SBRT: QA and Safety Considerations

SESSION: Therapy 4: Current Advantages and Safety Considerations in SBRT

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Presenters:
Stanley H. Benedict, Ph.D.
University of Virginia, Department of Radiation Oncology
and
Kamil M. Yenice, Ph.D.
University of Chicago, Department of Radiation Oncology

References


• Cunningham J, Coffey M, Knöös T, Holmberg D. Radiation Oncology Safety Information System (ROSIS): profiles of participants and the first 1024 incident reports. Radiother Oncol. 2010;97:601–607

• Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD, Benedick A. Finnie PhD, David Kavanagh MD, Carla Mavrouw MD, Todd Fenwick PhD, Louis Potters MD, Yoshiya Yamada MD. “Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy” Practical Radiation Oncology (2011)


The Questions I most often get

• Do you need a body frame to implement SBRT in the clinic?
• What patient and equipment specific QA do you do for SBRT?
• How do you verify treatment delivery for SBRT?
• Do I need a physicist at treatment for each SBRT procedure?
A few brief TG101 topics in this talk:

1. Clinical Implementation of SBRT: system commissioning and IGRT QA issues
2. Simulation Imaging and Treatment Planning
3. Participation in SBRT clinical trials

What is SBRT?

- SBRT refers to the precise irradiation of an image defined extra-cranial lesion associated with the use of high radiation dose delivered in a small number of fractions.

- In SBRT, confidence in this accuracy is accomplished by the integration of modern imaging, simulation, treatment planning, and delivery technologies into all phases of the treatment process; from treatment simulation and planning, and continuing throughout beam delivery (TG 101)

So... what is SBRT?
Frame Based Immobilization and Localization Systems

Frame systems provide a link between patient immobilization and localization: accurate localization relies on patient setup reproducibility.

Assumption: variations in the stereotactic location of the target are due only to organ motion and not to setup uncertainties.

Not true for most situations!

Patient Positioning, Immobilization, Target Localization, and Delivery

Recommendation (TG 101): For SBRT, image-guided localization techniques shall be used to guarantee the spatial accuracy of the delivered dose distribution.

• Body frames and fiducial systems are OK for immobilization and positioning aids
• They shall NOT be used as a sole localization technique!
SBRT Commissioning (I)

• “Commissioning tests should be developed by the institution’s physics team to explore in detail every aspect of the system with the goal of developing a comprehensive baseline characterization of the performance of the system.” (TG-101)

SBRT Commissioning (II)

• “If individual errors are small by themselves, cumulative system accuracy for the procedure can be significant and needs to be characterized through an end-to-end test using phantoms with measurement detectors and imaging” (TG-101)
The modified Winston-Lutz test should be performed at the time any SBRT system is initially commissioned, and it should be repeated monthly.

All SBRT procedures should include detailed information on how the registration software is to be applied.

Special moving phantoms should be used to demonstrate that gating and/or tracking techniques are accurate.

Multiple Imaging Modality Isocentricity (MiMi) Phantom from Standard Imaging

- **Easy Alignment due to Unique Design:**
  - "The MiMi Phantom incorporates five bone equivalent rods uniquely set so that four of beam intersect at 90° angles when viewed in DRRs or a 2D projection image. The rods traverse the entire phantom making them visible in any image or slice allowing for easy 2D/2D and 3D/3D matching for fast verification of isocenter position."

- **Test Integrated System Accuracy of:**
  - 3D Cone Beam
  - MV/kV
  - Lasers and Couch Table Adjustments
  - Optical Guidance Systems

- **Test Automatic Table Adjustments:**
  - "Additional cross-hair markers that are offset known distances from the true isocenter allow for verification of the shifts prescribed by automatic table positioning systems."

MiMi Phantom

Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago
Isocenter Coincidence Testing

Axial CT Scanning (0.75mm)
Align Phantom to Lasers

Center Phantom in Radiation Isocenter by MV imaging at 4 orthogonal angles
Measure Offset to kV Isocenter by imaging at 4 orthogonal angles
Measure Offset in CBCT Isocenter
Measure Offset to AlignRT Isocenter
Measure Offset to Laser Isocenter

Introduce Known Physical Shift & Measure Accuracy

Center Phantom in MV Isocenter by Imaging at 4 Gantry Angles

Measure Offset to kV Isocenter by 2D/2D Match at 4 Angles

Measure Offset to CBCT Isocenter
Measure Offset to AlignRT Isocenter
Measure Offset to Laser Isocenter


Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago
Measure Offset to CBCT Isocenter

Dependent upon CBCT Technique!
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

Measure Offset to Laser Isocenter

Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

Root Mean Square Distances of IGRT Isocenter Offsets

Trilogy couch precision: a factor in larger offset values
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago
Distance Error Criterion:

- ≤ 1 mm (TrueBeam)
- ≤ 2 mm (C-series)
Dr. Amols argued for the proposition:

"Linacs also are built better than they were 25 years ago, but we haven't changed our QA procedures accordingly. We still routinely check "cGy/mu," isocenter accuracy, laser drift, etc. Sure, we've added new QA procedures for modern accessories (EPIDs, MLCs, CBCT, etc.), but we never subtract....."

"How many patients have been mistreated recently because a laser drifted or a linac dose rate changed between Monday and Tuesday? None!"

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**SBRT Planning Issues**

- Treatment planning simulation
  - Patient positioning and immobilization
  - Motion management: 4DCT, gating, etc
- Number of beams and geometry
- PTV (and PRV) and Beam Margins
- Normal tissue tolerance and environmentally friendly dose disposal (term attributed to Michael Goitein)
- Intensity Modulation: whether to use or not and how to use it for moving targets

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**Respiratory Motion Management**

**Recommendation:** For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended.

- Quantifies motion expected over respiratory cycle
- Determines if techniques such as respiratory gating would be beneficial
- Helps in defining margins for treatment planning
- Allows compensation for temporal phase shifts between tumor motion and respiratory cycle
Simulation with Motion or Imaging Artifacts

Recommendation (TG 101): If target and/or critical structures cannot be localized accurately due to motion or metal artifacts……

STOP!

Do NOT pursue SBRT as a treatment option!

SBRT Target Margins

Recommendation (TG 101): At the current time, it remains difficult to base target margins directly on clinical results. The adequacy of ICRU definitions depend on:

• Understanding of how high absolute doses and sharp dose falloffs affect accuracy
• Limitations on in-house localization uncertainty
• Guidance from current peer-reviewed literature

Make an effort to gather and analyze your own clinical results to improve margin design!

Normal Tissue Tolerances

Recommendation: Normal tissue dose tolerances in the context of SBRT are still evolving. So…. CAUTION!

• If part of an IRB-approved phase 1 protocol, proceed carefully
• Otherwise, the evolving peer-reviewed literature must be respected!
Some Caveats

- There is sparse long-term follow-up for SBRT.
- Data in table 3 should be treated as a first approximation!
- Doses are mostly unvalidated, but doses are based mostly on observation and theory.
- There is some measure of educated guessing!

R. Timmerman, 10/26/09, pers. comm. (Stan Benedict, PhD)

SBRT Participation In Trials

Recommendation: The most effective way to further the radiation oncology community’s SBRT knowledge base is through participation in formal group trials

- Single- or multi- institution
- Ideally NCI-sponsored or NCI-cooperative groups (e.g. RTOG)
- If no formal trial, look to publications
- If no publications, structure as internal clinical trial
UCMC: Single Segment IMRT planning for Lung SBRT

Objects:
1. Improve SBRT delivery accuracy with gating
2. Control dose spillage of high and medium dose levels

Beams, Structures and Optimization
4D-CT Simulation
PTV = ITV + 5-7 mm margin

Generate multiple rind structures for optimization

Optimization

Decision Tree

Number of Beams
1 Segment/beam for all beams

Low number of segments for more efficient dose delivery

In contrast to Lung, multiple segment IMRT is the preferred SBRT Technique for Spine
Need a sharp dose gradient between the cord and PTV: High degree of modulation 12 Segments per beam (G=220°)

Spinal SBRT with IMRT

Evaluate the effect of setup/motion on delivered dose!

Know the limitations of your dose algorithm! (Pay attention to warnings in user’s manual)

If the dose algorithm is used with parameters outside the measured and tabulated values, the accuracy of the calculated dose cannot be guaranteed. You must ensure that all necessary parameters, in particular the field sizes, depth and off-axis distance for the patient treatment are included in the measured beam data.

The accuracy of all Bragg dose algorithms is directly dependent on the accuracy and the range of the beam data measurements. It must be ensured that the beam data measurement covers the range of field sizes and depths that will be used in subsequent treatment planning. This is especially the case for the measurements of the scatter kernels, the radial profiles and the depth dose.

Depending on the MLC type, the pencil beam algorithm uses kernels of a certain resolution that define the overall resolution of the dose calculation perpendicular to the beam axis. In the case of small structures in combination with a insufficient kernel grid size, the pencil beam dose calculation may be too coarse to identify every detail of the delivered dose distribution.
Recommendation (TG 101): SBRT commonly includes extremely high-dose gradients near the boundary of the target and often makes use of IMRT techniques. This report recommends the use of an isotropic grid size of 2 mm or finer. The use of grid sizes greater than 3 mm is discouraged for SBRT.

This vendor safety notice warns against two specific issues for potential inaccurate dose computation due to:

1. Use of conditions that require extrapolation of data beyond measurement range
2. Use of large grid size resulting in unexpected results for small structures

**Physicist Presence**

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Physicist Presence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-Fraction SRS</td>
<td>Physicist present for entire procedure</td>
</tr>
<tr>
<td>Multiple-Fraction SRS</td>
<td>Physicist present for 1st fraction and at setup of remaining fractions</td>
</tr>
<tr>
<td>SBRT</td>
<td>Physicist present for 1st fraction, and setup for every fraction to verify imaging, registration, gating, immobilization</td>
</tr>
</tbody>
</table>
What is the most effective way to further the radiation oncology community’s SBRT knowledge base?

1. Industry research to improve the technology and delivery
2. Attendance at national and regional meetings
3. Participation in SBRT clinical trials, ideally NCI sponsored or NCI cooperative groups
4. Using the internet to promote the sophisticated features and capabilities.
5. Developing theoretical and computer based radiobiological models

Answer: 3

Participation by clinicians in radiation oncology clinical trials, ideally NCI sponsored or NCI cooperative groups (i.e. RTOG), but also single or multi-institutional protocols.

- Although industry research making improvement to our equipment, attendance at meetings by clinicians, and research into radiobiological modeling will advance our knowledge base – the most effective way to truly further our SBRT clinical knowledge base is by participation in clinical trials and communicating the analysis of the data to our clinicians. There is no evidence that promoting the features of medical equipment on the internet furthers our knowledge base of SBRT at all.

- References:

When target and/or critical structures cannot be localized accurately due to motion or metal artifacts which of the following applies…

1. Utilize the deformable image registration features of the treatment planning system to develop a treatment plan
2. Contour the target and critical structures as best you can and increase the margins on the target to a level that is necessary to account for the motion
3. Reduce the dose and/or fractionation from the standard protocol to account for the errors in localization
4. Use orthogonal (AP and lateral) kV planar imaging to develop a 2D plan for treatment and set-up.
5. Do not pursue SBRT as a treatment option.
• If one is unable to localize the target and adjacent critical structures due to motion or metal artifacts SBRT should not be a treatment option.

• Deformation registration and other imaging tools may be instructive for targeting, but if the target and/or adjacent critical structures are not localizable than SBRT is not an appropriate delivery.

• Reference:

For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended for planning and delivery of SBRT. Which of the following is a suitable approach?

1. Adoption of a body frame will allow the planning, localization, and delivery for all thoracic and abdominal targets.
2. The use of external markers or fiducials will allow accurate assessment of tumor position and re-localization.
3. Employing abdominal compression has been shown to eliminate the need for tumor motion assessment
4. Developing a standard protocol for all target margins in the treatment planning process will eliminate the need for a patient specific tumor motion assessment.
5. The use of fiducials and body frames may be helpful for patient positioning in SBRT, but they are no substitute for employing IGRT technology such as CBCT. SBRT requires IGRT.

Answer: 5

• For SBRT, image-guided localization techniques shall be used to guarantee the spatial accuracy of the derived dose distribution. Other techniques, such as body frames, fiducials, and abdominal compression may be employed but they are no substitute for IGRT technology.

• Reference:
Acknowledgements

Karl Farrey, MS
Julien Partouche, MS
Tianming Wu, PhD

And now a word about … safety

SRS Event in the News…

Making a Complex Machine Even More Complex

ASTRO has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors.

1) Working with the Conference of Radiation Control Program Directors (CRCPD) and other stakeholders to create a database for the reporting of linear accelerator- and computed tomography-based medical errors.

2) Launching a significantly enhanced practice accreditation program, and beginning the development of additional accreditation modules specifically addressing new, advanced technologies such as IMRT, SBRT and brachytherapy.

3) Expanding our educational training programs to include specific courses on quality assurance and safety, and adding additional content to other educational programs.

4) Working with patient support organizations to develop tools for cancer patients and caregivers for use in their discussions with their radiation oncologists to help them understand the quality and safety programs at the centers where they are being treated. These tools will include questions to ask their treatment team, such as, “Do you have daily safety checks?” and “What kinds of safeguards do you have to make sure I’m given the right treatment?”

5) Further developing our Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO) connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

6) Providing our members’ expertise to policymakers and advocating for new and expanded federal initiatives to help protect patients, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Act to require national standards for radiation therapy treatment team members, additional resources for the National Institute of Health’s Radiological Physics Center to evaluate the safety of treatments; and funding for a national reporting database.

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1. ASTRO has no intention of enabling manufacturers to ensure safe transfer of information between systems.
2. ASTRO intends to further develop their Integrating the Healthcare Enterprise – Radiation Oncology connectivity compliance program to ensure technologies from different manufacturers can safely transfer information to reduce medical error.
3. ASTRO Equipment Board will assume responsibility for all manufacturer compliance and inter-connectivity.
4. ASTRO will work with only one leading manufacturer to ensure safety and compliance.
5. ASTRO recommends committing to a single manufacturer for each specialized treatment delivery and thereby eliminating problems associated with combining different technologies.
Answer: 2

- Further developing our Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO) connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

- Reference:
  - ASTRO six-point patient protection plan – 2010

ASTRO, AAPM, ACR and other organizations have developed guidance documents aimed at understanding radiation risks

- Several guidance documents aimed at understanding radiotherapy risks and mitigating radiotherapy errors have been forthcoming recently from national and international organizations, these include: the World Health Organization (WHO), the International Commission on Radiological Protection (ICRP), the National Health Service (NHS) of the United Kingdom and the Alberta Heritage Foundation for Medical Research.

- A list of some of the common factors contributing to radiotherapy incidents has been summarized from these documents and they include:

  - Lack of training, competence or experience
  - Inadequate staffing and/or skills levels
  - Fatigue and stress, staffing and skills levels
  - Poor design and documentation of procedures
  - Complexity and sophistication of new technologies
  - Over-reliance on automated procedures
  - Poor communication and lack of team work
  - Inadequate infrastructure and work environment
  - Changes in processes

The WHO has suggested a number of general preventative measures aimed at reducing radiotherapy errors:

- A thorough quality assurance program to reduce the risks of systematic equipment and procedural related errors;
- A peer review audit program to improve decision making throughout the treatment process; Extensive use of procedural checklists;
- Independent verification through all stages of the process;
- Specific competency certification for all personnel;
- Routine use of in-vivo dosimetry.


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**SRS Events Reported to the NRC**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Treatment Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient identification error on a SRS database</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Failure to respond properly during CT imaging</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Installation of automatic positioning mechanism following recalibration</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Right inguinal mass instead of left lymph node</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Failure to respond properly during CT imaging</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Medication setting incorrect coordinates</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Head not centered to stereotactic device (2 events)</td>
<td>Wrong treatment delayed</td>
</tr>
<tr>
<td>Patient mistakenly received 20 Gy instead of 10 Gy non-planning dose</td>
<td>Wrong dose delivered</td>
</tr>
<tr>
<td>Patient mistakenly received 10 Gy instead of 40 Gy (2 events)</td>
<td>Wrong dose delivered</td>
</tr>
<tr>
<td>Microscopic abnormality in a non-irradiated area</td>
<td>Treatment killed after 2-3 fractions</td>
</tr>
<tr>
<td>Confusion during treatment</td>
<td>Never present, but non-irradiated cancer</td>
</tr>
</tbody>
</table>


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**Radiation Oncology Safety Information System (ROSIIS) – Profiles of participants and the first 1074 incident reports**
Established in 2001, the aim of ROSIS is to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures.

A voluntary web-based cross-organizational and international reporting and learning system was developed.

ROSIS departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 brachytherapy units.

**Discipline who detected the incident**

![Pie chart showing the distribution of disciplines detecting incidents](Fig. 1. Discipline who detected the incident.)

**QA Incident Detection**

![Bar chart showing the types of incidents](Fig. 2. Quality assurance method by which the incident was detected.)
A recent report by Cunningham et al. on 1074 radiation oncology incident reports determined which discipline was most likely to detect an incident?

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Discipline</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>Radiation Oncologists</td>
</tr>
<tr>
<td>94%</td>
<td>Therapists</td>
</tr>
<tr>
<td>0%</td>
<td>Physicists</td>
</tr>
<tr>
<td>0%</td>
<td>Dosimetrists</td>
</tr>
<tr>
<td>5%</td>
<td>Unknown, it has not been determined</td>
</tr>
</tbody>
</table>

**Answer: 2**

- The majority of reported incidents were detected by the radiation therapists at the treatment unit and were found during a treatment appointment. Detection by the QC process was the next most common method of detection. Although QC checklists and checks by dosimetry and physicists are important, they are no substitute for vigilance at the machine, particularly on the first day of treatment.

- Reference:
  - Cunningham J, Coffey M, Knöös T, Holmberg O. Radiation Oncology Safety Information System (ROSIS)—profiles of participants and the first 1074 incident reports. Radiother Oncol. 2010;97:601–607

**QA and Safety in SRS/SBRT**

(Executive Summary and Supplemental Material)
Serious SRS Events Reported

- A calibration error on a radiosurgery linac that affected 77 patients in Florida in 2004-2005
- Similar errors in measurement of output factors affecting 145 patients in Toulouse, France in 2006-2007, and 152 patients in Springfield, MO from 2004 to 2009
- An error in a cranial localization accessory that affected 7 centers in the U.S. and Europe
- Errors in failure to properly set backup jaws for treatments using small circular collimators affecting a single arteriovenous malformation patient at an institution in France, 3 patients at an institution in Evanston, IL.38

Planning Aspects for New SBRT Program

Personnel Qualifications for an SRT Program
Commissioning of a SRS Program

Table 5. Essential commissioning elements of a stereotactic program.

<table>
<thead>
<tr>
<th>Element</th>
<th>Duration</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate treatment facilities, equipment, and personnel must be evaluated and reviewed prior to initiating a clinical SBRT program.</td>
<td>1 week</td>
<td>1</td>
</tr>
<tr>
<td>Independent assessment of personnel should be performed prior to initiating a clinical SBRT program.</td>
<td>1 week</td>
<td>1</td>
</tr>
<tr>
<td>Independent verification of safety calculations should be performed prior to initiating a clinical SBRT program.</td>
<td>1 week</td>
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<tr>
<td>Independent verification of safety calculations should be performed prior to initiating a clinical SBRT program.</td>
<td>1 week</td>
<td>1</td>
</tr>
<tr>
<td>Recommendations to guard against catastrophic failures:</td>
<td>2nd reviews</td>
<td>2</td>
</tr>
<tr>
<td>- Principals</td>
<td>2nd reviews</td>
<td>2</td>
</tr>
<tr>
<td>- Primary Reviews</td>
<td>2nd reviews</td>
<td>2</td>
</tr>
<tr>
<td>Develop checklists for your program.</td>
<td>2nd reviews</td>
<td>2</td>
</tr>
</tbody>
</table>

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, Practical Rad Onc, 2011

THE NEW YORKER
ANALYSIS OF MEDICINE
THE CHECKLIST
If something so simple can transform medical care, what else can it do?
BY ATUL GAONKAR
DECEMBER 05, 2007
Appendix: Example checklists from 3 Institutions for SBRT

• Frame-based SRS Checklist
• Frameless SRS Checklist
• SBRT Spine Worklist
• SBRT Lung Worklist
• SRS Checklist
• Trigeminal neuralgia SRS checklist
• SBRT Checklist
• SBRT – Elekta SBRT Frame
• Beam Configuration
• Planning

“Quality and Safety Considerations in SRS and SBRT”, Solberg et al., Practical Rad Onc, 2011

Sample Checklist for SRS Program: Lung

The use of procedural checklists can be particularly effective at ensuring compliance and minimizing error. Which of the following best describes the use of checklists for treatments?

1. Checklists are only helpful for the initial stages of an SBRT program
2. The adoption of the same site specific checklists from other institutions will usually suffice for initiating SBRT
3. Checklists are exclusively for the therapists to review and ensure that the patient has been set-up correctly.
4. Checklists used prior to daily treatment must be customized to the particular treatment planning and delivery systems.
5. Site specific and machine specific checklists should not be used because they add confusion to the therapists.
Answer: 4

- Checklists should be used, and they should be customized to match the technology and treatment site. These checklists should also be updated regularly to reflect any changes in procedures or technological updates in the SBRT program.

- Reference:
  - Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD, Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD, Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD. “Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy,” Practical Radiation Oncology (2011).

Be Efficient – Be Safe

Thank You!