U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-19555/92001(DRSS)

Docket No. 030-19555

License No. 13-17793-02 Category G(3) Priority 1

Licensee: Saint John's Medical Center
2015 Jackson Street
Anderson, IN 46014

Inspection Conducted: November 24, 1992

Inspectors: _____ 12/24/92
James R. Mullauer, M.H.S. Date
Nuclear Materials Inspection
Section 1

_____ 12/24/92
Michelle S. Barry, M.S. Date
Nuclear Materials Inspection
Section 1

Reviewed By: _____ 12/24/92
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: _____ for 12/24/92
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on November 24, 1992 (Report No. 030-19555/92001(DRSS))

Areas Inspected: A special, announced safety inspection was conducted to review the circumstances surrounding a teletherapy misadministration reported to the NRC on November 13, 1992. The inspection also consisted of a review of selected aspects of licensed teletherapy activities as described in Section 6 of this report. An NRC medical consultant assisted the NRC Region III Office in evaluating the medical significance of the misadministration.

Results: The licensee's radiation safety program for teletherapy activities appeared to be generally good. However, during the review of the misadminstration, problems associated with the implementation of the licensee's quality management program were found. Of the areas inspected, one unresolved item and six concerns were identified. The NRC medical consultant's investigation of the misadministration indicated that the dose delivered to the patient represents the peak tolerance of the brain, carrying a 5% risk of radiation necrosis in 4-12 months.

DETAILS

1. Persons Contacted

* James Moore, Vice President of Clinical Services
* James Courier, M.D., Medical Director of Oncology
* John Marvel, M.D., Radiation Oncologist
* Joe Sensing, Radiation Oncology Administrative Director
* Mary Hartson, Ph.D., Radiation Safety Officer (RSO) and Senior Medical Physicist
* Jane Cantwell, Medical Physicist
  Luanne Champney, Certified Medical Dosimetrist
  Linda Crawford, Therapy Technologist
  Alice Cunningham, Therapy Technologist
* Hans Messersmith, Indiana State Department of Health

* Denotes those present at the exit meeting on November 24, 1992.

2. Inspection History

Activities conducted under License No. 13-17793-02 were reviewed by the NRC twice within the past three years. No violations were identified during a routine inspection performed on November 21, 1991. Two violations of NRC requirements were identified during the June 21, 1989, routine inspection for failure to: (1) notify the NRC Region III office of a change in the teletherapy physicist and (2) maintain records for three years showing safety training of individuals.

3. Licensed Program

On January 25, 1982, Saint John's Medical Center was issued NRC License No. 13-17793-02 for possession and use of up to 7400 curies of cobalt-60 as a sealed source, to be used in an AECL Theratron 780 teletherapy unit for human treatment. The license was last amended in its entirety on March 30, 1988, and currently authorizes possession and use of 7400 curies of cobalt-60 in an AECL Theratron 780 teletherapy unit. Currently, 20 patients are treated on the Theratron 780 each month for a variety of applications.

The quantity, type and use of radioactive material are as authorized on the license.

No violations of NRC requirements were identified.

4. Teletherapy Misadministration Event Summary

In November 1992, a patient was treated for primary metastatic disease of the lung using external beam therapy on a linear accelerator. Since the metastasis involved the brain, whole brain irradiation followed by cone down palliative treatments using cobalt-60 external beam

teletherapy were scheduled. On November 6, 1992, a treatment plan was finalized which required a dose of 3000 centigray (rads) to be given to the whole brain of a patient in 10 fractions delivering 300 centigray per fraction. Each fraction was to consist of 2 ports (right and left lateral), delivering 150 centigray per port. Treatment began on November 6, 1992. By the fifth day of treatment, the licensee discovered that the patient had received a weekly cumulated dose of 2550 centigray rather than the weekly prescribed cumulated dose of 1500 centigray, representing a 70% overdose to the patient. As defined in 10 CFR 35.2, a teletherapy radiation dose, where the calculated weekly dose is 30% greater than the weekly prescribed dose, is a misadministration. The misadministration was discovered by the licensee on November 12, 1992 and reported to the NRC on November 13, 1992. The following is a summary sequence of events that occurred.

On Thursday, November 5, 1992, a written directive for teletherapy treatment was prepared by an oncologist, one of the licensee's authorized users. The written directive specified the treatment plan referenced above.

On Friday November 6, 1992, a dosimetrist measured the lateral cranial thickness of the patient to be 16 centimeters and determined the midline treatment depth of the brain to be 8 centimeters. The patient data sheet was filled out by the dosimetrist with all of the information required for the final calculation of the treatment time. However, instead of using the midline depth of 8 centimeters, the dosimetrist inadvertently used the total cranial thickness, 16 centimeters. As a result of this error, a treatment time of 2.56 minutes was calculated for each port rather than the required time of 1.51 minutes.

Two teletherapy technologists who were assigned this case reviewed the treatment form prior to treating the patient and questioned the unusually long treatment time indicated on the form. However, they did not pursue this matter with the oncologist or the dosimetrist. They verified that the information was correctly transferred onto the treatment form and treated the patient using the 2.56 minutes treatment time.

On Monday, November 9, 1992, the medical physicist, in the absence of the senior medical physicist, performed an unscheduled review of all teletherapy patient charts. However, the chart of the patient involved in the misadministration was not in the chart rack and therefore, was not reviewed.

The oncologist who prescribed the treatments reviewed the patient's chart and questioned a treatment field size irregularity in the dose calculations. After determining that the field size was correct, he briefly reviewed the remaining treatment parameters including the treatment depth and treatment time. However, the oncologist did not verify that the parameters used in the calculation were correct.

On Thursday, November 12, 1992, the medical physicist performed a routine weekly chart check and immediately upon reviewing this chart, identified the calculational error that was made on November 6, 1992. The licensee determined that this patient received a dose 70% more than that prescribed for the weekly treatments.

Upon return on Friday, November 13, 1992, the senior medical physicist confirmed the error. The patient's whole brain treatment was terminated until the effects of the error could be determined. The licensee made a telephone notification to the NRC Operations Center of the teletherapy misadministration pursuant to 10 CFR 35.33.

5. Teletherapy Misadministration Evaluation

The apparent root cause of the misadministration was an error in the transfer of information from the dosimetry sheet to the computer. The patient's lateral cranial thickness was used as input in the treatment time calculation instead of the prescribed treatment depth. Although the initial treatment calculation is not a subject addressed in the licensee's QMP, procedures exist in the QMP for identification and mitigation of calculation errors.

10 CFR 35.32(a)(3) and (a)(5) state, in part that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives: (1) that final plans of treatment and related calculations for teletherapy are in accordance with the respective written directive and (2) that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee established and implemented a written quality management program as required by 10 CFR 35.32 on January 27, 1992. The program requires a weekly chart check to be performed by a qualified person, (e.g., a radiation therapy physicist, dosimetrist, oncology physician, or radiation therapy technologist) in order to detect mistakes such as arithmetic errors, miscalculations, or incorrect transfer of data that may have occurred in the dose administrations. If the prescribed dose is to be administered in more than three fractions, the licensee's QMP requires the dose calculations to be checked within three working days after administering the first teletherapy fractional dose. The dose calculations should be checked by an authorized user or some other qualified person who did not make the original calculations. Computer-generated dose calculations, according to the licensee's QMP, should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations.

The authorized user (oncologist) who prepared the written directive checked the dose calculations within three working days after administering the first fractional dose. The oncologist, however, did not examine the computer printout to verify that the correct data for

the patient were used in the calculations. The NRC is in the process of reviewing this matter for its applicability to the requirements in 10 CFR Part 35. This omission appears to be contrary to the licensee's QMP and may have resulted in the failure of the QMP to meet the objectives of 10 CFR 35.32 (a)(3) and (a)(5) as previously stated. This matter is, therefore, considered to be unresolved at this time pending further review.

The NRC inspectors identified concerns relating to other events that contributed to the licensee's failure to identify in a timely manner that the misadministration was in progress. These are described below:

1. Prior to administering the first fractional dose, the two teletherapy technologists who were assigned this case questioned the long treatment time indicated on the treatment form. However, they did not share their concerns with the authorized user or with other supervisory staff.

2. The senior medical physicist, who is also the RSO, was on leave during this event. This person normally reviews all treatment calculations within 24 to 48 hours of the calculation. No one was assigned this task in the RSO's absence.

3. The medical physicist reviewed patient charts in the absence of the senior medical physicist on the day that the second fractional dose was administered. However, the chart of the patient in question was not in the chart rack and therefore, was not reviewed.

One unresolved issue and three concerns were identified.

6. Other Areas Inspected

The NRC inspectors identified other generic concerns associated with the licensee's QMP involving training and staffing assignments. Interviews with the therapy technologists revealed the lack of a standard method for validating treatment information. In addition, there does not appear to be a consistent understanding among staff members of what constitutes the "Plan of Treatment." With regard to staffing assignments, the licensee does not have a policy or system in place for assuring that the duties and responsibilities of key individuals in the QMP are reassigned during their absence.

The inspection also included a review of selected aspects of licensed activities associated with the routine teletherapy program including: organization, management controls and staffing, personnel qualifications and training, materials, facilities and equipment, external exposure control and monitoring, teletherapy unit calibration and spot checks, and posting and labeling.

No violations of NRC requirements were identified, however, three concerns were noted.

7. Medical Consultant's Report

The NRC contracted a medical consultant to evaluate the medical implications of the misadministration. The medical consultant's findings indicate that the dose delivered to the patient was equivalent to 200 rads in 25 fractions (5 weeks). This represents the peak tolerance of the brain, carrying a 5% risk of radiation necrosis in 4-12 months.

8. Exit Meeting

At the conclusion of the inspection, an exit meeting was held with those indicated in Section 1. The inspectors summarized the scope and findings of the inspection and the likely informational content of the inspection report. The licensee did not identify any of the information covered as proprietary.

In response to the inspectors' comments, the licensee discussed their preliminary corrective action which included a revision of the QMP. The revision requires that treatments of greater than three fractions be checked within two working days after the first administered fractional dose instead of three working days as previously required. This check will be performed by a physicist and an oncologist, neither of whom are involved in the original calculation.

Attachments:
1. Licensee's Misadministration Report
2. Medical Consultant's Report
3. Licensee's Quality Management Program

13-17793-02

Attachment 3

QUALITY MANAGEMENT PROGRAMS

SAINT JOHN'S HEALTH CARE CORPORATION
ANDERSON, INDIANA

POLICY

CODE: RO 4.9

SUBJECT: Quality Management Program
Teletherapy

APPROVED: Joseph B. Sensing
James E. Currier, M.D.
Mary E. Hartson, Ph.D.

EFFECTIVE DATE: 1/27/92

REVIEW	_____	REVISED	_____	EFFECTIVE	_____
REVIEW	_____	REVISED	_____	EFFECTIVE	_____
REVIEW	_____	REVISED	_____	EFFECTIVE	_____
REVIEW	_____	REVISED	_____	EFFECTIVE	_____
REVIEW	_____	REVISED	_____	EFFECTIVE	_____

DISTRIBUTION: Radiation Oncology Department

POLICY STATEMENT:

The purpose of the Quality Management Program is to ensure the safe administration of each teletherapy dose. The following action steps will be implemented to ensure that the objectives of 10 CFR 35.32 are met.

ACTION STEPS:

1. A written directive, signed and dated by an authorized user (on the teletherapy license), must be present prior to the administration of any teletherapy dose. If a medical emergency should arise, the requirement may be deviated from in accordance with 10 CFR 35.32 (a)(1) footnotes.

2. Before administering the teletherapy dose, the patient shall be identified by more than one method as the individual named in the written directive. First, identify the patient by asking the patient's name and confirming the name. Second, identify the patient by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet, hospital ID card, or medical insurance card, or the photograph of the patient's face.

3. An authorized user shall approve a plan of treatment that provides sufficient information and direction to meet the objectives of the written directive. Specifically, it should include: the total dose, dose per fraction, treatment site, and overall treatment period.

4. Before administering the teletherapy dose, the radiation therapy technologist will verify that the specific details of the administration are in agreement with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be compared with what is stated in the written directive and plan of treatment.

5. If the radiation therapy technologist does not understand how to carry out the written directive or cannot clearly read the written directive, he or she must contact the authorized user who wrote the directive and receive clarification before delivering the teletherapy dose.

6. After each teletherapy dose, a qualified person (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) shall make, date, and sign or initial the written record in the patient's chart or in another appropriate record which contains, for each treatment field, the treatment time, dose administered, and the cumulative dose administered. This will be done under the supervision of an authorized user in accord with the responsibilities and conditions of supervision contained in 10 CFR 35.25. The record of the administered dose will meet the requirements in 10 CFR 35.32(d)(2).

7. A weekly chart check will be performed by a qualified person,(e.g., a radiation therapy physicist, dosimetrist, oncology physician, or radiation therapy technologist) in order to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields or in connection with any changes in the written directive or plan of treatment. This will be done under the direction of an authorized user in accord with the responsibilities and conditions of supervision contained in 10 CFR 35.25.

8. If the prescribed dose is to be administered in more than three fraction, the dose calculations will be checked within three working days after administering the first teletherapy fractional dose. An authorized user or a qualified person (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who, whenever possible, did not make the original calculations, should check the dose calculations. If the prescribed dose is to be administered in three fractions or less, a procedure for checking dose calculations as described in this paragraph will be performed before administering the first teletherapy fractional dose. These checks will be performed under the supervision of an authorized user in accord with the responsibilities and conditions of supervision as contained in 10 CFR 35.25.

Manual dose calculations will be checked for:
(1) Arithmetic errors,
(2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,
(3) Appropriate use of nomograms (when applicable), and
(4) Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., patient contour, patient thickness at the central ray, depth of target, depth dose factors, treatment distance, portal arrangement, field sizes, or beam-modifying factors). Alternatively, the dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculation.

If the manual dose calculations are performed using computer-generated outputs or vice versa, particular emphasis will be placed on verifying the correct output from one type of dose calculation (e.g., computer) to be used as an input in another type of dose calculation (e.g., manual). Parameters used in the dose calculations, such as the transmission factors for wedges and the source strength of the sealed source used in the dose calculations will be checked.

9. A procedure for independently checking certain full calibration measurements has been established as follows:

After full calibration measurements due to replacement of the source, or whenever spot check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration, corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions will be performed. The independent check will be performed within 30 days following such full calibration measurements.

The independent check will be performed by either:

(1) An individual who did not perform the full calibration (this individual will meet the requirements specified in 10 CFR 35.961) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630(a)), or

(2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate to within 5 percent.

10. The full calibration procedure mandated by 10 CFR 35.632 will be expanded to include the determination of transmission factors for trays and wedges. Transmission factors for other beam modifying devices (e.g., nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) will be determined before the first medical use of the beam-modifying device and after replacement of the source.

11. A procedure has been established to make a physical measurement of the teletherapy output under applicable conditions prior to administration of the first teletherapy fractional dose if the patient's plan of treatment included (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration.

12. If an authorized user determines that delaying treatment to perform the checks of (1) dose calculations for a prescribed dose that is administered in three fractions or less (see Action Step 8) or (2) teletherapy output (see Action Step 11) would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The authorized user should make a notation of this determination in the records or the calculated administered dose. The checks of the calculations should be performed within two working days of completion of the treatment.

13. A procedure has been established for performance of acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations. Acceptance testing will be performed before the first use of this program. Acceptance testing will also be performed after full calibration measurements when the calibration was performed (1) before the first medical use of the teletherapy unit, (2) after replacement of the source, or(3) when spot-check measurements indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay. Computer generated beam data will be compared to measured beam data from the teletherapy unit. The treatment planning or dose calculating computer program will be assessed based on the institutions's specific needs and applications.

14. The Quality Management Program will be reviewed on an annual basis. A treatment record will be completed for each patient receiving teletherapy treatments. Any deficiencies found during the annual review of these records will indicate a need to review the Quality Management Program and make adjustments as needed. Also, any recordable event will be an alarm to review the program.

Attachment 1

November 20, 1992

St. John's Health Care Corp
2015 Jackson Street
Anderson, Indiana 46014

U.S. Nuclear Regulatory Commission
Radioisotopes Licensing Division
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: Teletherapy Misadministration
License #13-17793-01

Gentlemen:

Enclosed is a report of a teletherapy misadministration which was discovered at 4:00 P.M. November 12, 1992. It was reported to the NRC Operations Center at 9:17 A.M. on November 13, 1992.

Please contact me if any further information is required.

Sincerely,

Mary E. Hartson

Mary E. Hartson, Ph.D.
Teletherapy Physicist

9212280142

REPORT OF TELETHERAPY MISADMINISTRATION

1. Licensee's Name: St. John's Medical Center

2. Prescribing Physician's Name: John E. Marvel, M.D.

3. Brief Description of the Event:

On Friday November 6, 1992, a patient began a series of whole brain radiation treatments which was prescribed as 300 cGy per day to midline for 10 fractions (3000 cGy in 10 fractions). The separation between the two ports was measured to be 16 cm, thus midline was located at a depth of 8 cm. The dosimetrist incorrectly entered the treatment depth as 16 cm instead of 8 cm. The Cobalt-60 time calculation program prints out the input data as well as the calculated time. However, the error was not detected by either the dosimetrist who did the original calculation or the physician who checked it. The technologists on the machine did not question the unusually long treatment time. The medical physicist performs her weekly chart check on Thursday evening. The senior medical physicist who checks the charts on weekends, was attending an out of town meeting. The error was discovered by the medical physicist during her chart check the following Thursday evening. By this time, the patient had received five treatments at the incorrect dosage (510 cGy per day to midline instead of the 300 cGy per day to midline as prescribed). (The calculation check procedure was in compliance with NRC guidelines.)

4. Why the event occurred:

The initial error was a human error. Due to the coincidence of several highly improbable events, the error was not discovered before the patient had received five treatments.

5. Effect on the patient:

At the time the error was discovered, the patient had received a TDF of 69.5 instead of 62 which corresponded to the initial prescription. When the physician was informed of the error, he discontinued the whole brain ports and began the cerebellar boost with a revised prescription. The patient will receive a total TDF of 83.5 instead of 79 corresponding to the original prescription. The physician does not expect that the patient will be adversely affected by the change in dosage from the original prescription.

6. What improvements are needed to prevent recurrence:

If the prescribed dose is to be administered in more than three fractions, the dose calculations will be checked within two working days after administering the first fractional dose. Routinely, both a physician and a medical physicist, neither of whom made the original calculation, will check the dose calculations. When either the medical physicist or the physician is not available to check the calculation, a qualified member of the staff will be assigned this responsibility. If the prescribed dose is to be administered in three fractions or less, the procedure for checking dose calculations as described in this paragraph will be performed before administering the first fractional dose.

7. Actions taken to prevent recurrence:

The actions outlined above have been implemented.

8. Whether the licensee notified the patient and if so, what information was provided to the patient:

On Friday November 13, 1992, the patient was informed of the error. Quoting from the physician's progress notes in the patient's chart: "Patient informed of dosimetry calculation error (510 vs 300 to WB), of total dose change (2550 vs 3000), of change in # of fractions (5 vs 10), & of plan to still do a boost. Told effect on tumor roughly equivalent, & that I feel overall effect is similar."

The referring physician, Dr. Bright, was also notified.

ATTachment 2

University of Cincinnati
Medical Center

University of Cincinnati Hospital

234 Goodman Street
Cincinnati, Ohio 45267-0577

Eugene L. Saenger Radioisotope Laboratory
Mail Location #577
TELEPHONE (513) 558-4282

November 25, 1992

B.J. Holt
Nuclear Regulatory Commission
Region 3
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Ms. Holt:

My investigation of a teletherapy misadministration at St. John's Medical Center, Anderson, Indiana follows.

My source of information is John Marvel, M.D., the Radiation Oncologist.

The Misadministration

The patient was found to have a solitary cerebellar metastasis from carcinoma of the lung. Palliative radiation therapy was planned and the patient was noted to have a field 16 cm thick (presumably the skull) with the maximum tumor dose to be at 8 cm depth. The plan was to give 150 rads to each side of the cerebellum five days a week for two weeks to total 3,000 rads to the metastasis.

On November 6, the technologist entered into the computer the depth of the tumor as 16 cm (actually the thickness of the field) rather than 8 cm, which was the true tumor depth. The operator of the cobalt-60 unit indicated that the calculations "didn't look right" but did not call this to anyone's attention. The treatment began November 6. On November 9, the physician rechecked the calculations and missed the error which had been made. On November 12, 1992 the radiation physicist, who had been away at a meeting, returned, and on the third check of calculations, found the error. At this time, the treatment was stopped. The total dose received to the tumor was found to be 510 rads daily given for five days for a total of 2,550 rads.

Errors Leading to the Misadministration

The radiotherapy technologist entered an incorrect number into the computer. There was no cross check of the radiation technologist error at the time it was made. The timing of the physician's recheck of the treatment plan was appropriate. However, there was no one to check the physician, since the hospital physicist was at a meeting. When she returned, the radiation physicist, who was the third individual to review the calculation, caught the error.

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Recommendations

It would seem reasonable that two people at the doctoral level should review all calculations after the certified medical dosimetrist (technologist) has made them. This could involve the physicist and physician or two physicists. The Department administrator tells me that he has been given permission to hire a second medical physicist so that there will always be two individuals at the doctoral level checking calculations.

Medical Implications

The patient received 2550 rads in five doses rather than 3000 rads in 10 doses. The standard TDF calculations, relating to the work or Orton and Ellis, are not applicable because the Orton and Ellis research was done on a tissue capable of self-regeneration, i.e., skin, and brain tissue does not divide post-natally. Calculations for brain have been performed in our Division of Radiation Oncology employing the concept of the neuro-ret. These indicate the planned dose as 68 neuro-rets, while what was actually given equalled 83 neuro-rets, 22% higher than planned. This is equal to 200 rads in 25 fractions (5 weeks) and represents the peak tolerance of the brain, carrying a 5% risk of radiation necrosis in 4-12 months.

Sincerely,

Edward B. Silberstein

Edward B. Silberstein, M.D.
Professor of Radiology and Medicine

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