s) of its quality system to ensure that the
302 quality system complies with the quality system requirements [IR Art 8,10,11,12,13(1)]. The dates
303 and results of audits and follow-up audits shall be documented [IR Art 13(2)]

304 See [IV.C.2.](#) for further details of the requirements for audit reporting by the marketing authorisation
305 holder to competent authorities and the Agency.

306 ***IV.C.1.1.2. The qualified person responsible for pharmacovigilance in the EU (QPPV)***

307 The responsibilities of the QPPV in respect of audit are provided in [Module I](#). Furthermore, the QPPV
308 should receive pharmacovigilance audit reports, and provide information to the auditors relevant to the
309 risk assessment, including knowledge of status of corrective and preventative actions.

310 The QPPV should be notified of any audit findings relevant to the pharmacovigilance system in the EU,
311 irrespective of where the audit was conducted.

312 **IV.C.1.2. Competent authorities in Member States and the European** 313 **Medicines Agency**

314 ***IV.C.1.2.1. Requirement to perform an audit***

315 The Agency shall perform regular independent audits of its pharmacovigilance tasks [REG Art 28f] and
316 competent authorities in Member States shall perform a regular audit of their pharmacovigilance
317 system [DIR Art 101(2)]. Included in their obligation to perform audits of their pharmacovigilance

318 system/tasks, competent authorities in the Member States and the Agency shall perform risk-based
319 audits of the quality system as well, at regular intervals according to a common methodology to ensure
320 that the quality system complies with the requirements [IR Art 8,14,15,16,17(1)]. The dates and
321 results of audits and follow-up audits shall be documented [IR Art 17(2)].

322 ***IV.C.1.2.2. Common methodology***

323 In order to have a useful audit system, all audits at the competent authorities in the Member States
324 and the European Medicines Agency should have a common ground in terms of methodology. This
325 should ensure harmonised planning, implementation and reporting by every competent authority in
326 Member States and at the Agency.

327 ***IV.C.1.2.3. The Pharmacovigilance Risk Assessment Committee (PRAC)***

328 The mandate of the Pharmacovigilance Risk Assessment Committee (PRAC) shall cover all aspects of
329 the risk management of the use of medicinal products for human use, having due regard to the design
330 and evaluation of pharmacovigilance audits [REG Art 61a(6)].

331 ***IV.C.2. Requirements for audit reporting in the EU***

332 **IV.C.2.1. Reporting by the marketing authorisation holder**

333 The marketing authorisation holder shall place a note concerning the main audit findings* and audit
334 recommendations, including critical and major audit findings/audit recommendations of any audit
335 relating to the pharmacovigilance system in the pharmacovigilance system master file (PSMF). Based
336 on the audit findings*and audit recommendations, the marketing authorisation holder shall ensure that
337 an appropriate plan detailing corrective and preventative action is prepared and implemented. Once
338 the corrective and preventative actions have been fully implemented, the note may be removed [DIR
339 Art 104(2), IR Art 13(2)]. Objective evidence is required in order that any note of audit findings can be
340 removed from the pharmacovigilance system master file(see [Module II](#)).

341 The marketing authorisation holders should ensure that they comply with reporting commitments in
342 line with the legislation, GVP guidance and their internal reporting policies. The dates and results of
343 audits and follow-up audits shall be documented [IR Art 13(2)].

344 **IV.C.2.2. Reporting by competent authorities in Member States and the** 345 **Agency**

346 Competent authorities in Member States, and the Agency should ensure that they comply with
347 reporting commitments in line with the legislation, GVP guidance and their internal reporting policies.

348 Competent authorities in Member States shall report the results [of their pharmacovigilance system
349 audits] to the Commission on 21 September 2013 at the latest and then every 2 years thereafter [DIR
350 Art 101(2)].

351 The Agency shall report the results [of its pharmacovigilance system audits] to its Management Board
352 on a 2-yearly basis [REG Art 28f].

353 The reports to the European Commission will follow an agreed format.

354 ***IV.C.3. Confidentiality***

355 Documents and information collected by the internal auditor will be treated with appropriate
356 confidentiality and discretion, and also respect Directive 95/46/EC [Regulation (EC) No. 45/2001 for
357 Community institutions and bodies] and national legislation on the protection of individuals with regard
358 to the processing of personal data and on the free movement of such data.

359 ***IV.C.4. Transparency***

360 The European Commission shall make public a report on the performance of pharmacovigilance tasks
361 by the Agency on 2 January 2014 at the latest and subsequently every 3 years thereafter [REG Art 29]
362 and on the performance of pharmacovigilance tasks by the competent authorities in Member States on
363 21 July 2015 at the latest and then every 3 years thereafter [DIR Art 108(b)].

364

365 GLOSSARY OF TERMS

366 Audit: a systematic, disciplined, independent and documented process for obtaining audit evidence and
367 evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 19011
368 (3.1²).

369 Audit finding(s): results of the evaluation of the collected audit evidence against audit criteria
370 (ISO19011 (3.4)²).

371 Audit plan: Description of activities and arrangement for an individual audit (ISO19011 (3.12)²).

372 [Audit] recommendation(s): Describe the course of action management might consider to rectify
373 conditions that have gone awry, and to strengthen weaknesses in systems of [management] control.
374 [Audit] recommendations should be positive and as specific as possible. They should also identify who
375 is to act on them. (Sawyer, L.B. , Dittenhofer M.A. (2003), Sawyer's Internal Auditing, 5th Edition, The
376 IIA Research Foundation, p.358)

377 Auditee: [entity] being audited (ISO 19011 (3.7)²).

378 Benchmarking of the European Medicines Agencies (BEMA): HMA (Joint Human and Veterinary) has
379 established a benchmarking programme among the human and veterinary medicines agencies with the
380 broad aim to contribute to the development of a world-class medicines regulatory system based on a
381 network of agencies operating to best practice standards. A Steering Group has been established to
382 develop the programme and oversee its roll-out.

383 Compliance: Conformity and adherence to policies, plans, procedures, laws, regulations, contracts, or
384 other requirements (*IIA International Standards for the Professional Practice of Internal Auditing*³).

385 Control(s): Any action taken by management, ... and other parties to manage risk and increase the
386 likelihood that established objectives and goals will be achieved. Management plans, organises, and
387 directs the performance of sufficient actions to provide reasonable assurance that objectives and goals
388 will be achieved (*IIA International Standards for the Professional Practice of Internal Auditing*⁴).

389 Finding(s): see Audit findings

390 International Auditing Standards: Standards issued by International Auditing Standardisation
391 Organisations*.

392 International Auditing Standardisation Organisations: More details regarding **The Institute of**
393 **Internal Auditors** (IIA) standards can be found at [http://www.theiia.org/guidance/standards-and-](http://www.theiia.org/guidance/standards-and-guidance/ippf/standards/full-standards)
394 [guidance/ippf/standards/full-standards](http://www.theiia.org/guidance/standards-and-guidance/ippf/standards/full-standards); the **International Organisation for Standardisation** (ISO)
395 standard 19011 "Guidelines for quality and/or environmental management systems auditing."
396 <http://www.iso.org/iso/home.html>; **Information Systems Audit and Control Association** (ISACA)
397 standards can be found at <http://www.isaca.org/Standards> ; **The International Auditing and**
398 **Assurance Standards Board** (IAASB) standards can be found at [http://www.ifac.org/auditing-](http://www.ifac.org/auditing-assurance/clarity-center/clarified-standards)
399 [assurance/clarity-center/clarified-standards](http://www.ifac.org/auditing-assurance/clarity-center/clarified-standards); The International Organisation of Supreme Audit
400 Institutions (INTOSAI) can be found at <http://www.issai.org/composite-347.htm>

401 Organisation: unless otherwise specified, reference to "organisation" is deemed to refer to Marketing
402 Authorisation Holder or National Competent Authority or EMA.

403 Standards: see International Auditing Standards.

² the **International Organisation for Standardisation** (ISO) www.iso.org

³ **The Institute of Internal Auditors** (IIA) www.theiia.org

