

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30

Article type : AAPM Scientific Report

mechalaj@mskcc.org

Electronic Charting of Radiation Therapy Planning and Treatment: Report of Task Group 262

James G Mechalakos (Chair)

Dept. of Medical Physics
Memorial Sloan Kettering Cancer Center, New York, NY 10065
USA

Sonja Dieterich (Co-chair)

Dept. of Radiation Oncology
U.C. Davis Medical Center, Sacramento, CA 95618
USA

Luis E. Fong de los Santos

Dept of Radiation Oncology
Mayo Clinic, Rochester, MN 55905
USA

Sandra C. Fontenla

Dept. of Medical Physics
Memorial Sloan Kettering Cancer Center, New York, NY 10065
USA

Joseph Hanley

Radiation Oncology
Princeton Radiation Oncology, Monroe, NJ 08831
USA

Vijay A. Harwalkar

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1002/MP.15116](https://doi.org/10.1002/MP.15116)

31 Radiation Therapy Dept.
32 Louis Stokes V.A. Medical Center, Cleveland, OH
33 USA

34 **Linda X. Hong,**
35 Dept. of Medical Physics
36 Memorial Sloan Kettering Cancer Center, New York, NY
37 USA

38 **Y. Jessica Huang,**
39 Radiation Oncology
40 University of Utah, Salt Lake City, UT 84109
41 USA

42 **Grace Gwe-Ya Kim,**
43 Radiation Medicine and Applied Science
44 Univ. of California San Diego, La Jolla, CA 92093-0865
45 USA

46 **Susan L. Richardson**
47 Radiation Oncology
48 Swedish Medical Center, Seattle, WA 98104
49 USA

50 **Steven G. Sutlief**
51 Banner MD Anderson Cancer Center
52 Gilbert, AZ
53 USA

54 **Sridhar Yaddanapudi**
55 Dept. of Radiation Oncology
56 University of Iowa, Iowa City, IA 52242
57 USA

58 **Sue Merkel**
59 Dept. of Radiation Oncology
60 University of Michigan, Ann Arbor, MI 48109-5010
61 USA

62 **Mark Parry**

63 Security Operations Center
64 Mayo Clinic, Rochester, MN 55905
65 USA

67 Running Title: Electronic Charting in RT: AAPM TG 262

69 Corresponding author:
70 James Mechalakos
71 David H. Koch Center for Cancer Care
72 Memorial Sloan Kettering Cancer Center
73 530 E. 74th St.
74 New York NY 10021

75 **Disclosure Statement**

76 The Chair of the AAPM Task Group 262 has reviewed the required Conflict of Interest statement on file
77 for each member of AAPM Task Group 262 and determined that disclosure of potential Conflicts of
78 Interest is an adequate management plan. Disclosures of potential Conflicts of Interest for each member
79 of AAPM Task Group 262 are found at the close of this document.

80
81
82
83

84 **ABSTRACT**

85 While most Radiation Oncology clinics have adopted electronic charting in one form or another,
86 no consensus document exists that provides guidelines for safe and effective use of the Radiation
87 Oncology electronic medical records (RO-EMR). Task Group 262 was formed to provide these guidelines
88 as well as to provide recommendations to vendors for improving electronic charting functionality in the
89 future. Guidelines are provided in the following areas: Implementation and training for the RO-EMR,
90 acceptance testing and quality assurance (QA) of the RO-EMR, use of the RO-EMR as an information
91 repository, use of the RO-EMR as a workflow manager, electronic charting for brachytherapy and non-
92 standard treatments, and information technology (IT) considerations associated with the RO-EMR. The
93 report was based on a literature search by the task group, an extensive survey of task group members

94 on their respective RO-EMR practices, an AAPM membership survey on electronic charting, as well as
95 group consensus.

96
97 Key words: Electronic Medical Records, EMR, Electronic Charting, Radiation Oncology, workflow design,
98 Quality assurance, implementation committee, chart check, checklist, IT infrastructure, electronic
99 document, care path, prescription, treatment history, electronic approval, written directive.

100
101

102	Table of Contents	
103	1. LIST OF SYMBOLS AND ACRONYMS.....	8
104	2. INTRODUCTION	9
105	2.A. Charges of the task group	12
106	2.B. Methods and materials	13
107	2.B.1. TG-262 member survey	13
108	2.B.2. AAPM member survey	14
109	2.C. Structure of this report	15
110	3. SUMMARY OF RECOMMENDATIONS.....	16
111	3.A. Implementation	16
112	3.B. Acceptance Testing and QA	17
113	3.C. Information Management.....	17
114	3.D. Workflow and Communication	18
115	3.E. Brachytherapy and Non-Standard Devices	19
116	3.F. IT Infrastructure and Management.....	19
117	3.G. Challenges and Future Improvements for both Users and Vendors	20
118	4. IMPLEMENTATION OF THE RO-EMR.....	21
119	4.A. Committee team and size.....	21

120	4.B. Definition of goals and milestones of the RO-EMR system.....	23
121	4.C. Project timelines and protected time	25
122	4.D. Resources for comparison of charting systems.....	26
123	4.E. Test environment.....	27
124	4.F. Pilot or transition period.....	28
125	4.G. Transition and Training	28
126	4.H. Ease of transition and “buy-in”	29
127	5. ACCEPTANCE TESTING and QA OF THE RO-EMR	29
128	5.A. Acceptance testing and commissioning.....	30
129	5.B. Ongoing management of the system	31
130	5.C. QA program	31
131	5.D. Software Upgrades.....	33
132	5.E. Automation and Standardization.....	35
133	6. INFORMATION MANAGEMENT	35
134	6.A. Matched user group rights and approval rights	40
135	6.B. Document design and storage: Format, input, efficacy, scope, traceability and	
136	accessibility (FIESTA).	42
137	6.C. Document repositories	44
138	6.D. Free text notes.....	44
139	6.E. Consistent entry of information.....	45
140	6.F. Electronic signatures	45
141	6.G. Simulation orders.....	46
142	6.H. Prescription	46
143	6.I. Treatment plan documentation.....	48
144	6.J. Checklists	48

145	6.K. Special circumstances	49
146	6.L. Incomplete treatment sessions or courses	50
147	6.M. Treatment course changes	51
148	6.N. Emergency and urgent cases.....	52
149	6.O. Chart reviews	52
150	6.P. Preparation and transmission of patient records.....	53
151	7. WORKFLOW DESIGN AND COMMUNICATION IN THE RO-EMR.....	53
152	7.A. Connecting tasks to form a workflow.....	55
153	7.B. Creating tasks for the workflow.....	56
154	7.C. Linkage of documents with workflow tasks	57
155	7.D. Simulation orders in the workflow	58
156	7.E. Prescription entry in the workflow.....	59
157	7.F. Incorporating automated charge capture in workflows.....	59
158	7.G. Formalizing the release of workflows into the clinic	60
159	7.H. Ongoing refinement of workflows.....	60
160	7.I. Consistency in communication	61
161	7.J. “Handoffs” and “handshakes”.....	61
162	7.K. Standardization of user interfaces.....	62
163	8. BRACHYTHERAPY AND NON-STANDARD DEVICES.....	62
164	8.A. Definitions of RO-EMR Connectivity Categories.....	63
165	8.A.1. Standalone.....	63
166	8.A.2. Limited connectivity	64
167	8.A.3. Full connectivity	64
168	8.B. Shortcomings	64
169	8.C. Brachytherapy-specific challenges	66

170	8.C.1. Requirements of written directive.....	66
171	8.C.2. Guidance on electronic signatures specific to Brachytherapy	70
172	8.D. Additional Recommendations.....	71
173	8.D.1. RO-EMR connectivity software and new non-standard devices	71
174	8.D.2. Stakeholders working with the non-standard devices on RO-EMR implementation	
175	committee	71
176	8.D.3. Prescription entry for non-standard devices	72
177	8.D.4. Plan documentation and documentation of billable activities	73
178	9. IT INFRASTRUCTURE AND DATA MANAGEMENT.....	73
179	9.A. IT infrastructure:	74
180	9.B. Peopleware & Management Strategies:	76
181	9.B.1 Team members	76
182	9.B.2 Familiarity with terminology, technical concepts, architecture and management of the	
183	IT infrastructure.	77
184	9.C. Hardware Infrastructure Type and Design:.....	77
185	9.C.1. Clinical needs, institutional restrictions, and constraints	78
186	9.C.2. Deployment and Design.....	80
187	9.D. Database Architecture.....	80
188	9.D.1. Disaster recovery (DR) and high availability (HA) solutions	81
189	9.D.2 Mobile device connectivity.....	82
190	9.D.3. Electronic storage capacity	82
191	9.D.4. Information security threats	83
192	9.D.5. Test environment	84
193	9.D.6. Electronic screen space (dual monitor setup)	85
194	9.D.7. Application services.....	85
195	9.D.8. Risk of running database queries on clinical production systems.	86

196	10. CHALLENGES AND FUTURE IMPROVEMENTS FOR BOTH USERS AND	
197	VENDORS	88
198	10.A. Continued focus on automation	88
199	10.B. Checklist functionality	89
200	10.B.1. Multi-user checklists	89
201	10.C. More granular approval mechanisms	89
202	10.D. Vendor sandbox	90
203	10.E. More flexibility in structure and filtering of document repositories	90
204	10.F. Stronger communication tools	91
205	10.G. Greater flexibility and efficiency in workflow managers	91
206	10.H. Handshake functionality and acknowledgment	93
207	10.I. Concurrent use of different workspaces and custom views	93
208	10.J. Improved connectivity with H-EMR and non-standard systems	94
209	10.K. RO-EMR in Standard database format with access – API functionality	94
210	10.L. Databases should be sufficiently robust to queries.	95
211	10.M. Provision of optional interfaces for non-standard systems	95
212	11. DISCUSSION	96
213	12. REFERENCES	100
214	13. APPENDICES	104
215	Appendix 1- Acceptance criteria for a new RO-EMR system	104
216	Appendix 2- Sample questions for clinic visitations	104

217
218

219 **1. LIST OF SYMBOLS AND ACRONYMS**

220	AAPM	American Association of Physicists in Medicine
221	API	Application programming interface

222	ASTRO	American Society for Radiation Oncology
223	CIED	Cardiovascular Implantable Electronic Device
224	DICOM	Digital Imaging and Communications in Medicine
225	DIBH	Deep inspiration breath-hold technique
226	DNR	Do not resuscitate
227	DR	Disaster recovery
228	DRR	Digitally reconstructed radiograph
229	DVH	Dose volume histogram
230	EMR	Electronic medical record
231	EOT	End of treatment
232	ERP	Enterprise resource planning
233	FIESTA	Format, Input, Efficacy, Scope Traceability, and Accessibility
234	H-EMR	Hospital EMR (Epic™, for example)
235	HA	High availability
236	HDR	High dose rate brachytherapy
237	HITECH	Health Information Technology for Economic and Clinical Health
238	H&P	History and physical
239	IEC	International Electrotechnical Commission
240	IHE	Integrating the Healthcare Enterprise
241	IGRT	Image-guided radiation therapy
242	IMRT	Intensity-modulated radiation therapy
243	IS	Information systems
244	IT	Information technology
245	LDR	Low dose rate
246	OAR	Organ-at-risk
247	OIS	Oncology information system
248	OR	Operating room
249	P&P	Policies and procedures
250	QA	Quality assurance
251	RO-EMR	Radiation Oncology Electronic Medical Record
252	RT-PACS	Radiotherapy picture archiving and communication system
253	R&V	Record and verify

254	SBRT	Stereotactic Body Radiation Therapy
255	SIB	Simultaneous integrated boost
256	SQL	Structured Query Language
257	SSN	Social security number
258	TMS	Treatment management system
259	TPS	Treatment planning system
260	VMAT	Volumetric modulated arc therapy
261	VPN	Virtual private network
262		

263 2. INTRODUCTION

264

265 Electronic medical record (EMR) usage has increased significantly since the Health Information
266 Technology for Economic and Clinical Health (HITECH) Act in 2009^{1,2}. Many studies have shown the
267 effectiveness of the EMR in reducing errors and increasing efficiency³⁻¹⁰. As different medical specialties
268 would have their own challenges in adopting information technology into their specific clinical practices,
269 it is important for each individual specialty to define their own standards and guidelines. Adoption and
270 maintenance of the Radiation Oncology electronic medical record (RO-EMR) requires significant effort
271 and presents unique challenges compared to other EMR systems as related in a number of publications
272 and presentations. Benedetti presented a comprehensive overview of the transition of a Radiation
273 Oncology clinic from paper to electronic charting for both external beam therapy and brachytherapy¹¹.
274 Kirkpatrick et al. discussed their institution’s clinical experience implementing RO-EMR including a
275 discussion of the interplay between the RO-EMR and the more general hospital electronic medical
276 record (H-EMR)¹². Both experiences are common in that a multidisciplinary team is formed which
277 focuses on management of documentation and workflow with investment in hardware and software,
278 and an increased reliance on IT support. Colonias et al discussed development and integration of an
279 EHR system, including the design of modules for information acquisition, tracking and analysis¹³. Weeks
280 and Coleman discuss the electronic medical record and its part in Radiation Oncology, noting that while
281 Radiation Oncology adopted computerization early through computerized treatment planning systems,
282 EMR adoption “struggled with overcoming legal and communication continuity concerns” which
283 contributed to the adoption of RO-EMR systems after computerized treatment planning had
284 progressed¹⁴. Mechalakos and Dieterich discuss radiation oncology electronic charting within the larger

285 context of quality and safety¹⁵. Additional reports on in house and commercial system development
286 utilization are available¹⁶⁻¹⁹. Although focusing primarily on the record and verify (R&V) system, IAEA
287 HHR No.7²⁰ and IEC 62274ED.1.0²¹ provide a comprehensive list of tests. While the aforementioned
288 publications discuss various aspects of the RO-EMR from different perspectives, a synthesis of overall
289 clinical guidelines is lacking. Electronic charting has been shown to improve the quality and safety of
290 patient care as well as efficiency of workflow^{12,22,23}, so if the system is properly configured to meet the
291 needs of the clinic while providing safe care, the gains in efficiency and safety can offset the costs and
292 effort of configuration. Facilities and committees adopting a new RO-EMR system would benefit from a
293 set of guidelines from those who have implemented various RO-EMR systems and overcome many of its
294 challenges. Therefore a task group dedicated to the electronic charting for external beam radiation
295 therapy and brachytherapy was created.

296 The “electronic chart” is broadly defined as the electronic analog of the traditional “paper chart”
297 and the RO-EMR replaces the traditional “paper chart” that was specifically used in Radiation Oncology
298 which was passed between different members of the clinical team (medical physicists, dosimetrists,
299 radiation therapists, radiation oncologists, nurses, support staff) as needed. Clinics typically purchase an
300 RO-EMR system from one of the vendors of such systems and it is often part of a larger system called
301 the Oncology Information System (OIS) which includes the R&V system which sends and receives
302 treatment data to and from the treatment machine.

303 The goal of the task group was to create basic guidance on the radiation oncology electronic
304 charting process that includes recommendations for management of the system configuration,
305 interfacing with the hospital EMR system, and basic quality assurance (QA) associated with
306 implementation and maintenance of a RO-EMR. The scope of this report includes those facets of
307 electronic charting (i.e. prescription, treatment planning, QA documents, treatment planning workflow,
308 task lists, and billing to name a few) related to external beam radiotherapy for linac based systems that
309 typically employ one of the commercially available RO-EMR solutions, as well as for brachytherapy
310 treatment, and for “non-standard” delivery systems from the electronic charting perspective such as
311 Tomotherapy, Cyberknife, etc which may not be compatible with the commercial systems typically used
312 by linac based practices but may offer custom solutions. Items such as clinic appointments and follow up
313 scheduling are beyond the scope of this task group, except as they relate to the planning and delivery
314 process. Explicit guidance on treatment delivery systems and record and verify (R&V) systems, even
315 though they may be part of the same software suite as the electronic chart, is also beyond the scope of

316 this report, except in areas where the R&V system communicates with the electronic chart, for example
317 in transferring the treatment record.

318 Conversion to electronic charting or between different systems requires the time and effort of a
319 dedicated committee, as each document is evaluated and converted and workflows are restructured. In
320 addition, adequate time is required to train staff. A committee directing such a transition will invariably
321 encounter roadblocks along the way in which potential advantages of the system can become
322 disadvantages if not managed properly. Potential challenges can be avoided or handled more
323 expediently if the committee and the clinic is prepared for them. For example, insufficiently
324 consolidated storage of patient records, even though they can be accessed from anywhere, can cause
325 confusion. Inadequate training or an overly granular electronic workflow manager can cause
326 inefficiency and disrupt workflow. Also, the electronic approval system may be troublesome if it is
327 overly restrictive or not sufficiently adaptable. Most importantly, the transition to electronic charting
328 fundamentally alters the workflow, communication, and QA paradigms of the clinic. Guidance can help
329 a facility's committee identify a suitable RO-EMR system, transition and implement it in a way that
330 supports efficiency and does not compromise patient safety due to excessive confusion, ineffective
331 workflows, inadequate/incorrect documentation, or poor communication.

332

333 **2.A. Charges of the task group**

334 The charges of task group 262 are as follows:

- 335 1. To provide guidance in the administration, design, and implementation of electronic charting for
336 simulation, planning, and treatment using external beam radiotherapy and brachytherapy.
- 337 2. To provide guidance in maintaining safe clinical processes and communication when designing
338 an electronic charting system- both during the transition to the new system and once the
339 system is implemented.
- 340 3. To provide guidance in implementation and management of electronic charting in the context of
341 other systems in the clinic and other programs in the hospital (billing, IT, medical records).
- 342 4. To provide a list of desired features for a robust electronic charting system and warn of
343 potential pitfalls based on accumulated clinical experience.

344

345 **2.B. Methods and materials**

346 An extensive literature search on electronic charting found that data on good clinical practice in
347 electronic charting for radiation oncology were scarce. Therefore, in order to formulate consensus
348 guidelines for this report, the task group carried out two surveys of current clinical practice:

- 349 1. TG-262 member survey: a survey of task group members on their RO-EMR practice (12
350 respondents)
- 351 2. AAPM member survey: A survey of the AAPM membership on their RO-EMR practice (421
352 respondents)

353

354 The two surveys are briefly described below.

355 **2.B.1. TG-262 member survey**

356 The TG-262 member survey consisted of 150 questions developed by task group members. The
357 format of the survey included both open-end and multiple-choice questions. A total of 12 respondents
358 (3 from community centers, 8 from academic centers, and one from a government center) completed
359 the survey and results were collected and summarized.

360 The task group members were evenly divided between the two major commercially available
361 systems at the time (ARIA™, Varian Medical System, Palo Alto, CA and MOSAIQ™, Elekta, Sunnyvale,
362 CA). Respondents reported having between 2 to 22 linear accelerators in their clinics, and all provide a
363 range of brachytherapy and non-standard treatments.

364

365 **2.B.2. AAPM member survey**

366 The most relevant questions from the TG-262 member survey were selected and adapted for a
367 survey of AAPM membership on their RO-EMR practice. Question formats were made more consistent
368 with only sparse free response questions to ensure brevity. Responses from 421 AAPM members
369 (including task group members) were received. The AAPM membership survey was divided into six
370 subsections:

371

- 372 1. Demographics
- 373 2. Implementation and QA
- 374 3. Information Storage and management
- 375 4. Workflow

376 5. Brachytherapy and non-standard treatment devices

377 6. IT infrastructure

378

379 Survey respondents were divided between small clinics (<50 pts/day- 45%), medium clinics (51-100
380 pts/day-31%) and large clinics (>100 pts/day- 24%) Most respondents (98%) used one of the two major
381 commercially available charting systems in use at the time of the survey (ARIA™, MOSAIQ™). The rest
382 used either in-house systems or other commercial systems (LANTIS™, Oncochart™, IKnowMed™).

383 Respondents were from the US (89%), Canada (4%) and other countries (4%). Forty seven of 50 states
384 were represented by at least one respondent; Alaska, Hawaii, and Nebraska did not have respondents.
385 The five states with the most respondents were California (30), Texas (24), Florida (23), New York (20),
386 and Pennsylvania (20).

387

388 Results of the surveys were collated and reviewed by the task group members. Task group members
389 were divided into subgroups aligned with the subsections of this report. These subgroups
390 independently formulated recommendations related to their topic based on survey results, available
391 literature if any, and group consensus. The full list of recommendations was then reviewed by a panel
392 consisting of the leaders of each of the individual subgroups in a face to face meeting.

393

394 **2.C. Structure of this report**

395 The report presents recommendations of each of the subgroups, followed by a list of
396 recommendations to the vendors developed by the panel of subgroup leads.

397

398 Rather than provide detailed instructions for configuration and use of existing RO-EMR systems, the
399 task group provides general guidelines for configuration and management in key areas of the RO-EMR
400 experience. This is primarily for two reasons:

- 401 1. The scope of the task group is too large and detailed recommendations for various software systems
402 would make the report excessively long.
- 403 2. Commercial electronic charting systems do not share a consistent configuration except that they
404 contain functionality for storing information and managing workflow. These systems are constantly

405 changing and an overly specific report at this stage of their development would have a higher
406 chance of becoming obsolete within a few years.

407 Each section consists of an introduction followed by recommendations with brief explanations and
408 supporting documentation. The exception is Section 8 on Brachytherapy and Non-Standard Devices
409 which describes an application of electronic charting that is not as developed as that for external beam
410 therapy. This section begins with a broader birds-eye view narrative of the topic followed by a list of
411 specific recommendations. Specific recommendations in the body of the report are in boldface and
412 section 3 lists a summary of all the recommendations for quick reference.

413 The focus of this report is the Radiation Oncology Electronic Medical Record (RO-EMR) which
414 has two primary functions: storing information related to the patient's treatment and managing
415 workflow within the radiation therapy department. Many clinics and hospitals also use a separate
416 Hospital Electronic Medical Record (H-EMR) which is not dedicated to radiation oncology. H-EMR's are
417 beyond the scope of this report.

418

419 **3. SUMMARY OF RECOMMENDATIONS**

420

421 This section summarizes the recommendations of the task group for quick reference . Please refer
422 to the body of the report for discussion and rationale of each recommendation.

423 **3.A. Implementation**

424

- 425 1. Form a multidisciplinary committee to manage the implementation of the electronic chart.
- 426 2. The implementation committee should include representatives from all stakeholders.
- 427 3. The committee should consist of 5 and 10 members based on clinic size, with possible exceptions for
428 larger institutions. Hospital networks sharing an RO-EMR should make sure there is representation from
429 satellite sites such that any differences in workflow are taken into account.
- 430 4. Having a physician champion is highly recommended. Having a project manager is also highly
431 recommended.
- 432 5. The implementation committee should clearly define the goals of the RO-EMR system and milestones in
433 the implementation process at the outset and allocate sufficient time for each.
- 434 6. Protected time for committee members and adherence to upfront deadlines is recommended for a timely
435 rollout and proper implementation.

- 436 7. The committees should create a list of priorities for their systems gleaned from a variety of resources to
437 present to vendors when choosing a system.
- 438 8. A test environment should be maintained for the implementation and for ongoing testing.
- 439 9. A carefully designed and time-limited pilot or transition period between charting systems is
440 recommended for successful implementation of a new RO-EMR. The transition period should be no
441 longer than 6 months.
- 442 10. "Champions" should be identified for initial training to facilitate a smooth transition.
- 443 11. Competency assessment upon the completion of training should be considered to ensure all staff have
444 the knowledge to efficiently and effectively use the new electronic charting system.
- 445 12. Ongoing training by the training team should be considered when new staff are onboarded, during
446 software upgrades, and during introduction of new technology.
- 447
- 448

449 **3.B. Acceptance Testing and QA**

- 450 1. A vendor representative should be present for the initial use of the system to troubleshoot any early
451 issues associated with clinical implementation.
- 452 2. Use of the system should be monitored by the implementation team during the initial clinical rollout. Any
453 issues raised by users be addressed by the team in consultation with the vendor.
- 454 3. After implementation of the RO-EMR is completed, an RO-EMR management committee should be
455 formed to manage the system and perform requested amendments.
- 456 4. Establish a QA program to determine if the RO-EMR is up to date with clinical developments and to
457 determine when improvements can be implemented.
- 458 5. In addition to developing a QA program for the management and maintenance of information and
459 workflows, it is essential to develop a QA and QC program to test the interconnectivity between the RO-
460 EMR and other systems within the facility, including H-EMR, Treatment Planning System (TPS), delivery
461 systems, and other supporting information systems.
- 462 6. Automation and standardization should be leveraged to the extent possible in the electronic charting
463 system as an error prevention tool.
- 464
- 465

466 **3.C. Information Management**

- 467 1. User group rights in the RO-EMR should be configured to the extent possible to reflect the approval rights
468 paradigm of the clinic and regulatory requirements.

- 469 2. Only attending physicians should be given rights to approve prescriptions. Editing rights without approval
470 should be offered as sparingly as possible to satisfy regulations but enough to not disrupt the clinical
471 workflow.
- 472 3. Plan documentation in the RO-EMR should be consistent with treatment and be updated any time a plan
473 is revised, prior to the next treatment.
- 474 4. RO-EMR software may have built-in features to inhibit treatment if an embedded prescription is amended
475 after treatment commences. Users should take advantage of these functionalities when possible and
476 practical.
- 477 5. When designing documents for the electronic chart and choosing a native storage format, the
478 implementation committee should consider the format, input, efficacy, scope, traceability, and
479 accessibility (FIESTA) of the document.
- 480 6. When possible, chart elements should be stored using native storage functionalities of the system.
- 481 7. Forms, or structured documents designed for the RO-EMR system, should be used for consistency
482 whenever possible.
- 483 8. Document repositories in RO-EMR systems should be configured consistently for all users such that
484 documents are easily identifiable and categorized appropriately to prevent errors.
- 485 9. Documents should be sorted and categorized consistently if possible. Clutter should be minimized and the
486 number of documents should be minimized.
- 487 10. Avoid using free text notes “for lack of a better place”.
- 488 11. It is the responsibility of all users to use the chart consistently with respect to entry of information, both
489 in terms of where and how the information is entered. Redundancy should be minimized.
- 490 12. To the extent possible, consistency in documentation entry should be enforced.
- 491 13. Electronic signatures should be used where clinically appropriate and be sufficiently secure to adhere to
492 local regulations. They should be easily accessible for audits by regulators, credentialing bodies, billing
493 compliance personnel, and other entities.
- 494 14. When choosing a signature format, the most efficient method that satisfies regulatory requirements
495 should be used.
- 496 15. To the extent possible, forcing functions should be employed to enforce proper practice in completing
497 documents.
- 498 16. Simulation orders should clearly reflect site-specific procedures and avoid superfluous information.
- 499 17. Users should take advantage of the capabilities for prescribing that are provided by the RO-EMR.
- 500 18. The task group recommends that vendors and clinics join to make prescriptions “smarter” by making
501 prescription parameters sufficiently flexible, capitalizing on the ability to mine data in an electronic
502 prescription, and by checking the prescription for self-consistency and against the treatment plan.
- 503 19. An explicit prescription check should be performed as the first part of a chart checking process.

- 504 20. Treatment plan documentation should be accessible for easy internal review as well as documentation for
505 outside institutions or departments when requested.
- 506 21. Checklists and similar tools within the RO-EMR should be used to provide a systematic and comprehensive
507 approach to ensure standardized patient care, thereby decreasing errors and improving patient
508 workflows.
- 509 22. The RO-EMR should be used to communicate special circumstances including but not limited to
510 pregnancy, prior radiation, radiation-sensitive implanted medical devices, allergies, and infectious
511 diseases.
- 512 23. Special circumstances should be documented using forms where possible to ensure consistency.
- 513 24. A system should be put in place to capture and appropriately document incomplete treatment sessions or
514 courses on documentation in the RO-EMR, either automatically or manually via standard QA checks.
- 515 25. The treatment history of the RO-EMR should be checked for accuracy in the event of an incomplete
516 treatment.
- 517 26. A process should be in place to detect save-back failures (the failure of treatment records to be saved
518 back to the RO-EMR history) of the treatment history.
- 519 27. Changes in the treatment course such as early completion of treatment should be documented with a
520 valid attending physician signature if they deviate from the prescription as originally written.
- 521 28. A department should have procedures for using the RO-EMR for emergency and urgent cases in an
522 efficient, safe, and consistent way.
- 523 29. Chart reviews (plan checks, weekly chart checks, end of treatment checks, etc) should be documented
524 electronically in the RO-EMR.
- 525 30. A clear procedure should be in place for preparation and transmission of patient records to outside
526 institutions.

527
528

529 **3.D. Workflow and Communication**

- 530 1. The committee should establish process maps before configuring the workflow manager.
- 531 2. When designing the workflow, the committee should consider the following for each task: Who, What,
532 When, How, Why, hard or soft stop, and possible risks.
- 533 3. Documentation such as checklists should be linked by the system to workflow tasks when possible.
- 534 4. Safety barriers should be established to prevent simulation without completion of an accurate simulation
535 order.
- 536 5. The institution should incorporate prescription entry as one of the workflow tasks; consider when it
537 should be entered initially, and the proper timeframe to finally approve it.

- 538 6. If a 3rd party prescription application is utilized, a system of checks needs to ensure the consistency of
539 information and proper data transfer with the primary RO-EMR to prevent possible discrepancies
540 between two different systems.
- 541 7. When the RO-EMR is used for billing purposes, automated charge capture should be used if available.
- 542 8. Formalizing the process of releasing workflow management tools (discussion by RO-EMR management
543 committee, pilot and formal release with proper notification) is recommended to prevent potential errors
544 or unanticipated clinical inefficiencies.
- 545 9. Clinics should utilize task completion metrics and feedback from different clinical groups to refine RO-
546 EMR workflows as part of ongoing QA.
- 547 10. The clinic should establish clear consensus on the channels for transfer of specific types of time-sensitive
548 information and enforce its use.
- 549 11. Implementation committees should focus on known lapses in communication in the workflow
550 development phase to ensure that the clinical workflow design is robust against these sort of unexpected
551 changes in care.
- 552 12. "Handoffs" and "handshakes" should be clearly identified for different types of communication
- 553 13. User interfaces should be standardized within the same user group.
- 554

555 **3.E. Brachytherapy and Non-Standard Devices**

- 556 1. If mobile devices are not permitted in the OR, a paper written directive may be used, which should be
557 scanned into the RO-EMR in a timely manner after the completion of the procedure. The scanned
558 electronic document should be stored in a consistent location and with clear labeling in the RO-EMR.
- 559 2. For an electronic written directive, the history of the written directive should be easily accessible to users
560 of the RO-EMR. Historical versions (which should be saved within the RO-EMR) should include the date,
561 time and electronic signature of the directive. Any changes or amendments to the written directive should
562 follow regulations and be documented appropriately.
- 563 3. Each Radiation Oncology Department should develop policies and procedures (P&Ps) defining how
564 electronic signatures are to be validated.
- 565 4. The availability, cost, and functionality of the RO-EMR connectivity software should be assessed for
566 existing non-standard devices and prior to purchase of new non-standard devices and brachytherapy
567 afterloaders.
- 568 5. The RO-EMR implementation committee should include representatives from all stakeholders *working*
569 *with the non-standard devices*.
- 570 6. For all devices, the prescription should be entered and signed in a similar method as for standard devices.

- 571 7. For all prescriptions, the applicable federal, state, and local regulations pertaining to the written directive
572 should be followed. Note that paper format for the written directive is typically used when electronic
573 records are not available, such as in the OR, or when regulators still require paper documentation
574 8. Plan documentation should be exported as file and imported into the RO-EMR. If this is not possible and
575 documentation is needed, then it can be printed and scanned.

576
577

578 **3.F. IT Infrastructure and Management**

- 579 1. Discussions regarding the IT infrastructure should include members of the clinical team as well as medical
580 physicists since they will be responsible for highlighting the needs of the practice.
- 581 2. Medical physicists should familiarize themselves with the terminology, technical concepts and main issues
582 regarding the architecture and management of the IT infrastructure.
- 583 3. While the task group does not recommend that the Medical Physicist assume primary responsibility for
584 the IT infrastructure and support for the RO-EMR, it is important that medical physicists be part of the
585 ongoing decision making process.
- 586 4. Clinical needs, institutional restrictions, and constraints need to be clearly defined when building the IT
587 infrastructure for the RO-EMR environment.
- 588 5. Disaster recovery, and when possible, high availability solutions are essential when designing failover
589 processes for the RO-EMR.
- 590 6. Clinics should have a system and processes for disaster recovery (i.e. backups) as well as processes to
591 validate those backups. A monitoring system is also recommended, either automated or manual, to
592 verify that the backup process took place.
- 593 7. Each practice should determine the amount of downtime that the clinic can accept and implement a HA
594 and/or DR solution that meets those needs.
- 595 8. Mobile device connectivity must be secure. Users must evaluate mobile platforms for compatibility with
596 all accessible electronic chart functions. If a mobile device is used for image review, the screen size and
597 resolution must be appropriate.
- 598 9. Manual or automated processes should be in place to monitor the growth of the RO-EMR database and
599 ancillary storage devices and warn the IT team that more space is needed.
- 600 10. Usage and storage capacity should be monitored on a real time basis to warn the administrators of near
601 capacity storage and provide time to amend system.
- 602 11. Clinical Teams need to be aware of information security threats and work with both the
603 department/institutional IT teams and the vendor to mitigate this risk.

- 604 12. It is important that the medical physicist partner with institutional and departments IT teams as well as
605 vendors to mitigate the risks and prevent data breaches in radiotherapy both to maintain adequate
606 security and to protect the integrity of the RO-EMR system.
- 607 13. The Clinical Team should consider including a test environment as part of the RO-EMR environment
608 deployment and design strategy.
- 609 14. Dual monitor setup should be a minimum standard with adequate screen resolution to support all of the
610 RO-EMR functionalities as specified by the vendor.
- 611 15. Members of the clinical team should become familiar with and partner with IT team members to develop
612 application services that optimize the connectivity among systems as well as data collection and analytics
613 from the RO-EMR environment and other information systems.
- 614 16. Clinical Team users should be familiar with the robustness and potential risk of running database queries
615 on clinical production systems.
- 616

617 **3.G. Challenges and Future Improvements for both Users and Vendors**

- 618 1. The task group recommends a continued focus on automation.
- 619 2. The task group recommends that checklist functionality be enhanced.
- 620 3. The task group recommends that approval mechanisms be enhanced, including consideration of more
621 granular approval mechanisms such as approval at the field level of a document or template.
- 622 4. The task group recommends that online interactive versions of their software be available for testing and
623 training.
- 624 5. Configuration of document repositories should be flexible and customizable so that clinics can display the
625 documents in a way that works best for them.
- 626 6. The task group recommends that communication tools within the electronic chart be enhanced based on
627 input from industry experts, clinicians, and researchers.
- 628 7. The task group recommends that flexibility of workflow managers should be increased to adapt more
629 easily to the wide range of workflows in practice. Workflows should be more efficient by more tightly
630 integrating the virtual task in the workflow with the work in the system that it represents.
- 631 8. The task group recommends that tools be made available to acknowledge communications electronically.
- 632 9. The RO-EMR should allow for the concurrent use of different workspaces and minimize the need to open
633 an excessive number of windows.
- 634 10. Communication between the RO-EMR and H-EMR as well as between RO-EMR systems and non-standard
635 systems should be improved.
- 636 11. Vendors should design the RO-EMR database in a standard database format such as Structured Query
637 Language (SQL). Users should be provided with information of the database structure and access to the
638 database for data analysis and data mining. A feature-rich API should be available.

- 639 12. Databases should be sufficiently robust to queries.
- 640 13. Vendors not currently pursuing modules and components to support interfaces with non-standard
- 641 systems should consider doing so, or alternatively provide the user information on their interface module
- 642 so that users could develop their own interfaces.
- 643

644 **4. IMPLEMENTATION OF THE RO-EMR**

645 The first and arguably most important step in successful RO-EMR deployment is the configuration of

646 the RO-EMR system for the clinic. A carefully structured implementation is essential to maximizing the

647 benefits in efficiency and safety afforded by the RO-EMR system as well as to ensuring acceptance of the

648 new system by clinicians and other stakeholders. A number of references describe implementations at

649 various institutions,^{11-13,16-19} and the TG-262 member survey and AAPM member survey undertaken by

650 this task group provide a glimpse of the current practices in the community.

651 This section provides recommendations for safe and efficient implementation of an electronic

652 charting system. It is accepted that this task group was initially motivated by the sometimes onerous

653 and challenging transitions of task group members from paper to electronic charting. It is also accepted

654 that the majority of institutions have transitioned from paper charting to electronic charting at the time

655 this report is released. However, the task group believes these guidelines remain relevant. Many

656 institutions switch systems or have to adopt a second RO-EMR at one of their clinics. Also, groups may

657 choose to overhaul their existing RO-EMR system and need a structured roadmap for the process.

658

659 **4.A. Committee team and size**

660 **The task group recommends that a multidisciplinary committee be formed to manage the**

661 **implementation of the electronic chart.** A dedicated committee for the implementation of an

662 electronic chart spreads ownership of the chosen RO-EMR system and engages all stakeholders to

663 efficiently work together to more rapidly implement its proper setup and ensure training of all necessary

664 colleagues.¹¹

665 **The task group recommends that the implementation committee include representatives from all**

666 **stakeholders.** Team representation may include members from the relevant subspecialties: physicists,

667 therapists, dosimetrists, nurses, MDs, residents, administrators, IT, vendor, engineers, and those that

668 work with non-standard devices. Everyone should have a clearly defined role in the committee,

669 primarily as the representative of their particular clinical subspecialty or as an administrative or vendor

670 representative. Finally, a multidisciplinary team is more likely to include institution wide priorities and
671 goals from the onset and increase satisfaction.

672 The number of team members depends on the size of the clinic. Some clinics commonly have some
673 staff members serve multiple roles; for example, nurses in a smaller clinic may perform follow up visits
674 and participate in certain aspects of the simulation process whereas residents in a larger clinic may be
675 involved in these duties. Representation from these areas should be proportional to the clinic size. **The**
676 **task group recommends a committee size of between 5 and 10 members; larger institutions (i.e. those**
677 **with broader clinical teams including residents, dedicated radiation oncology IT, and others that**
678 **expand the pool of representation required on the committee) may require larger committees to**
679 **manage the workload. Hospital networks sharing an RO-EMR should make sure there is**
680 **representation from satellite sites such that any differences in workflow are taken into account.**

681 The committee should gather input from the various clinical groups through their representatives on
682 the implementation committee, including ancillary staff who might not be responsible for task
683 completion but still are critical to the process. This broad input has been shown to facilitate increased
684 compliance from the team and quick adoption of the system.¹⁸

685 **Having a physician champion is highly recommended. Having a project manager is also highly**
686 **recommended.** The physician champion can play a vital role in “buy-in” from the clinic and the project
687 manager can keep the team on schedule and monitor the need for resources as the implementation
688 progresses. The Medical Physics Leadership Academy has provided training on project management at
689 past meetings.

690

691 **4.B. Definition of goals and milestones of the RO-EMR system**

692 **The implementation committee should clearly define the goals of the RO-EMR system and**
693 **milestones in the implementation process at the outset and allocate sufficient time for each.** The task
694 group suggests the following milestones for consideration when formulating an implementation plan.
695 Not all may be relevant to all clinics.

- 696 • Definition of roles and responsibilities for members
- 697 • Formulation of a timeline. The implementation team should provide periodic updates to
698 the relevant administrative bodies and clinical leads through the process. The schedule of
699 these updates should be included in the timeline and correspond with scheduled milestone
700 dates.

- 701
- 702
- 703
- 704
- 705
- 706
- 707
- 708
- 709
- 710
- 711
- 712
- 713
- 714
- 715
- 716
- 717
- 718
- 719
- 720
- 721
- 722
- 723
- 724
- 725
- 726
- 727
- 728
- 729
- 730
- 731
- Definition of goals for the RO-EMR system: A discussion by team members on the expectations for the RO-EMR in consultation with the clinical stakeholders can provide a framework on which to move forward with the design and transition. Some general goals and expectations may include:
 - Expectations for ease of use in various procedures
 - Comprehensive information storage with easy accessibility
 - A clinically efficient workflow which minimizes redundancy except where needed for quality assurance and distills the number of steps to complete each task to the minimum required with extraneous steps removed
 - A robust IT infrastructure which maintains sufficient uptime and provides adequate disaster recovery such that the clinical operations are not significantly affected and patient information (data) is not jeopardized. The clinic should decide on a maximum acceptable downtime and design/invest in an IT infrastructure to provide that.
 - Adequate support for users- this should be prescribed by the required response time at different hours of the day (during treatment, after treatment, weekends) and for different clinical activities (simulation, treatment planning, treatment, status checks, QA checks, etc).
 - A well planned transition with well defined start and endpoints and stages clearly mapped out. A feedback mechanism should be in place such that superusers and champions can monitor progress and make changes if necessary.
 - Appropriate level of training- the required training will differ depending on role. A program should be designed such that each member of the clinical team is trained on the basic components of the RO-EMR as well as provided more detailed training on the specific components relevant to their workflow. Training should also be provided for updates to the system as they pertain to different members of the clinical team. Finally, retraining/refresher training, should be considered for those who may not use the system for a given period of time, for example 6 months or one year.
 - Choice of RO-EMR system
 - Configuration of the test environment for end to end tests and pilot studies

- 732 • Configuration of the IT infrastructure, including backup and disaster recovery, consistent
733 with the goals of IT infrastructure robustness defined above
- 734 • Creation of user groups and assignment of security roles- (see section 6.A.1). Information
735 storage regarding user rights assignment
- 736 • Demarcation between hospital H-EMR and RO-EMR- what documents will be stored in
737 each? How will the 2 systems communicate?
- 738 • Design of forms (refer to the design guidance provided in Section 5. Information Storage)
- 739 • Configuration of the workflow management software, if any (refer to the workflow guidance
740 provided in Section 6- Workflow management)
- 741 • Establishment of procedures for ad hoc events that are not part of the standard workflow
742 such as re-planning due to treatment related changes or chart rounds, bolus placement, etc
- 743 • Establishment of communication channels for clinically relevant information
- 744 • Configuration of the billing infrastructure, if it exists
- 745 • Writing procedures and making them easily available everywhere the RO-EMR is accessed.
- 746 • Delegation of superusers/champions for support and training
- 747 • Planning of training for initial rollout and transition period
- 748 • Formulation of ongoing QA policies and procedures- see chapter 4
- 749 • Delegation of a team to manage ongoing chart maintenance/modifications/upgrades- see
750 chapter 4

751

752 **4.C. Project timelines and protected time**

753 **Protected time for committee members and adherence to upfront deadlines is recommended for**
754 **a timely rollout and proper implementation.** Time should be available for meetings of the
755 implementation team and work between meetings. The task group recommends 10-20% protected
756 time for RO-EMR design as a reasonable goal for clinical members of the implementation team. The
757 bulk of the effort at surveyed clinics was spent in the areas of the development of processes and
758 configuration of the RO-EMR.

759 An estimate of percent effort required for the 5 major phases of RO-EMR design based on the AAPM
760 survey is given in Table I. This can be used as a starting point for planning the transition roadmap.
761 Implementation times depend on department size and resources, among other factors. Also given is a

762 rough estimate of the range of time to budget for each step based on results of the TG262 and AAPM
763 surveys.

764

765

766 **4.D. Resources for comparison of charting systems**

767 When assessing which charting system is appropriate for a particular clinic, a variety of resources
768 should be considered and used. Table II summarizes factors that can drive RO-EMR selection. **The task**
769 **group recommends that implementation committees create a list of priorities for their systems**
770 **gleaned from a variety of resources to present to vendors when choosing a system.**

771

772 When visiting another facility to observe their RO-EMR system, it is helpful to have questions
773 prepared. Some applicable questions adapted from the AAPM member survey are provided in Appendix
774 2.

775

776

777 **4.E. Test environment**

778 **The task group recommends that a test environment be maintained for the implementation and**
779 **for ongoing testing.** Having access to a test environment during RO-EMR configuration and prior to the
780 installation of the clinical system is common and provides a platform to test configurations, test
781 documents and workflows, and to provide initial and ongoing training. It is equally valuable in the
782 implementation process and for ongoing management for the same reasons.

783

784 **4.F. Pilot or transition period**

785 **A carefully designed and time-limited pilot or transition period between charting systems is**
786 **recommended, when possible, for successful implementation of a new RO-EMR.** Although a transition
787 period is not mandatory, the consensus of the task group is that a set timeframe be established for this
788 process to keep the clinic on task with regards to phasing out the old system. Furthermore, additional
789 resources such as champions and superusers can be more easily allocated for a definite time period
790 rather than in an open-ended transition. In the survey of AAPM members, those most satisfied with the
791 initial transition from paper to electronic charting had an average transition period of 6 months and

792 those either satisfied or neutral had average transition periods of approximately 10 months. Longer
793 transition periods were not as common and were associated with lower overall satisfaction with the
794 transition. **The task group recommends a transition period no longer than 6 months when changing**
795 **from one system to another (whether paper to electronic or electronic to electronic).** If the old and
796 new systems are independent of each other (such as would have been the case if transitioning from
797 paper) transitions should be organized in such a way that users know which system to use in which
798 circumstance. For example, a subset of physicians could be chosen to adopt the new system during the
799 transition period to work out the “kinks” – this is more of a pilot type transition. The transition period, if
800 there is one, should not be used if it creates more disruption than a clean break from the old system. If
801 a transition period is impossible then adequate training and preparation as well as appropriate support
802 after go-live is critical for success.

803

804 **4.G. Transition and Training**

805 **“Champions” should be identified for initial training to facilitate a smooth transition.** The training
806 team should include representatives from each clinical group, preferably a subgroup of the
807 implementation committee. The training process begins with the vendor pre-installation as well as
808 during the installation of the electronic charting system. Subsequently the champions are the key
809 individuals that continue the training process to support staff collaboratively. **Competency assessment**
810 **upon the completion of training should be considered to ensure all staff have the knowledge to**
811 **efficiently and effectively use the new electronic charting system.**

812 **Ongoing training by the training team should be considered when new staff are onboarded,**
813 **during software upgrades, and during introduction of new technology, or when a significant deviation**
814 **has occurred and led to an unexpected result.**^{13,19,24}

815

816 **4.H. Ease of transition and “buy-in”**

817 Support is critical for a successful implementation.²⁵ The task group has identified three critical
818 components necessary for a successful transition. First is the importance of a detailed project plan
819 which needs to be communicated to the entire department to ensure buy-in throughout all phases of
820 conversion to a new system. Secondly, there needs to be champions or superusers that utilize the new
821 system first, as cited above. By having these champions use the new system first, most if not all patient
822 workflow processes will be familiar to the other clinical staff members when it is their turn to use it.

823 Lastly, it is imperative to have a clear process for addressing concerns or enhancements of workflows as
824 the clinical staff uses the new system.
825

826 **5. ACCEPTANCE TESTING and QA OF THE RO-EMR**

827 Periodic QA of electronic charting is not standardized as of the writing of this report. Therefore the
828 task group recommends the following guidelines for acceptance testing and ongoing QA of the RO-EMR.

829 **5.A. Acceptance testing and commissioning**

830 Radiotherapy departments are becoming more and more complex with potentially many connected
831 systems comprising the suite of clinical software and potentially interfacing with the RO-EMR. In
832 addition, replacing or upgrading an existing system is a complex process because the patient treatment
833 process should experience minimal interruption while a safe and smooth transition from the old system
834 is carried out. Acceptance testing and commissioning is therefore recommended for the RO-EMR as
835 with any major clinical system. IAEA HHR No.7 ²⁰ and IEC 62274ED.1.0 ²¹ provides a comprehensive test
836 list for R&Vs, some of which are also relevant to RO-EMR systems.. The task group has created a list of
837 recommended acceptance criteria adapted from the IAEA and IEC recommendations with additional
838 items specific to document repositories and workflow managers. These criteria are listed in Appendix 1.

839 Commissioning of RO-EMR systems does not occur in the same sense as it would for a treatment
840 machine or treatment planning system. One does not gather data to enter into the system in the same
841 sense that one measures depth dose and profiles for a treatment planning system. The RO-EMR is
842 configured for use and much of this task group applies to that process. Therefore we recommend that
843 users refer to the guidelines in this report for configuration.

844 As recommended for R&V systems in the IAEA and IEC reports, **it is recommended by the task group**
845 **that a vendor representative be present for the initial use of the system to troubleshoot any early**
846 **issues associated with clinical implementation. It is also recommended that the use of the system be**
847 **monitored by the implementation team during the initial clinical rollout and that any issues raised by**
848 **users be addressed by the team in consultation with the vendor.**

849

850 **5.B. Ongoing management of the system**

851 **After implementation of the RO-EMR is completed, the task group recommends that an RO-EMR**
852 **management committee composed of clinical stakeholders be formed to manage the system. The**

853 group should have well-defined roles and responsibilities and meet periodically. This RO-EMR
854 management group should be responsible for approving and implementing modifications to the RO-
855 EMR system, updating written policies and procedures, addressing concerns / suggestions, and for
856 ongoing user management, such as activation/deactivation of user accounts, and verification of
857 appropriate training.

858 **5.C. QA program**

859 **The task group recommends that a QA program be established to determine if the RO-EMR is up**
860 **to date with clinical developments and to determine when improvements can be implemented.**

861 Ongoing QA is essential to ensure that the RO-EMR system is still serving the needs of an evolving clinic.
862 To ensure that the RO-EMR remains current and is functioning optimally, we recommend that a set of
863 pre-defined use cases across the range of treatment techniques be reviewed at least yearly to
864 determine the following:

- 865 • Are general policies and procedures for access and use of the RO-EMR being observed?
- 866 • Are existing forms up to date with respect to clinical processes?
- 867 • Are new forms required for new processes?
- 868 • Are there forms that should be retired?
- 869 • Are forms being used as per policies and procedures, i.e., are they being filled in properly, are
870 they being signed by appropriate personnel, and are they being reviewed if necessary?
- 871 • Is the workflow manager up to date with respect to current clinical practices?
- 872 • Are there new clinical processes requiring integration into the workflow manager?
- 873 • Are there any processes in the workflow manager that should be refined or retired? (see section
874 7H)
- 875 • Is the workflow manager being used properly as per policies and procedures, i.e., what is the
876 compliance rate of electronic task completion? Are appropriate personnel interacting with
877 workflow tasks in the system?
- 878 • Have any near misses or adverse events been reported in the hospital incident reporting system
879 related to the RO-EMR or are there changes to the RO-EMR that can help prevent one?

880

881

882 Assessment of the aforementioned situations is consistent with recommendations of credentialing
883 bodies to review policies and procedures each year and can be considered part of the ongoing review
884 process.²⁶

885 There are also some special circumstances when ad hoc QA should be implemented:¹⁸

- 886 • Software/hardware updates of the RO-EMR system- basic functionality tests should be
887 performed (see Section 5.D.)
- 888 • Introduction of new technology- basic accessibility and functionality tests should be performed
889 and workflows should be assessed
- 890 • Any modification of network infrastructure- basic accessibility and functionality tests should be
891 performed
- 892 • In response to a significant adverse event or near miss

893 **In addition to developing a QA program for the management and maintenance of information and**
894 **workflows, it is essential to develop a QA and QC program to test the interconnectivity between the**
895 **RO-EMR and other systems within the facility, including H-EMR, Treatment Planning System (TPS),**
896 **delivery systems, and other supporting information systems.** The process of developing and
897 implementing a connectivity QA and QC program has been well outlined and described by Siochi et al. in
898 the upcoming report of TG 201, “Quality Management of External Beam Therapy Data Transfer”. Their
899 recommendation follows the TG 100 approach²⁷, and provides a framework that each facility can follow
900 to perform their own safety and risk evaluation, which in turn will guide the selection process of the
901 necessary connectivity QA and QC tests as well as their corresponding frequency. As part of TG 201
902 framework, they highlight that a first step is for each facility to map and understand their IT
903 infrastructure, IT and IS configuration and corresponding system dependencies. Then in order to
904 perform the risk analysis, they proposed the utilization of two tools: Data Transfer Matrices and Fault
905 Tree Analysis. Providing a full description of the risk analysis, connectivity, and data transfer tests is
906 beyond the scope of this task group. However, it is important to emphasize the need of developing an
907 interconnectivity QA and QC program when implementing a RO-EMR and TG 201 provides a baseline of
908 tests that at minimum should be performed annually and for any upgrades of the system.

909 **5.D. Software Upgrades**

910 Software upgrades require extensive preplanning because they may also involve the record and
911 verify system and the treatment planning system in addition to the RO-EMR. Therefore, upgrade
912 preparation for the RO-EMR may occur in concert with preparation for upgrades of other components of
913 the OIS. Database migrations may be a part of the upgrade which can fundamentally affect clinical
914 processes plus multiple vendors may be involved. Finally, upgrades often take place on a constrained
915 schedule (such as over a weekend), consequently detailed preparation well in advance of the upgrade is

916 essential¹⁵. A detailed description of the upgrade process for the OIS in general is beyond the scope of
917 this task group however for the RO-EMR in particular:

- 918 1. Training should be performed for all clinical stakeholders in all new and modified features.
- 919 2. A test system should be used to
 - 920 a. evaluate new features
 - 921 b. test basic functionality of the information storage system- can documents be
922 created, opened, edited, closed? Can document templates, questionnaires and
923 checklists be created and implemented properly?
 - 924 c. test basic functionality of the workflow manager- can tasks and workflows be
925 created and implemented as they are in the clinic
 - 926 d. test the integrity of migrated information (documents, data tags, etc) if the upgrade
927 involves a database migration
 - 928 e. confirm connectivity with other systems (see recommendations for
929 interconnectivity tests above)
 - 930 f. Test accessibility of information by members of the clinical team.
- 931 3. Standard QA of the RO-EMR described in Section 5.C should be performed.
- 932 4. The RO-EMR workflow manager can be used during the upgrade to guide specific processes
933 such as patient data review. For example, if the upgrade involves the record and verify
934 system one of the steps in the upgrade workflow could be the moding up of the patient plan
935 at the treatment machine.
- 936 5. Documentation of upgrade tests for patients on treatment can be stored in the RO-EMR via
937 a patient note, completion of a task, or completion of a questionnaire or checklist. This
938 documentation can be reviewed as an audit of the upgrade process, for example therapists
939 can be instructed to confirm the presence of upgrade check documentation for all patients
940 prior to the first treatment after the upgrade, plus this documentation can be reviewed in
941 subsequent weekly chart checks by therapists and by medical physics.

942 As stated earlier, upgrades of the RO-EMR do not typically occur in a vacuum and are often part of a
943 larger OIS upgrade. We have only focused on the RO-EMR here in terms of what to check and how the
944 system can be used to document checks. More comprehensive recommendations can be found in the
945 literature ¹⁵.

946 **5.E. Automation and Standardization**

947 **Automation and standardization should be leveraged to the extent possible in the electronic**
948 **charting system as an error prevention tool.** This can be accomplished through the use of templates,
949 document indexing, statistical process control via customizable reporting tools that come with the
950 system or through an application programming interface (API), and protocols such as checklists or
951 questionnaires. Independent double check systems for ease of performing physics QA should also be
952 considered. Forcing functions²⁷ or hard stops within the electronic chart should be used when possible.
953 Lastly, to aid in error prevention, the administrator of the RO-EMR system should if possible automate
954 notifications of outstanding, unscheduled or unapproved items to ensure adequate compliance and take
955 advantage of the reporting systems of the RO-EMR to the fullest extent possible.

956 Automation should also be utilized to minimize manual data entry and transcription of information.
957 Redundancy should be minimized (see section [6.A.5](#)); if possible, it is ideal if data is entered once and
958 visible in multiple modules rather than expecting users to maintain and enforce consistency of
959 redundant entries.

960

961 **6. INFORMATION MANAGEMENT**

962

963 Patient documentation usually is used for one or more of the following purposes: a record of
964 treatment decisions (e.g., plan) or status (e.g., weekly physician's note) for future review and for charge
965 capture, reference for future use by other sites that may provide additional treatment, and for reviews
966 by accreditation or legal/regulatory agencies. Typical types of documentation found in RO-EMR systems
967 are listed in Table III. An important consideration in the design of forms is how data is entered and how
968 it is stored in the system. Regarding data entry, consideration should be given to whether the form is
969 templated (i.e. all users see the same blank form) or not, i.e. how much guidance/restriction that the
970 user encounters in filling out the form. Should only certain values be allowed? What functionalities
971 exist within the system to enforce limitations in what can be entered? Is free text required for certain
972 types of information?

973 Regarding storage, consideration should be given to whether the data entered into the form is
974 queryable. Queryable data can be used to create reports or to populate other parts of the chart (patient
975 name, ID, and diagnosis for example). Data that is entered in a templated fashion may not necessarily
976 be queryable due to limitations of that form, the template may simply serve to guide the data entry.

977 Therefore templating and queriability should both be considered independently when designing forms,
978 since one does not necessarily imply the other. Templating is desirable in terms of the format of the
979 form being consistent, while queriability/minability is desirable in terms of how data is entered and
980 stored on the form.

981 Table IV, which is a snapshot of current practices, reflects the variety of ways in which RO-EMR
982 documentation elements are utilized.

983
984 Documentation plays an important role in charge capture, external chart requests, and error
985 investigation. A common practice is to automatically capture charge codes using an electronic task tied
986 to an activity capture system. Most descriptions of radiotherapy errors rely directly on the
987 documentation record of the prescription, plan, and treatment.²⁹

988
989

990 **6.A. Matched user group rights and approval rights**

991 **User group rights in the RO-EMR should be configured to the extent possible to reflect the**
992 **approval rights paradigm of the clinic and regulatory requirements.** Write-access to documents
993 requiring approval such as the prescription can be managed by user rights assignment. These rights are
994 commonly administered through the creation of user groups within the RO-EMR system. In creating
995 these groups, the implementation committee should carefully consider the roles and responsibilities of
996 the different clinical team members so groups with different editing and approval roles are separated to
997 the greatest extent possible. Editing rights of prescriptions and other such documents should be
998 structured such that they are available only to those whose responsibilities are to edit these documents
999 and no more. This setup leverages the approval power of the system to enforce the roles and
1000 responsibilities of the clinical team.

1001 Practices vary as to which users can “touch” a prescription and a variety of workflows are possible
1002 for the prescription process. **The task group recommends that only attending physicians be given rights**
1003 **to approve prescriptions and that editing rights without approval be offered as sparingly as possible**
1004 **to satisfy regulations but enough to not disrupt the clinical workflow.** For example, medical residents
1005 should have editing rights as it is a necessary part of their training but not approval rights.

1006 TG-262 identified lack of consistency between the printed plan documentation and the treatment
1007 when a change is made to a treatment plan as a vulnerability. **The task group recommends that plan**
1008 **documentation in the RO-EMR be consistent with treatment and be updated any time a plan is**

1009 **revised, prior to the next treatment.** If changes are made to any treatment parameters, doses, or
1010 approvals, the documentation should be updated to reflect that since it is consulted at treatment, status
1011 checks, and weekly chart checks. **RO-EMR software may have built-in features to inhibit treatment if**
1012 **an embedded prescription is amended after treatment commences, and the task group recommends**
1013 **that users take advantage of these functionalities when possible and practical.**

1014

1015 **6.B. Document design and storage: Format, input, efficacy, scope, traceability and** 1016 **accessibility (FIESTA).**

1017 **When designing documents for the electronic chart and choosing a native storage format, the**
1018 **implementation committee should consider the format, input, efficacy, scope, traceability, and**
1019 **accessibility (FIESTA) of the document.** These elements are summarized in Table V. *Format* refers to
1020 how easy a document is to read. *Input* refers to how data is entered into a document. It should be
1021 automated to the fullest extent possible. Note that macros are sometimes disabled due to security
1022 restrictions put in place by the institution which may inhibit certain kinds of automation of input. RO-
1023 EMR systems also may have built-in tools which can be customized for information entry such as vital
1024 sign assessments or checklists.

1025 *Efficacy* alludes to how the information fits into the workflow management system or, in the case of
1026 vital patient specific information such as a CIED or bolus, how the information can be stored so as to be
1027 easily detected during the standard workflow - for example a particular type of form may be attached to
1028 a task in the workflow manager making it easy to fill in without excessive clicking. *Scope* refers to how
1029 the document is grouped with respect to other documents in the system. Documents that are usually
1030 accessed together such as a prescription and a plan are easier to use if they are in the same part of the
1031 system rather than in different parts. *Traceability* refers to whether previous versions are saved (not
1032 overwritten) and can be reviewed. This is useful for comparison to previous versions when
1033 modifications are made for root cause analyses. Finally, *accessibility* refers to how easy a document is
1034 to access after it is completed and how quickly it can be made available for writing, particularly
1035 important in high throughput environments like the treatment machine.

1036 **When possible, chart elements should be stored using native storage functionalities of the**
1037 **system.** RO-EMR information formats include simple data formats like parameter lists and check lists.
1038 They also include free text formats like internal messaging that do not enforce an entry format. There
1039 are also structured documents and imported documents in formats such as PDF and MS Word. **Forms,**

1040 or structured documents designed for the RO-EMR system, should be used for consistency whenever
1041 possible.

1042 **6.C. Document repositories**

1043 Document repositories in RO-EMR systems should be configured consistently for all users such
1044 that documents are easily identifiable and categorized appropriately to prevent errors. Electronic
1045 document repositories within the RO-EMR may not be optimally designed and may become cluttered if
1046 not enough features are available to categorize and compartmentalize them. This may lead to errors:
1047 for example, a prescription from an earlier course may be opened if the sorting of the documents is not
1048 immediately apparent to the user. **The task group recommends that documents be sorted and**
1049 **categorized consistently if possible and that clutter be minimized and the number of documents**
1050 **should be minimized.** Clutter reduction strategies include moving forms that may not be necessary for
1051 access during treatment and not required by regulators into ancillary storage such as on a secure server.
1052 Short of that, at least the ancillary forms can be sequestered from the main clinical document
1053 repository. In such a scenario it is important that all staff be aware of the location of these documents
1054 via the electronic chart documentation and that clinically necessary documents remain within the main
1055 clinical repository.

1056 **6.D. Free text notes**

1057 Free text notes are a valuable resource in the RO-EMR and can be used by clinical personnel for ad
1058 hoc entries.

1059 **It is recommended that use of free text note or journaling functionality be avoided except for**
1060 **ad hoc entries.** Free text notes are not easily minable and not consistently entered. In addition, they
1061 often need to be consulted for important information that actually does belong there, such as changes
1062 in treatment for a particular fraction. Therefore, efforts should be made to find a “home” for standard
1063 information elements so that free text notes are only used for ad hoc entries during treatment and not
1064 unnecessarily cluttered.

1065 **6.E. Consistent entry of information**

1066 **It is the responsibility of all users to use the chart consistently with respect to entry of**
1067 **information, both in terms of where and how the information is entered. Redundancy should be**
1068 **minimized. i.e. the same data should not have to reside in different parts of the chart such that**
1069 **consistency needs to be maintained.** Inconsistent information entry makes errors more likely due to

1070 failed communication. QA checks such as initial chart checks or weekly checks may not easily detect
1071 these errors. For example, the prescription may call for gating or bolus to be used, requiring the
1072 reviewer to navigate to and check the consistency of settings in multiple locations of the electronic
1073 chart, which can be challenging. If consistency of usage is good and not unnecessarily redundant, the
1074 check is more efficient and workflow delays can be avoided. In addition, according to the white paper
1075 by TG-201, standard nomenclature is essential.³⁰ **To the extent possible, consistency in documentation**
1076 **entry should be enforced.**

1077

1078 **6.F. Electronic signatures**

1079 **Electronic signatures should be used where clinically appropriate and be sufficiently secure to**
1080 **adhere to local regulations. They should be easily accessible for audits by regulators, credentialing**
1081 **bodies, billing compliance personnel, and other entities.**

1082 Each Radiation Oncology Department should develop policies and procedures (P&Ps) defining how
1083 electronic signatures are to be validated. Electronic signatures were addressed by Public Law 106-229
1084 (the "Electronic Signatures in Global and National Commerce Act") in 2000.³¹ Electronic signatures are
1085 more robust than paper signatures as future editing may invalidate the signature, although this should
1086 be verified by the user. **When choosing a signature format, the most efficient method that satisfies**
1087 **regulatory requirements should be used.**

1088 A locked document can be disruptive to workflow, especially when documents have to be
1089 reapproved for small changes such as typographical errors. Documents requiring signatures should be
1090 designed in such a way that the need for re-approvals is minimized. For example, less sensitive
1091 information that does not have to be signed that currently resides on a signed document can be moved
1092 to an unsigned document. **To the extent possible, forcing functions should be employed to enforce**
1093 **proper practice in completing documents.** For example it may be possible to inhibit saving a document
1094 unless all required elements are entered. However, this kind of functionality is often not available or
1095 restricted in its use by local IT policies that prohibit macros and user compliance has to be relied upon.

1096

1097 **6.G. Simulation orders**

1098 **Simulation orders should clearly reflect site-specific procedures and avoid superfluous**
1099 **information.** Any special concerns related to a particular patient should be indicated in the simulation
1100 order and communicated to the simulation staff ahead of the time.

1101 Post simulation, simulation documents which include patient setup description and photos, and
1102 maybe additional isocenter coordinate information when applicable, should be uploaded and later
1103 reviewed by appropriate sim staff for correctness and completeness in the RO-EMR.

1104 **6.H. Prescription**

1105 **Users should take advantage of the capabilities for prescribing that are provided by the RO-EMR.**

1106 ASTRO (American Society for Radiation Oncology) has provided guidance on items to include to improve
1107 standardization of dose prescriptions.³²

1108 Dose volume constraints can be considered as part of the prescription or as a separate document of
1109 intent to ensure that treatment planning obtains the complete information to begin the plan, thus
1110 limiting the need for unnecessary communication or revision downstream. These constraints can be
1111 explicitly stated or standard department constraints can be referenced with explicit exceptions listed for
1112 the particular case. Any modification to constraints will result in a prescription modification if the
1113 document is approved. Institutional standards for personalized dose constraints alleviate this
1114 inefficiency by requiring explicit documentation of constraints which differ from the institutional norm.

1115 Common failure modes associated with the prescription fall into 3 general categories:

- 1116 1. Incomplete information and typographical errors
- 1117 2. Mismatches between the prescription and the treatment plan
- 1118 3. Changes to the prescription that are not communicated to the clinic

1119 **The task group recommends that vendors and clinics join to make prescriptions “smarter” by making**
1120 **prescription parameters sufficiently flexible, capitalizing on the ability to mine data in an electronic**
1121 **prescription, and by checking the prescription for self-consistency and against the treatment plan.**

1122 Flexibility in electronic prescriptions not only refers to allowing flexibility in existing fields but
1123 allowing for custom fields in the electronic prescription. Missing information can be managed by
1124 introducing forcing functions into the prescription that require entry of mandatory elements. The task
1125 group believes that confirmation of the internal consistency of the prescription and consistency
1126 between the prescription and the plan are crucial in the prevention of errors and that software should
1127 be developed to provide this check. Currently, there are some commercial systems with this
1128 functionality. However, there is still work to be done to make electronic prescriptions flexible enough to
1129 be suited to a variety of clinical workflows.

1130 **The task group recommends that an explicit prescription check be performed as the first part of a**
1131 **chart checking process.** The check should include a thorough review of the prescription as well as a
1132 check of concordance between the prescription and the treatment plan. This “prescription first” policy

1133 should be reinforced and documented as part of the QA process, for example if there is a checklist an
1134 explicit check of the prescription should be first.

1135

1136

1137 **6.I. Treatment plan documentation**

1138 **Treatment plan documentation should be accessible for easy internal review as well as**
1139 **documentation for outside institutions or departments when requested.** A treatment planning system
1140 may offer a short form and long form report for treatment plan documentation or users can create their
1141 own forms using scripting. Sparseness of documentation must be considered against the need to easily
1142 access the treatment plan information by different members of the clinical team. Treatment plan
1143 documentation should be designed to adhere to all applicable regulatory requirements (such as state or
1144 local laws and any requirements of certifying bodies), and easily provide access to necessary information
1145 for plan review by physics (weekly checks, end of treatment (EOT) checks), therapists, and physicians
1146 (chart rounds, status checks). In addition, a version suitable for export to outside institutions or for
1147 review by other departments should be available but could be compiled when such requests are made.
1148 (See section 6.P).

1149

1150 **6.J. Checklists**

1151 **Checklists and similar tools within the RO-EMR should be used to provide a systematic and**
1152 **comprehensive approach to ensure standardized patient care, thereby decreasing errors and**
1153 **improving patient workflows.** Checklists are a valuable safety tool for Radiation Oncology³³ and can
1154 interlock downstream actions; for example, a treatment can be prevented until the checklist is signed.
1155 In addition, checklists will ensure a consistent process is followed. Checklist design cannot be taken
1156 lightly, a poor checklist can lead to “checklist fatigue” or miss crucial elements. The task group
1157 recommends that implementation committees and RO-EMR management committees refer to the
1158 AAPM Medical Physics Practice Guideline on Development, implementation, use and maintenance
1159 of safety checklists when designing checklists for their RO-EMR system³⁴

1160 Radiation therapists frequently use checklists for the pre-treatment time out when they ensure that
1161 the correct patient is being treated with the correct plan and setup. TG-262 recommends that a
1162 consistent and efficient method be chosen at the institution to document time outs, preferably using
1163 existing functionalities of the system suited to that purpose.

1164

1165 **6.K. Special circumstances**

1166 **The RO-EMR should be used to communicate special circumstances including but not limited to**
1167 **pregnancy, prior radiation, radiation-sensitive implanted medical devices, allergies, and infectious**
1168 **diseases.** Special circumstances can have a critical impact on clinical decisions or effective infection
1169 control for other patients and clinical staff. To ensure no treatment proceeds in ignorance of such
1170 circumstances, they should be documented consistently in the RO-EMR. Policies and procedures for the
1171 RO-EMR should explicitly address each special circumstance to ensure roles and responsibilities are
1172 clearly defined. Dedicated workflows are also recommended (General RO-EMR workflow design is
1173 discussed in Chapter 6). **The task group recommends that special circumstances be documented using**
1174 **forms where possible to ensure consistency.** Consistency must be maintained with the H-EMR if this
1175 information is also contained there, therefore automated transfer of this information is recommended
1176 when available.

1177 This information should be easily noticeable especially given that it is not common and therefore
1178 unless there is a prompt for the reader of the chart to look for it, it will easily be overlooked. Important
1179 items that need to be managed prior to treatment such as pregnancy tests should be in a checklist,
1180 while items that need to be checked daily should be in a document that is accessed daily such as setup
1181 instructions or in a machine alert mechanism if one is available in the RO-EMR. This is an example of
1182 efficacy and of accessibility described in section 6.B, it is extra important that vital patient information
1183 be detectible within the normal workflow – users should not be solely expected to check for this kind of
1184 information in a part of the chart that is not usually accessed routinely.

1185

1186 **6.L. Incomplete treatment sessions or courses**

1187 **A system should be put in place to capture and appropriately document incomplete treatment**
1188 **sessions or courses in the RO-EMR, either automatically or manually via standard QA checks.** This
1189 scenario is a potential safety issue where patients could receive less than the prescribed dose. About
1190 97% of AAPM survey respondents document incomplete treatments, more than 85% document missed
1191 appointments, and more than half document machine failures in the RO-EMR. RO-EMR design can help
1192 simplify and standardize documentation for deviations from the appointment schedule.

1193 **The task group recommends that the treatment history of the RO-EMR be checked for accuracy in**
1194 **the event of an incomplete treatment.** This is in addition to any checks which may be performed as
1195 part of the weekly chart check of the RO-EMR treatment history. Notes should be added to the RO-EMR
1196 for missed appointments and machine failures as well, since a missed treatment may cause confusion
1197 downstream that is more likely to be resolved if this information is readily available.

1198 When an external beam treatment is administered under the direction of a treatment management
1199 system (TMS), a record of that treatment is saved back to the TMS under normal conditions. A “save-
1200 back failure” is a failure to save the record, thus leaving the TMS with an incorrect number of delivered
1201 treatments and potentially leading to overtreatment if not detected and corrected. A clinic using an RO-
1202 EMR may choose to rely on the saved history from the treatment management system as the history of
1203 record of the patient. Therefore **a process should be in place to detect save-back failures of the**
1204 **treatment history.**

1205

1206 **6.M. Treatment course changes**

1207 **Changes in the treatment course such as early completion of treatment should be documented**
1208 **with a valid attending physician signature if they deviate from the prescription as originally written.**
1209 The course of a treatment often changes due to unexpected changes in clinical condition of the patient,
1210 new findings, or other reasons. Often it is not appropriate to modify the prescription to indicate these
1211 changes as it represents the intent of the treating physician. For example, if a course of treatment is
1212 completed early due to deteriorating clinical condition, it may not be deemed appropriate to modify the
1213 prescription because the prescription represents the intended treatment. In that case a note in the
1214 chart may be more appropriate. Another example is the case of a patient being prescribed twice daily
1215 treatment and missing one of the treatments on one day due to unforeseen circumstances. In cases
1216 such as these in which there is a change requested by the physician that deviates from the prescription
1217 without an overall change in treatment intent, the physician should document this deviation in a signed
1218 note and add it to the RO-EMR.

1219 Transfers of the patient between treatment machines should be documented. Permanent
1220 transfers to machines that are dosimetrically equivalent, where dosimetric equivalence implies that
1221 delivery of the same plan will produce the same dose distribution, should be annotated in the treatment
1222 plan document to avoid confusion by the treatment team even though there is no significant change in

1223 the dose delivered. Temporary transfers to a dosimetrically equivalent machine can be annotated as a
1224 free text note. Transfers to non-dosimetrically equivalent machines will require review by physics and
1225 the need for a new plan is dependent on the change in delivered dose due to the transfer. A detailed
1226 discussion of dosimetric equivalence in the context of machine transfers is beyond the scope of this task
1227 group. The treatment machine ID for each delivery should be saved in the treatment history which may
1228 at first glance obviate the need for annotation however these annotations can minimize confusion and
1229 be helpful to the treatment team. Even if machines are dosimetrically equivalent there is still some
1230 work needing to be done for transfers such as possibly reimaging and recapturing couch coordinates.
1231 Specialized workflows can be designed for machine transfers or campus transfers in larger institutions to
1232 help standardize the process (see chapter 7 for a discussion on workflows).

1233

1234 **6.N. Emergency and urgent cases**

1235 **A department should have procedures for using the RO-EMR for emergency and urgent cases in an**
1236 **efficient, safe, and consistent way.** The approach to documentation for clinically emergent cases such
1237 as cord compressions or bleeding, which are often treated with simple single or parallel opposed fields,
1238 is more varied than that for planned cases with electronic documents, electronic forms, and paper
1239 printouts all in clinical use. Since this process is typically carried out on a short timescale and often also
1240 outside regular treatment hours, forms and workflows should be designed such that all of the efficiency
1241 tools of the electronic chart can be exploited as much as possible. Short forms with only the necessary
1242 information can be designed.

1243

1244 **6.O. Chart reviews**

1245 **Chart reviews (plan checks, weekly chart checks, end of treatment checks, etc) should be**
1246 **documented electronically in the RO-EMR.** They are an essential step in the routine QA process and
1247 touch all subspecialties: physicists, dosimetrists, physicians, therapists, nurses, and others. These chart
1248 reviews are also reviewed by regulators. Therefore it would be advisable that documentation of the
1249 particular review be easily accessible within the chart. Review could be represented by a task
1250 completion or a signed checklist if a checklist is part of the process, or both. The association of the
1251 review with a username is advisable, a scanned document with a signature does not take advantage of
1252 the data mining capabilities of the system. An electronic signature within the system is preferable.

1253

1254 **6.P. Preparation and transmission of patient records**

1255 **A clear procedure should be in place for preparation and transmission of patient records to**
1256 **outside institutions.** This process is more complex for an electronic chart due to the decentralization of
1257 relevant data and often involves DICOM elements. The process for sending chart documents should be
1258 easy to complete by administrative staff who often prepare these transfers. DICOM transfers should be
1259 handled or supervised by Medical Physics personnel. External record requests should be considered
1260 when configuring documentation formats: are patient documents stored in such a way that they can be
1261 easily exported, as pdf's for example, and transmitted to another facility? The task group recommends
1262 that a plan printout or comparable summary be sent with DICOM data to confirm the completeness of
1263 the DICOM dataset. Also, the final treatment summary must be reviewed prior to sending the
1264 information to ensure that the treatment course corresponds to the plan information being sent and
1265 that no changes are missed in the transmission that are not reflected in the documentation which was
1266 created prior to treatment.

1267

1268

1269 **7. WORKFLOW DESIGN AND COMMUNICATION IN THE RO-EMR**

1270

1271 In the days of paper charting, passing of the chart from one group to another guided the workflow.
1272 In RO-EMR systems, workflow managers provide clinical team members with the status of the patient in
1273 the planning and treatment process as well as triggering the successive steps in the workflow. In the RO-
1274 EMR, a “workflow” is basically a process map represented as a sequence of “tasks” that are to be
1275 completed to represent the progression of patient care.

1276 Figure 1 is a hypothetical RO-EMR workflow represented as a task sequence. The red and yellow
1277 symbols between tasks demonstrate potential hard stops (red) or soft stops (yellow) installed in the
1278 workflow. A hard stop is a mechanism to stop the workflow from moving forward if the previous task is
1279 not completed accordingly in the RO-EMR. The stopping mechanism can be manual or automatic,
1280 depending on the software capability. A soft stop gives the user the option to stop but does not force
1281 the stop using the functionality of the system. If there is neither a hard nor soft stop, the workflow will
1282 proceed without any interruption or warning from the system. Certain documents (not shown in
1283 diagram) may be associated with each of the tasks such as a simulation order with the simulation step, a
1284 prescription and treatment plan with the treatment planning step, a checklist with the Physicist Plan
1285 Check task, etc...

1286

1287

1288

1289 Workflows inherently act as a form of communication. For example when one task is
1290 completed, RO-EMR systems trigger the next task in the workflow and the person responsible for that
1291 task is alerted that it is their turn in the chain. If a change is made in a patient's plan of care midstream,
1292 for example if a replan is requested due to a new finding, the workflow design has to be agile enough to
1293 move that change forward and notify the appropriate personnel. Therefore *workflow design is*
1294 *fundamentally linked to communication in the clinic* and that concept should not be lost on the
1295 implementation committee when they design the various workflows for the RO-EMR.

1296 In this chapter, we present recommendations for design of workflows using the RO-EMR. We
1297 then touch on some specific key documents as they pertain to the workflow such as the simulation
1298 order and checklists. We then discuss proper communication in the clinic and its relation to a smooth
1299 workflow. Finally, we touch upon the importance of standard configuration of user interfaces and their
1300 importance in the execution of an efficient workflow.

1301

1302 **7.A. Connecting tasks to form a workflow**

1303 **The committee should establish process maps before configuring the workflow manager.** Process
1304 maps should be constructed to chart serial and parallel events in the clinical workflow. These process
1305 maps can in turn feed the configuration of workflow management systems.^{18,35}

1306 The most skeletal workflow should support handoff between the various groups in the clinical
1307 process. At least one task from each of the groups should be included in the baseline or skeleton list as
1308 a starting point to move the chart from each group to the next. The individual groups can then add
1309 additional steps within their section of the workflow, thus building the workflow into something
1310 clinically usable. A task sequence for a particular workflow can be built by

- 1311 1. Entering a primary task for each section to pass the chart from one section to the next
- 1312 2. Adding tasks to the baseline task list in each section if additional passing is required within
1313 that section

1314 Figures 2A and 2B illustrate how a task sequence can be developed. A baseline task list (2A) is
1315 followed by team-specific tasks which are provided by each team based on their internal workflow (2B).

1316

1317
1318
1319
1320
1321
1322
1323
1324
1325
1326
1327
1328
1329
1330
1331
1332
1333
1334
1335
1336
1337
1338
1339
1340
1341
1342
1343
1344
1345

7.B. Creating tasks for the workflow

When designing the workflow, the committee should consider the following for each task: Who, What, When, How, Why, hard or soft stop, and possible risks.

- *Who* – Who should perform this task? Do they have the appropriate rights?
- *What* – What information element, if any, will be used to document this task? Is there a checklist to be completed? Is this a document to be filled and/or approved?
- *When* – What time interval should this task be given for completion? Does this task happen sequentially after a previous task? Does this step prevent the next task from occurring? Can this task be performed in parallel to other tasks?
- *How* – How can the completion of a particular task be confirmed (electronic approval of a document, completion of a task or checklist item, signature on paper to be scanned or imported, etc.)?
- *Hard or soft stop* – Should an incomplete task create a hard stop or soft stop to the following task?
- *Possible risks* - Are there other possible errors that could happen but not yet included in the workflow design?

7.C. Linkage of documents with workflow tasks

Documentation such as checklists should be linked by the system to workflow tasks when possible. Documentation, where appropriate, provides proof of what had been done in the task, rather than only a record of the completion of a task item. Therefore, documentation is often linked to certain workflow tasks.³⁵ Documentation could be in different formats depending on workflow design. For example, a checklist may be attached to an electronic task for physics initial chart check. Another example of documentation linked to a workflow task could be a scanned consent document in the consenting task. A completed scheduled task item that is linked to a workflow task could also be useful in confirming and documenting the completion of a task item, although having an attached form is preferable if possible.

1346 **7.D. Simulation orders in the workflow**

1347 **Safety barriers should be established to prevent simulation without completion of an accurate**
1348 **simulation order.** The simulation order often serves as the initial source of information for the clinical
1349 team and provides the intended treatment for the patient. Accuracy of the simulation order is essential
1350 for a smooth simulation process and for avoiding unnecessary resource reallocation downstream in the
1351 planning process. For example, information such as previous treatment is valuable when assigning
1352 treatment planning resources, as non-planned cases matching to a previously treated area may require
1353 a special physics consultation during the simulation to set the isocenter and define the fields. When
1354 simulating for stereotactic radiosurgery, the simulation order should state the correct number of lesions
1355 (if known) which aids in allocating planning resources and scheduling adequate time on the treatment
1356 machine.

1357 The simulation order often involves the synthesis of information from a variety of sources, many of
1358 which may be stored on the H-EMR. This often leads to a debate concerning where the simulation order
1359 should reside. The H-EMR may also have more robust features for control of data entry such as required
1360 fields, more robust approval mechanisms, and more connectivity to other departments. More
1361 streamlined connectivity between the H-EMR and RO-EMR (ie any synchronization functionality which
1362 eliminates the need to manually transfer certain documents between the two systems) is always
1363 advantageous and the document could be synthesized in either of the systems and reside in one or both
1364 systems.

1365 Built-in features of the RO-EMR may aid in the enforcement of an accurate, complete and signed
1366 simulation order. There are a number of ways in which clinics currently enforce completion of the
1367 simulation order. A time out procedure or checklist is commonly used as a template in the RO-EMR.
1368 Crucial steps in the simulation workflow such as completion of the sim order can be incorporated into
1369 the automated workflow manager.

1370

1371 **7.E. Prescription entry in the workflow**

1372 **The institution should incorporate prescription entry as one of the workflow tasks; consider when**
1373 **it should be entered initially, and the proper timeframe to finally approve it.** Prescription entry serves
1374 as a basis for treatment planning to begin and is an important task in the workflow management. While
1375 at times the treatment beam energy or technique could be flexible and may only be finalized after a

1376 computerized treatment plan is done in the treatment planning system, the planner has a critical need
1377 to know the physician's intent to begin and efficiently proceed through the planning process.

1378 **If a 3rd party prescription application is utilized, a system of checks needs to ensure the**
1379 **consistency of information and proper data transfer with the primary RO-EMR to prevent possible**
1380 **discrepancies between two different systems.** The prescription should be easily accessible by the
1381 clinical team. Maintaining a copy of the prescription that is not automatically updated introduces risk of
1382 there being two different versions of the prescription. This sort of redundancy should be avoided.

1383

1384 **7.F. Incorporating automated charge capture in workflows**

1385 **When the RO-EMR is used for billing purposes, automated charge capture should be used if**
1386 **available.** The committee should take this functionality into consideration when configuring workflow
1387 managers. Forms should be designed such that billing compliance can be easily verified. Utilizing
1388 automated charge capture helps to ensure billing charges are correct as they are tied to a specific task
1389 completion activity.

1390

1391

1392 **7.G. Formalizing the release of workflows into the clinic**

1393 **Formalizing the process of releasing workflows (discussion by RO-EMR management committee,**
1394 **pilot and formal release with proper notification) is recommended to prevent potential errors or**
1395 **unanticipated clinical inefficiencies.** Workflow management tools fundamentally affect the functioning
1396 of the clinic. As discussed, they should be configured to mirror the sequence of serial and parallel tasks
1397 in a clinical process. Therefore, formalizing the development, release, and modification of these tools is
1398 recommended to ensure adequate vetting and testing prior to release. Workflows that are poorly
1399 designed can cause potentially serious delays in the clinic. Like documents, workflows should be
1400 carefully designed by the implementation committee, tested, piloted if possible with a small subset of
1401 clinical cases, and approved prior to general release.^{13,18,35}

1402

1403 **7.H. Ongoing refinement of workflows**

1404 **Clinics should utilize task completion metrics and feedback from different clinical groups to refine**
1405 **RO-EMR workflows as part of ongoing QA.** As described in Chapter 4: QA of the RO-EMR, workflow
1406 refinement is one of the tasks recommended for ongoing QA of the RO-EMR. A combination of

1407 feedback from various groups^{18,19} using workflows as well as analysis of task completion metrics
1408 provides valuable information in determining if the workflow is serving the clinic and not the other way
1409 around. Recommended task completion metrics include percent task completion at each step and the
1410 bottleneck for completion for each task (potentially indicating that an individual or a group may need
1411 more training).

1412

1413

1414 **7.I. Consistency in communication**

1415 In the same way that consistency is essential in information entry, consistency in communication
1416 within the RO-EMR is essential. Clinics rely on the RO-EMR to communicate time-sensitive information
1417 regarding the patient from one group of staff member to another. When the channels of
1418 communication are inconsistent, some vital information may not reach its intended audience in the
1419 necessary timeframe. **The clinic should establish clear consensus on the channels for transfer of**
1420 **specific types of time-sensitive information and enforce its use.** For example, if a change is requested
1421 in chart rounds, the change has to be communicated to treatment planning consistently because an
1422 electronic system has no paper chart to pass the information which would initiate the requested change.
1423 In addition, the therapists must be notified that a revision of the treatment plan is in process.

1424 Flaws in communication were identified by the task group, particularly when changes were made to
1425 a patient's chart after the patient began treatment. Similarly, the communication of changes in
1426 treatment parameters (such as discontinuation of bolus) remains a concern. **The task group**
1427 **recommends that implementation committees focus on known lapses in communication in the**
1428 **workflow development phase to ensure that the clinical workflow design is robust against these sort**
1429 **of unexpected changes in care.** Stops in the process and/or forcing functions to compel notification are
1430 helpful here.

1431

1432 **7.J. "Handoffs" and "handshakes"**

1433 **"Handoffs" and "handshakes" should be clearly identified for different types of communication.**
1434 By "handoff" the task group means a transfer of work from one user to another that does not require
1435 confirmation. Examples include the passing of the plan from physician to physics at the conclusion of
1436 contouring. The physician does not check that the information was received and relies on the workflow
1437 manager to convey it. A "handshake" is more rigorous and requires confirmation from the receiving

1438 party. An example could be the reduction of fractions from the treatment course (prescription
1439 modification). The physician should confirm that the information was received by the intended party
1440 whether it be physics staff, therapy staff, or both.

1441 The task group would like to note that handoffs and handshakes within the RO-EMR system by no
1442 means obviate verbal communication which can serve as confirmation as well as provide clarification
1443 when it is needed. These handoffs and handshakes can be thought of as the systemic means of
1444 communication within the RO-EMR which can initiate a more detailed verbal communication. The RO-
1445 EMR should not substitute effective verbal communication currently in place but rather efficiently
1446 support it.

1447

1448

1449 **7.K. Standardization of user interfaces**

1450 **User interfaces should be standardized within the same user group.** A customizable RO-EMR user
1451 interface by staff type would be appropriate and aid in easy access to the necessary items/menus for
1452 individual users. It would also facilitate a more efficient workflow and facilitate training. An admin user,
1453 typically a department Information Technology/Information Systems (IT/IS) personnel should be able to
1454 configure RO-EMR layouts based on the user staff type.

1455

1456

1457 **8. BRACHYTHERAPY AND NON-STANDARD DEVICES**

1458

1459 Brachytherapy and non-standard devices such as Tomotherapy (Accuray Inc., Tomotherapy Inc.,
1460 Madison, WI), CyberKnife (Accuray Inc., Accuray Corporate HQ, Sunnyvale CA), Gamma Knife (Elekta AB,
1461 Stockholm, Sweden) and Viewray (Viewray Technologies, Inc., Mountain View, CA) share core
1462 characteristics in their limited connectivity to the RO-EMR. Brachytherapy and other non-standard
1463 devices do not have the same standard workflows as external beam radiotherapy, and consequently
1464 make universal application of an electronic chart complex. In this section, we will describe the current
1465 state of electronic charting for these systems and make suggestions about the future environments and
1466 directions that the RO-EMR may migrate into. We then provide recommendations on how to design the
1467 RO-EMR for non-standard devices in each connectivity category such that it closely replicates the
1468 standard RO-EMR chart while not creating undue burden for the clinic.

1469
1470
1471
1472
1473
1474
1475
1476
1477
1478
1479
1480
1481
1482
1483
1484
1485
1486
1487
1488
1489
1490
1491
1492
1493
1494
1495
1496
1497
1498

8.A. Definitions of RO-EMR Connectivity Categories

8.A.1. Standalone

Standalone devices are devices which do not connect to RO-EMR at all. Examples of standalone devices at the time of this report are:

- Intraoperative devices located outside the Radiation Therapy Department (operating room (OR), Nuclear Medicine Floor): electron linacs, kV devices including electronic brachytherapy, Low dose rate (LDR) prostate seed implants, orthovoltage devices, and nuclear medicine ablative procedures handled by radiation therapy departments.
- Devices located within the Radiation Therapy Department, but with no connectivity to EMR or for which connectivity modules have not been purchased: non-communicative HDR afterloaders, Gamma Knife, non-C-arm linacs, and new devices for which connectivity modules have not yet been developed.
- 3rd party software systems or devices such as MIM Symphony LDR (MIM Software Inc, Cleveland, OH), Oncentra seed (Elekta AB, Stockholm, Sweden) or Variseed (Varian, Palo Alto, CA) when used in the OR for LDR brachytherapy procedures. iPads (Apple Inc., Cupertino CA) are routinely used to remotely perform Therasphere³⁶ or COMS³⁷ eye plaque calculations. These instruments can be used either in the RO department or outside (e.g. Interventional Radiology, operating room (OR)).

8.A.2. Limited connectivity

Devices with limited connectivity have connectivity modules available to connect to most commercial RO-EMR systems but are not part of the R&V functionality of the RO-EMR. These connectivity modules are developed by device manufacturers, RO-EMR vendors, or 3rd-party vendors. A typical connectivity module allows for the bidirectional flow of information. In the RO-EMR-to-Device direction, patient demographics flows to the connected device, and scheduled treatment plans are made available to the machine for delivery. In the device-to-RO-EMR direction, the treatment data is automatically recorded back to the EMR after each delivered fraction. Other data such as setup images may be part of data transfer in this direction as well.

1499 **8.A.3. Full connectivity**

1500 Full connectivity occurs when the device is driven by the RO-EMR exactly like current C-arm linacs.
1501 The recommendations in the other sections of this task group report apply to these devices. In the case
1502 of fully connected HDR afterloaders, the special considerations regarding the Written Directive are
1503 discussed in Section 8.B.1.

1504

1505 **8.B. Shortcomings**

1506 In some systems, the patient can be scheduled, queued, treated, and recorded all within the use of
1507 the RO-EMR. With other vendor combinations, such interplay between RO-EMR and delivery system
1508 does not exist. Some vendors currently are not pursuing modules or components to allow this
1509 connection to happen at all. However, allowing non-standard devices to lag technologically hinders the
1510 workflow and efficiency of the process. For some combinations of RO-EMR and devices, creating
1511 connectivity requires the purchase of an extra license or module. This is costly in some clinics and a
1512 financial burden that prohibits its implementation.

1513 For some device/RO-EMR combinations, partial connectivity is established. The issues with partial
1514 connectivity can be multi-faceted, depending on the equipment being used. Some non-standard devices
1515 such as CyberKnife lack a way to incorporate and record shifts from the treatment imaging into the RO-
1516 EMR; others such as low dose rate (LDR) brachytherapy lack a method of handling dose tracking and
1517 accumulation even in a simplistic way. Some non-standard devices cannot handle complex patient
1518 situations such as multiple courses or sites. A lack of dose tracking can be a significant issue with certain
1519 systems, particularly if the course or plan has changed over the course of a patient's treatment and
1520 there is no way to modify or edit the information on the third-party system.

1521 Furthermore, the workflow for procedures using non-standard devices can significantly differ from
1522 standard devices, and also be more varied across clinics. This variability results in difficulty customizing
1523 the available workflow tools for these devices. Even the clinical space needed for moving to an
1524 electronic environment can be difficult due to the number of extra computers and monitors needed-
1525 this is not unique to brachytherapy but may be more extreme. A suggested minimum of two separate
1526 RO-EMR workstations (for concurrent usage by different clinical team members for example), plus the
1527 treatment computers, and potentially a planning system requires significant console area space.

1528 Another hurdle to implementation of electronic recording of patient treatments in the realm of
1529 brachytherapy is the acceptance of electronic documentation by regulatory bodies. While this was
1530 discussed previously, the AAPM member survey indicated numerous times that regulators (one

1531 respondent mentioned an NRC audit for example) were not accepting electronic signatures. The work-
1532 around to the clinic was to print the electronic prescription/written directive, have the physician sign it,
1533 then scan back into the RO-EMR system for storage. Concerns over complying with regulators and HIPAA
1534 are still valid.

1535 One of the largest concerns found in the AAPM member survey regarding an all-electronic
1536 environment was the inability to treat the patient if the network went down or if there was a
1537 communication failure³⁸. For conventional linear accelerators, if the machine or network goes down
1538 before the plan has been transferred from planning system to device, the procedure is usually just to
1539 remove the patient from the table and have them wait until the connection is restored. In the case of
1540 HDR brachytherapy, a patient may be sedated and have uncomfortable applicators in place. During
1541 intraoperative radiation therapy (IORT), the patient may be anesthetized and have an open surgical
1542 procedure occurring. In the case of HDR, one way of mitigating this potential risk is to test the
1543 connectivity between the afterloader and planning system during daily QA. The planning system may
1544 also have a method for transferring the plan to the afterloader via USB drive.

1545

1546

1547 **8.C. Brachytherapy-specific challenges**

1548 ***8.C.1. Requirements of written directive***

1549 Part of the complexity in adopting electronic charting in brachytherapy is the requirements of a
1550 written directive. In the United States, facilities agree to follow the regulations in 10 CFR 35 and all
1551 state and local regulations. The written directive is covered in 10 CFR 35.40. Figure 3 and Figure 4 show
1552 an example of an electronic written directive in ARIA and MOSAIQ respectively, each containing the five
1553 required components of radionuclide, treatment site, dose per fraction, number of fractions, and total
1554 dose. However, unlike a typical radiotherapy EMR, it does not control any devices or treatment delivery
1555 in most cases, and therefore exists to fulfill regulatory requirements only.

1556 Limited access to the inter-departmental RO-EMR systems can be a barrier to using an electronic
1557 written directive. Examples include brachytherapy procedures taking place in procedure rooms outside
1558 the radiation oncology department, such as interventional radiology or an OR. Access to the RO-EMR
1559 may be limited to one (or a few) shared workstations running Citrix or remote desktop applications.
1560 Additionally, **many hospitals prohibit the use of mobile devices in the OR, effectively preventing access**
1561 **to the RO-EMR. In these circumstances, a paper written directive may be used, which should be**
1562 **scanned into the RO-EMR in a timely manner after the completion of the procedure. The scanned**

1563 **electronic document should be stored in a consistent location and with clear labeling in the RO-EMR.**

1564 Figure 5 shows an example of a paper written directive. Once the document is scanned into the RO-
1565 EMR, the original document may be discarded in a HIPAA-compliant manner.

1566 Figure 6 shows an example for an unsealed source. 10 CFR 35.40(b)(6) stipulates that the written
1567 directive may be amended before the formal completion of the procedure. **For an electronic written**
1568 **directive, the history of the written directive should be easily accessible to users of the RO-EMR.**
1569 **Historical versions (which should be saved within the RO-EMR) should include the date, time and**
1570 **electronic signature of the directive. Any changes or amendments to the written directive should**
1571 **follow regulations and be documented appropriately.** While 10 CFR 35.40 does not require applicator
1572 information to be part of the written directive, including the information as best as the RO-EMR
1573 prescription field allows is an added safety feature. With regards of other components of the written
1574 directive, ASTRO has published a white paper with recommendations for the standardization of
1575 radiation treatment prescriptions.³² In general, regulations and guidelines published by regulatory
1576 agencies such as the NRC in the US take precedence over AAPM or ASTRO society recommendations.

1577

1578

1579 **8.C.2. Guidance on electronic signatures specific to Brachytherapy**

1580 As described in section 7.F, in the US, the Electronic Signatures in Global and National Commerce
1581 Act (Public Law 106-229 from June 30, 2000) defines which types of electronic signatures “may not be
1582 denied legal effect”).³¹ The Report of the NRC Advisory Committee on the Medical Uses of Isotopes for
1583 Electronic Signatures from April 16, 2012 specifically endorses the NRC to accept as compliant any
1584 electronic signatures following the guidance of Public Law 106-229.³⁹ It has been the experience of
1585 some members that the NRC has accepted electronic signatures but the physicist should discuss with
1586 local regulators prior to implementation. **Each Radiation Oncology Department should develop**
1587 **policies and procedures (P&Ps) defining how electronic signatures are to be validated.**⁴⁰ This is of
1588 particular interest in brachytherapy treatments because of slowly changing rules and regulations for
1589 these types of procedures. It is recommended that those developing a brachytherapy RO-EMR work
1590 with local regulators and inspectors to alleviate any potential concerns.

1591

1592 **8.D. Additional Recommendations**

1593 ***8.D.1. RO-EMR connectivity software and new non-standard devices***

1594 **The availability, cost, and functionality of the RO-EMR connectivity software should be assessed**
1595 **for existing non-standard devices and prior to purchase of new non-standard devices and**
1596 **brachytherapy afterloaders.** This assessment should dictate the design of the RO-EMR for these
1597 devices. Hospital IT should be consulted regarding the server needs, firewall and security settings,
1598 backup capabilities and other considerations falling under the IT Department responsibility. Some
1599 technologies require "send and query access" to remote servers. In community clinics and free-standing
1600 clinics, the medical physicist may have to take on these IT responsibilities.

1601
1602 ***8.D.2. Stakeholders working with the non-standard devices on RO-EMR implementation***
1603 ***committee***

1604
1605 **The RO-EMR implementation committee should include representatives from all stakeholders**
1606 ***working with the non-standard devices.*** Committee members should identify areas in which
1607 functionality and use of non-standard devices can be kept identical or as closely aligned as possible with
1608 the external beam chart. The committee should include individuals knowledgeable about the rules and
1609 requirements for the technology in that state such as a qualified medical physicist and/or a radiation
1610 safety officer.

1611 The AAPM member survey asked about which elements of the chart modality for non-standard
1612 devices were handled as paper only, scanned paper, or electronic (results shown in Figure 7). Given that
1613 less than ten percent of chart elements for non-standard device were paper only, a clear opportunity
1614 exists to standardize RO-EMR chart design across modalities with the only changes being scanned paper
1615 versus electronic chart elements.

1616

1617

1618 ***8.D.3. Prescription entry for non-standard devices***

1619 **For all devices, the prescription should be entered and signed in a similar method as for standard**
1620 **devices.**

1621 ***For all prescriptions, the applicable federal, state, and local regulations pertaining to the written***
1622 ***directive should be followed. Note that paper format for the written directive is typically used when***

1623 *electronic records are not available, such as in the OR, or when regulators still require paper*
1624 *documentation.*

1625

1626 **8.D.4. Plan documentation and documentation of billable activities**

1627 Two general methods are commonly used for handling plan documentation and depend on the need
1628 for print documentation. **Plan documentation should be exported as file and imported into the RO-**
1629 **EMR. If this is not possible and documentation is needed, then it can be printed and scanned.** The
1630 electronic signature functions of the RO-EMR can be used for plan documentation approval. For
1631 treatment plans that cannot be readily saved to a shared drive, or in situations such as an OR
1632 environment where a paper printout is essential for documentation, the treatment plan document is
1633 later scanned into the RO-EMR.

1634 **Documentation for billable activities associated with non-standard devices should also be**
1635 **considered.** When designing the RO-EMR for these devices the implementation team should consider
1636 the associated billable activities and determine if adequate documentation exists in the proposed RO-
1637 EMR design.

1638

1639 **9. IT INFRASTRUCTURE AND DATA MANAGEMENT**

1640

1641 IT infrastructure and data management processes form the backbone of the RO-EMR system.
1642 Additionally, modern RO-EMR environments do not work in isolation; rather they are one piece of a
1643 network of multiple systems in charge of managing patient care in a radiotherapy practice. Modern RO-
1644 EMR systems also contribute to information management and exchange with other hospital information
1645 systems. Understanding the connectivity between all the systems involved in a radiotherapy practice as
1646 well as the IT infrastructure are fundamental requirements for providing high quality and safe patient
1647 care.

1648 Using published evidence as well as the data collected by our two surveys, TG-262 developed the
1649 recommendations in this section on best practices for management of IT infrastructure which supports
1650 the RO-EMR environment. It is important to emphasize that both surveys have a relatively equal
1651 distribution of the two primary types of environments: the Single-Vendor environment (i.e. delivery,

1652 treatment planning and RO-EMR environment are from the **same** vendor; 52.4% in the AAPM member
1653 survey) and the Multi-Vendor environment (i.e. delivery, planning and RO-EMR environment are from
1654 **different** vendors; 47.6% from the AAPM member survey). Therefore, recommendations driven by the
1655 survey data are not biased toward a specific type of environment, and could apply to institutions that
1656 would like to pursue or already have either a single- or multi-vendor environment.

1657

1658 **9.A. IT infrastructure:**

1659

1660 IT infrastructure refers to “the composite hardware, software, network resources and services
1661 required for the existence, operation and management of an enterprise IT environment. It allows an
1662 organization to deliver IT solutions and services to its employees, partners and/or customers and is
1663 usually internal to an organization and deployed within owned facilities.”⁴¹ In order to provide an overall
1664 structure for the recommendations as well as a framework to facilitate future discussions, we divided
1665 the IT infrastructure into the following 4 domains:

1666

- 1667 • **Peopleware** (the human role in software and hardware development and interaction):^{42,43}
 - 1668 ○ Network, database and system administrators
 - 1669 ○ Developers
 - 1670 ○ Designers
 - 1671 ○ Generic end users with access to any IT appliance or service for maintenance and
 - 1672 support

- 1673 • **Hardware Infrastructure:**

- 1674 ○ Physical and/or Virtual servers
- 1675 ○ Server connectivity
- 1676 ○ Internet connectivity
- 1677 ○ Firewall and security
- 1678 ○ Cloud-based deployment
- 1679 ○ High availability and redundant systems
- 1680 ○ Networking
- 1681 ○ Data backup systems and processes
- 1682 ○ Performance
- 1683 ○ Test environments

- 1684 ○ Mobile Device Connectivity
- 1685 ● **Software supporting IT infrastructure:**
- 1686 ○ Enterprise resource planning (ERP)
- 1687 ○ Productivity applications
- 1688 ○ Operating system
- 1689 ○ Database management system (DBMS)
- 1690 ○ Communications protocols
- 1691 ○ Anti-virus software
- 1692 ○ Compilers
- 1693 ○ Other development tools
- 1694 ● **Application Services:**
- 1695 ○ Reporting
- 1696 ○ Mining and data analytics
- 1697 ○ Data and information exchange with other hospital-based systems and devices

1698 This report primarily focused on peopleware, hardware, and application services. Software
1699 supporting the IT infrastructure beyond the actual RO-EMR software covered by this report is essential
1700 but outside the scope of this task group.

1701

1702 **9.B. Peopleware & Management Strategies:**

1703 ***9.B.1 Team members***

1704 Implementation, deployment, maintenance and everyday clinical operations of the IT Infrastructure
1705 require the collaboration of the following three main groups: 1) Clinical Practice (i.e. medical physicists,
1706 therapists, dosimetrists and/or physicians), 2) Department or Institutional IT, and 3) Vendor. Siochi et
1707 al.⁴⁴ emphasize the importance of medical physicists and/ or representatives of the clinical team
1708 partnering with equipment service engineers, vendors, RO IT staff, and hospital or clinic IT staff. They
1709 argue that reliance on just the IT staff alone is not sufficient, since they do not fully understand the
1710 critical needs of the RO-EMR environment as well as the needs of the practice.

1711 As the management and needs of the RO-EMR environment become more complex, the role of the
1712 institutional IT team will be highly valuable in order to maintain a secure, effective and safe IT
1713 infrastructure. However, **the task group recommends that members of the clinical team as well as**
1714 **medical physicists participate in the discussion regarding the IT infrastructure, since they will be**

1715 **responsible for highlighting the needs of the practice.** Inadequate collaboration between medical
1716 physics and institutional IT has caused frustration among practices when a lack of harmonization exists
1717 between the needs of the institutional IT team and the clinical team.

1718

1719 ***9.B.2 Familiarity with terminology, technical concepts, architecture and management of the***
1720 ***IT infrastructure.***

1721 **Medical physicists should familiarize themselves with the terminology, technical concepts and**
1722 **main issues regarding the architecture and management of the IT infrastructure.** This is especially
1723 important when no radiation oncology specific IT support exists. Historically, the role of medical physics
1724 in radiotherapy has been focused on the management of the radiotherapy clinical processes and
1725 systems and the medical physicist was often the IT person in the department. As modern treatment
1726 planning and delivery systems become more complex and connectivity outside the department becomes
1727 more prevalent, the role of the medical physicist increasingly requires specialization in the IT domain.

1728 There is continuing debate concerning the level of involvement of medical physicists in the IT
1729 domain.⁴⁵ However both surveys show that practices frequently rely on medical physicists to take a lead
1730 role in some or all the aspects of the RO-EMR environment. **While the task group does not recommend**
1731 **that the Medical Physicist assume primary responsibility for the IT infrastructure and support for the**
1732 **RO-EMR, it is important that medical physicists be part of the ongoing decision making process.**
1733 Therefore, Medical Physicists should become familiar with some of the terminology and concepts
1734 related to the IT infrastructure and data management, so they can have meaningful and constructive
1735 conversations with both the department/institutional IT teams and the vendor. The 4 IT infrastructure
1736 domains described above provide a high level set of topics that medical physicists, involved on the
1737 management of their RO-EMR IT infrastructure, could use as a training checklist to become more
1738 knowledgeable in the areas of IT infrastructure and data management. The local IT representative can
1739 recommend training resources that best suit the IT infrastructure being used in the clinic if desired.

1740 **9.C. Hardware Infrastructure Type and Design:**

1741

1742 ***9.C.1. Clinical needs, institutional restrictions, and constraints***

1743 **Clinical needs, institutional restrictions, and constraints need to be clearly defined when building the**
1744 **IT infrastructure for the RO-EMR environment.** There are primarily four architectural models for

1745 RO-EMR IT infrastructures: thick clients only (e.g., conventional desktop PC software
1746 deployment), remote virtual clients only (e.g. Citrix managed by the institution), combination of
1747 institutional thick and remote virtual clients, and Cloud-based (both RO-EMR database and
1748 remote virtual servers are managed by the vendor).

1749 These can be deployed via servers in the department, servers on institutional supported networks,
1750 and servers on remote locations. The pros and cons of thick clients versus virtual environments like
1751 Citrix or cloud based is given in Table VI.

1752 Each model has its own clinical and economic advantages and disadvantages; thus it is important
1753 that each practice collaborates with their departmental/institutional IT teams as well as the vendor to
1754 clearly define the needs and restrictions on each of the 4 IT infrastructure domains.⁴⁶ What is best for a
1755 specific practice will depend on many factors, which include economic restrictions, IT infrastructure
1756 support, treatment delivery and planning systems, and specific clinical needs.

1757 **9.C.2. Deployment and Design**

1758 There are a variety of deployment strategies for an RO-EMR system that are highly dependent on
1759 the resources that each practice has available to them. Therefore the task group does not feel that it
1760 would be appropriate to recommend any one type of deployment over another. The most common RO-
1761 EMR environment deployment as seen by the task group surveys was a combination of thick clients and
1762 a virtual deployment (i.e. Citrix). Using this hybrid approach, users have access to the system through
1763 either a thick client or through an application virtualization process like Citrix. A hybrid approach has
1764 two main benefits: it provides a balance between a cost effective and efficient system deployment
1765 provided by the application virtualization process, and it also maintains a fallback system in case the
1766 virtual deployment fails. However, hybrid deployments tend to be more costly. The stability and efficient
1767 accessibility of the RO-EMR environment through the virtual deployment (i.e. Citrix) is highly dependent
1768 on the specifications of the infrastructure sustaining the virtualization process. The task group did not
1769 learn of any patient related incidents or near misses directly caused by the utilization of Citrix and its
1770 downtime. However, some reported slow access to RO-EMR environment or a down network.

1771 **9.D. Database Architecture**

1772 Relying on centralized hospital or institutional based IT infrastructure models is becoming a more
1773 common approach. Most clinics rely on the institutional IT infrastructure model, which provides a
1774 designated group of resources and people to maintain the infrastructure. The most common

1775 deployment encountered was through institutional servers, followed by a hybrid approach (i.e.
1776 combination of institutional and department data centers as well as cloud-based systems), and cloud-
1777 based only.

1778 Some of the institutional IT teams may lack a full understanding of the relevance of the systems in
1779 radiation oncology which may lead to disharmony between the clinical needs of the department and the
1780 priorities of the IT group supporting the infrastructure. This issue emphasizes the need for a constant
1781 dialogue as well as direct involvement of the members of the clinical team on everyday decisions
1782 regarding the IT infrastructure. Early communication could resolve potential issues and minimize delays.
1783 Most importantly, mutual understanding and respect between the Medical Physicist and the IT
1784 representative regarding each others' roles, responsibilities, and expertise is essential to a productive
1785 partnership in the management of the RO-EMR system and its infrastructure.

1786 ***9.D.1. Disaster recovery (DR) and high availability (HA) solutions***

1787 **Disaster recovery, and when possible, high availability solutions are essential when designing**
1788 **failover processes for the RO-EMR.** A common concern among users is the loss of clinical data due to
1789 catastrophic failure or corruption of the system. Modern RO-EMR environments and corresponding IT
1790 infrastructures offer multiple solutions to mitigate that risk. Among these solutions, it is important to
1791 differentiate between two main concepts: High Availability and Disaster Recovery. High availability (HA)
1792 is the measurement of a system's ability to remain accessible in the event of a system component
1793 failure. Disaster recovery (DR) is the process by which a system is restored to a previous acceptable state
1794 and is more commonly known as a "backup". While they both increase overall availability, "high
1795 availability" refers to the retaining of the service and "disaster recovery" to the retaining of the data.
1796 During implementation of disaster recovery solutions, a slight loss of service for a specified duration
1797 occurs while the disaster recovery plan is executed, and the system is restored.⁴⁷ **The task group**
1798 **recommends that clinics have a system and processes for disaster recovery (i.e. backups) as well as**
1799 **processes to validate those backups. A monitoring system is also recommended, either automated or**
1800 **manual, to verify that the backup process took place.**

1801 Since high availability solutions add an additional cost to the overall IT infrastructure architecture,
1802 HA solutions are still not commonly adopted in the field of Radiation Oncology. More investigation is
1803 needed regarding the value of adopting HA solutions as part of an IT infrastructure for an RO-EMR
1804 environment. Continuity of care is essential, therefore **each practice should determine the amount of**

1805 **downtime that the clinic can accept and implement a high availability and/or disaster recovery**
1806 **solution that meets those needs.**

1807 ***9.D.2 Mobile device connectivity***

1808 **Mobile device connectivity must be secure. Users must evaluate mobile platforms for**
1809 **compatibility with all accessible electronic chart functions. If a mobile device is used for image review,**
1810 **the screen size and resolution must be appropriate.** Mobile technologies are becoming a common
1811 solution in health care systems, providing new models for caregivers and patients.⁴⁸ Given this demand,
1812 mobile device connectivity will require the implementation of new infrastructure that supports this new
1813 deployment model. How this trend will affect the area of radiation oncology remains to be seen. The
1814 main concern is information security. The task group found that institutions that provide mobile device
1815 connectivity use a secure virtual private network (VPN) connection and Citrix to deploy the application
1816 on mobile devices. The field is slowly moving in the direction of data portability from mobile devices,
1817 which will require IT infrastructure to support it.

1818 ***9.D.3. Electronic storage capacity***

1819 **Manual or automated processes should be in place to monitor the growth of the RO-EMR database**
1820 **and ancillary storage devices and warn the IT team that more space is needed.** TG-262 members
1821 identified this issue as a common failure mode, given that some TG members' RO-EMR systems stopped
1822 clinical operations when the RO-EMR database or ancillary storage devices (e.g. imaging storage) did not
1823 have sufficient space. **The task group recommends monitoring the usage and storage capacity on a real**
1824 **time basis to warn the administrators of near capacity storage and provide time to amend system.**
1825 Clinics should request recommendations or requirements from vendors on the necessary
1826 storage overhead needed to function properly so appropriate limits can be monitored.

1827

1828 ***9.D.4. Information security threats***

1829 **Clinical Teams need to be aware of information security threats and work with both the**
1830 **department/institutional IT teams and the vendor to mitigate this risk.** Information security is quickly
1831 becoming a relevant concern in the health industry. According to the Office of Civil Rights, there were
1832 253 breaches in the healthcare industry in 2015, affecting 500 individuals or more with a combined loss
1833 of over 112 million records.⁴⁹ A very tangible example occurred at MedStar Health systems, where all
1834 information systems were shut down due to a ransomware attack, causing radiotherapy treatment

1835 delays for two days.⁵⁰ Even though radiation oncology is a small section of the overall health industry,
1836 the reality is that all systems including RO-EMR environments and radiotherapy systems are exposed to
1837 this risk. Either the IT team alone or IT team working with medical physicists are responsible for secure
1838 access to the information in the RO-EMR environment. The responsibilities of medical physicists are
1839 extending beyond monitoring the quality and safety of the treatment delivery and now include the
1840 monitoring of the safety of the patient information and systems against information security threats,
1841 including cyber attacks. Since this new responsibility requires a new set of knowledge, **it is important**
1842 **that the medical physicist partner with institutional and departments IT teams as well as vendors to**
1843 **mitigate the risks and prevent data breaches in radiotherapy both to maintain adequate security and**
1844 **to protect the integrity of the RO-EMR system.** Most clinics maintain either secure access through
1845 network logging in privileges, secure access provided within the RO-EMR software itself, or a
1846 combination of both. The effectiveness of these preventive measurements will most likely be dependent
1847 on each institution's infrastructure and staff culture around information security.

1848 ***Information security good practices and strategies for RO-EMR Environments:***

- 1849
- 1850 • From the IT Infrastructure:
 - 1851 ○ Keeping patch level current.
 - 1852 ○ Monitor system performance closely with an automated tool for system abnormalities.
 - 1853 • From the System Administration:
 - 1854 ○ Use a personal account for daily activities (i.e. email, web browsing, administrative
 - 1855 tasks) and a service account with the minimum level of permissions for system
 - 1856 maintenance activities.
 - 1857 • From the individual user safety practices:
 - 1858 ○ Only use local administrative permissions when required. Do not run as administrator at
 - 1859 all times.
 - 1860 ○ Use complex passwords and a password vault (i.e. Keypass, Lastpass, 1Password).

1861

1862 ***9.D.5. Test environment***

1863 **The Clinical Team should consider including a test environment as part of the RO-EMR**
1864 **environment deployment and design strategy.** The RO-EMR test environment allows users to test

1865 upgrades pre-clinically. Test environments are also very useful during the initial phases of
1866 implementation of an RO-EMR environment, and can be used for validating workflows and system
1867 configurations, testing connectivity, data migrations, as well as pre-clinical deployment training. Even
1868 though a test environment adds additional cost to the overall RO-EMR environment implementation and
1869 continuous maintenance of both systems, this test component has been proven to be very valuable to
1870 all surveyed practices and minimizes the likelihood of issues with the RO-EMR environment during the
1871 implementation of upgrades and new features. It affords users the opportunity to test new workflows,
1872 scripts, and functionalities prior to their release into the clinic.

1873 ***9.D.6. Electronic screen space (dual monitor setup)***

1874 Adequate screen space in the electronic environment is analogous to adequate desk or tabletop
1875 space in the paper environment. The clinical team should consider the available electronic screen space
1876 for all users and all clinical contexts. The need to scroll or rearrange windows should be minimized (this
1877 may be due to inadequate resolution settings which should be verified with the vendor initially and with
1878 each upgrade); information just off the screen may be missed and lead to error. **The task group**
1879 **recommends that a dual monitor setup be the minimum standard with adequate screen resolution to**
1880 **support all of the RO-EMR functionalities as specified by the vendor.** Information in the RO-EMR
1881 environment workflow is distributed among several systems and applications and necessitates several
1882 open windows. For example, information from treatment planning systems, hospital EMRs, radiology
1883 imaging reviewing systems, among many others, are needed throughout the radiation oncology
1884 workflow. In addition, certain busy environments such as the treatment machine cannot afford to take
1885 the time to move between various subsystems required for appropriate information access.

1886 ***9.D.7. Application services***

1887

1888 **Members of the clinical team should become familiar with and partner with IT team members to**
1889 **develop application services that optimize the connectivity among systems as well as facilitating the**
1890 **collection of data and analytics from the RO-EMR environment and other information systems.**
1891 Several radiation oncology practices are part of a hospital or a bigger cancer care center, and thus they
1892 have a basic need to exchange information between the radiation oncology department and other
1893 departments within or outside the main hospital or cancer center. The task group has identified a need
1894 for better and more efficient mechanisms for information exchange. Robust connectivity will require

1895 continuous discussion and direct support from both institutional IT groups and vendors with feedback
1896 and guidance from the clinical team.

1897 In the era of “Big data analytics”, the community must continue analyzing and learning from the
1898 information gathered by the RO-EMR environment and continue developing tools to access and retrieve
1899 data from the system. These tools can be a combination of vendor-provided and in-house developed
1900 tools. The task group notes that practices are using the tools provided by the vendors but lack the
1901 knowledge and resources to implement more sophisticated data mining strategies. A whole section
1902 issue on the Red Journal (www.redjournal.org/issues Volume 95, Issue 3, July 2016) is dedicated to
1903 providing a review on the topic of Big Data in Radiation Oncology^{51,52}

1904 ***9.D.8. Risk of running database queries on clinical production systems.***

1905 **Clinical Team users should be familiar with the robustness and potential risk of running database**
1906 **queries on clinical production systems.** TG-262 members recognized that performing RO-EMR database
1907 queries without considering the potential load on the system can potentially bring down the whole
1908 system. Therefore, clinical team members should become familiar with the risk introduced when
1909 running both vendor-provided as well as custom queries. Additional disk space can potentially be
1910 added to a RO-EMR to be utilized as scratch space or virtual memory in support of running large queries,
1911 but at the cost of performance. Depending on the external storage interface being utilized this could be
1912 orders of magnitude slower than main storage and memory. In addition, the option of running queries in
1913 the background typically requires a database administrator. It should be noted that for large queries,
1914 this may be suboptimal depending on how soon the data is need as it may not complete in time. Also,
1915 not all vendor database systems currently support this.

1916 ***Potential risk of running database queries on clinical production systems and mitigation strategies:***

- 1917
- 1918 • Risks:
 - 1919 ○ Running an unbounded or complex query can result in all system resources being
 - 1920 consumed by the query. This would result in a system outage and potential impact to
 - 1921 patient care.
 - 1922 ○ Running any kind of query that can potentially write to the database may circumvent
 - 1923 application controls that provide patient safety.
 - 1924 • Mitigation Strategies:

- 1925 ○ Using vendor supplied query/reporting/analytics.
- 1926 ○ Using vendor supplied applications for data manipulations.
- 1927 ○ Replicating the production database to non-production infrastructure.
- 1928 ○ Automatically scheduling mining tasks to run outside of clinic hours
- 1929 ○ Setting low priority for data mining tasks

1930
1931
1932
1933
1934

1935 **10. CHALLENGES AND FUTURE IMPROVEMENTS FOR BOTH USERS AND**

1936 **VENDORS**

1937 TG-262 is composed of individuals who have had extensive involvement with the configuration and
1938 maintenance of electronic charting systems, and the task group has collected data on the practices in
1939 the medical physics community. Based on this body of knowledge, we present suggestions to vendors
1940 for future enhancements to RO-EMR software to improve the user experience and optimize efficiency
1941 and safety.

1942 **10.A. Continued focus on automation**

1943 **The task group recommends a continued focus on automation.** Several studies have shown that
1944 automation in the RO department reduces the error rate.^{53,54} Automation is useful in avoiding
1945 unnecessary delays and more importantly in preventing errors arising from manual repetitive processes.
1946 Some desired automation functions are listed below:

- 1947 - Prompts for comment for incomplete treatments and overrides
- 1948 - Automated notifications for certain events such as delivered dose disparity with prescription.
- 1949 - Notifications should be configurable and include email functionality

1950 One of the byproducts of automation is that staff may become increasingly reliant on the computers and
1951 gradually lose their awareness of the treatment process that has been automated. Clinics should be
1952 aware of potential failure modes associated with each new automation feature introduced. A review of
1953 associated QA procedures should always accompany the introduction of a new automated feature and
1954 the potential failure modes should be accounted for in subsequent checks.

1955

1956 **10.B. Checklist functionality**

1957 One of the most important tools to improve patient safety is the use of checklists.^{33,34} Paper
1958 checklists, if well designed, are easy to use and review. While electronic checklists offer functionality
1959 that go above and beyond paper checklist functionality, such as the use of a checklist for forcing
1960 function or interlock, the implementation in RO-EMRs is currently still suboptimal and warrants
1961 improvement.

1962 **10.B.1. Multi-user checklists**

1963 **The task group recommends that checklist functionality be enhanced.** Many checklists used
1964 clinically in high-stakes procedures such as pre-treatment checklists for SRS, SBRT, or brachytherapy are
1965 multi-user due to the interdisciplinary nature of patient care. Users signing off the checklists typically
1966 include physicists, dosimetrists, physicians, nurses, radiation therapists, and administrative staff.
1967 Because there is currently no RO-EMR implementation of a multi-user checklist that offers the same
1968 level of functionality, ease of use, and signature recognition that could match a paper checklist, we
1969 request vendors to add a multi-user checklist with functionality comparable to a paper checklist.

1970 **10.C. More granular approval mechanisms**

1971 **The task group recommends that approval mechanisms be enhanced, including consideration of**
1972 **more granular approval mechanisms such as approval at the field level of a document or template.**

1973 One common complaint among RO-EMR users is that document re-approval is needed for even the
1974 smallest of modifications since approvals only occur at the document level. A more granular approval
1975 functionality that allows for approval of certain easily identifiable fields of a form while leaving other
1976 fields editable will allow for more versatile document configuration and possible consolidation of
1977 information and less clutter. This allows for flexibility in editing while still protecting vital clinical
1978 elements.

1979

1980 **10.D. Vendor sandbox**

1981 **The task group recommends that online interactive versions of their software be available**
1982 **for testing and training.** A “vendor sandbox” is a space in which users can test software prior
1983 to purchasing to determine whether it best suits their clinic. It can also serve as an online
1984 interactive training resource for users that have already purchased the product that highlights
1985 the safety and efficiency elements of the software. While TG-262 recommends that users have

1986 a test system to validate upgrades, an online testing area would make a valuable evaluation and
1987 training tool.

1988 **10.E. More flexibility in structure and filtering of document repositories**

1989 **Configuration of document repositories should be flexible and customizable so that**
1990 **clinics can display the documents in a way that works best for them.** Paper charts were very
1991 flexible when it came to organizing documents and RO-EMR's may not translate that flexibility
1992 as well. Often documents for multiple courses are in the same repository and are sometimes
1993 not easy to distinguish since they are largely represented by text descriptors. Filtering has to be
1994 done by clicking radio buttons or checkboxes. Sorting is available but can be error prone, for
1995 example if a dosimetrist accidentally sorts the documents in reverse chronological order and
1996 plans based on an old prescription. More flexibility in structuring document repositories would
1997 be helpful and would be a worthwhile QA step. More attention to the appearance and
1998 structure of the document list and how documents are tiered would provide users with the
1999 flexibility to construct their document lists the way that works best for them. Also, the added
2000 ability to associate documents using different tags or keywords would be of benefit.

2001

2002 **10.F. Stronger communication tools**

2003 **The task group recommends that communication tools within the electronic chart be enhanced**
2004 **based on input from industry experts, clinicians, and researchers.** RO-EMR systems have started to
2005 provide some features to use as a communication tool among clinicians and their patients such as
2006 integrated email, instant messaging, pop-up warning messages etc. However many clinicians are still
2007 experiencing communication barriers when they are using suboptimal communication tools in RO-EMR
2008 system. Communication is a key element for patient safety and high quality care. Ineffective
2009 communication costs US hospitals an estimated \$12 billion annually.⁵⁵ Stronger tools for
2010 communication and meaningful use of RO-EMR should be developed and improved by the vendor,
2011 based on cooperative work of informatics professionals, clinicians, and researchers. TG-262 requests
2012 that vendors consider making the following communication tools available within the system: integrated
2013 email, instant messaging, and internal video meeting tools for collaborative review of the chart without
2014 having to launch an external application. One unfortunate consequence of electronic charting is that it
2015 is no longer necessary to be physically present to review a chart or a treatment plan together. While

2016 this is a plus for efficiency due to ease of access, it can have the unintended consequence of reducing
2017 face to face interaction in the clinic. Communication tools should be available to easily facilitate one on
2018 one communication.

2019 **10.G. Greater flexibility and efficiency in workflow managers**

2020 **The task group recommends that flexibility of workflow managers should be increased to adapt**
2021 **more easily to the wide range of workflows in practice. Workflows should be more efficient by more**
2022 **tightly integrating the virtual task in the workflow with the work in the system that it represents.**

2023 Greater flexibility for assignment of work and collection of statistics from the workflow managers could
2024 streamline the workflow process and its subsequent analysis for internal and external reports,
2025 respectively. A workflow manager, through its enumeration of necessary tasks in the clinical process,
2026 can provide important information on the frequency of certain clinical processes for departmental
2027 statistics. For example, the number of end of treatment checks can be determined by counting the
2028 corresponding tasks completed in the manager. Although this report can be configured by IT in many
2029 cases, an easier procedure so that the user can compile this report themselves would be beneficial.
2030 Other reports include number of plans per planner, completion metrics for treatment plans, and
2031 statistics for on-time performance of tasks in the workflow. In addition, certain tasks may be done by
2032 rotating staff and the reassignment of resources to these kinds of tasks would be too burdensome every
2033 time a new person rotated onto that team. For example, end of treatment checks may be performed by
2034 a team and not the planner who planned the case. Therefore assignment of a person to the end of
2035 treatment task may be difficult since it is not known who will be on the team when it becomes available.
2036 The option to collect and monitor for the tasks themselves regardless of resource would add welcome
2037 flexibility to the system.

2038 In addition, more flexibility in the way that visual workflow management tools work would be
2039 helpful. For example, medical physics workflows can involve recurrent replans and checks. Facilitating
2040 that sort of looping workflow with appropriate decision path functionality would be helpful.

2041 A common complaint regarding workflow managers is the disconnect between the task that needs
2042 to be completed and the associated workflow task item. For example, a physician approves volumes
2043 and then has to complete a virtual task that says the volumes are approved. The same goes for plan
2044 approval. Virtual tasks are not completely without links; for example a task may hyperlink to the
2045 workspace where the work is done if the workspace is within the RO-EMR ecosystem. Additional
2046 integration of the virtual tasks in the workflow and completion of the work they are supposed to
2047 represent would enhance efficiency.

2048 **10.H. Handshake functionality and acknowledgment**

2049 **The task group recommends that tools be made available to acknowledge communications**
2050 **electronically.** “Handshake” functionality (see section 7.J) should be available such that requests for
2051 change will send back a confirmation when all of the receiving parties have acknowledged that the
2052 information has been received, or a warning is sent when it has not. We have provided examples of
2053 issues that can occur due in the RO-EMR environment: for example, changes in chart rounds not being
2054 communicated to physics or to the machine. One way to mitigate this issue would be to introduce
2055 communication tools that require verification of receipt within the system. Then, when ad hoc events
2056 require an atypical “passing of the chart”, a receipt system, such as an automated email sent upon
2057 receipt for example, is in place to ensure that the workflow is still moving forward. These requests for
2058 receipts should be configurable.

2059 **10.I. Concurrent use of different workspaces and custom views**

2060 **The RO-EMR should allow for the concurrent use of different workspaces and minimize the need**
2061 **to open an excessive number of windows. The creation of custom views should be possible.** During
2062 chart review, chart checks, weekly checks, and end of treatment (EOT) review, several elements of the
2063 charts need to be checked against each other for consistency. A RO-EMR system should allow the user
2064 to see multiple workspaces for the same patient concurrently, and allow the use of dual monitor viewing
2065 of tabs or windows within the RO-EMR to do so. Many clinics have adopted digital “whiteboards”
2066 showing the current status of patients, MD’s, or dosimetrists. More or this type of functionality and/or
2067 closer integration with external whiteboards would be a welcome feature.

2068 RO-EMR systems generally allow some customization of certain interfaces however going
2069 farther by providing tools to design custom views that can access certain database elements would
2070 increase flexibility. For example, a clinic may want to see certain specific elements of the chart for a
2071 weekly chart check on one place rather than clicking through tabs or opening multiple workspaces.
2072 Some clinics create their own whiteboards using the API of the RO-EMR to fill in the gaps between what
2073 is available in the system vs what is needed in the clinic. A custom workspace design module would be a
2074 welcome addition and allow more flexibility within the system.

2075

2076 **10.J. Improved connectivity with H-EMR and non-standard systems**

2077 **Communication between the RO-EMR and H-EMR as well as between RO-EMR systems and non-**
2078 **standard systems should be improved.** Effective communication between the RO-EMR and H-EMR has

2079 a number of advantages, including elimination of the need for transcribing information between the two
2080 systems, real time availability of Radiation Oncology data in the hospital system, and the inclusion of
2081 Radiation Oncology data in the permanent part of the health record in a common database which is
2082 useful for abstraction of data and comparable effectiveness research.⁵⁶ A recent AAPM education
2083 session covered important points about data transfer between the two major electronic charting
2084 systems (ARIA and MOSAIQ) and Epic^{57,58} and data transfer is addressed more generally in the report of
2085 AAPM Task Group 201. The utility of automated transfers is clear; however, there are still obstacles to
2086 effective transfer of information for all clinical scenarios, and improvement and further standardization
2087 of communication between these systems is still needed.

2088 Enhanced connectivity between non-standard systems and RO-EMR systems would be a benefit
2089 to the community. It would further promote centralization of chart elements, especially for those
2090 patients receiving multi-modality treatments. A centralized treatment history and accumulated dose
2091 can help enhance safety features to prevent overtreatment in one modality due to insufficient
2092 familiarity with the dose given via the other modality.

2093 **10.K. RO-EMR in Standard database format with access – API functionality**

2094 **Vendors should design the RO-EMR database in a standard database format such as Structured**
2095 **Query Language (SQL). Users should be provided with information of the database structure and**
2096 **access to the database for data analysis and data mining. A feature-rich API should be provided.** The
2097 power of EMR implementation in general is in the promise of easier access to data for data mining. In
2098 contrast to any study involving paper charts, which typically involves administrative assistants spending
2099 many hours pulling data from paper charts and entering them in a single-purpose research database, a
2100 comprehensive electronic patient database could facilitate automation of the data collection task
2101 through scripted database queries. Vendors could facilitate this process by designing the database in a
2102 standard database format and providing tools for the database users to mine their clinic data.

2103 A feature-rich API would allow users to more safely query the database and potentially automating
2104 certain repetitive actions in the RO-EMR – this would facilitate the creation of custom software for the
2105 clinic.

2106 **10.L. Databases should be sufficiently robust to queries.**

2107 **Databases should be sufficiently robust to queries.** If feasible, vendors should offer a means to expand
2108 working memory to ensure clinical functionality is not compromised by large database queries. This may
2109 include allowing the end-users to install additional RAM or external hard drives to accommodate the
2110 extra load.

2111

2112 **10.M. Provision of optional interfaces for non-standard systems**

2113 **Vendors not currently pursuing modules and components to support interfaces with non-standard**
2114 **systems should consider doing so, or alternatively provide the user information on their interface**
2115 **module so that users could develop their own interfaces.** For non-standard devices and brachytherapy
2116 devices, connectivity modules are not always available or are too costly. Vendors should support user
2117 capability to develop custom connectivity modules by providing interface information and some
2118 database write-access that does not compromise data integrity or compromise patient safety.

2119

2120 **11. DISCUSSION**

2121 The RO-EMR is the fundamental means of information storage in the clinic and often workflow
2122 management as well. The electronic chart should be configured and managed to optimize efficiency and
2123 maximize safety. Electronic charts for radiation oncology differ from other departments in fundamental
2124 ways and therefore require specific guidelines for their use beyond what general charting guidelines can
2125 offer. It is in this context that TG-262 was convened. With the increasing pace and complexity of
2126 modern Radiation Oncology departments, optimization of chart usage becomes more and more
2127 essential.

2128 The collective experience of the task group members provided the foundation for building
2129 consensus recommendations. The operative word is “consensus” since there was not an extensive body
2130 of literature on the subject at the writing of this report. Therefore we relied on an exhaustive survey of
2131 task group members and a more general survey of the medical physics community to provide our
2132 recommendations rather than consolidating already existing recommendations, which is a common
2133 practice for many task groups.

2134 TG-262 group decided that the recommendations should be general for two reasons. First, since
2135 electronic charting software is constantly evolving, finely detailed reports now carry the risk of
2136 becoming quickly obsolete. Secondly, the scope of these systems in the context of our charges,
2137 particularly the inclusion of external beam therapy, brachytherapy, and non-standard treatment devices
2138 would be excessively resource intensive and make for an excessively large document if
2139 recommendations were not sufficiently general. We stress that we are not advocating or providing
2140 recommendations for any one particular system. We have strived to remain sufficiently neutral such
2141 that our recommendations can be applied to all systems.

2142 Users of a new RO-EMR system face a challenging task, whether they be a small private clinic or a
2143 large academic facility when initially configuring the system. There are different forms of information
2144 storage available and not everything has to be an electronic document. The format, input, efficacy,
2145 scope, traceability, and accessibility (“FIESTA”, see Section 6.A) should be considered and characterized
2146 for each type of information storage available to pick the best mode of information storage for each
2147 particular clinical form. Clinics should rely on feedback from users and periodic QA to constantly update
2148 the charting system.

2149 Resource allocation for implementation is important, and different clinics have reported different
2150 levels of resource allocation for their implementation teams. Clinics should read this report to get a
2151 sense of the breadth of tasks required of the implementation team and plan accordingly, given the
2152 experience of their RO and IT teams and limitations of their clinic. Adequate protection for
2153 implementation time is essential for the best user experience, because insufficient resource allocation
2154 for chart configuration will lead to issues with efficiency, workflow, and possibly safety down the line.
2155 All stakeholders should have representatives in the implementation process to the extent possible, and
2156 goals and deadlines should be set and monitored closely. It is easy to become bogged down in overly
2157 speculative details that delay rollout when the better course in certain instances may be to decide on a
2158 functional starting point for the chart and make changes based on feedback down the road. The ideal
2159 prescription form will likely not be the first one, no matter how much time is spent making minor
2160 modifications.

2161 The need for champions to provide support in the transition process and beyond cannot be
2162 understated. Champions from the different stakeholder groups and end user groups not only foster
2163 satisfaction but also foster compliance. Compliance is essential for a smooth workflow in the RO-EMR.
2164 Physician champions as well as administrative support is essential to provide encouragement and
2165 incentive to users as there will always be resistance to change. This is a lesson learned in hindsight by
2166 many, and it is best to make that clear in the beginning.

2167 Since the primary purposes of the electronic chart are to store information in an easily accessible
2168 way and to drive workflow, periodic QA should primarily address whether those goals are being met and
2169 no new goals need to be added. A team entrusted with management of the system in the context of a
2170 living and evolving clinic should be periodically assessing whether the chart is optimized for efficiency
2171 and safety for the clinic in its current state. This should be the basis of the ongoing QA program. The
2172 level of review should be realistic so it does not unnecessarily overburden the team and potentially lead
2173 to no QA at all.

2174 There are many documents and forms to consider in the configuration of RO-EMR systems. That is
2175 one reason that the recommended QA includes a review of the current documents to see which are out
2176 of date. This minimizes unnecessary signatures and duplication of data. Also, discussion of the
2177 interactive connection between documents and workflow managers in the electronic system should be
2178 part of the equation. A home should be found for each type of information, and the temptation to use
2179 free text for things other than ad hoc notes should be avoided.

2180 Workflow managers play a critical role in the RO-EMR ecosystem. These workflow managers must
2181 be optimized for efficiency so they do not unnecessarily slow down the workflow. However, not
2182 everything needs a task, and each clinical group in the workflow should determine which items or tasks
2183 they need to add to the system so it works best for them. Workflow managers can also enhance the
2184 collection of statistics for the clinic as a task can not only drive the workflow but act as a “token” for a
2185 certain clinical process (such as IMRT QA or an end of treatment check). The frequency of that process
2186 can be determined by counting the number of a specific task that are completed, in progress, or
2187 planned.

2188 The use of the RO-EMR for non-standard systems and for brachytherapy is not as developed as it is
2189 for external beam therapy. Many non-standard systems do not have interfaces into RO-EMR systems,
2190 and it becomes difficult to consolidate treatment information for patients receiving multimodality
2191 therapy that may include external beam and brachytherapy for example. We have provided guidelines
2192 for electronic charting of these systems in their existing state as well as guides for their development in
2193 the future. We also believe that the template laid down for external beam therapy provides a usable
2194 framework for the development of non-standard charting systems.

2195 The collaboration between medical physics and IT is essential for effective and safe chart
2196 maintenance. IT and medical physics are essential core team members in the maintenance and
2197 management of the system. Adequate network availability and disaster recovery resources are essential
2198 because a network or systems failure can potentially cripple the clinic not only through the disabling of
2199 the R&V system but also through the unavailability of the chart. Network failures may affect patient
2200 treatments and lead to inaccuracies in the treatment record if an adequate system for catching failures
2201 to save the treatment history in the RO-EMR (“save-back failures”) is not in place. A redundant system
2202 for recording patient history should at least be in place if an automated system is not available. An
2203 assessment of whether current IT resources are adequate for an ongoing monitoring of hardware and
2204 software needs at the time of installation is an important first step. A slow chart is unacceptable in a
2205 fast paced clinic.

2206 Finally, in the effort to maximize the potential for an electronic system to enhance efficiency and
2207 safety and to maximize flexibility, we have provided general suggestions for ongoing enhancement of
2208 systems. Vendors should consider adding automation and enhancement of information storage and
2209 approval capability, more flexibility in existing functionalities such as checklists, and sufficient computing
2210 power (or prioritizing mechanisms) for analyses to ensure that electronic charting keeps pace with
2211 clinical complexity.

2212

2213 **Disclosure Statement**

2214 The members of AAPM Task Group 262 listed below disclose the following potential Conflict(s) of
2215 Interest related to subject matter or materials presented in this document.

2216 a) S. Yaddanapudi- Has received speaker fees from Elekta for a Gamma Knife presentation, not
2217 related to this work.

2218 b) V Harwalkar- nothing to disclose

2219 c) L Hong- nothing to disclose

2220 d) S. Sutlief- nothing to disclose

2221 e) J. Hanley- nothing to disclose

2222 f) G. Kim- provides consulting services for Varian Medical Systems related to the clinical use of
2223 Varian Products, which is unrelated to the content of the TG (HyperArc SRS technique)

2224 g) S. Dieterich- has received research funding from Varian which is unrelated to the content of
2225 the TG (4D imaging studies in companion animals at the Vet School).

2226 h) J. Huang- has received honoraria from Elekta for presenting in their user meetings in 2018
2227 and 2019 about brachytherapy.

2228 i) J. Mechalakos- is part of a grant from Varian medical systems unrelated to the contents of this
2229 report

2230 j) L Fong de los Santos- nothing to disclose

2231 k) M Parry- nothing to disclose

2232 l) S Fontenla- nothing to disclose

2233 m) S Merkel- nothing to disclose

2234 n) S Richardson- nothing to disclose

2235

2236

2237 The data that supports the findings of this study are available in the supplementary
2238 material of this article.

2239 **12. REFERENCES**

2240

- 2241 1. HITECH Act Enforcement Interim Final Rule, Section 13410(d)
- 2242 2. Jha AK, DesRoches CM, Campbell EG, et al. Use of electronic health records in U.S. hospitals. *N.*
2243 *Engl. J. Med.* 2009;360:1628-1638.
- 2244 3. Jha AK, DesRoches CM, Kralovec PD, Joshi MS. A progress report on electronic health records in
2245 US hospitals. *Health Aff.* 2010;29:1951-1957.
- 2246 4. Devaraj S, Kohli R. Information technology payoff in the health-care industry: a longitudinal
2247 study. *J. Manag. Inform. Syst.* . 2000;16:41-67.
- 2248 5. Devaraj S, Ow TT, Kohli R. Examining the impact of information technology and patient flow on
2249 healthcare performance: a Theory of Swift and Even Flow (TSEF) perspective. *J. Oper. Manag.*
2250 2013;31:181-192.
- 2251 6. Menachemi N, Burkhardt J, Shewchuk R, Burke D, Brooks RG. Hospital information technology
2252 and positive financial performance: a different approach to finding an ROI. *J. Healthc. Manag.*
2253 2006;51:40-58.
- 2254 7. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information
2255 technology: a review of the recent literature shows predominantly positive results. *Health Aff*
2256 *(Millwood)*. 2011;30:464-471.
- 2257 8. Jones SS, Rudin RS, Perry T, Shekelle PG. Health information technology: an updated systematic
2258 review with a focus on meaningful use. *Ann Intern Med.* 2014;160:48-54.
- 2259 9. Atasoy H, Greenwood BN, McCullough JS. The Digitization of Patient Care: A Review of the
2260 Effects of Electronic Health Records on Health Care Quality and Utilization. *Annu Rev Public*
2261 *Health.* 2018;40:487-500.
- 2262 10. Reis ZSN, Maia TA, Marcolino MS, Becerra-Posada F, Novillo-Ortiz D, Ribeiro ALP. Is There
2263 Evidence of Cost Benefits of Electronic Medical Records, Standards, or Interoperability in
2264 Hospital Information Systems? Overview of Systematic Reviews. *JMIR Med Inform.* 2017;5:e26.
- 2265 11. Benedetti L. Clinical Implementation of Electronic Charting. <https://vimeo.com/90160027>
2266 Accessed 2013.

- 2267 12. Kirkpatrick JP, Light KL, Walker RM, et al. Implementing and integrating a clinically driven
2268 electronic medical record for radiation oncology in a large medical enterprise. *Frontiers in*
2269 *oncology*. 2013;3:69.
- 2270 13. Colonias A, Parda DS, Karlovits S, et al. A Radiation Oncology Based Electronic Health Record in
2271 an Integrated Radiation Oncology Network. *Journal of Radiation Oncology Informatics*. 2011;3:3-
2272 11.
- 2273 14. Weeks A, Coleman AM. Electronic Charting and Image Management. in *Principles and Practice of*
2274 *Radiation Therapy*, edited by Washington CM, Leaver D, Trad M St. Louis, Missouri: Elsevier;
2275 2021:484-496.
- 2276 15. Mechalakos J, Dieterich S. Quality and the Electronic Medical Record in Radiation Oncology. in
2277 *Quality and Safety in Radiation Oncology*, edited by Dicker AP, Williams TR, Ford EC Springer
2278 Publishing Company; 2016:287-296.
- 2279 16. Fraass BA, McShan DL, Matrone GM, Weaver TA, Lewis JD, Kessler ML. A computer-controlled
2280 conformal radiotherapy system. IV: Electronic chart. *International journal of radiation oncology,*
2281 *biology, physics*. 1995;33:1181-1194.
- 2282 17. Han Y, Huh SJ, Ju SG, et al. Impact of an electronic chart on the staff workload in a radiation
2283 oncology department. *Japanese journal of clinical oncology*. 2005;35:470-474.
- 2284 18. Kovalchuk NN. Optimizing efficiency and safety in a radiation oncology department through the
2285 use of ARIA 11 Visual Care Path. *Practical radiation oncology*. 2015;5:295-303.
- 2286 19. Nowlan AW, Sutter AI, Fox TH, Johnstone PA. The electronification of the radiation oncology
2287 treatment cycle: the promises and pitfalls of a digital department. *Journal of the American*
2288 *College of Radiology : JACR*. 2004;1:270-276.
- 2289 20. *Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing,*
2290 *Commissioning and Quality Control*. Vienna:2013.
- 2291 21. (IEC) IEC. *INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment,*
2292 *Safety of Radiotherapy Record and Verify Systems*. Geneva:2005.
- 2293 22. Shen X, Dicker AP, Doyle L, Showalter TN, Harrison AS, DesHarnais SI. Pilot study of meaningful
2294 use of electronic health records in radiation oncology. *Journal of oncology practice / American*
2295 *Society of Clinical Oncology*. 2012;8:219-223.
- 2296 23. Shen X, Dicker AP, Doyle L, Showalter TN, Harrison AS, DesHarnais SI. Pilot study of meaningful
2297 use of electronic health records in radiation oncology. *Journal of oncology practice / American*
2298 *Society of Clinical Oncology*. 2012;8:219-223.

- 2299 24. Patton GA GD, Moeller JH. Facilitation of radiotherapeutic error by computerized record and
2300 verify systems. *International journal of radiation oncology, biology, physics*. 2003;56:50-57.
- 2301 25. Kotter JP. Leading Change: Why Transformation Efforts Fail, in *Harvard Business Review*
2302 (Harvard Business School Publishing, 1995), pp. 59-67.
- 2303 26. Radiology ACo. Radiation Oncology Practice Accreditation Program Requirements, (2017).
- 2304 27. Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM:
2305 Application of risk analysis methods to radiation therapy quality management. *Medical physics*.
2306 2016;43:4209-4262.
- 2307 28. Miften M, Mihailidis D, Kry SF, et al. Management of radiotherapy patients with implanted
2308 cardiac pacemakers and
2309 defibrillators: A Report of the AAPM TG-203. *Med. Phys*. 2019;46:e757-e788.
- 2310 29. Amols HI. New technologies in radiation therapy: ensuring patient safety, radiation safety and
2311 regulatory issues in radiation oncology. *Health physics*. 2008;95:658-665.
- 2312 30. Siochi RA, Balter P, Bloch CD, et al. A rapid communication from the AAPM Task Group 201:
2313 recommendations for the QA of external beam radiotherapy data transfer. AAPM TG 201:
2314 quality assurance of external beam radiotherapy data transfer. *Journal of applied clinical*
2315 *medical physics / American College of Medical Physics*. 2011;12:3479.
- 2316 31. An act to facilitate the use of electronic records and signatures in interstate or foreign
2317 commerce., Vol. *Public Law 106-229* (Government Publishing Office (US), 2000).
- 2318 32. Evans SB, Fraass BA, Berner P, et al. Standardizing dose prescriptions: An ASTRO white paper.
2319 *Practical radiation oncology*. 2016;6:e369-e381.
- 2320 33. Gawande A. *The Chewcklist Manifesto: How to Get Things Right*. New York: Metropolitan Books,
2321 Henry Holt and Co.; 2009.
- 2322 34. Fong de Los Santos LE, Evans S, Ford EC, et al. Medical Physics Practice Guideline 4.a:
2323 Development, implementation, use and maintenance of safety checklists. *Journal of applied*
2324 *clinical medical physics / American College of Medical Physics*. 2015;16:5431.
- 2325 35. Albuquerque KV, Miller AA, Roeske JC. Implementation of Electronic CHecklists in an Oncology
2326 Medical Record: Initial Clinicl Experience. *Electronic Health Records in Oncology*. 2011;7:222-
2327 226.
- 2328 36. Yttrium-90 Microsphere Brachytherapy Sources and Devices -TheraSphere® and SIR-Spheres®-
2329 Licensing Guidance, (2016).

- 2330 37. Group COMS. Design and methods of a clinical trial for a rare condition: The Collaborative
2331 Ocular Melanoma Study: COMS Report No. 3. *Control Clin. Trials*. 1993;14:362-391.
- 2332 38. RO-ILS. *RO-ILS Case Study 8- IT Permissions Disrupt HDR Delivery*. PSO C; pp.
2333 <https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/ROILS>
2334 [_Case08.pdf](https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/ROILS_Case08.pdf) 2021.
- 2335 39. *The Report of the NRC Advisory Committee on the Medical Uses of Isotopes for Electronic*
2336 *Signatures* <https://www.nrc.gov/docs/ML1218/ML12185A145.pdf> 2012.
- 2337 40. Kroger L. personal communication.
- 2338 41. techopedia. IT Infrastructure. <https://www.techopedia.com/definition/29199/it-infrastructure>
2339 Accessed 2016.
- 2340 42. Lorenzi NM, Riley RT. *Organizational Aspects of Health Informatics: Managing Technological*
2341 *Change*. New York, N.Y.: Springer-Verlag; 1995.
- 2342 43. Gremy F. Hardware, software, peopleware, subjectivity - A philosophical promenade. *Methods*
2343 *of Information in Medicine*. 2005;44:352-358.
- 2344 44. Siochi RA, Balter P, Bloch CD, et al. Information technology resource management in radiation
2345 oncology. *Journal of Applied Clinical Medical Physics*. 2009;10:16-35.
- 2346 45. Siochi RAC, Brack CD, Orton CG. The Chief Information Technology Officer in a Radiation
2347 Oncology department should be a medical physicist. *Med. Phys*. 2009;36:3863-3865.
- 2348 46. Fong de los Santos LE, Herman MG. Radiation oncology information systems and clinical practice
2349 compatibility: Workflow evaluation and comprehensive assessment. *Practical Radiation*
2350 *Oncology*. 2012;2:e155-e164.
- 2351 47. Microsoft. High Availability and Disaster Recovery (Middleware) - a Technical Reference Guide
2352 for Designing Mission - Critical Middleware Solutions. [https://technet.microsoft.com/en-](https://technet.microsoft.com/en-us/library/hh393522(v=sql.110).aspx)
2353 [us/library/hh393522\(v=sql.110\).aspx](https://technet.microsoft.com/en-us/library/hh393522(v=sql.110).aspx) Accessed 2016.
- 2354 48. Steinhubl SR, Muse ED, Topol EJ. The emerging field of mobile health. *Science translational*
2355 *medicine*. 2015;7:283rv283-283rv283.
- 2356 49. Munro D. Data Breaches In Healthcare Totaled Over 112 Million Records In 2015.
2357 [http://www.forbes.com/sites/danmunro/2015/12/31/data-breaches-in-healthcare-total-over-](http://www.forbes.com/sites/danmunro/2015/12/31/data-breaches-in-healthcare-total-over-112-million-records-in-2015/#4cb0afc97fd5)
2358 [112-million-records-in-2015/#4cb0afc97fd5](http://www.forbes.com/sites/danmunro/2015/12/31/data-breaches-in-healthcare-total-over-112-million-records-in-2015/#4cb0afc97fd5) Accessed 2015.
- 2359 50. Woodrow Cox J. MedStar Health turns away patients after likely ransomware cyberattack, in *The*
2360 *Washington Post* (2016).

- 2361 51. Benedict SH, El Naqa I, Klein EE. Introduction to Big Data in Radiation Oncology: Exploring
2362 Opportunities for Research, Quality Assessment, and Clinical Care. *International Journal of*
2363 *Radiation Oncology*Biological*Physics*. 2016;95:871-872.
- 2364 52. Benedict SH, Hoffman K, Martel MK, et al. Overview of the American Society for Radiation
2365 Oncology–National Institutes of Health–American Association of Physicists in Medicine
2366 Workshop 2015: Exploring Opportunities for Radiation Oncology in the Era of Big Data.
2367 *International Journal of Radiation Oncology*Biological*Physics*. 2016;95:873-879.
- 2368 53. Macklis RM, Meier T, Weinhaus MS. Error rates in clinical radiotherapy. *Journal of clinical*
2369 *oncology : official journal of the American Society of Clinical Oncology*. 1998;16:551-556.
- 2370 54. Fraass BA, Lash KL, Matrone GM, et al. The impact of treatment complexity and computer-
2371 control delivery technology on treatment delivery errors. *International journal of radiation*
2372 *oncology, biology, physics*. 1998;42:651-659.
- 2373 55. Agarwal R, Sands DZ, Schneider JD. Quantifying the economic impact of communication
2374 inefficiencies in U.S. hospitals. *Journal of Healthcare Management*. 2010;55:265-281.
- 2375 56. Russo GA. When Electronic Health Records (EHRs) Talk, Everyone Can Win: Our Experience
2376 Creating a Software Link Between Hospital and Radiation Oncology EHRs. *International journal*
2377 *of radiation oncology, biology, physics*. 2016;94:206-207.
- 2378 57. Surucu M. Practical considerations for ARIA and Epic EMR integration.
2379 <http://www.aapm.org/education/VL/vl.asp?id=12283> Accessed December 3, 2017.
- 2380 58. Yu U. Practical considerations for MOSAIQ and Epic EMR integration.
2381 <http://www.aapm.org/education/VL/vl.asp?id=12284> Accessed December 3, 2017.

2382

2383

2384

2385 **13. APPENDICES**

2386

2387

2388 **Appendix 1- Acceptance criteria for a new RO-EMR system**

2389 The task group has created a list of recommended acceptance criteria adapted from the IAEA²⁰ and IEC²¹
2390 recommendations with additional items specific to document repositories and workflow managers.
2391 These criteria are listed here.

2392

- 2393 1. All values of radiation quantities displayed shall include units.
- 2394 2. Display of date and time should be unambiguous. Timestamps shall be assigned correctly.
- 2395 3. Means shall be provided to prevent unauthorized changes to RO-EMR data. Check by creating
2396 test users with different rights levels and verify that data is locked according to specified
2397 authorization.
- 2398 4. Connect the RO-EMR to the network and confirm that access is limited to authorized users.
- 2399 5. If there is an electronic prescription workspace, confirm that parameters are transferred
2400 correctly to the treatment planning system, treatment machine and any other system
2401 connected to it.
- 2402 6. Treatment history cannot be modified except by an authorized user. If treatment data is
2403 modified it should be apparent by a visual indicator.
- 2404 7. Means shall be provided to back up data. Standardizing the backup process is highly desirable.
- 2405 8. Means shall be provided to archive data. Standardizing the archive process is highly desirable.
- 2406 9. Confirm that transfer of history from the treatment machine to the RO-EMR is correct and
2407 means exist to warn the user if such transfer does not take place.
- 2408 10. Test the document repository by creating and saving a range of document types supported by
2409 the system.
- 2410 11. Test the workflow management system by running a range of sample clinical workflows with
2411 test users.
- 2412 12. Examine user task lists for completeness and correctness using mock tasks. Test interplay
2413 between user task list and workflow manager (task status update correctly regardless of where
2414 they are edited, etc., tasks that are autocompleted function properly, etc)
- 2415 13. Stress test the system to determine whether there is appropriate IT infrastructure for
2416 anticipated clinical load.
- 2417 14. Test that all forcing functions work properly (for example, inhibiting treatment if a linked
2418 prescription is unapproved)

2419

2420 **Appendix 2- Sample questions for clinic visitations**

2421

2422 The following questions may be helpful when visiting a clinic to gather information on
2423 electronic charting:

2424

- 2425 1. How many patients are treated per day?
- 2426 2. Was a committee formed to transition? Who was represented? How often did you meet?
- 2427 3. How long did it take the committee to configure the chart and how long was a hybrid system in
2428 place?
- 2429 4. How was training administered for staff?
- 2430 5. What were the major challenges of implementation? Of training?
- 2431 6. What do you consider the most effective features on your RO-EMR for preventing errors?
- 2432 7. In what form is the prescription or written directive stored? Other documents?
- 2433 8. How are MD approvals recorded? Physics approvals?
- 2434 9. How is workflow managed? What specific tasks are included in your RO-EMR workflow
2435 manager?
- 2436 10. What barriers to efficiency or communication have you experienced with your current RO-EMR
2437 workflow?
- 2438 11. Have you experienced any QA issues related to the RO-EMR that you can share? How did you
2439 mitigate them?
- 2440 12. Who maintains the RO-EMR? How are changes made?
- 2441 13. Do you use the RO-EMR for brachytherapy or other non-standard treatments? How is it used
2442 differently for these treatments?
- 2443 14. How is your RO-EMR system deployed? Locally? Remote servers? Both?
- 2444 15. How is your RO-EMR accessed?
- 2445 16. How many licenses are needed for each user type?
- 2446 17. Which aspects of your process live in the H-EMR and why?
- 2447 18. Do you have a test system?
- 2448 19. How is your RO-EMR backed up?
- 2449 20. Does your RO-EMR interface with other systems in the clinic, such as the H-EMR? How are
2450 these interfaces structured?

- 2451 21. How well would you rate your RO-EMR system in the following categories?
- 2452 a. Implementation
- 2453 b. Training
- 2454 c. Communication
- 2455 d. Information/Documents
- 2456 e. Workflow
- 2457 22. What questions do you wish you had asked when first purchasing your system?
- 2458 **23.** Are there additional functions you wish were available or are there existing functionalities you
- 2459 wish worked better?

2460

2461 **FIGURE LEGENDS**

2462 Figure 1. Sample RO-EMR workflow flow chart. IMRT: intensity-modulated radiation therapy; MD:

2463 physician; QA: quality assurance; Hard stop: red symbol sign; Soft stop: yellow symbol, Tx: treatment.

2464 Figure 2. Evolution of a task sequence. Figure 2A shows the baseline task sequence and figure 2B shows

2465 the team specific tasks that replace the baseline sequence in each of the baseline categories.

2466 Figure 3: Sample screenshot of a written directive for HDR in ARIA.

2467 Figure 4. Example of a written directive for HDR in MOSAIQ.

2468 Figure 5. Sample written directive for an unsealed source in a standalone procedure. The written

2469 directive is later scanned into the RO-EMR.

2470 Figure 6. Example of a written directive for an unsealed source in MOSAIQ.

2471 Figure 7. Format of chart elements for brachytherapy and non-standard treatments from AAPM survey

2472 results.

Table I.

Tasks	Average % of total time (duration of effort)	Estimated time to budget (months)
Software selection	10%	1-4
Process Development	30%	4-6
Configuration	25%	3-4
Training	20%	1-3
Go live	15%	1-2

Estimate of percent effort for various steps in the RO-EMR implementation timeline.

Table II.

Method	Percentages
RO-EMR already in use as our record and verify system	23 %
Vendor presentations at your facility	21 %
Consulting with colleagues in other clinics	16 %
Visiting other clinics	13 %
Conversation with vendors during national meetings (e.g., ASTRO, AAPM, etc.)	13 %
Virtual or testing system provided by the vendor to your institution	10 %
Other / unknown	4 %

Factors that can drive RO-EMR selection ranked by prevalence in the AAPM member survey.

Table III:

Type	Method	Examples
Parameters	Direct input and display through the RO-EMR graphical user interface	Demographic information, planned couch coordinates, actual couch coordinates
Template form	Embedded word processing document	Treatment summary, physics consult, simulation document
Free text document	Embedded word processing document	Consult, treatment plan document
Checklist	Native format in the RO-EMR	Weekly chart check
Questionnaire	Native format in the RO-EMR with stored data elements	Physicist plan checks

Types of documentation.

Table IV.

Document Categories	Examples
Patient demographics	Typically the patient's full name, date of birth, gender, address, and phone number. It may additionally include doctor information and SSN, legal guardian, emergency contact information, DNR, and health insurance information.
Diagnosis	One or more ICD-10 codes.
Consult note	Typically contains diagnostic imaging evaluation, lab test results, history and physical evaluation, leading to an impression, plan, and informed consent.
Simulation Order	Instructions from the physician as to site, desired immobilization, orientation, etc., necessary to carry out the simulation. May also contain prescription and imaging information that aids in assignment of a treatment unit.
Prescription / Directive	Dose per fraction, number and frequency of fractions, total dose, energy, modality, imaging, dose constraints, special instructions.
Treatment Planning Directive	Treatment planning information that may not be explicitly indicated on the prescription such as planning goals. This may or may not be signed.
Simulation document	Setup instructions (e.g., immobilization) and photos, bolus, imaging parameters (number of slices, kV, mAs, slice thickness), special notes (e.g., bladder full/empty, Gating/DIBH notes), contrast media.
Physics Consults	In vivo dosimetry, Cardiovascular Implantable Electronic Device (CIED) dose calculation and risk assessment ²⁸ , pregnancy, prior radiation assessment, image fusion reports, gating/DIBH notes, discussion with patient/MD.

Previous treatment	Commonly obtained in pdf format (DICOM RT files are also sent when requested but these are not normally stored in the RO-EMR).
Treatment plan	PDF, scanned signed PDF, or the electronic version in the EMR.
Patient QA forms	Physics initial chart check, therapist initial chart check and pre-treatment check (timeout), weekly chart checks by physics and radiation therapy. Checklists are often used for this purpose.
Patient specific dosimetry	Patient dosimetry verification: independent dose calculations, in vivo measurements, portal dosimetry with or without the patient, film and chamber measurements, or diode/chamber array measurements.
Daily Treatment Record	In addition to the electronic record of treatment that should be maintained by the RO-EMR via the treatment history, there may also exist a manually recorded document stored in the RO-EMR that can be reconciled with the RO-EMR history as part of a QA process.
Unplanned issues	On-treatment items, missed appointments, machine failures, incomplete treatments.
Imaging/IGRT	Imaging studies with shift/matching data may be stored in the RO-EMR
Image Review	This is usually handled through data elements within the RO-EMR.
End of Treatment notes	This could be an electronically generated form.
Weekly on-treatment visits and follow up notes	These could also be forms and may go into the hospital EMR and/or the RO-EMR.

Non-patient QA forms	This includes periodic machine QA. Most institutions do not store this information in their RO-EMR, although it may be convenient to have non-patient periodic imaging tests associated with a fictitious patient for easy test retrieval. Most modern machines require IGRT imager QA (kV, MV and cone-beam CT (CBCT)) on a daily basis and these images may be part of a QA patient stored in the RO-EMR.
Patient reported outcomes	Quality of life patient questionnaires.
Other	Allergy alerts, on treatment alerts that appear at the console for a particular patient, ad hoc treatment notes, etc.

Documentation categories and examples of elements currently seen in practice.

Table V.

<u>Element</u>	<u>Definition</u>	<u>Example</u>
<u>F</u>ormat	Ease of reading	Appropriate font, clear wording, lean content
<u>I</u>nput	How data is entered	Use of dropdowns, radio buttons, etc, minimization of free text
<u>E</u>fficacy	How document fits into the workflow of the clinic	Is data minable, does the form appear automatically when it is needed such as a checklist attached to a task, etc.?
<u>S</u>cope	How the document is grouped with respect to other documents	Are prescription and plan stored together? Are documents needed by therapists grouped for easy and quick access?
<u>T</u>raceability	Are early version retrievable?	Early versions of a prescriptions, plans, etc, are useful for determining what changes are made.
<u>A</u>ccessibility	How easy a document is to access	Is the number of clicks to access a document excessive? Are documents needed when a patient is on the table quickly accessible?

Elements of Document Design.

Table VI.

Client Type	Pros	Cons
Thick Client	<ul style="list-style-type: none"> • If one thick client breaks, it does not affect the rest of the environment. • Easier to implement. • Generally better performance for things like contouring. 	<ul style="list-style-type: none"> • Expensive to maintain during upgrades. • Requires a very robust network. • May require “non-standard” hardware on end user desktops. • Uniform system security standard may be more challenging
Virtual Environment (i.e. Citrix, cloud based**)	<ul style="list-style-type: none"> • Cost Effective. • Easy to maintain during upgrades. • Lower system requirements on end user desktops. 	<ul style="list-style-type: none"> • Highly dependent on infrastructure. • Single point of failure in the absence of adequate redundancy, ie with no alternatives, a failure (network outage for example) can cut off access to the RO-EMR. • Very complex to implement. • Slow access
Hybrid: Thick Clients and Virtual Environment	<ul style="list-style-type: none"> • Provides the most flexibility on accessing the application. 	<ul style="list-style-type: none"> • Highest cost solution. • Most complex solution. • Hardest to maintain.

Comparison of Thick Clients vs Citrix vs hybrid systems.

** Note: Cloud-based environments introduce another level of complexity since the vendor is taking ownership of the infrastructure and corresponding maintenance, data security and uptime. So it is important that the practice/group is aware, understands and agrees with the vendor's roles and responsibilities for supporting the virtual environment.

FIGURE 1

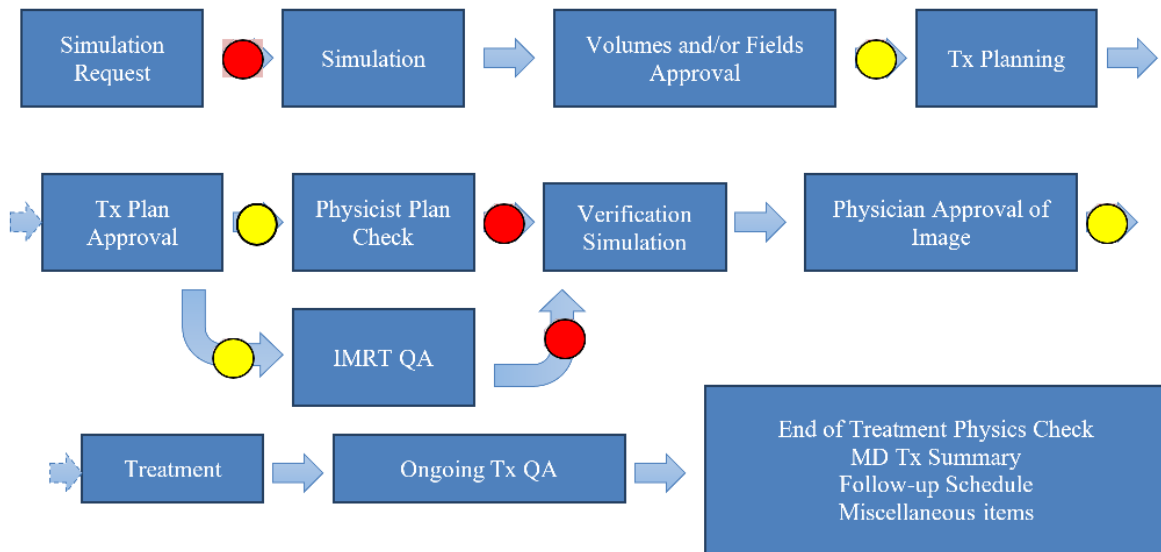


FIGURE 2A.

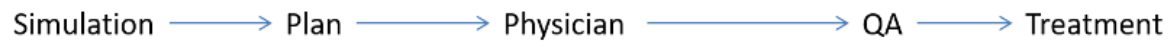


FIGURE 2B

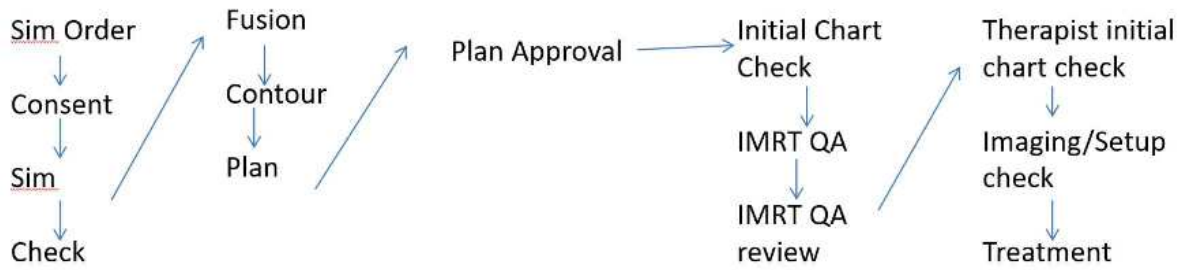


FIGURE 3

Treatment Prescription	Prescription Coverage Constraints	Treatment Management
Prescription Name: prostate test Rx Site: Prostate Fractions: 1 Prescribe To: Volume Add prostate PTV 1500.0 1500.0 Primary/Boost: Boost Mode: Brachy- HDR Technique: Brachytherapy- Volume Energy: Iridium HDR Frequency: 1 Friday Start: 0 Day(s) None Other: Notes: followed by External Beam	Add Structure Min Dose: Max Dose: At least: % of at No more than: % of at Add Structure Organ at Risk Constraints Add Structure Mean: cGy Max: cGy Volume: < Add Constraint	Imaging: FUSION for contouring; OTHER (see notes); Pre Tx, Ob... Clating: None Bolus: None None Breakpoint: None Labs: Simulation: Yes No
		Linked Plans:

FIGURE 4

Radiation Prescriptions - MR#: 5551212 TESTY, TEST

Dx: 7/11/2008: II: *Prostate Gland Mets: Pulmonary, Brain, Bone Course: 6

» Site	Technique	Modality	Fractions				Rx Dose	
			Act	Rx	Dose	Pattern	Act	Rx
Pelvis	Per Plan	06 X		25	180 cGy	Daily		4,500 cGy
Vaginal cuff	HDR Cylinder	Ir-192 HDR		4	500 cGy	TuTh/TuTh		2,000 cGy

Rx Site: Vaginal cuff Status: Approved RLS 11/06/2017 View Fractions: By Course

Technique: HDR Cylinder Number Fractions: By Course

Modality: Ir-192 HDR

Dose Spec: Depth 0.5 cm

Start this Site 1 day(s) after fraction 25 of Site Pelvis.

Week	S	M	T	W	T	F	S
1			1	2	3	4	5
2			6	7	8	9	10
3			11	12	13	14	15
4			16	17	18	19	20
5			21	22	23	24	25
6			26			27	
7			28			29	

Rx Dose	Fractional Dose	Number of Fractions	Fractionation Pattern	Status
2,000 cGy	500 cGy	4	TuTh/TuTh	

Dose Limits
Total Cum:

Pattern: 3.5cm diameter/VL13cm/AL4.5cm
Comment: S/p EBRT

Radiation Rx is View Only

Buttons: Close, Add, Change, Delete, Dosimetry, Note, Plan Dgcs, Status, Fx Notes

FIGURE 5

RADIUM 223 XOFIGO THERAPY WRITTEN DIRECTIVE

Pre-Treatment: *infusion*
 Patient's weight 95 kgs on _____ (date) _____
 Prescribed Dose determined by weight (1.49 microCi/kg) Total number of fractions: 6 _____
 Radium-223 XOFIGO Therapeutic Dose 142 μ Ci, via IV injection

MD's signature/ _____ MD - Print Name _____ Date _____

Procedure Requirements:
 Confirm the following: (Check Yes or No)
 Is the consent form signed, dated and timed? Yes No
 Is the consent formed witnessed? Yes No
 Are the CBC results available? Yes No

Required for treatment:
 1. Is the absolute Neutrophil Count (ANC): greater than $1.5 \times 10^9/L$ for the initial treatment: Yes No
 a. Subsequent Treatments: $1.0 \times 10^9/L$
 2. Is the Platelet count: greater than $100 \times 10^9/L$ for the initial treatment? Yes No
 a. Subsequent Treatments: $50 \times 10^9/L$
 3. Is the Hemoglobin greater than 10g/dL? Yes No


Treatment:
 Dose assay within +/- 10% of the prescribed dose? Yes No
 (If "no", has the MD approved and signed the dose change prior to administration?) Yes No *N/A*

MD signature _____
 Is the Patient Identification verified by Name and DOB per SMC policy? Yes No
 Treatment Number 1 of 6
 Radium-223 XOFIGO Measured Dose Given 138.5 μ Ci, given I.V. at _____
 Dose Administered by SME MD initials _____

Post Administration:
 Room Survey performed by GR Survey result 0.08 *After Admin* mR/hr or cpm
 Survey Instrument Inspector 22072 Background reading 0.005 mR/hr or cpm
 Survey Instrument calibration date: _____
 Dose ordered by: _____

Place Dose Sticker Here

PATIENT LABEL



Product: Ra-223 Dichloride UD (BA)
 Disp Amt: 73.24 μ Ci
 Calibration: _____
 Administer Intravenously
 Indication: Tx of CRPC Bone Mets
 Dispense Date: _____ Use By: _____
 Lot: M16338-8001 Physician: _____
 NDC: 50419-208-01
 Order Amount: 75.89 μ Ci Volume: 5.05 mL
 Date: 13.85 μ Ci/mL

FIGURE 6

Dx: Liver cell carcinoma Course: 1

» Site	Technique	Modality	Fractions				Rx Dose	
			Act	Rx	Dose	Pattern	Act	Rx
right liver lobe	Brachytherapy	Yttrium		1	12,700 cGy	Daily		12,700 cGy

Rx Site: right liver lobe Status: Approved ADM 9/09/2016 View Fractions: By Course
 Technique: Brachytherapy Number Fractions: By Course
 Modality: Yttrium
 Dose Spec: Plan

Rx Dose	Fractional Dose	Number of Fractions	Fractionation Pattern	Status
12,700 cGy	12,700 cGy	1	Daily	

Week	S	M	T	W	T	F	S
1		1					

Dose Limits: Total Cum: 1 cGy Pattern: Comment:

Radiation Rx is View Only

FIGURE 7

